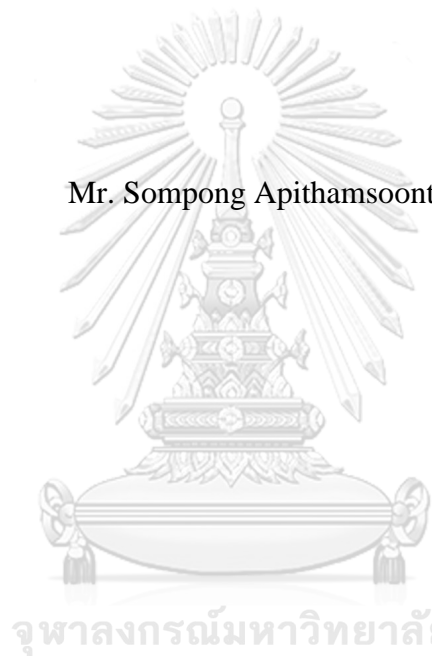


STRATEGIC FIT FOR OUTSOURCING OF PHARMACEUTICAL
MANUFACTURING: A SCENARIO STUDY IN THAILAND

Mr. Sompong Apithamsoonthorn



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กลยุทธ์ที่เหมาะสมสำหรับการจัดจ้างบริษัทภายนอกในการผลิตยา: การศึกษาสถานการณ์ใน
ประเทศไทย



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การจัดจ้างบริษัทภายนอก ได้รับการยอมรับว่าเป็นหนึ่งในปัจจัยสำคัญของการบริหารจัดการห่วงโซ่อุปทานของยาและเวชภัณฑ์ที่มีประสิทธิภาพ บริษัทขายจำนวนมากนิยมใช้การว่าจ้างบริษัทภายนอกระหว่างประเทศ เพื่อให้สามารถอยู่รอดได้ในธุรกิจที่มีการแข่งขันสูงทั่วโลก เนื่องจากปัจจัยความสำเร็จที่สำคัญของการเป็นพันธมิตรทั้งภายในและระหว่างประเทศนั้นขึ้นอยู่กับรูปแบบของความสัมพันธ์แบบการเป็นหุ้นส่วนและประเภทของการบริหารเชิงกลยุทธ์ที่เหมาะสม ซึ่งประเทศไทยยังไม่เคยมีการวิจัยเชิงประจักษ์ในเรื่องดังกล่าว ดังนั้นผู้วิจัยจึงทำการสำรวจบริษัทยาของไทยและต่างชาติทั้งที่เป็นบริษัทว่าจ้างและบริษัทรับจ้าง เพื่อหาความสัมพันธ์อย่างมีนัยสำคัญทั้งในรูปแบบเชิงกลยุทธ์ที่เหมาะสมและในการเป็นหุ้นส่วนกัน รวมถึงผลต่อการดำเนินงานของบริษัทคู่ค้าทั้งคู่ด้วย งานวิจัยนี้ประกอบด้วยสองส่วน ส่วนแรกคือการวิเคราะห์ถึงความสัมพันธ์ระหว่างกันของประเภทความเป็นหุ้นส่วน (ประเภท 1,2,และ 3) และประเภทเชิงกลยุทธ์ที่เหมาะสม (เหมาะสมน้อย,ปานกลาง,และ มาก) ส่วนที่สองศึกษาถึงผลต่อการดำเนินงาน (รายได้ และอัตราการเติบโต)ของบริษัทคู่ค้าทั้งคู่ ซึ่งผลการวิจัยพบว่าบริษัทจัดจ้างในธุรกิจผลิตยาของประเทศไทย ส่วนใหญ่เป็นความสัมพันธ์แบบหุ้นส่วนประเภท 2 และมีความสัมพันธ์เชิงกลยุทธ์ที่เหมาะสมเป็นประเภทปานกลาง และทั้งสองรูปแบบของการจัดจ้างดังกล่าวมีความสัมพันธ์ระหว่างกันอย่างสูง อย่างไรก็ตามไม่จำเป็นที่ความสัมพันธ์ในรูปแบบการเป็นหุ้นส่วนประเภท3จะดีที่สุดเสมอ ทั้งนี้อาจขึ้นอยู่กับความเหมาะสมในเชิงกลยุทธ์ระหว่างบริษัทคู่ค้าในแต่ละคู่ด้วย ในส่วนของผลการดำเนินการของบริษัท เช่นรายได้และอัตราการเติบโตสามารถคาดการณ์ได้จากแต่ละประเภทของรูปแบบความร่วมมือที่มีต่อกัน และในประเทศไทยนโยบายรวมถึงเป้าหมายเชิงกลยุทธ์ของภาครัฐจะเป็นปัจจัยหลักของความสำเร็จในธุรกิจนี้

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Outsourcing is recognized as one of the critical factors for efficient execution of pharmaceutical supply chain management, many pharmaceutical companies engage in international outsourcing of services (IOS) to survive in global highly competitive business. Since the key success factors for both domestic & international alliances are partnership characteristics and strategic fit management, but there is no empirical research on this issue in Thai pharmaceutical partnership offshore outsourcing. Therefore, this survey of Thai and foreign companies, both contract providers (CPs) and contract manufacturers (CMs), seeks to indicate significant relationships among both outsourcing strategic fit type and partnership type, including outsourcing performance outcome. This research is two-fold. First, the partnership types (type I, II, & III), the strategic fit types (low fit, moderate fit, & good fit), and their correlations are analyzed. And second, their outsourcing performance (company revenues and growth rates) are presented. The results showed that most of the Thai pharmaceutical outsourcing manufacturing relationships are classified as the partnership type II, as well as the moderate strategic fit, and strongly support the relationship between these two models. However, it is not necessary that the most integrative type of partnership, Type III, will be always the best, because it depends also on the strategic fit between each pair of partners as well. The company revenue and growth rate could predict the company performance outcomes for each of partnership type and strategic fit type. In Thailand, the government policies and strategic goals are the key success factors in this industry.

Field of Study: Logistics Management Student's Signature

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LIST OF ABBREVIATIONS

ACCSQ	ASEAN Consultative Committee on Standards and Quality
ACTD	ASEAN Common Technical Dossier
AEC	ASEAN Economic Community
AHP	Analytic Hierarchy Process
ANP	Analytic Network Process
API	Active Pharmaceutical Ingredient
BOI	Board of Investment
CAGR	<i>Compound Annual Growth Rate</i>
CDER	Center for Drug Evaluation and Research
CDMO	Contract Development and Manufacturing Organization
CM	Contract Manufacturer
CMMI	Capability Maturity Model Integration
CMO	Contract Manufacturing Organization
CP	Contract Provider
CRAM	Contract Research and Manufacturing service
CRO	Contract Research Organization
CSF	Critical Success Factor
DCF	Discounted Cash Flow
DRA	Drug Regulatory Affairs
EDI	Electronic Data Interchange
ERC	Ethical Review Committee
EU	The European Union
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
FTA	Free Trade Agreement
GDP	Gross Domestic Product
GMP	Good Manufacturing Practice
GPO	The Government Pharmaceutical Organization
HRM	Human Resource Management

HTA	Health Technology Assessment
IEC	Independent Ethics Committee
IOS	International Outsourcing of Services
IPR	Intellectual Property Rights
IS	Information Systems
ISM	Interpretive Structure Modeling
IT	Information Technology
JP	Japan
LMIC	Low and Middle Income Countries
MA	Marketing Authorization
MNC	Multinational Corporation
MPF	Meeting Process Facilitator
M&A	Mergers and Acquisitions
M&S	Marketing and Sales
NCE	New Chemical Entities
OEM	Original Equipment Manufacturers
OTC	Over-the- counter
PhRMA	Pharmaceutical Research and Manufacturing Association
PIC/S	Pharmaceutical Inspection Cooperation Scheme
PPWG	Pharmaceutical Product Working Group
PSM	Partnership Model
PST	Partnership Type
R&D	Research and Development
RDT	resource dependence theory
SCM	Supply Chain Management
SFM	Strategic Fit Model
SFT	Strategic Fit Type
TH	Thailand
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TTM	Thai Traditional Medicine
TUSFTA	Thailand-United States Free Trade Agreement
USA	United States of America

WHO World Health Organization

WTO World Trade Organization



จุฬาลงกรณ์มหาวิทยาลัย
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CHARTER 1

INTRODUCTION

1.1 Background and Problem Review

In spite of its recent initiation in 1960s (Grabowski, 2011), pharmaceutical industry has become a topic of interests of researchers, especially pharmaceutical researchers, and the amount of pharmaceutical research and development (R&D) and strategic management research, has been greatly increased (van Vierssen Trip, 2013), as well as its expansion in terms of investment, income, number of pharmaceutical firms, and its rapid growth (Angwin & Meadows, 2015; JSB Intelligence, 2005). The evidence of growth can be seen from the IMS report (IMS, 2011) of the pharmaceutical industry volume had surged from US\$ 647 billion in 2005, to US\$ 875 billion in 2010, corresponding to an increase of 35.2%.

The business sector leaders and researchers have gradually paid great attention on pharmaceutical industry because of at least 4 reasons: a) being one of the most powerful and successful industry as presented above; b) instead of expansion and extension as in other industries when facing unprecedented both internal and external competition (Palmer & Lyons, 2012), there are, on the contrary, a major consolidations in pharmaceutical industry through mergers and outsourcing which require the range of strategies, and types of strategic choices (Capo et al., 2014; Davidovic, 2014). The consequences of which, in turn, can be seen in maximization of its value chain productivity and minimization of its costs (Pricewaterhouse Coopers International Limited, 2008); and more focusing on outsourcing of R & D work in the Big pharmaceutical companies (Pandya & Shah, 2013); c) being quite different from other industries in terms of complex and time-consuming, but well-organized, and systematic process (Rahalka, 2012; Shah, 2004), and a multi-function organization and network of the pharmaceutical manufacturing (Encyclopedia.com, 2015); and d) an interesting differences of the strategic management techniques, including strategic fit for outsourcing supply chain management, among developed and developing countries

(Guennif & Ramani, 2008; Strand, 2014) are drawing attention from pharmaceutical researchers to learn more lessons in order to apply to the developing nations.

Most manufacturing companies, including pharmaceutical manufacturing companies, in the last decade, attempt to innovative, speed up their value chains by offering new more products and fast services to markets, and applied strategic management techniques, especially strategic fit for outsourcing supply chain, both in the general manufacturing companies (Baines et al., 2009; Lay et al., 2010; Martinez et al., 2010; Neely, 2008; Smith et al., 2014; Wilkinson et al., 2009; Zhen, 2012), and in the pharmaceutical manufacturing companies (Copestake, 2006; Jiang, 2006; Lad et al., 2012; Reddy et al., 2013; Scott, 2006). The advantages they can anticipate to get from outsourcing application are cost savings; fast product development; time reduction for product marketing; technology transfer and gains from the external outsourcing companies' skills, knowledge and expertise; and assurance from legally contracted outsourcing services (Ernst & Young, 2010; Jiang & Qureshi, 2006; Lau et al., 2006; Power et al., 2004).

The strategic management techniques, especially strategic fit for outsourcing supply chain, have been proposed and applied to industry. Before the last three decades, only a few focused on pharmaceutical industry, and greatly on other industries. But During the last three decades there have been more and more research work on pharmaceutical industry, which not only in technology transfer, but also with PSM (Lambert et al., 1999, 2004) as well. Searching with 'Google Scholar' search engine, the researcher have acquired approximately 100 research papers, the proportion of papers on strategic fit, outsourcing, and/or supply chain management (SCM) classified into pharmaceutical industry as compared to other industries are 76: 42. Of those 76 papers, only 20 papers, all of which none have been working on PSM were conducted in Thailand. Due to a dearth of research in Thai pharmaceutical industry, and only a few of lesson learned, on Thai strategic fit, outsourcing, and/or supply chain management in additional to lack of PSM in pharmaceutical industry, the researcher, under the supervision of his major dissertation supervisor, **Professor Dr. Kamonchanok Suthiwartnarueput, and Assoc. Prof. Dr. Pongsa Pornchaiwiseskul**, have agreed to utilize scenario analysis for this study to learn more broad and extensive, but comprehensive lessons, which combination of traditional

strategic management (the strategic fit for outsourcing supply chain model) and PSM in this study. This idea has been confirmed by Walker et al. (2009) whose study used exploratory methods incorporating qualitative and quantitative empirical data and the consequences.

The research objectives and questions are, therefore, rather broad and comprehensive covering PST and SFT of Thai pharmaceutical industries as follows:

1.2 Research Objectives

- 1) To study the pharmaceutical outsourcing trends and strategic fit management in outsourcing manufacturing between Thai and foreign countries from literature review.
- 2) To study, analyze, compare, and summarize the outsourcing manufacturing outcomes based on the PSM and the outsourcing SFM, in order to identify the PST and SFT using empirical study of both Thai and foreign CPs, and CMs in Thailand.
- 3) To post-evaluate for finding the appropriate policies, and strategic goals from Thai Government in outsourcing pharmaceutical industry.

1.3 Research Questions

Upon studying and synthesizing the related literature and research reports, the researchers concludes the research questions to be studied in 3 questions as follows:

- 1) What are the pharmaceutical outsourcing trends and strategic fit management in outsourcing manufacturing between Thai and foreign countries?
- 2) What are the comparison results of the outsourcing manufacturing outcomes based on the PSM and the outsourcing SFM, in order to identify the PST and SFT using empirical study of both Thai and foreign CPs, and CMs in Thailand?
- 3) What are the appropriate policies, and strategic goals from Thai government in outsourcing pharmaceutical industry?

1.4 Scope of Study

The research population in this study covers with our specification and following criteria: 1) only private sector, Thai and foreign pharmaceutical companies, located in Bangkok Metropolitan area. 2) the pharmaceutical companies must conduct

outsourcing business, either CPs or CMs, 3) both partner companies must have either a branch office or factory located in Bangkok Metropolitan area, 4) All CMs are modern medicine GMP (Good Manufacturing Practice) compliance manufacturers under Thai FDA (Food and Drug Administration) approval.

1.5 Research Advantages

1) The practical advantages: the pharmaceutical CM companies with CP companies, being selected as the cases for this study, will have informational advantages in terms of the present existing and future trend of their PSTs and SFTs, all of which will be quite useful for them as guidelines for their strategic outsourcing fit in the competitive world.

2) The academic advantages: this study will be helpful for the doctoral students interesting in pharmaceutical industry, as a pilot study, and they can extend their research further to a full scale. Moreover, this study will be useful for the university dissertation supervisor in terms of using as an exemplar pilot study using scenario study, which is quite rare, for both positive and negative criticism, in order to further improve the quality of dissertation.

3) The policy related advantages: this study aims to study broadly but comprehensively on the application of partnership relations and strategic fit for outsourcing in manufacturing of the selected pharmaceutical manufacturing companies in Thailand. The consequent results cover: a) the scenario of the future trends of PST and SFT of pharmaceutical outsourcing, and b) the appropriate outsourcing scenarios for future situations of Thai pharmaceutical industry, all of which will be a useful guidelines for the government authority in terms of policy decision making in order to drive the enhancement of Thai pharmaceutical industry into the competitive market both in the ASEAN Community and the worldwide pharmaceutical industry.

CHARTER 2

LITERATURE REVIEW

Regarding the main focus of this study in terms of the strategic fit for outsourcing in Thai pharmaceutical manufacturing, there are some problems concerning application of the focus strategic fit, used in other industry, to pharmaceutical one. The problems stem from the differences between pharmaceutical and other industries. The pharmaceutical manufacturing industry, not only just occurs in the 1960s, it also rapidly develop to be one of the most power and successful business (Grabowski, 2011) with radical change of structure in terms of consolidation of organizations (Davidovic, 2014). Moreover, the differences can be seen in term of more complex research-based developed, time-consuming, and patent protection, but systematic manufacturing process (Rahalka, 2012; Shah, 2004), with multi-function organization and network (Encyclopedia.com, 2015), as compared to direct, quick, and adaptable process, with few-function organization in other industries. Considering the aforementioned regards, the researcher decides to present literature review beginning with the pharmaceutical industry context in order to obtain clear understanding before applying the concept of strategic fit for outsourcing manufacturing. The six topics in this review, therefore, consist of 2.1) overview and nature of pharmaceutical industry, 2.2) outsourcing manufacturing in pharmaceutical industry, 2.3) strategic fit for outsourcing manufacturing in pharmaceutical industry, 2.4) the outsourcing PSM, 2.5) related research literature, and 2.6) research framework and hypotheses, as follows:

2.1 Overview and Nature of Pharmaceutical Industry

The global pharmaceutical industry had shown rapid growth over the years and emerged as one of the fastest growing industries in the world. According to IMS Health (an international consulting and data services company), in 2010, world pharmaceutical market was valued at US\$ 875 billion with the growth rate of 4.1% over the previous year at the constant exchange rate. The volume of pharmaceutical industry had surged from US \$ 647 billion in 2005 to US\$ 875 billion in 2010, corresponding to an increase of 35.2% (IMS, 2011).

There are many of previous research papers on pharmaceutical industry, such as: Davidovic (2014); Encyclopedia.com (2015); Grabowski (2011); Rahalka (2012); and etc. The researcher collects, analyzes, synthesizes and presents this review in six sub-topics, therefore, consist of 2.1.1) past and present situation of pharmaceutical industry, 2.1.2) pharmaceutical product and classification, 2.1.3) pharmaceutical manufacturing process, 2.1.4) distinguishing characteristics of pharmaceutical industry, 2.1.5) Thai pharmaceutical markets and situation, and 2.1.6) conclusion, as follows:

2.1.1 Past and Present Situation of Pharmaceutical Industry

The historical overview to display the past and present situation of pharmaceutical industry in developed and developing countries are quite different. For developed countries, as in the USA, it can be divided into 3 periods: the beginning of modern pharmaceutical industry with the import drug for acts for quality control system (1840s-1900), the occurrences of vaccine tragedy and the beginning of the modern highly organized pharmaceutical industry and controlled system of Drug Regulatory Affairs (DRA) (1901-1950), and the requirement of the Kefauver-Harris Drug Amendments 1962 for supported with efficacy as well as greater safety data, Good Manufacturing Practices (GMPs) and prior Marketing Authorization Approval was mandated by FDA (1951 to present) (Generic Pharmaceutical Association (GPHA), 2014; Rahalka, 2012).

On the contrary, developing countries such as India, there are 5 eras, all of which follows the similar track with approximately 20-40 years later, as follows: the government control of cheap drugs (1900-1960), the early stage of growth era (1961-1970), the government control by means of regulation and acts (1971-1980), the investment in infrastructure and active pharmaceutical ingredient/substance (API) (1981-1990), the expansion of domestic market (1991-2000), and the innovative and research era (2001-present) (Rahalka, 2012). Shah (2012) described Indian and Gujarat perspective of pharmaceutical industry that, the key discoveries of insulin and penicillin in 1920s - 1930s, resulted in major Western pharmaceutical companies with greater R&D expenditure and extensive regulation, in the late 19th and early 20th, consequently, those changes were significantly good for Indian pharmaceutical industry in term of

driving force for global competitiveness. As a result, pharmaceutical industry in India and Gujarat had become the world's third largest in term of value. The forecasting in 2020 predicted that India would join among the league of top 10 global pharmaceutical markets with value reaching US\$50 billion. Some of the major pharmaceutical companies included Sun Pharmaceutical, Cadilla Healthcare, and Piranal Healthcare. Unlike other countries, differences between biotech and pharmaceutical drugs reminded stable that the Indian biotech market dominated by biopharmaceutical drugs, 75% of the revenues came from biopharmaceuticals with 30% yearly growth. On the contrary, Gujarat, given its strong and established engineering sector, found global opportunity in the manufacturing of pharmaceutical machinery. According to industry estimates, a great chunk-almost 40 per cent-of machinery used in the pharmaceutical manufacturing in India had been produced in Gujarat. Unfortunately, due to the highly fragmented engineering sector, the ability to produce the technology-driven machinery was too restricted to meet a global as well as a local demand.

Going in more detail, the pharmaceutical industry structure in 1950s-1960s was quite different from the current one. The companies initially focused on relatively small biological (biotechnology pharmaceutical industry) targets whereas the research was to chemically synthesize (traditional pharmaceutical industry) and test a large number of compound using trial and error to study the biological responses. The manufacturing factories have just started establishing a large scale of crude drug. But the multiple tragedies i.e. sulfanilamide elixir, vaccine tragedy and thalidomide tragedy have resulted in substantial increase of legislations for drug products quality, safety and efficacy. In U.S.A., the Biologics Control Act of 1902 was the result of the vaccine tragedy, which was stricter norm for Marketing Authorization (MA) and GMP (Rahalkar, 2012). But after few decades from the World War II, there were many introductions of new products including antibodies such as penicillin, streptomycin, tetracycline, several new vaccines; therapeutic advances such as corticosteroids, diuretics, beta blockers; new classes of tranquilizers, antidepressants, and initial oral contraceptives (Grabowski, 2011).

During the end of World War II to the 1980s, the pharmaceutical industry structure was vertically integrated multinational company encompasses R&D laboratories, production facilities and marketing divisions (Grabowski, 2011). This was

viewed as a strategic response to the risks involved in developing new pharmaceuticals -in particular, long investment periods, high costs, and variable outcomes.

The horizontally extension of the pharmaceutical industry structure began later after the World War II. The entry of biotech start-ups and development-stage companies with venture financing originated during the 1970s, but were still in their infancy compared to later decades. Biopharmaceuticals have accounted for several significant new drug introductions and are source of much therapeutics under development. Biotechnology describes any technological process that harnesses cellular and bio-molecular processes to develop technologies and products that help improve our lives and the health of our world (Song, 2009). Advance in molecular biotech have played a key role in the evolution of the industry's approach to drug discovery (Robbins-Roth, 2000). The global biopharmaceutical industry is currently worth over \$145 billion (60% mammalian and 40% microbial), compared to \$140 billion in 2011 and it's estimated that the industry should exceed \$167 billion in 2015. On the contrary, the generic drug industry came of age after the passage of the 1984 Hatch-Waxman Act, and now the growth of generics drug account approximately to three quarters of all US prescriptions, and other parts of the world as well (Berndt & Aitken, 2011). From then on, pharmaceutical industry has been extended to other major type of drug manufacturing.

Regarding the pharmaceutical market, the past and present are quite different. At the beginning, the pharmaceutical market situation is quite certain, reliable supply, promising of high income due to less competitor, and consequently in less needs of strategic management. But at the beginning of the 21st century, the pharmaceutical market features are at high level of uncertainty, strong competitive environment, shorter product life cycle, and unspecified demand and unreliable supply (Mercanoglu & Ozer, 2015). Besides, the pharmaceutical market has begun its complex and challenging time of emerging market and has consequently attempted to develop new and innovative product for the new emerging market (Quinn, 2012). During the first decade of the 21st century, creative and innovation product development has been rapidly increased, many strategic management such as outsourcing and merging has become a new trend at the pharmaceutical market (Howells et al., 2008), in responding to the forecasting trend stating that "pharmaceutical consumer spending in developing

countries and emerging markets will rise to USD 22 trillion by 2020” (RolandBurger.com, 2013).

Considering the definition of pharmaceutical industry, Rahalka (2012) defined it as “an industry with well organized, systematic and compliant to international regulatory standards for manufacturing of Chemical and Biological drugs for human and veterinary consumption as well as medical devices, traditional herbal products and cosmetics. It also included companies which involve in medical devices, diagnostic products, biomarkers and other therapeutic products as well. Alves (2015) described that Biopharmaceuticals differ from pharmaceuticals in terms of controlling quality and production. In what concerns R&D, pharmaceuticals focus their work on products modified by chemical processes, while biopharmaceuticals target natural substances and produce drugs that are modified through biological platforms.

The stages of pharmaceutical value chain started from discovery research, basic R&D, through to clinical trials, and last as the manufacturing. Sousa et al., (2011) explored and defined five key players in pharmaceutical industry, as follows: 1) Large research and development based multinationals with global presence and branded products (both ethical/prescription and over-the-counter), 2) Large generic manufacturers (who produce out-of-patent ethical products and over-the-counter products), 3) Local manufacturing companies which operate in their home country (producing both generic products and branded products under license or contract), 4) Contract Manufactures without their portfolio, and 5) Biotechnological companies mainly concerned with drug discovery.

In conclusion, there has been great evolution between the past and current situation of pharmaceutical industry. Before the World War II there were mostly relatively small biological while during the end of World War II to the 1980s, there were many introductions of new products including antibodies. In terms of the pharmaceutical industry structure, there was vertically integrated multinational company encompasses R&D laboratories, production facilities and marketing divisions as a strategic response to the risks involved in developing new pharmaceuticals. The pharmaceuticals industry consists of all who contribute to the discovery, creation and supply of products and services of prescription medicines and biologics. It also included companies which involve in medical devices, diagnostic products, biomarkers and other

therapeutic products as well. In sum, they consist of all who are responsible for the pharmaceutical value chain.

2.1.2 Pharmaceutical Product and Classification

To get a clear and concise meaning of pharmaceutical product, the definition sets by the World Health Organization (WHO) is probably the most popular and recognized one. The WHO, established in 1948 as a specialized agency of the United Nations serving as the directing and coordinating authority for international health matters and public health, one of WHO's functions is to provide objective and reliable information and advice in the field of human health, a responsibility that it fulfills in part through its extensive program of publications. WHO secures the broad international distribution of its publications and encourages their translation and adaptation to all of WHO member states (WHO, 2015). Among several publications, there are some concerning with the definition of the term: pharmaceutical product. The WHO's definition, a quite popular and recognized one, defined pharmaceutical product as *“any substance or mixture of substances manufactured, sold, offered for sale or represented for use in the diagnosis, treatment, mitigation or prevention of disease, abnormal physical state or the symptoms thereof in man or animal; restoring, correcting or modifying organic functions in man or animal”* (WHO, 2004).

Regarding the pharmaceutical classification, WHO has also classified the overall meaning of pharmaceutical products based upon its usage into 2 major categories of oral drugs and non-oral drug (WHO, 2004). Later, more detail classification has been in the publishing process for different purposes, for example, the future classifications aiming to publish regulatory guidelines on specifications for medicines for quality control and assurance for regulators, logisticians, pharmaceutical and professionals manufacturers in industry are as follows: pediatric medicines and radiopharmaceuticals consisting of medicines for maternal, newborn, child and adolescent health; anti-malarial medicines; antiviral medicines including anti-retroviral; anti-tuberculosis medicines, specifically for the treatment of drug resistant tuberculosis; medicines for neglected tropical diseases; medicines considered as life-saving commodities for women and children (WHO, 2015). However, due to this study focus, the classification

details are not appropriate, the researcher, therefore concentrates more on gross classification. Several researchers, for example, Baines (2010); Dorocki (2014); and Sousa, et al. (2011) had attempted to classify pharmaceutical products roughly, using different criteria as relevant to their research work, as shown in Table 2.1.

Table 2.1: Pharmaceutical product classification

Researcher (Year)	Selected Criteria	Classification Results
WHO (2004)	Usage types	- Oral drugs - Non-oral drugs
Joshi (2003); WHO (2015)	Component types	- Active pharmaceutical ingredient (API) - Bulk & finished goods
Dorocki (2014)	Material types	- Chemical medicines - Biological medicines
Baines (2010); Shah (2004)	Medicine types	- New chemical medicines - New biological medicines - Generic medicines
Sousa, et al. (2007)	Manufacturing stages	- Primary manufacturing - Secondary manufacturing
Sousa, et al. (2011)	Business sectors	- Originator chemical drugs - Originator biological drugs - Generic manufacturer - Local manufacturer - CM

In summary, WHO, as a specialized agency of the United Nations serving as the directing and coordinating authority for international health matters and public health, has defined pharmaceutical products as “*any substance or mixture of substances manufactured, sold, offered for sale or use for public health*”; and classified the pharmaceutical products, both roughly or grossly into two major categories of oral drugs and non-oral drug, and delicately into several types depending on its usage and function. The evidences of rough or global definition can be seen from other pharmaceutical research papers, some of which will be used in this study.

2.1.3 Pharmaceutical Manufacturing Process

The process of pharmaceutical products covers from the initiation of products via R&D including clinical trials and the government approval, the production and quality insurance process, to the distribution of the products. In other words, pharmaceutical

drug development pipeline, as in USA, includes R&D aiming for drug discovery, pre-clinical and clinical trials, the U.S.-FDA review, and production and marketing phases (Hassanzadeh et al., 2014). As this study focuses on strategic management, therefore, the researcher presents the pharmaceutical manufacturing process, without the R&D phase, consisting only of the production and marketing phases.

In many production operations, pharmaceutical manufacturers have developed a high degree of automation. Milling and micronizing machines, which pulverize substances into extremely fine particles, are used to reduce bulk chemicals to the required size. These finished chemicals are combined and processed further in mixing machines. The mixed ingredients may then be mechanically capsulated, pressed into tablets, or made into solutions. After the finish production process, the next process of quality control and quality assurance were vital in this industry. Many production workers were assigned full time to quality control and quality assurance functions, whereas other employees may devote part of their time to these functions. For example, although pharmaceutical company sales representatives, often called detailers, work primarily in marketing, they engage in quality control when they assist pharmacists in checking for outdated products (Pharmaceutical Research and Manufacturers of America, PhRMA, 2006).

When a drug successfully passes animal and clinical tests, the Center for Drug Evaluation and Research (CDER) on behalf of the U.S. Food and Drug Administration (FDA) by must review the drug's performance on human patients before approving the substance for commercial use. The entire process, from the first discovery of a promising new compound to FDA approval, could take over a decade and cost hundreds of millions of dollars (Pharmaceutical Research and Manufacturers of America, PhRMA, 2006).

Regarding the medicine manufacturing, at the beginning, the pharmaceutical industry concentrated more on generic drug manufacturing, and less on new medicines from R&D results. However, at the first decade of the 21st century, The pharmaceutical industry has seen its R&D productivity decline significantly as the consequence of the overall economic downturn, the rising cost of healthcare and the costs associated with the development and sales of pharmaceuticals (DiMasi et al., 2003, Grabowski & Vernon, 2000). The features characterize 21st century of pharmaceutical market are:

high level of uncertainty, strong competitive environment, shorter product life cycle, unspecified demand and unreliable supply (Mercanoglu & Ozer, 2015). Driven by the need to ameliorate or to grow better the R&D productivity and efficiency, and the traditional generation of new chemically based small molecules dwindling and to have access to untapped markets, global pharmaceutical companies have increasingly outsourced operations to CROs, outsourcing and diversification; mergers and acquisitions (M&A); recent spate of partnerships; and/or licensing agreements and downsizing in both human and capital resources (Baines, 2010; Hassanzadeh et al., 2014).

Two competing strategies are outsourcing and merger which aim for opposite direction. The nature of outsourcing areas, aiming for diversification, include information technology (IT) and IT support, human resource, R&D, procurement and logistics. Arguably, pharmaceutical companies are turning to supply chain outsourcing as a way to improve product pipeline and gain strategic competitive advantage. Pharmaceutical global outsourcing has become a viable and a lucrative business strategy that is enabling firms to transfer non-core activities to external partners in order to restructure their distribution networks, leverage resources, spread risks, focus on issues imperative to survival, competitive advantage, and future growth (Sink & Langley, 1997; Wang & Regan, 2003). Thus, R&D costs, regulatory pressure, patent expiry, declining blockbuster pipeline chain, among others have caused pharmaceutical manufacturers to focus on their core competencies by outsourcing supply chain non-core activities to CMOs and/or CROs (Enyinda et al., 2009). For example, the case with Johnson and Johnson, Novartis or Abbot that has significant business activities outside of the traditional pharmaceutical arena engaging in areas such as consumer products, healthcare services, medical devices and medical diagnostics. Yet other companies have taken the path of focusing on the 'Emerging Markets' that are in some ways considered largely untapped potential like Astra Zeneca and Glaxo Smith Kline's focus on China and India respectively (Baines, 2010).

On the contrary, aiming for mergers, the big pharmaceutical companies look to cooperate with the smaller companies and biotech to provide competences or additional resources to help spur R&D as well as marketing and sales growth; whereas the smaller companies in turn get much needed funding to continue their work, either as partners

or as a part of the larger company. Companies are also trying to improve their manufacturing capacity and efficiency and commercial models, many with a variety of Six Sigma process improvements (Baines, 2010). Four types and examples of big pharmaceutical mega mergers in 1995-2014 as reported by Datamonitor (2009) are as followed: 1) Buy Growth Companies aimed primarily on activity to increase the growth of prescription sales, e.g. Roche-Genentech, Johnson & Johnson, and Abbott-Solvay, 2) Buy Scale Companies aimed at the activity to increase product pipeline, R&D, M&S etc., e.g. Merck-Schering-Plough, Glaxo Smith Kline, Sanofi Aventis, AstraZeneca, and Bayer AG, 3) Multi M&A Companies focused their merging activity to utilize two or more of the strategies, e.g. Pfizer-Wyeth, and Novartis. Lastly, and 4) Organic Growth Companies aimed to avoid M&A as a core strategy e.g. Eli Lilly, and Bristol-Myers Squibb.

To summarize, there is no doubt that the pharmaceutical industry is facing challenging times, and only the long term success companies are those capable of improving their manufacturing process with appropriate strategic management. For their long term success, the companies, therefore must employ critical strategic management process consisting of: 1) make decision and execute the carefully developed strategy, such as either outsourcing or M&A; 2) carefully assess and manage the risks; 3) make the right portfolio and business decisions, and 4) improve their manufacturing processes.

2.1.4 Distinguishing Characteristics of Pharmaceutical Industry

The major distinct characteristic of the pharmaceutical industry is operated not only on the basis of market conditions (demand-supply), but it also governs by numerous laws and regulations on safety, quality, patents, etc. (Festel et al., 2014). FDA being highly regulated organization in the USA and followed the WHO's advisory practices, regulates pharmaceutical business through designing and enforcing the appropriate laws (rules) throughout all details and process of manufacturing, so that the drugs meeting the highest standards of quality are brought into the Global Trade. Rules and regulations are being prepared considering Global, Regional and National pharmaceutical trade as well as necessity of the drugs based on patient population. Therefore, once an approval was granted, the pharmaceutical manufacturing companies

use the approved source for a long period, at the minimum of 5 years. The consequences of those strong regulations have also expressed in term of strict quality checks during the manufacturing process, which extended the long production lead time substantially (Shah, 2004).

Other distinguished characteristics are the drastic changes and rapid growth. In terms of the structure, in the past, pharmaceutical industry has been gaining enormous global importance, and the industry's supply chain structure has been getting more and more complicated (Abuhamad, 2014). The aim of the pharmaceutical supply chain is to provide sufficient drugs for the population in two main aspects: pharmaceuticals safety and pharmaceuticals service security. The sensitive nature of pharmaceutical products required consistent, safe, effective and high quality products delivered to the consumers. Therefore numerous national and international administrations supervise the approval of pharmaceuticals and oblige pharmaceutical manufactures to implement several guidelines, e.g. GMP, etc.

Differences between pharmaceutical industry and other industries can be group into four topics. Firstly, even of their recent initiation in 1960s (Grabowski, 2011), pharmaceutical industry in developed countries (e.g. USA & UK), are one of the most powerful and successful because of their commitment in R&D, its consequent intellectual property and patent protection bring them sufficient revenues and success. On the contrary, for developing countries, new drug inventions are quite rare, the development process is quite slow, and the sole opportunity is to be a platform for outsourcing (Barker & Darnbrough, 2007). Secondly, the rapid development during the last 30 plus years, instead of expansion and extension as in other industries, there are a major consolidations in pharmaceutical industry through mergers and acquisitions which require the range of strategies that have been employed, and types of strategic choices that seem to be preferred by certain companies or groups. Some pharmaceuticals prefer sequential acquisitions of smaller players, some turn to sequential acquisitions of similarly sized companies, and some others tend to like mergers of industry behemoths (Davidovic, 2014). Thirdly, pharmaceutical industry is quite different from other industries in terms of process and organization. For process, the pharmaceutical manufacturing process is quite complex and time-consuming, but well-organized, and systematic one. The 6-step process includes a) discovery from

research and development, b) experimenting, c) creating, d) getting the government granted patent exclusive rights to market an invention for certain years before others may duplicate and sell it, e) manufacturing the innovative product, and f) providing supply of prescription of medicines and vaccines (Rahalka, 2012; Shah, 2004). For the organization, the pharmaceutical manufacturing must have a multi-function organization and network (Encyclopedia.com, 2015). And lastly, the consequence of the above difference exists in terms of difference in the amount of research. The strategic management techniques, including strategic fit for outsourcing supply chain, have been proposed and applied only a few to pharmaceutical industry, but mostly applied to other industries. Therefore the application results on pharmaceutical industry are sparse as compare to those of other industries. Therefore research findings and theories applicable to other industries may not work as well as with pharmaceutical industry.

2.1.5 Thai Pharmaceutical Market and Situation

The global pharmaceutical industry had shown rapid growth over the years and emerged as one of the fastest growing industries in the world. According to IMS Health (an international consulting and data services company), in 2010, world pharmaceutical market was valued at US\$ 875 billion with the growth rate of 4.1% over the previous year at the constant exchange rate (IMS, 2011). The 10 largest drugs companies control over one-third of this market, several with sales of more than US\$10 billion a year and profit margin of about 30%, six are based in the United States and four in Europe.

The rapid growth in the pharmaceutical market and research environment in emerging economies, leading to a gradual migration of economic and research activities from Europe to these fast-growing markets. Furthermore, Southeast Asia is one of the growing pharmaceutical markets. The member states of ASEAN have taken initial steps towards seeking more harmonized regulation of their respective pharmaceutical and medical-device industries. With a population of more than 600 million, this market represents another rapidly growing emerging market. In general, the market has become more attractive in recent years as wages have risen and country governments have made healthcare sector growth a priority (TIR, 2015).

Looking at Thailand specifically, Thai pharmaceutical market is dominated by generic drugs in terms of volume. The new medicines are coming up and showing good efficacy over the old generics, yet the country still needs to import a lot of pharmaceutical products. Thai pharmaceutical market is large and growing fast, with the government remaining the biggest client for the industry. Previously, 60 % of the market share used to go to hospitals and 40% to the OTC (over-the-counter) or drugstore market. With the introduction of the 30-baht scheme, it appeared that market distribution has shifted with 70% for hospitals and 30% for OTC.

Regarding the GMP standards, the local industry has learned and improved greatly in the last five years. The Thai FDA applied for Pharmaceutical Inspection Cooperation Scheme (PIC/S) membership so the entire local industry now has to comply with the PIC/S' GMP. Moreover, the Thai Pharmaceutical Manufacturers Association conducts PIC/S GMP training sessions. Some companies have entered the program and only around 50% of them have been approved by the Thai FDA. It is worth mentioning that in Thailand, the market is based on government tenders and with the newly implemented GMP standards; the products of local manufacturers are not different from those of the multinationals.

Currently, Thai products also have been exported to neighboring countries for decades. The market share of Thai pharmaceuticals is being challenged more and more by emerging countries like Indonesia and Malaysia (TIR, 2015). On the other hand, the Thai pharmaceutical industry has been expanding every year when compared to neighboring countries. When considering the country's strengths, Thailand is the best location for investment and its market is set to experience more growth with the implementation of GMP standards and ASEAN's economic integration.

There are two main bodies of law applicable to drugs in Thailand. The first, the law of patents, relates to the intellectual property protection of new drugs, while the second body of law, principally codified in the Drug Act 1967 (BE 2510) and subsequent amendments, sets out a regulatory regime for the supervision of drug production, importation, sale and marketing of drugs in Thailand. The sale of drugs and medicines in Thailand is supervised by FDA, which functions under the Ministry of Public Health. Part of the FDA's mandate is to supervise pharmaceuticals in accordance with the Drug Act. In fact, the Drug Control Division of the Thai FDA has responsibility

for drug licensing, inspection, registration and post-market surveillance, in line with the various rules and supplementary ministerial regulations promulgated to govern the FDA approval process. New drugs must be registered and approved before being sold on the open market. The Trade Secrets Act also comes into play when it involves the implementation of regulations that deal specifically with confidential clinical safety data that has been submitted to the FDA during the regulatory approval process.

Likewise, for new drug applications, the ASEAN Common Technical Requirements and Dossier are accepted. At present, licenses do not have an expiration date. What's more, import and manufacturing licenses are valid for one calendar year and need to be renewed annually. Interestingly, Thailand has been part of the ASEAN Consultative Committee on Standards and Quality (ACCSQ) since 1992. Then in 1999, the Pharmaceutical Product Working Group (PPWG) was formed as part of the ACCSQ. Regulatory harmonization is expected to benefit pharmaceutical companies that are looking to launch a new product in several countries simultaneously, as it reduces drug registration costs and approval times. Since January 1, 2009, one of the main aims of the ACCSQ-PPWG has been to create a harmonized scheme among ASEAN member states to standardize and regulate the production and distribution of pharmaceuticals. The convergence of standards and regulations aims to ensure the free flow of cheap, quality, safe medicinal drugs in the region, through the reduction of trade barriers and an increase in cooperation between ASEAN members (TIR, 2015). The ASEAN Common Technical Dossier (ACTD) is another important legal instrument as it ensures the homogenization of quality, safety and efficacy of administrative data and product information for pharmaceuticals across the ASEAN region.

Worth mentioning, Thailand has a universal health insurance structure that provides at least basic care to all Thai citizens. This system is divided into three programs: 1) the Civil Servant Medical Benefit Scheme gives approximately 7 million government workers excellent healthcare benefits, 2) the Social Security Scheme covers about 10 million private sector workers and is based on an employer contribution system, and finally, 3) the Universal Coverage Scheme provides free basic healthcare coverage to the remaining 50 million Thais. As a percentage of total government expenditures, the Thai government spends 14% of the budget on healthcare, more than many developed European countries. In addition, hospitals purchase about 75% of all

medicinal drugs fabricated and sold locally in Thailand, usually on the basis of generic tenders or negotiated contracts for brand name pharmaceuticals. Without a doubt, Thailand's pharmaceutical industry is one of the largest and most developed in Southeast Asia, with projections that it will have the eighth largest pharmaceutical market in the Asia Pacific region in 2016 (TIR, 2015). The country's unique universal medical scheme and its position as a hub of regional distribution have formed a highly attractive market. As the Thai population grows, urbanizes, becomes more affluent, ages and is increasingly sedentary, demand for better healthcare will increase. Equally significant, the Thai generic sector is growing, especially in the public sector, where the government has encouraged its use over patented drugs in order to cut costs. For instance, Greater Pharma has recently launched its first generic inhaler drug for the treatment of osteoporosis, making it the first pharmaceutical company in Southeast Asia to manufacture successfully of this drug.

The number of Thai domestic drug companies has been growing quickly over the past decade. The government is now funding more R&D, encouraging the local drug industry to move up the value chain. In 2014, pharmaceutical exports were valued at 13.85 billion baht and were shipped primarily to other Southeast Asian countries like Vietnam, Cambodia, Philippines and Myanmar. The government, with the recent introduction of biotech parks and attractive tax incentives, also promotes biotechnology. Medical tourism is another priority for Thailand. The country annually around 1,500 hospitals see more than 2.1 million foreign patients (TIR, 2015). Although almost 80% of the drug companies operating in Thailand are local companies, imported pharmaceuticals make up a significant portion of the market by value. More than US\$1.1 billion worth of drug products is imported each year. Actually, in 2014, Thailand imported 62.93 billion baht in pharmaceutical products. The major sources of these imports were companies based in Switzerland, United States, France, Germany, Spain, and India, which together accounted for about 44% of all imported drug sales. Prominent foreign pharmaceutical manufacturers and distributors operating in Thailand include Meiji, Baxter, Mega Life sciences, Linaria, Otsuka, Sanofi, Pfizer, Merck, Novartis and GlaxoSmithKline (TIR, 2015). Normally multinational pharmaceutical companies, employ several large Thai CMs either to re-package their imported drugs or to produce locally. Industry experts agree there is room for growth for the Thai

healthcare business when the AEC opens. Apart from hospital services having international standards, Thailand is developing bio-pharmaceutical products and medical devices to reduce reliance on import.

Examining the production chain, the sector is divided into upstream industries, intermediate industries, and downstream industries. For the pharmaceutical market, the upstream segment includes the development of new medicinal drugs or research for curing emerging illnesses. Meanwhile, the midstream segment includes production of active ingredients and requires the use of the latest technology and the input of substantial capital investment. This is done usually through a joint venture. Lastly, the downstream segment includes the production of finished medicines.

With a robust chemicals industry and great biodiversity to support pharmaceutical manufacturing, Thailand provides many benefits for foreign companies looking to fabricate or source their products in Thailand - including a skilled workforce, strong medical training, a friendly regulatory environment and a well-established infrastructure. Thailand has applied for membership in PIC/S, so GMP standards meet international benchmarks. The government also offers incentives like tax holidays and reduced import duties for equipment to foreign pharmaceutical investors.

As Thailand has developed into the medical hub of Asia, its pharmaceutical market also has experienced significant growth. Thailand's cost-effective and high-quality manufacturing base has been a key driver in attracting foreign pharmaceutical companies. In recent years, the increasing numbers of medical tourists, an aging population, and high levels of health awareness among the Thai population have boosted the country's pharmaceutical image. Plus, Thailand currently produces 25 APIs, including sodium chloride, camphor, and menthol. However, most active ingredients are still imported from manufacturers overseas, leaving sizable room for new pharmaceutical investors (TIR, 2015). Moreover, there are no specific laws regulating the conduct of clinical trials in Thailand. A variety of Ministry of Public Health Departments have control over different aspects of clinical trials – the FDA, Department of Medical Services, Department of Communicable Diseases Control, National Sub-Committee of HIV Vaccine, and the Ethical Review Committee (ERC) for Research in Human Subjects (Pacific Bridge Medical, 2014).

2.1.6 Conclusion

The globalization has changed the structure of the world economic. Companies, especially in pharmaceutical industry, were facing unprecedented both internal and external competition. Many challenges of these two industries; Pharmaceutical and Biotechnological companies, are restructuring their supply chains with the aim of reducing costs and maximizing productivity. The consolidation of the industry, resulting from the wave of mergers and acquisitions that has interested the pharmaceutical and biotechnological world, has led many plants to become redundant; many players have productive capacities that exceed the actual demand. The challenge situation has pushed most pharmaceutical companies to outsource by starting with their noncore business functions and products to third-party service or contract manufacturing organization. In these recent two decades, there are many and continuously changes happening in the global pharmaceutical industry. Big pharmaceutical companies more focusing on their core business works: R & D and new drugs synthesis. These require huge funds available and long lead time with them, so instead of investing their own limited capital in manufacturing facilities, pharmaceutical companies prefer outsourcing instead. That cause nowadays' economy outsourcing is very preferable and important in both international and Thai pharmaceutical industry. However, the key success factors are how pharmaceutical companies can find for their strategic partners, and work as strategic fit with their CMs as winning partnership situation and sustainable growth in the final.

2.2 Outsourcing Manufacturing in Pharmaceutical Industry

Globalization has more integrated and interdependent results in current economy world, where business organizations choose to focus or disperse value adding activities around the world, according to potential location advantages (Farrell, 2010). Outsourcing is a common practice among both private and public organizations, and is a major element of the business and supply chain strategy. It is also, as described by Harland et al. (2005), 'Sourcing activities externally that an organization has internal capability to perform'. Outsourcing now is growing at an exponential rate, as the increasingly global marketplace sees an array of competitive factors such as cost, speed,

quality, volume, flexibility and innovation becoming increasingly important, leading companies to move from transactional outsourcing to using more strategic outsourcing as a means of achieving competitive success. The process of outsourcing can be looked upon as a strategic move among businesses (Soriano-Meier et al., 2012).

Nowadays, most manufacturing companies attempt to innovative and speed up their value chains by offering new more products and fast services to markets, that cause service based manufacturing is an increasingly popular concept in literature (Baines et al., 2009; Lay et al., 2010; Martinez et al., 2010; Neely, 2008; Smith et al., 2014; Vandermerwe & Rada, 1988; Wilkinson et al., 2009; Zhen, 2012). In this kind of scenario (service based manufacturing), the manufacturer and supplier relationship does not practice by traditional customer- supplier relationship (Festel et al., 2014). The new relationship followed by customer needs to add more values to the product via design, innovation, marketing, and branding, and manufacturing service provider takes responsibility and focuses on the manufacturing response to customization and speed to market. Schönsleben (2007) highlighted the transformation of supply chain with this dynamic character in the customer-supplier relationship into a strategic partnership, according to five characteristics: quality, costs, delivery, flexibility, and co-operation in the supply chain network.

In this recent decade, global pharmaceutical production and consumption are still unevenly dispersed with highly innovative, although imitation, marketing and price competition (Malerba & Orsenigo, 2015). The strategic outsourcing has assumed an increasingly important role in the operations of established as well as emerging pharmaceutical companies (Lowman et al. 2012).

According to this section, the researcher presents the review in seven sub-topics, therefore, consists of 2.2.1) overview of supply chain management (SCM), 2.2.2) pharmaceutical supply chains, 2.2.3) outsourcing background, 2.2.4) outsourcing in the pharmaceutical industry, 2.2.5) existing situation of pharmaceutical outsourcing in Thai and foreign countries, 2.2.6) empirical research using strategic fit for outsourcing in supply chain management (SCM), and 2.2.7) conclusion, as follows:

2.2.1 Overview of Supply Chain Management (SCM)

A supply chain may be defined as an integrated process where several business entities work together to produce goods, services, etc. Christopher (1998) gave the definition of SC as a network of various organizations involved both through upstream and downstream linkages in different kinds of activities and processes. SC also was defined, described by Chopra & Meindl (2010), as networks, which fulfill a business task more efficient than a single enterprise by concentrating on the core competences of every supply chain partner. In another view, a supply chain could be 'owned' by one large company with several sites, often located in different countries. So, planning and coordinating the materials and information flowed within such a worldwide operating company could be still a challenging task. Meanwhile, Stadler (2004) summed up the many definitions of SCM by various researchers as 'the task of integrating organizational units along a supply chain and coordinating materials, information and financial flows in order to fulfill customer demands with the aim of improving competitiveness of the supply chain as a whole, for final could create products or services value to end user'.

The key elements of SCM from these definitions were therefore the upstream parties, the downstream parties and the integration of all the organizations involved, together with the internal function of an organization itself. The upstream parties as been described by Handfield & Nichols (1999) consisted of an organization's functions, processes and network of suppliers, while the downstream function on the other hand concerned the distribution channels, processes and functions where the product passed through to the end customer. SCM also deal with the integration of business processes from end customer through original suppliers that provide products, services, and information that add value for customers (Cooper et al., 1997).

De Kok & Graves (2003) concluded that SCM was a very broad area and had been studied by different disciplines. In general, its problems could be divided into three categories:

- *Supply chain design*, which deal with long-term strategic decisions, such as the decision on the production location, and the distribution channels.
- *Supply chain coordination*, which deal with medium-term decisions on the contract design, information sharing, and collaboration between supply chain partners.

- *Supply chain operations*, which deal with short-term decisions with respect to matching demand and supply. The focus was on releasing and allocating materials and resources within the supply chain to meet customer demands.

For more understanding of configuration components of strategic SCM, Cohen & Roussel (2004) explained the five critical strategic components are; operations strategy, outsourcing strategy, channel strategy, customer service strategy and asset network. However, until now, each company address what and how to implement these strategic components as part or whole of its functional strategy related to sales, purchasing, or manufacturing ,which is critical for company's competitiveness and survival (Samad & Nor, 2015). Most companies accept that supply chain optimization is an excellent way to increase profit margins and is also becoming current practice in all area of business; include pharmaceutical industry as well (Sousa et al., 2011).In terms of the benefit from employing strategic analysis in supply chain, the research from He & Wong (2014) found the significance of Haier's strategic analysis was the one of strategic issues of the Chinese Multinational Corporation (MNC) in providing the global investors an accuracy of investment decision making.

2.2.2 Pharmaceutical Supply Chains

In pharmaceutical industry, the key objective of the pharmaceutical supply chain is to provide sufficient drugs and medicines for the population. There are several reasons for pharmaceutical products shortages, but the highest problems came from manufacturing. That causes, pharmaceutical manufacturer plays as one of the key actors in pharmaceutical supply chain (Pedroso & Nakano, 2009), who directly associate with material (medical), suppliers, wholesalers, order distributors (3PLs), competitors, customers (hospitals and physicians), academia (university and research institutions), government, and regulatory institutions.

So, supply chain collaboration by creation of strategic alliance can be driven by motivations of cost-reduction, supply chain flexibility, sustainability, and future opportunity. For increasing competition, pharmaceutical supply chain had become lean and highly complex. Characteristics of these supply chains need optimized flow of goods, liquidity and information, include high capacity utilization and minimized total lead times. (Blackhurst et al., 2005; Christopher & Peck, 2004; Ewers & Mohr,

2010). There are normally four stages in business manufacturing products: discovery research; developmental trial; production; and market access & commercialize (Howells et al., 2008), as shown in Figure 2.1

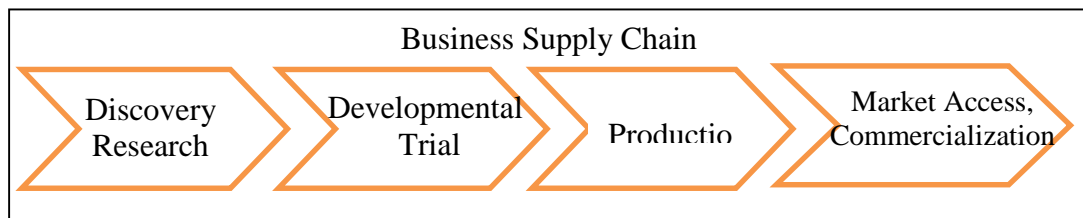


Figure 2.1: Four stages of business supply chain process

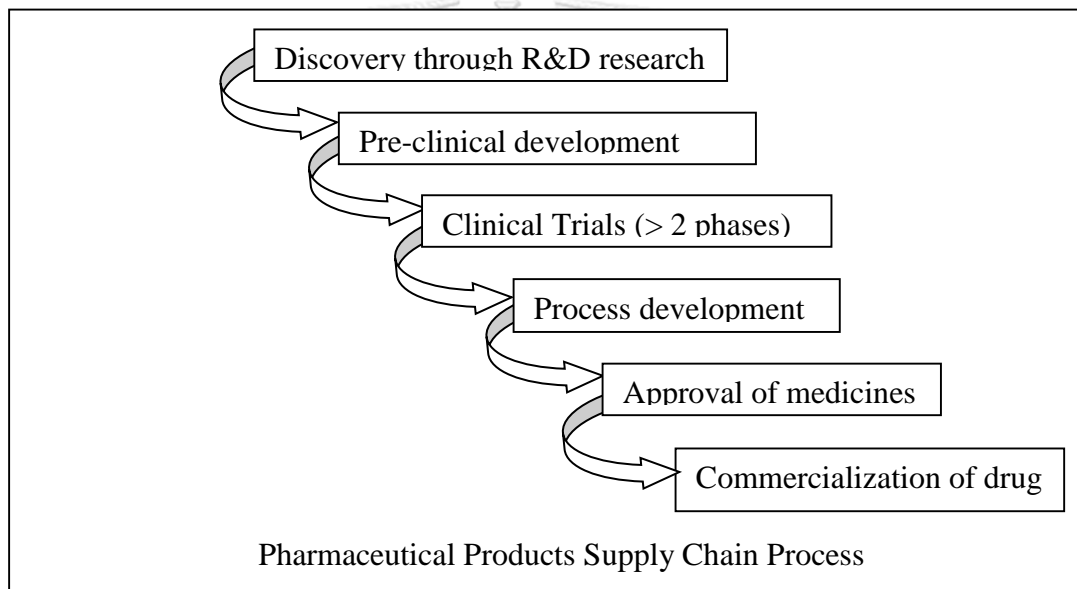


Figure 2.2: Six stages of pharmaceutical supply chain process

After many years of recorded growth and profitability, the pharmaceutical industry is quite challenging. As a result, to remain viable they are looking toward new business model to improve their pharmaceutical supply chains and total costs (Chris, et al., 2009). According to Cohen & Roussel (2004), there are five critical strategic managements in supply chain management. They are; operations strategy, outsourcing strategy, channel strategy, customer service strategy and asset network. The increasingly global nature of the pharmaceutical/biotech industry endorses **outsourcing strategy**, among these five strategies, as the most tend to exploit the market by gaining highly competitive advantage.

2.2.3 Outsourcing Background

Definition: Outsourcing has been defined by Chase et al. (2004) as an '*act of moving some of a firm's internal activities and decision responsibilities to outside providers*'. According to Gnuschke et al. (2004), "outsourcing occurs when an organization transfers some of its tasks to an outside supplier and offshore outsourcing occurs when these tasks are transferred to other countries". Then after, it refers to assigning an individual or a specific project, task or area of responsibility to a source, which is not a direct part of the organization. The third-party unit can be a contractor, development house or a specialized firm. "Outsourcing is the process of establishing and managing a contractual relationship with an external supplier for the provision of capacity that has previously been provided in-house" (Momme & Hvolby, 2001). Perunović & Pedersen (2007) have designed a framework to facilitate the understanding of the outsourcing process. In their framework, they also have grouped and shown the various stages that the outsourcing process consists of a sequence of stages such as: preparation, vendor selection, transition, managing relationship and reconsideration. Their contention is also related to the complex process of outsourcing too.

Evolution: The concept of outsourcing was initiated in 1950s (Dibbern et al., 2004). Hätönen & Eriksson (2009) studied and identified for the evolution of outsourcing, as three era (broad waves): (1) the era of the Big Bang (1950s -1980s), for the organizational practicality. It was quite noteworthy to say that, during this wave, companies outsourced noncore business processes basically to cut operational costs (Corbett, 2004); (2) The era of the Bandwagon (1990s), the sole motive of outsourcing was not to achieve cost efficiency anymore, but to seek external skills, competences and knowledge to provide value to more complex and strategically important organizational processes (Lacity & Hirschheim, 1993); and (3) the era of Barrierless Organizations, the popularity of outsourcing had led to the situation where outsourcing as such no more was a competitive differentiator; it had become a norm rather than an exception (Lawton & Michaels, 2001). Outsourcing has evolved to a stage where companies can achieve operational flexibility without incurring the costs associated with bureaucracy.

Outsourcing is a broad phenomenon and a form of strategic alliance which can cover many areas and industries, but it is not simple or easy to create, develop, and support (Zineldin & Bredenlow, 2003). Kavčič (2014) defined Outsourcing as a strategy for managing company complexity, in which a company outsources some of its activities, which could also be carried out by the outsourcing company, by more or less preserving its core competences.

Strategic outsourcing is the process of engaging the services of a provider to manage essential tasks that would otherwise be managed by in-house personnel. This is often done to allow a business to arrange the use of its assets to best advantage, and allow the company to move closer to the achievement of its goals. An outsourcing strategy normally helps to reduce the cost of operations as well as allow available resources to be allocated to the other necessary functions that are still managed within the organization proper. In the last few years, a number of researchers analyze and explore outsourcing in various industries (Boulaksil & Fransoo, 2007). Strategic outsourcing also has assumed an increasingly important role in the operations of established as well as emerging pharmaceutical companies (Lowman et al., 2012).

Motivation: For customers (outsourcers) perspective, the motivations for outsourcing were evolving from a primary focus on cost reduction, or reducing operating cost to an emerging emphasis on improving business performance d (DiRomaulda & Gurbaxani, 1998; Robert et al., 2013). Such cost reduction aimed to improve productivity, higher quality, higher customer satisfaction, time to market, and ability to focus on their core areas (Dhar & Balakrishnan, 2006), and in short, to increase the market share (Kotabe et al., 2011). For opposite view, outsourcing from suppliers perspective, aimed to move away from a commodity product market to products that customers were willing to pay a higher price for, and also build stronger relationships with their customers (Nordigarden, 2015).

Another outsourcing motivation focused for huge gains in efficiency, productivity, quality and revenues. An argument for this motivation was the realization that outsourcing for cost saving yielded but a quick and short-lived “fit”, why the available benefits lied in the opportunity obtained from the complex process of outsourcing (Alon et al., 2007). He et al. (2011) further extended this focus to include the firm internal capabilities to explore multiple options of production quickly and

efficiently, to increase primarily volume driven in the saving amount of time and efforts, to ensure product quality within the timeline, to establish a longer relationship with client companies and partnership with outsourcing firms, and to maximize the possibility of success. A significant consideration concerning outsourcing motivation, the companies had to play great attention on what a dual outcome of outsourcing. Although companies might be able to increase their market share as a result of outsourcing, however market share also decreased as a consequence of further outsourcing, implying that there had been a negatively curvilinear relationship between outsourcing and market share (Kotabe et al., 2011). In other words, the companies had to plan carefully and make sure for optimum outsourcing strategies in order to get the maximum benefits from their outsourcing investments.

In summary, the researcher concluded that the outsourcing motivations focused primarily on cost reduction or saving, and secondly on enormous gain from the complex outsourcing process. Whereas the first motivation was criticized as a quick and short-lived benefit and “fit”, the second one was also criticized as a dual outcome: both positive and negative benefits; and the efficient outsourcing strategies were significant and implemented with caution.

Advantages: The benefits as cost-reduction often were ascribed to outsourcing, inherent challenges exist even to gain such a benefit. Despite the number of organizations that consider themselves to be successful at global outsourcing, the need continues to further identify, comprehend, and manage the risk factors that underlie both the outsourcing process and the realities of doing business in international locations (Elmuti & Kathawala, 2000). Festel et al. (2014) explored that the main advantages from outsourcing were costs reduction of and better allocation of resources in a project with variable demand, access to specific technology, expertise or skills either not present internally or less expensive, and quicker than the internal alternative, greater flexibility, better management or spread of risk and freedom to concentrate on core functions. Jiang & Qureshi (2006) identified expected benefits of outsourcing and sort them loss some of quality and regulatory compliance control greater difficulty of co-ordination and management of external collaborations and contracts, less transparency (e.g. problems of evaluating and monitoring supplier performance), time taken to negotiate contracts, difficulties in agreeing on ownership or splitting of

intellectual property rights, instability risks in case the external party became financially insolvent, merged or was acquired and generally dependent on the supplier (Bath,2003; Linna et al., 2008).

Table 2.2: Expected advantages regarding to short & long-term company policy

The period of current policy	The period of fundamental policy
<ul style="list-style-type: none"> - Reduction, control over direct expenses - Reduced need for investments in non-strategic business functions. - Sale of equipment to outsourcee. - The enterprise does not have the necessary_resources - The function is difficult to manage and control 	<ul style="list-style-type: none"> - The possibility for increased business focus - Access to the best capabilities - Benefits stemming from accelerated renewal - Shared risk. - Release of resources for other purposes

Notes: Modified from Kavčič (2014, 23)

Disadvantage: Risks may exist in any outsourcing activities. As the modalities for the creative arbitrage of labor, the major wage gap that existed between developing and industrialized nations had expanded within a global environment, an additional priority was added: understanding the business and technological intricacies associated with specific location. Nordigarden (2015) recommended for practitioners to investigate in depth what new competencies were required before entering into an outsourcing agreement. It was critical that the manufacturing taken over was profitable in itself, and that the costs arise were covered by the revenues of the components delivered. To achieve this, it was important to capture the values that customers had failed to achieve, which could also mean taking an investment risk.

Decision making: The ability to make successful outsourcing decisions depends on various factors and considerations. There are two forms of outsourcing decisions that form the basis for long-term or short-term benefits to the firm. These, according to (Soriano-Meier et al., 2012) are as follow:

- Strategic outsourcing

It is based upon a strategic decision of the firm, the firm decides if it wants to make or buy a type of product. If the decision is to buy the product or service then it closes the facilities that currently produce those products. This shows the importance

of the strategic decision of closing down its production facilities, left with no other option than trusting an external supplier for its production.

- Tactical outsourcing

It is based on a tactical decision of the firm, the firm decides if it wants to make or buy a specific part to manufacture the product in-house. It is nearly possible that a series of tactical decisions may lead to a strategic outsourcing decision. A tactical decision is looked upon as an experimental stage of trial and errors in certain particular cases. The buyer-supplier relationship formed during a tactical decision is completely different to the one formed during the strategic decision-making process. A tactical outsourcing decision may always be perceived as short term association.

Contract manufacturing: can be characterized as a supply chain arrangement that allows a manufacturing company to outsource some of its internal manufacturing processes, e.g., assembly operations to CMs (Kim, 2003). While contract manufacturing was initially a top-gap arrangement that firms employed to meet demand when internal manufacturing capacity was insufficient (Carbone, 2000; Gregory, 1995; Harrington, 2000; Kador, 2001), it is now seen as shedding activities once considered strategic to focus their efforts and resources on core competencies in pursuit of sustainable competitive advantage (Kroes & Ghosh, 2010).

2.2.4 Outsourcing in the Pharmaceutical Industry

In pharmaceutical industry, CMs can provide a relief valve from market pressures such as patent expiration and the demand for generics, discovering off-label uses for current formulas, pressure to speed up clinical trials, or keeping abreast on the development of new processes (Lad et al., 2012). Since 1980s, Contract research and manufacturing services (CRAMs) had emerged and became one of the fastest growing sectors in pharmaceutical and biotechnology industry. The pharmaceutical market used outsourcing services from low cost providers in the form of CROs and CMOs (Reddy et al., 2013).

The global contract manufacturing market for the pharmaceutical sector is forecasted to increase at a rate of 8% per year and to exceed \$26 billion by 2011 (*Corporate Catalyst India*, 2011) There has been an impact that is unique, innovative, and state-of-the-art processes and production technologies, which have been offered by

CMOs in 761 scripting the success story of the pharmaceutical industry (Scott, 2006). The manufacturers need to bear in mind the need for huge investments in procuring modern technologies and resorting to new practices if they do not favor outsourcing. Although cost is an important driver (Copestake, 2006; Jiang & Qureshi, 2006; Lau & Zhang, 2006), it is not the only one. In addition to cost and capacity issues, the academic literature also mentions other important factors (i.e. key drivers) that influence organizations to outsource. These include fast cycle development, expertise, technology and performance.

According to Jiang & Qureshi (2006) the following are the reasons why pharmaceutical companies must resort to outsourcing.

- ***Cost savings and cost restructuring:*** Outsourcing transfers the balance of fixed costs to variable costs. Additionally, the overall costs can be lowered by selecting low cost economies, such as China and India as offshore locations for outsourcing (Jiang & Qureshi, 2006; Power et al., 2004)

- ***Reduced time for product marketing:*** Outsourcing enables to reduce the total time allotted to a project for developing or manufacturing drug substances. This in turn shortens the time to market the product. This is translated to quicker income and long duration of patent life. Consequently, the company develops the capacity to introduce new products into the market.

- ***Flexibilities:*** Outsourcing renders flexibility to the outsourcing firm. The outsourcing firm can make strategies to lower company expenditure by reducing fixed costs and modifying capacities.

- ***New Technologies:*** With outsourcing, a company can gain access to technology. Owning complex, new technology may not be feasible. On the other hand, outsourcing provides access to this technology on a need basis thereby imparting organizational flexibility.

- ***Skills, knowledge and operational expertise:*** Outsourcing gives access to external intellectual property rights, a larger talent pool and a sustainable source of skills that would be too difficult to gain or time consuming to develop in-house.

- ***Contract:*** Outsourcing services will be contractual and legally binding in nature, accompanied with financial penalties and legal regress.

The main reasons to outsource in the pharmaceutical industry, as suggested by both CPs and CMs, were found to be (1) cost reduction, (2) flexibility, (3) technology transfer, (4) fast product development, and (5) expertise acquisition. To be able to focus on core competences and executing an expansion plan are the two benefits that created a difference in opinion, as stated by CPs and CMs. Focusing on core competences is said to be one of the important advantages. Although cost is an important driver, it is not the only driver (Ernst & Young, 2010; Lau & Zhang, 2006; Power et al., 2004). The outsourcing expectations are directly linked to the reasons for outsourcing. The findings indicate that the CMs know exactly what the needs of the CPs are and thus they try to fulfill all their objectives. Hence, it is not about manufacturing at low cost, but there are other aspects attached to it as well (Lau & Zhang, 2006). The making or buying criteria according to the respondents were either a strategic development or future plan of expansion. Both the CPs and CMs were reluctant to give an in depth idea of what goes in to making or buying criteria.

2.2.5 Existing Situation of Pharma Outsourcing in Thai & Foreign countries

The global pharmaceutical industry is currently dynamic change, under high pressure to contain costs and risks of market uncertainty management, many big pharmaceutical companies have remodeled their traditional pharmaceutical operations, leading to an increased demand for contract manufacturing of marketed pharmaceuticals since the 1990s (BCC Research Website, 2005; Zhang, 2011), when US & EU pharmaceutical companies faced increased costs resulting from the expiration of many older drug patents, competition from the generic drug industry, and stricter government oversight of new drug development. Contract manufacturing has evolved as one of the integral components of the pharmaceutical market. Started initially as a one-off activity, contract manufacturing has evolved into a dynamic business model, currently most prevalent in manufacturing, outsourcing is steadily spanning the entire pharmaceutical value chain. With CMOs now offering the entire multitude of services from design and discovery to final packaging, the concept of ‘one stop shop’ service provider is gradually gaining pace (Chrai, 2004; Escabar, 2008; Fox, 2004).

The spending on contract services; in process of manufacturing, testing, preclinical, clinical, and product development; have also increased steadily since 2002, especially small molecule generic drugs (BCC Research Website, 2005; Zhang, 2011). It is estimated that about a quarter of commercial manufacturing is outsourced, CMOs capture approx. \$64.4bn of the commercial manufacturing market, and it is increase 33% by 2011 for a compound annual growth rate of 6–8% from 2004 to 2011 (BCC Research press release, 2007).

The global CMO sector is experiencing strong demand for both APIs and intermediates of the marketed pharmaceuticals, in particular, generic drugs. Moreover, as more pharmaceutical companies now pursue personalized, it is expected the demand for related outsourcing services will become stronger in the future. Meanwhile, as pharmaceutical companies of all sizes are gradually increasing their focus on biologic drugs, the outsourcing demand for biopharmaceutical products is also rapidly growing (Zhang, 2011). As the CMOs are the critical for the marketed products, the decision to outsource manufacturing or development is also complex. Many factors come into concern and consider, such as: internal capacities, financial, and strategic fit. Although abundant information are available online, the networking within the pharmaceutical community still should be key tools in choosing a CMO. Big Pharmaceuticals should consider not only their own needs and what CMs have to offer, but also be aware of constraints that might complicate their choices (Haslam, 2008). For international outsourcing, Big Pharmaceuticals should be more aware of the interactions that may occur between laws of different countries as well as the impact of domestic and foreign regulatory requirements (e.g., import/export), include time, travel costs, cultural differences, and communication barriers (Caplan & Wu, 2003; Chrai, 2004; Escobar, 2008; Fox, 2004; Horn, 2008). Due-diligence auditing will be necessary to thoroughly evaluate these characteristics, particularly in two fastest-growing regions of contract manufacturing in Asia, China and India (Ghosh, 2008; Langer, 2008; Singh et al., 2008), These two countries are leading the pack with huge market growth potential, and also as new power houses for manufacturing and innovation in the biotechnology & pharmaceutical sectors (Calo-Fernandez & Martinez-Hurtado, 2012). US pharma companies began partnering with Indian and Chinese CMOs, because they have highly educated workforces that carry out drug research, development and manufacturing at

lower costs. Industry observers initially predicted that most pharmaceutical contract manufacturing would eventually be done by Indian and Chinese CMOs. However, complaints about rising costs and quality issues connected with Indian and Chinese pharmaceutical CMOs have caused some pharmaceutical companies to stop working with them and sign contracts with CMOs operating in North America and Europe instead. Big Pharmaceuticals could take advantage of in order to expand its presence in China and generally in Asia to ensure a sustainable growth in the upcoming years. A change in one or many of these political, economic, social, technological or environmental factors will definitely affect Big Pharmaceuticals' strategy in the country and on a global level. China also being the first exporter of APIs in the world represents an R&D outsourcing destination of choice, and predicted to be the largest Pharmaceutical market in 2020 (Chitour, 2013).

In the past, Thai contract manufacturing was not an area that interested the local manufacturers due to the propriety of know-how. And most multinationals went directly to the two main international CMs in Thailand; OLIC (now owned by Fuji Pharma) and Interthai Pharmaceutical Manufacturing (under F.E. Zuellig Group); with two reasons, firstly, the confidentiality agreements were very tight for the Thai local companies, and secondly, Thai contractors were not feeling comfortable. However, local CMs have been growing very fast for the last 5 years, as they can produce drugs much cheaper and the market has started to shift in favor of any company that gives the lowest price. Today, the situation is different and contract manufacturing is viewed as an enormous opportunity with the opening of the ASEAN market. It means much more investment will flow into Thailand as pharmaceutical companies can export throughout the ASEAN region. As a result, interest in contract manufacturing has been expressed not only by local pharmaceutical industry but also by multinationals that are re-considering their own investments in ASEAN. Opportunities are emerging, and the Board of Investment (BOI) now is making an effort to invite multinational pharmaceutical companies to invest in Thailand (TIR, 2015).

2.2.6 Empirical research using Strategic Fit for Outsourcing in SCM

From literature review, the researcher identified related four research articles pertaining to an application of strategic fit for outsourcing in supply chain management.

Those four papers are Dibbern et al. (2012), Silvius et al. (2013), Hansson & Jansson (2013), and Festel et al. (2014), the brief summary of which are as follows:

-The first one by Dibbern et al. (2012) on “Systemic determinants of the information systems outsourcing decision: A comparative study of German and United States firms”

The practice of information systems (IS) outsourcing is widely established among organizations. Nonetheless, evidence suggests that organizations differ considerably in the extent to which they deploy IS outsourcing.

This variation has motivated research into the determinants of the IS outsourcing decision. Most of this research is based on the assumption that a decision on the outsourcing of a particular IS function is made independently of other IS functions. This modular view ignores the systemic nature of the IS function, which posits that IS effectiveness depends on how the various IS functions work together effectively.

This study proposes that systemic influences are important criteria in evaluating the outsourcing option. It further proposes that the recognition of systemic influences in outsourcing decisions is culturally sensitive. Specifically, we provide evidence that systemic effects are factored into the IS outsourcing decision differently in more individualist cultures than in collectivist ones. Our results of a survey of United States and German firms indicate that perceived in-house advantages in the systemic impact of an IS function are, indeed, a significant determinant of IS outsourcing in a moderately individualist country (i.e., Germany), whereas insignificant in a strongly individualist country (i.e., the United States). The country differences are even stronger with regard to perceived in-house advantages in the systemic view of IS professionals. In fact, the direction of this impact is reversed in the United States sample. Other IS outsourcing determinants that were included as controls, such as cost efficiency, did not show significant country differences.

-The second one by Silvius et al. (2013) “The relationship between IT outsourcing and business and IT alignment: an Explorative Study”

Outsourcing of business processes and information technology (IT) operations is an important trend in large and middle sized organizations. However, outsourcing could affect the organization’s ability to align its IT with business strategy and operations.

This article reports a qualitative study into the relationship between IT outsourcing and business and IT alignment. It aims to provide recommendations for outsourcers and service providers on how outsourcing relationships should develop in order to support business and IT alignment.

The research question of the study is “What is the effect of IT outsourcing on the business and IT alignment of companies that have outsourced their IT?” After a review of relevant literature and concepts, four cases are reported. The study revealed that a higher level of motivation for outsourcing paired with a higher level of the relationship between outsourcer and service provider and with a higher level of alignment maturity of the outsourcer.

The study also showed that the information technology outsourcing relationship is influenced by organizational turbulence on one or either side of the relationship and that the service providers tend to assess the relationship on a higher level than the outsourcers. These conclusions provide relevant directions for both outsourcers and service providers for improvement of their relationship.

-The third one by Hansson & Jansson (2013) “Exploring Trust and Commitment in Inter-firm Relationships when Outsourcing R&D”

The Swedish pharmaceutical industry is going through structural changes due to the increased cost of drug development. This has led pharmaceutical companies to outsource clinical trials to CROs.

This thesis explores the inter-firm relationships between pharmaceutical firms and CROs in the Stockholm area, with focus on the development of trust and commitment. The empirical material gathered from nine qualitative interviews with representatives from both parties suggests that trust and commitment are both important factors. Trust is based on competence and reputation whilst commitment is developed through communication. Commitment is highly valued by the companies that wished to develop long-term relationships. The results also point to challenges in the area mainly regarding patient recruitment that due to the high competition amongst the CROs can lead to opportunism when they are overly optimistic of what they can deliver. This is an issue that needs to be addressed as it affects the whole industry.

-The forth one by Festel et al. (2014) “Outsourcing of pharmaceutical manufacturing – A strategic partner selection process”

The pharmaceutical industry is a growing industry, but companies struggle to capitalize on this growth because of a variety of challenges: shortening patent lives, strong pressure on prices, strict regulations, and the shifting of growth to emerging countries. Outsourcing of manufacturing is increasingly seen as a way to reduce operating costs and improve competitiveness. But external manufacturing is moving away from a purely opportunistic approach of transferring overcapacity to external partners or outsourcing of manufacturing to low-cost countries to reduce costs towards a more strategic approach, where external service providers are seen as partners. The ability to establish and manage strategic partnerships is seen as a key competence.

This paper addresses this aspect and focuses on strategic partnerships to increase competitiveness of large pharmaceutical companies by outsourcing activities from chemical production through partly finished products to finished goods packaging. An action research approach was used based on a single case study of a global leading pharmaceutical company. A partner selection process consisting of seven consecutive steps, including the criteria for the partner selection, was developed for pharmaceutical companies with their highly regulated, quality focused manufacturing processes and history of vertically integrated production. It was also shown that, besides having the right process in place, the appropriate organizational structure has to be established.

From the four articles above, the researcher plan to use the model presented by Dibbern et al. (2012), and the case study method conducted by Festel et al. (2014) in studying the selection process of the outsourcing partner, and use the empirical causal studies conducted by Silvius et al. (2013), and Hansson & Jansson (2013). The method in details will be presented in the data collection topic in the research methods.

2.2.7 Conclusion

In summary, the researcher conclude that the outsourcing motivations focus primarily on cost reduction or saving, and secondly on enormous gain from the complex outsourcing process. Whereas the first motivation is criticized as a quick and short-lived benefit and “fit”, the second one was also criticized as a dual outcome: both

positive and negative benefits and the efficient outsourcing strategies were significant and implemented with caution.

In recent decade, the contract manufacturing sector of the pharmaceutical industry has matured to the point where outsourcing manufacturing is a viable option for most products. As a result, the “make vs. buy” decision is a relevant decision for a large percentage of products and, increasingly, for firms of all sizes. Manufacturing outsourcing is a key industry trend towards greater operational efficiency and is related to the discussion of strategic core competencies. An important area is the outsourcing of the production of active ingredients. Most pharmaceutical products involve primary active ingredient production, and secondary (formulation) production. Both of these stages are characterized by low manufacturing velocities and are hampered by the need for quality assurance activities at several points. The researcher studies the issue of contract manufacturing at the strategic-tactical level and approach the topic from a multi-criteria decision-making perspective, since service, cost, quality, and more long-term value-related aspects are involved.

Finally, there is a broad opening to conduct future research on the related topic of strategic fit for outsourcing manufacturing in pharmaceutical industry. In particular, there is scope of future research to perform qualitative and quantitative research with facts and figures. It can be interesting to see the effects of outsourcing on the overall performance (i.e. measuring the performance of outsourcing so as to determine the effectiveness of the outsourcing decision). Also, there is opportunity to investigate the social side of outsourcing, for example, what goes into building a successful outsourcing relationship or partnership. A study how about outsourcing can lead to sustainable and win-win relationship between the CMs and the CPs.

2.3 Strategic Fit for Outsourcing Manufacturing in Pharmaceutical Industry

As industry complexity is increasing and customers demand full solutions rather than individual products or services, the inter-company collaboration has consequently become a crucial component in the pursuit of company competitive advantage. Strategic arrangements are complex to manage successfully, partly because of the difficulty of matching the goals and aspirations of autonomous organizations or

alliances, and partly because of so many flexible alternatives that the company has to make a precise and optimal decision. According to Nielsen (2010), the good intentions and rational motives behind these alliances are often not congruent with the strategic direction of either company on its own, let alone the strategic direction of both in unison. Consequently, alliances often exhibit instability and poor performance. Alliances are cooperative agreements between companies in which partners may contribute capital, technology or other company specific resources and capabilities. Due to heightened competitive and uncertain business environment, many companies have formed alliances to survive. Researchers argue that the success of alliances stems from each partner's ability to match, or strategic fit (Hofer & Schendel, 1978; Zajac et al., 2000).

Strategic fit is a core concept in normative models of strategy formulation (Hofer & Schendel, 1978; Zajac et al., 2000). Strategic fit also implies the efficiency with which organizational resources and capabilities are aligned with the complementary resources and capabilities that an alliance brings. Specifically, in alliances, co-alignment posits higher effectiveness (performance) for organizations that have reconciled the competing needs of the partnering companies (Das & Teng, 1997). Zaman & Mavondo (2008) also suggested that there must be a certain degree of 'fit' between the partners, which in turn increases the probability of achieving positive alliance outcomes.

Regarding the strategic fit process, Dess & Lumpkin (2013) asserted that the process involved management of all other internal elements within an organization to ensure that the implementation process was successful. Strategic fit had been conceptualized in various ways. The relationships here were causal ones in which the strategies must match with the external conditions if the company was to survive and gain a competitive advantage (Porter, 1980, 1985). Therefore, strategic fit could be one of the major key successful factors for a company's success. Waterman (1982) argued that the possibility of successfully executing a strategy depends on the interaction among elements among elements in the McKinsey 7-S framework: strategy, structure, systems, skills, staff, style and shared values. In addition, the congruence among internal organizational elements should be reached if the organization was to achieve competitive advantage (D'Aveni et al., 2004). Hitt et al. (2000), proposed the notion of

strategic fit, based on many studies in examining the co-alignment of (a) partner characteristics, (b) alliance relationship management, (c) organizational capabilities and their relationship to (d) alliance success, in selection of an appropriate partner which had been a very critical decision in an alliance engagement.

There are many pieces of previous research papers about strategic fit, such as: Das & Teng, 1997; Dess & Lumpkin, 2013; Zajac, et al., 2000; Zaman & Mavondo, 2008. The researcher, therefore, collects, analyzes, synthesizes and presents this topic review in five sub-topics of: 2.3.1) conceptualization of strategic fit, 2.3.2 the role and the importance of strategic fit, 2.3.3) strategic fit for outsourcing supply chain, 2.3.4) strategic fit for pharmaceutical industry, and 2.3.5) conclusion, as follows:

2.3.1 Conceptualization of Strategic Fit

Strategic fit, being referred to as congruency, contingency, matching or co-alignment, is an important emerging concept both in strategic management and strategic marketing research (Venkatraman, 1989; Vohries & Morgan, 2003; Xu et al., 2006). Strategic fit is a notion that asserts the environment and organizational strategy interact in a dynamic co-alignment process and a match between them. The results suggest that coaligning or reconciling the alliance attributes such as *partner characteristics, relationship management and organizational capabilities* have considerable influence on alliance success and that the fit model is significantly superior to a direct effect model (Zaman & Mavondo, 2008).

The important and key nature of strategic fit conceptualization, consist of four topics, therefore: a) definition; b) dimension; c) approach; and d) perspective of strategic fit, as follows.

a) Definition: There were several definitions of strategic fit in different context. In term of general context, Venkatraman (1989) defined strategic fit as the match between related variables. According to Ensign (2001), strategic fit was an internal consistency or alignment; and it had also been defined as an important building block in the development of strategic management theory (Drazin & Van De Ven, 1985). In conclusion, strategic fit had been a core concept in normative models of strategy formulation (Hofer & Schendel, 1978; Zajac et al., 2000).

b) Dimension: The level of strategic fit of an operation had two different dimensions (Miller, 1992; Ruffini et al., 2000), as follows:

(1) **External Fit:** Consistency between the competitive configuration in the market and the operations processes and infrastructure in the business.

(2) **Internal Fit:** Consistency between the operations strategy and the overall business strategy; consistency with the other functions in the company; and consistency between the constituent elements and processes of the operations system.

As per Boyer & McDermott (1999) comment: For a strategy to be effective it must not only be appropriate (i.e. be well-fitted to its competitive environment), but it also must be communicated and widely understood throughout the organization. Smith & Reece (1999) supported this view and stated: Although less advanced than the field of general strategy, researchers in operations strategy had also noted the distinction between external and internal fit. For building on this work, strategic fit was seen to exist in the following situations:

- External strategic fit exists when the actions and interests of all company employees are focused on key goals (Robinson & Stern, 1998).

- Internal strategic fit exists when employees from different levels and functions within an organization agree on what is most important for the organization to succeed.

An assessment of the level of internal strategic fit within a service operation could be made by reviewing the level of agreement across various functions and levels of employees and processes within an organization (Boyer & McDermott, 1999). The functions to be reviewed were those that assist operations in supporting the market served by the business such as marketing, sales and customer service. Two seminal works in same context were the internal fit between a firm's strategy and structure, and Lawrence & Lorsch (1967) on external fit, the cornerstone of what had also become known as "contingency theory."

c) Approaches: Considering the approach, Dess & Lumpkin (2013) asserted that the strategic fit process involved management of all other internal elements within an organization to ensure that the implementation process was successful. Strategic fit had been conceptualized in various ways. The relationships here were causal ones in which the strategies must match with the external conditions if the firm was to survive and gained a competitive advantage (Porter, 1980, 1985).

Drazine & Van De Ven (1985) had examined fit through three different approaches along the management process as follows: selection, interaction and systems. In the Selection Approach, fit was interpreted as an assumed premise underlying congruence between context and structure without looking into the impact of context. In the Interaction Approach, fit was understood as an interaction effect of organizational context and structure on performance. The last, Systems Approach, defined fit as the internal consistency of multiple contingencies and multiple structural characteristics that had performance effects.

d) Perspectives: Bergeron et al. (2001) and Venkatraman (1989) proposed six perspectives of fit; moderation, mediation, matching, covariation, profile deviation, and gestalts. Based upon function functional form as follows, they described each perspective along the three dimensions of a) the degree of specificity of the functional form of fit, b) the number of variables in the equation, and c) the presence- or absence- of a criterion variable, including its particular conceptualization of fit. The corresponding verbalization of hypothesized relationships and the appropriate analytical schemes for testing the relationships of these **six types of fit** were as follows:

(1) Fit as moderation

The moderation perspective posited the existence of a moderating factor (production strategy) having effect on the effect between antecedent (firm strategy) and outcome variable (firm success). In other words, the interactive effect of the firm strategy and its production strategy would have implications on firm success (Bergeron, et al., 2001; Venkatraman, 1989). In this criterion-specific perspective, as shown in Figure 2.3 (along with the other five), fit was conceptualized as the interaction between two variables: firm strategy and production strategy, on the outcome-firm success. When this perspective of fit was adopted, regression analysis, with interaction terms, was the appropriate testing technique. Moderation perspective in contingency theorists asserted that an interaction existed between two variables which predict a third variable. The basic notion of moderation perspective was: there was no universally superior strategy and that the impact of the predictor variable (firm success), strategy orientation/strategic fit on the criterion variable (firm performance) was dependent on the level of a third variable (production strategy) implementation practices. This perspective was relevant because most studies on strategic fit (Loius & Francois, 2007;

Xu, et al., 2006; Yin & Zajac, 2004) reviewed above, revealed mixed results. The third variable could therefore be relevant to performance.

(2) *Fit as mediation*

The mediation perspective posited the existence of an intervening factor (production strategy) between antecedent (firm strategy) and outcome variable (firm success). This criterion-specific perspective adopted a conceptualization based on intervention or mediation. It implied that there existed an intervening variable between one or several antecedent variables and the consequent variable. In Figure 2.4, the corresponding mediating effect of production strategy between the antecedent of firm strategy and the outcome of firm success, indicating that there were both direct effect and indirect effect of firm strategy via production strategy on the firm success. Complete mediation was obtained when the main direct effect of firm strategy on the firm success was not significant, whereas an indirect effect via mediator of production strategy, must be significant (Venkatraman, 1990). On the other hand, partial mediation was derived when both the main direct and indirect effect are statistically significant. When this perspective of fit was adopted, the appropriate analytical scheme is path analysis or the analysis using structural equation model (SEM).

(3) *Fit as matching*

Venkatraman (1989) explained that the matching perspective was invoked for strategy concepts in which fit was a theoretically defined match between two related variables. In other words, a measure of fit between two variables was developed independent of any performance or outcome. Bergeron et al. (2001) further explained that matching was a departure from the previous two perspectives (moderation and mediation), because fit as matching was specified without reference to a criterion variable, although, subsequently, its effect on a set of criterion variables could be examined. In Figure 2.5, the corresponding matching fit existed when production strategy matches environmental uncertainty (or matches structure, or firm strategy). Whether the match improves firm success would then be tested. Adopting this perspective should be three analytical schemes: deviation score analysis, residual analysis, and analysis of variance.

(4) Fit as covariation

The covariation perspective viewed fit as a pattern of internal consistency among a set of underlying, theoretically related variables, in this case, strategy, structure, and processes. This perspective defined fit as a pattern of covariation or internal consistency among a set of underlying theoretically related variables. In the context of production strategy, it would mean that it was the appropriate co-alignment of environmental uncertainty, structure, firm strategy, and production strategy that would influence firm success, as shown in Figure 2.6. In this perspective, the second-order factor analysis was the appropriate analysis technique for testing the propositions.

(5) Fit as profile deviation

Fit as profile deviation was defined as the internal consistency of multiple contingencies. In this criterion-specific perspective, an ideal profile was assumed to exist, and deviations from this ideal profile should result in lower performance. Venkatraman's graphic representation of fit as profile deviation was reproduced in Figure 2.7. In terms of the research variables of interest in the present study, adopting a profile deviation perspective would imply the following verbalization: the degree of adherence to a specified profile of strategic product strategy, environmental uncertainty, structure, and firm strategy, had a significant effect on firm success. When adopting this perspective, a subsample of high performers was selected from the larger sample. The management profile - in terms of the independent variables under study - of these high performers was estimated. Then, the degree of adherence to the ideal profile was obtained by calculating the Euclidean distance in an n-dimensional space. The profile deviation perspective viewed fit as adherence to an externally specified profile, which was identified as an ideal configuration to implement a strategy (Zajac et al., 2000). Adherence to the ideal profile is expected to be associated with higher performance whereas deviation implies poor performance. This perspective was useful when the focus was on severally closely related variables (Venkatraman, 1989). Since strategic fit, strategy orientation, and strategy implementation were all internally related and controllable by management.

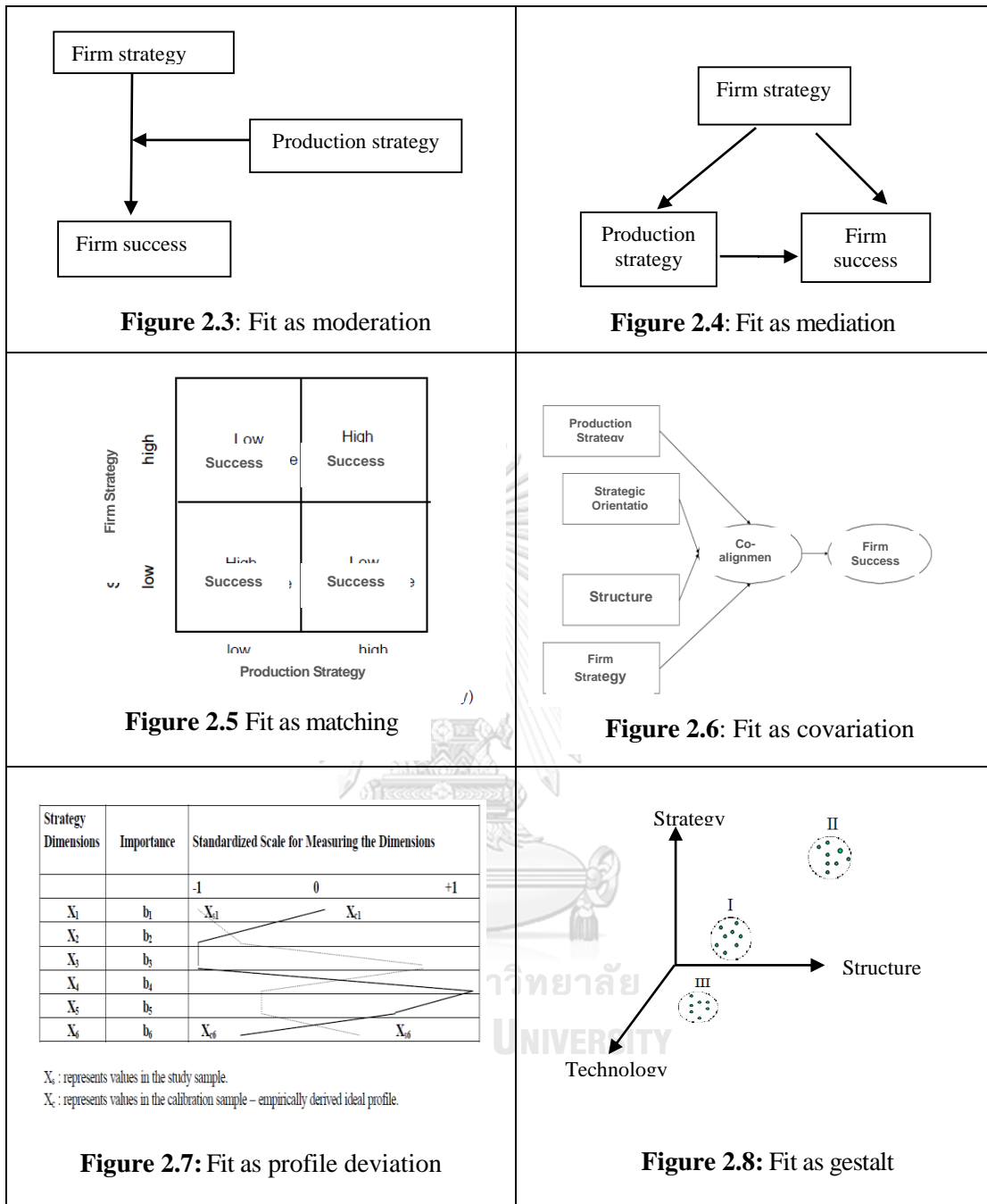
(6) Fit as gestalts

Gestalts perspective stated that when fit was conceptualized and specified using two variables, it was possible for investigators to invoke alternate perspectives that had precise functional forms, as shown in Figure 2.8. However, when many variables were used, the degree of precision must be relaxed. A multivariate perspective was defined as analytical means, in terms of the degree of internal coherence among a set of three theoretical dimensions.

This study from Bergeron, et al. (2001) was the first to encompass the concept of “fit” in empirical strategic IT management research in such a comprehensive, systematic manner. While the relatively low response rate puts some limits on the generalizability of the study, results reinforce Venkatraman’s contention that different conceptualizations, verbalizations, and methods of analysis of fit will lead to different results.

Relative to the theory, the results suggest that neglecting to specify the exact perspective of fit used in earlier studies may have often lead researchers to obtain contradictory, mixed, or inconsistent results. These various perspectives are so singular in their nature, consequences, and explanatory power that they cannot be selected indifferently neither can they simply be labeled as competing theories. The results of this study on the conceptualization and analysis of fit lead us to recommend that future research clearly specify the type of fit examined, i.e., moderation, mediation, matching, covariation, profile deviation, or gestalts. Authors should also theoretically support their choice before conducting their study and discuss the results with respect to the theory and the selected perspective of fit. The results also suggest that a systems perspective of fit is richer and will provide fuller explanation than bivariate approach. As to the choice of a particular systems approach, the profile deviation and covariation perspectives of fit appear to be better suited to theory testing while the gestalts perspective would be more appropriate to theory building (Bergeron et al., 2001).

However, Venkatraman (1989) argued that researchers should either justify their choice of a particular perspective or apply a multiple-method approach because results were sensitive to the selection and a convenient choice might lead to wrong conclusions.



2.3.2 The Role and the Importance of Strategic Fit

Strategic fit is a notion that asserts the environment and organizational strategy interact in a dynamic co-alignment process, and a match between them has significant and positive implications on performance. With respect to alliances, the concept of strategic fit has not previously been empirically examined. Zaman & Mavonda (2008)

studied and suggested that there are three critical decisions for consideration and selection for fitting alliance success depend on each company organization and structure, as follows:

1) Partnership Characteristics and Alliance Success

Selection of an appropriate partner is a very critical decision in an alliance engagement (Hitt et al., 2000). *Goal congruence* is a crucial element which affects the extent to which business orientations, abilities and activities of partners can be integrated successfully (Spekman et.al., 1998).

2) Relationship Management and Alliance Success

Extant literature identifies commitment, cooperation, communication, trust, and conflict management as the key determinants for the development of an effective long term inter-company relationship (Cobianchi, 1994; Cravens et al., 1993; Spekman et al., 1998).

-*Cooperation* offers significant advantages for alliance partners lacking in particular competencies or resources (Dyer & Singh, 1998).

-*Commitment* is a critical element of relationship capital (Madhok & Tallman, 1998). Committed partners are likely to be more cooperative, communicative and flexible and demonstrate persistent willingness to make future relation- specific investments (Anderson & Weitz, 1992).

3) Organizational Capabilities and Alliance Success

Organizational capability is a broad concept with many elements and attributes. Barney (2002) defines organizational capabilities as the firm attributes that enable organizations to coordinate and utilize their resources.

The study implies that higher the degree of co-alignment, the better the alliance performance (Zaman & Mavonda, 2008).

For the importance of strategic fir, Miles and Snow's research (1978) proposed a relatively complex strategic typology interrelating organizational strategy, structure and process variables within a theoretical framework of co-alignment. Ansoff & Sullivan (1993) developed a strategic-success-formula (SSF) that is based on the thesis that to optimize a company's performance, management must align the company's strategies and capabilities with the state, or turbulence level of the environment. The more turbulent the environment the more aggressive must be the company's response,

but common experience shows that some companies take full advantage of the opportunities offered by turbulence and others lag behind (Truch & Bridger, 2004).

2.3.3. Strategic Fit for Outsourcing Supply Chain

In the context of SCM, strategic fit in the business is quite important for the success of the organization (Chopra & Meindl, 2010). A successful strategy must be consistent with “the characteristics of the external environment and with the characteristics of the company’s internal environment” and therefore a “lack of consistency with either the internal or external environment” might lead to the failure of a company (Grant, 2005).

There are four critical elements that guide the selection of compounds for Big Pharma: strategic fit, quality of the opportunity, feasibility and competitiveness- all contributing to the overall economics of the opportunity (Fischette, 2004). Ransohoff (2004) also explored key elements that should be considered in the pharmaceutical outsourcing supply chain decision, could separate into four major categories: outsourcing feasibility, strategic fit, risk, and financial considerations as follows:

1) Outsourcing feasibility: For any given product, the “make vs. buy” decision may be made several times during the product life cycle. The decision and requirements for a product entering Phase I clinical trials will be very different from the decision and requirements for commercial supply of an approved product. In each case, though, the feasibility of the outsourcing option must be considered from a number of perspectives including: manufacturing scale, manufacturing technology requirements, availability of qualified service- providers, and capacity availability.

2) Strategic fit: Increasingly, biopharmaceutical firms are viewing manufacture decisions as strategic because of their long-term organizational, financial and competitive implications.

3) Risk (management and assessment): Understanding the risk associated with any decision is the first step in managing it. The risks relevant to the “make vs. buy” decision are numerous, ranging from risk of product failure to risk of delays in construction or poor execution in manufacturing. The pitfalls associated with deciding to invest in facility construction early in the clinical trial process were described. For

“make vs. buy” decisions to support products in clinical development, the risk of product failure to risk of due to delays. A range of estimates for product success rates as a function of development phase have been published for biopharmaceutical products. Once the proper assessment of risk has been completed, steps can be taken to properly manage risk. These may involve measures to improve the probability of a satisfactory outcome, or measures to minimize the damage caused by a negative outcome where probabilities cannot be easily influenced. In any event, assessing and managing risk is undoubtedly a very important element of the “make vs. buy” decision.

4) Financial consideration: The decision to make or buy will have a significant impact on a company’s capital requirements and operating cost structure. Even though financial considerations often are not the primary driving force behind “make vs. buy” decisions, conducting sound financial analyses is an important part of the decision process – if only to clarify the decision’s financial ramifications. One method for comparing alternative approaches to manufacturing is to use discounted cash flow (DCF) analyses to estimate net present values for each approach. An important assumption in any DCF analysis is the discount rate that should be used for discounting future cash flows back to present dollars. As the risk of the project increases, the discount rate used should increase. There are many different ways of estimating appropriate discount rates, which is beyond the scope of this article, but clearly the project discount rate decreases as the probability of success increases.

There are many researcher papers about strategic fit for outsourcing supply chains, such as; Adopting a conceptualization of fit as gestalts, Bergeron, et al. (2001) examined the impact of co-alignment among business strategy, business structure, IT strategy, and IT structure on business performance. Chopra & Meindl (2010) suggested efficiency and responsiveness were two main strategies for the SC. The importance of strategic fit in SCM from various perspectives, such as: (1) Alliance: Nielsen (2010) explained knowledge outcome of collaborative relationships be determined by the match of partner motives, influenced by the mix of contractual and alliance governance; (2) Industrial analysis: Shah (2004) found that supply chain integration improves the operations of CMs; (3) Company performance: Burton et al. (2004) discovered a positive relationship between organizational strategy and firm performance; (4) The relationship between the supply chain strategic fit and formulation of future strategies:

Tsai & Tien (2011) also found that strategic fit from the perspective of the degree of vertical integration and the degree to which a company fits in the local supply chain can affect the propensity for strategic change; (5) And others: Ala-Risku et al. (2010) found that reliable inventory tracking in the SC could improve a company's overall performance.

Alon et al. (2007) explored that the concept of strategic fit have the factors relevant to the outsourcing decision or process may prove helpful. For 'fit' to exist, the various components of any system must be internally consistent both with each other, and with those components' external purpose. When this occurs, the opportunity for high performance is concluded to be optimal. The concept has been extensively investigated in Western organizations and in more limited studies in emerging economies such as China's (Lucas et al., 2001), with positive results. To better consider their elements' mutual fit, strategic outsourcing initiatives may be evaluated through viewing the factors most pertinent to outsourcing success through the lenses of three related conditions or levels of analysis: (1) the Individual level, (2) the Intra-Organizational level, and (3) the Inter-Organizational level. In the following sections, the researchers investigated briefly each level for its implications for performance and for fit with the firm's outsourcing conditions, identifying those level-specific programs for strategic action which seem to offer the potential for important performance increments for the outsourcing firm. The framework offered, while suggestive, should be adapted as appropriate for any specific outsourcing initiative.

The strategic fit for outsourcing supply chain is focusing on core competences and executing an expansion plan were the two benefits that created a difference in opinion, as stated by CPs and CMs.

The research of strategic fit for outsourcings supply chain mostly are in IT & IS service industries, such as; Liu & Chen (2011) studied in IT service industry in Taiwan, and showed five functions of technology competence leveraging that influence CMs strategic growth. Plugge et al. (2013) also found that IT of CMs who establish a fit between their outsourcing capabilities and their customers' organizational structures were less susceptible to problems resulting from unexpected change in the clients' environment.

For researches of relationship and degree of fit: Bolat & Yilmaz (2009) examined the relationship between the outsourcing process, and perceived organizational performance, and found support for the hypothesis that outsourcing had a positive effect on organizational performance (organizational effectiveness, productivity, profitability, quality, continuous improvement, quality of work life, and social responsibility levels). Kroes & Ghosh (2010) studied the degree of congruence (fit or alignment) between outsourcing drivers and competitive priorities, i.e., outsourcing decisions should be made in alignment with the competitive priorities of the firm. They also evaluated the impact of congruence on both supply chain performance and business performance. The main findings were that outsourcing congruence across all five competitive priorities were positively and significantly related to supply chain performance.

2.3.4 Strategic Fit for Pharmaceutical Industry

Pharmaceutical industry is a highly innovation driven industry which throughout its history has contributed to the well-being of the humans by providing new medicines to address various diseases and have grown into one of the major sectors in the world (Raja & Sambandan, 2015). Big Pharma face many challenges: shrinking pipelines, pricing pressures, reimbursement hurdles, increasingly stringent regulatory requirements, increased competition, high promotional expenses, demand for pharmaco-economic analyses, hostile consumer groups, skeptical governments, a need for a steady source of products with high commercial potential, and unblinking critical eyes on quarterly reports in the public sector. The current trend in the Pharmaceutical industry also shows that many Big Pharma are outsourcing their manufacturing and small molecule drug discovery along with clinical trials to CMOs & CROs, and Biotechnology companies in emerging countries like china and India (Zhang, 2014). Big Pharma also form alliances with other Big Pharma to access production capacity and distribution channels in order to commercialize the new drug discovered as well (Bianchi et al., 2011). So, nowadays, the pharmaceutical supply chain outsourcing provide services ranging from new drug discovery & development to manufacturing, include logistics and commercialization of a product. That causes any contract businesses are established in the market - usually specializing on certain parts of the pharmaceutical value chain.

Ransohoff (2004) described the strategic fit of a potential manufacturing capability with the company's overall business needs to be considered outsourcing decision, with the following questions are among those addressing :

- Does the company have a pipeline of products that will require similar manufacturing capability?
- Can the company establish and maintain a competitive advantage through establishing strong process and manufacturing capabilities for this type of product?
- Is there a potential to develop proprietary manufacturing technology?
- Are there unique or difficult aspects to the manufacturing requirements?
- Will manufacturing capacity and capability help enhance the company's ability to in-license new products?
- At what development stage are the products that could utilize in-house manufacturing facility?
- Does the company have an organizational or cultural bent towards in-house manufacturing or outsourcing?

Quinn (2000) suggested that strategic outsourcing of innovation is a necessary action to gather enough knowledge and handle the insecurities of a rapidly changing world. According to this anecdotal article almost any stage of the innovation process can be profitably outsourced. Abuhamad (2014) investigated and found that the strategic practices associated with participation in international collaboration, company's innovation performance was operationalized in terms of the dominant type of innovation (process or product innovation) and degree of innovation (basic, intermediate and advanced level).

2.3.5 Conclusion

Based on the principle that the supply chains in a competitive business environment depends on the consistency between "Customer expectation" and "Supply chain performance" which forms the concept of "Strategic Fit", is very important and need to concern in term of growth and sustainable of business.

The pharmaceutical manufacturing industry, not only is innovative and important for the human life, but also rapidly develop to be one of the most power and successful

business. The outsourcing with the right strategic partners, not only for manufacturing, but also for drug discovery & research as well, are the trends and very important in pharmaceutical industry. Considering the aforementioned regards, the researcher decides to study the research of the pharmaceutical industry context in order to obtain clear understanding the concept of strategic fit for outsourcing pharmaceutical manufacturing, and will use Thai pharmaceutical companies and business structure as a case study of the research.

2.4 The Outsourcing Partnership Model

Mentzer et al. (2004) found that partnering between firms is one way to find and maintain competitive advantage. The ability to effectively and efficiently build and maintain tailored business relationships may become a key competency for executives looking for competitive advantage. As an increasing number of businesses are incorporating significant technology-driven components into their service product innovations (Boone, 2000), there is a growing interest in understanding how current technological context, in which a firm's service product innovation is embedded, influences its behavior and performance. According to the logic of the resource dependence theory (RDT) (Pfeffer, 1982), establishing a collaborative relationship between partners constitutes a bridging strategy. Because organizations are rarely self-sufficient, they enter into collaborative relationships with other organizations to obtain critical resources. Firms often struggle to find a balance between what they must own and what they must acquire, or "source", through collaboration, partnerships, alliances, joint ventures, and the like (Witzeman et al., 2006).

While the benefits of partnering have been well documented, the pitfalls and dangers have received less attention. Lieb & Randall (1996) suggested that the most serious concerns to shippers in the use of third party providers include the potential for loss of direct control over logistics activities, uncertainties about the service level to be provided, and questions concerning the true cost of outsourcing. Ackerman (1996) had identified numerous reasons logistics partnerships, in particular, may be "doomed to fail," including a lack of understanding between the parties about the job to be done, over-promising and under-delivering by the seller, deliberate attempts by personnel in

the buying firm to make the partnership fail, unprofitability for the seller and subsequent poor service, and no orderly process for separation. Ellram (1990) identified the main factors leading to partnership failure as poor communications, lack of top management support, lack of trust, lack of supplier total quality management programs, poor up-front planning, lack of strategic direction for the partnership, and lack of shared goals. For the most part, these causes of conflict fall into two general categories suggested by Stuart & McCutcheon (1995): (1) a mismatch in perceptions over the appropriate degree of partnering or (2) improperly executing the partnership building process.

The researcher, therefore, collects, analyzes, synthesizes and presents this topic review in seven sub-topics of 2.4.1) definition of partnership, 2.4.2 the importance of partnership, 2.4.3) overview of the PSM, 2.4.4) the conversion of outsourcing PSM, 2.4.5) sustaining the relationship and measuring performance, 2.4.6) empirical research using PSM for outsourcing in SCM, and 2.4.7) conclusion, as follows:

2.4.1 Definition of Partnership

A partnership is a tailored business relationship based on mutual trust, openness, shared risk and shared rewards that results in business performance greater than would be achieved by the two firms working together in the absence of partnership (Lambert, et al., 1996 & 1999). The ability of partnerships to achieve is cost savings and reducing duplication of efforts by the companies involved (Whipple et al., 1996; Zinn & Parasuraman, 1997). For buyers, partnerships can improve profitability, reduce purchasing costs, and increase technical cooperation (Ailawadi et al., 1999; Han et al., 1993). And for suppliers, partnerships with industry leaders can enhance operations and prestige (Anderson & Narus, 1991; Spekman, 1988), and provide stability in unstable markets (Fram & Presberg, 1993).

2.4.2 The Importance of Partnership

Partnership can be an important aspect of successful supply chain management. A well designed facilitation process for establishing the appropriate level of partnership with other members of the supply chain network can have substantial benefits. These benefits are especially relevant when addressing an organization's critical supply chain

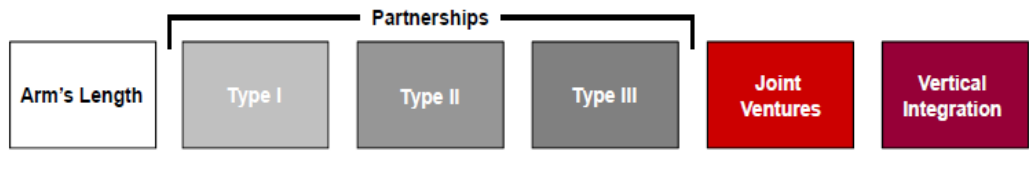
linkages. Although supply chain management offers many internal opportunities for improvement, the real opportunities will come from reaching out to other members of the supply chain and forming efficient and effective relationships (Lambert et al., 2004).

2.4.3 Overview of the Partnership Model

Lambert et al. (1996 & 1999) was originally developed the PSM, using 18 case studies and validated by fitting the model to the same case studies. The method of partnership development and implementation, the model also should guide managers' decisions. It was developed after in-depth analysis of 18 relationships in leading-edge firms. The industries represented were consumer products, electronics, manufacturing, retailing, telecommunications, third-party logistics, and transportation. Sixty interviews, ranging from one to four hours, were conducted with managers at various levels and functions in both firms involved in each relationship. A comprehensive, pretested interview guide of 45 questions was used. Transcriptions were returned to the interviewee for review. A detailed case study of each relationship was then developed and these were also reviewed by the parties involved.

The model is comprised of four steps: examination of the drivers of partnership, examination of the facilitators of partnership, calibration of the components of partnership, and the measurement of outcomes.

- Drivers are the compelling reasons to partner, and must be examined first when approaching a potential partner.
- Facilitators are characteristics of the two firms that will help or hinder the partnership development process. It is the combination of facilitators and drivers that prescribes the appropriate type of partnership.
- Components are the managerially controllable elements that can be implemented at various levels depending on the amount of partnership present. How they are actually implemented will determine the ultimate type of partnership that exists.
- Outcomes are the extent to which each firm has achieved its expected performance.



Source: Douglas M. Lambert, Editor. *Supply Chain Management: Processes, Partnerships, Performance, Third Edition*, Sarasota, FL: Supply Chain Management Institute, 2008. P.257

Figure 2.9: Type of Partnership

There are three levels of partnership exist:

- Type I – components are present at a low level
- Type II – components are present at a medium level
- Type III – components are present at a high level

Table 2.3: Propensity to partner matrix

		Driver Points		
		8-11 Points	12-15 Points	16-24 Points
Facilitator Points	8-11 Points	Arm's Length	Type I	Type II
	12-15 Points	Type I	Type II	Type III
	16-24 Points	Type II	Type III	Type III

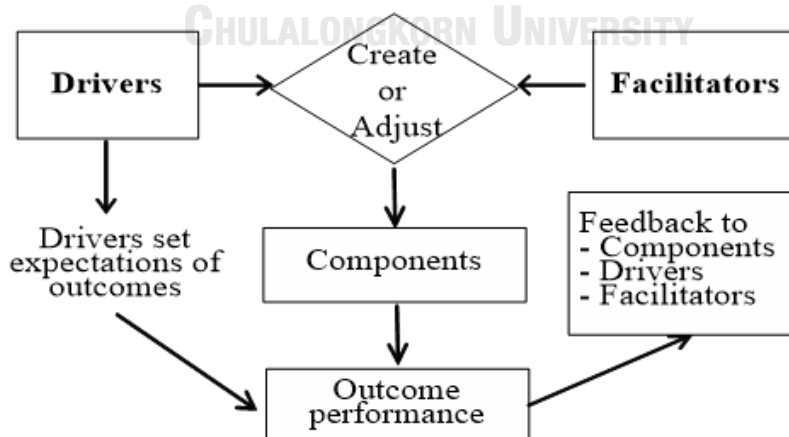


Figure 2.10: The Partnership Model (adapted from Lambert et al. (2004))

An overview of quality criteria of accessing validity describes a trustworthiness approach that is appropriate (Halldorsson & Aastrup, 2003). This trustworthiness approach has four major components that correspond to internal validity, reliability, external validity, and objectivity. They are respectively: credibility, dependability, transferability, and conformability.

Partnership in practice requires a repeatable managerial process that will guide the analysis and implementation of appropriate levels of relationship components. For each specific managerial component we have some additional suggestions. Based on our experiences, we would recommend the following changes and adjustments to the management components: planning, joint operating controls, Communications, Risk and reward sharing, Trust and commitment, Contract style, Scope, and Investment (Lambert et al., 2004).

Drivers and facilitators only establish the potential for a relationship, management components determine how it is achieved. Even with strong drivers and facilitators, a partnership can still fail if the components are not implemented appropriately. The way in which they are put into place and managed will determine how the partnership operates (Lambert et al., 2004). Components need to be examined three times, each with a different goal: 1) to determine the current state; 2) to determine desired state; and 3) to make sure nothing was omitted.

The model uses a three by three matrix to prescribe PST and therefore is subject to the difficulties present with any grid approach. The MPF (meeting process facilitator) needs to be sensitive to the fact that a single point change on either drivers or facilitators can from a Type II partnership to a Type III or to a Type I. The prescriptions near the intersections of the boxes need to be evaluated with care.

2.4.4 The Conversion of Outsourcing Partnership Model

Research by Kedia & Lahiri (2007) suggested that despite an increase in international outsourcing of services (IOS) to survive in today's highly competitive business, there have not received adequate attention in the scholarly literature. They thus seek to elaborate type of outsourcing PSM and classified 3 types: tactical, strategic, and transformational using the value propositions and nature of involvement with providers in different ways. For **the first generation outsourcing - tactical PSM**,

operational cost reduction or cost saving and arm' length relationship are a primary drivers in terms of value and involvement respectively for both the companies and their providers, whereas for **the second generation outsourcing -strategic PSM**, the companies experiences competitive pressure and seek to focus on core competencies advantages (value, rareness, imperfect inimitability and non-substitutability attributes of resources) from their providers, and for **the third generation outsourcing - transformational PSM**, the matching of three drivers: namely need for risk sharing and flexibility, and business transformation between the partners helps spurred the adoption of this model. They further try to identify factors that may have impacts on the outsourcing partners' continuity, but their attempt was to include those effects that appear to be most relevant in the context of the outsourcing partnerships.

The conversion from an outsourcing relationship to the partnership relationship has been further investigated and made clearer by Ali & Khan (2016) who identify and analyze factors that are important for vendors in conversion of their existing outsourcing relationship to partnership, using a systematic literature review process for the identification of critical success factors (CSFs) from a sample of 111 articles. They further categorized the identified CSFs into five partnership levels based on Capability Maturity Model Integration (CMMI) and the Outsourcing Vendors' Readiness Model. The 5 partnership levels are as follows: 1) **Initial contract** - the first level defined as the purely contractual relationship, or the ordinary outsourcing with no CSF; 2) **Successful contract** – the second level defined as a continuous improvement to make the contractual relation successful, the CSFs are effective and timely communication, quality production, success previous projects and cross cultural understanding; 3) **Partnership readiness** - the third level where need for partnership is feeling and readiness is evaluated, CSFs are mutual interdependence and shared values, mutual trust, organizational proximity, and bidirectional transfer of knowledge (BTK); 4) **Conversion to partnership** - the fourth level where conversion and implementation has been successfully done, CSFs are 3C (coordination, cooperation and collaboration), flexible level agreements, and joint management infrastructure; and 5) **Maturing partnership** - the fifth level with an emphasis on maturing the relationship through continuous management, CSFs are long-term commitments, governance and control, access to new technologies, and markets and complementary skills.

2.4.5 Sustaining the Relationship and Measuring Performance

A significant amount of research has focused on defining partnerships and on the development of PSMs. What is lacking is a mechanism for providing feedback from both successes and failures into those models. Theory building usually moves from descriptive, to predictive, to normative models. The next step in partnership research should be the systematic collection and analysis of data on partnership performance over the long term. First, additional study is needed to determine what metrics are appropriate for measuring the outcomes of the partnership. In other words, what is the correct way to determine whether the partnership has met the expectations of both parties? Second, longitudinal studies would help identify appropriate actions if outcomes are not as expected. Third, determining whether failure is more often caused by improper execution of the components or by a poor assessment of the drivers and facilitators would help identify the most appropriate way to present and implement the model. Third, studies over time would specify other variables that may influence the partnership decision and that may lead to fine-tuning of the model.

2.4.6 Empirical Research using Partnership Model for Outsourcing in SCM

From literature review, the researcher identified related three research articles pertaining to an application of PSM for outsourcing in supply chain management. Those three papers are Lambert et al. (2004), Chen & Wu (2010), and Moe et al. (2014), the brief summary of which are as follows:

-The first one by Lambert et al. (2004) on “Supply chain partnerships: model validation and implementation”

Without a foundation of effective relationships, efforts to manage the flow of materials and information across the supply chain are likely to be unsuccessful (Handfield & Nichols, 1999). Partnering between firms is one way to find and maintain competitive advantage (Mentzer et al., 2000). The ability to effectively and efficiently build and maintain tailored business relationships may become a key competency for executives looking for competitive advantage.

The Lambert et al.’s model (1996 & 1999) was originally developed using 18 case studies and validated by fitting the model to the same case studies. The model was used

in three other relationships offering some support for its validity (Lambert, et al., 1996). There were additional uses of the model, but the purpose was not for systematic validation of the model (Lambert et al., 1999). There have been many calls in other disciplines for validation and replication as an indispensable ingredient in the scientific process. This research examines the presence of these qualities in the model.

Clarity with respect to practitioner implementation of the model was also lacking. This is evidenced by the following statement by one senior manager involved in the research: “I did not fully appreciate the difficulties associated with the process surrounding the implementation of the model until I tried to use it in my company.” Another goal of this research is to provide *specific* guidelines on how to use the model.

Based on the facilitation of 20 partnership cases in a wide variety of contexts this research provides a systematic validation of the model and addresses a number of specific guidelines on how to implement the model. One difficulty when moving research from theory to practice is that researchers often ignore the complexities of implementing their models. This research provides direction for managers who want to use the model to build and maintain successful relationships.

-The second one by Chen & Wu (2010) on “A systematic procedure to evaluate an automobile manufacturer–distributor partnership”

Automobile manufacturer–distributor partnerships are fundamental to the success of automobile companies. The complexity of the overall PSM often causes difficulties in partnership study.

This paper presented a systematic procedure to evaluate an automobile manufacturer–distributor partnership consisting of a large number of system variables. Firstly, Interpretive Structure Modeling (ISM) is used to sort system variables into groups of various characteristics. This sorting process provides an effective means to develop a three-stage hierarchic/network model of the partnership, including Stage I: partnership selection, Stage II: partnership establishment, and Stage III: partnership maintenance. Secondly, Analytic Hierarchy Process (AHP)/Analytic Network Process (ANP) are applied to partnership evaluation based on as many as 20 system variables. Relative importance weight of all variables is quantitatively determined. The most investment-worthy variables found are management strength and power.

Finally, this paper made a comparison between the optimum distributors identified by the present procedure and in practical cases. The usefulness and efficiency of the proposed procedure are ascertained with highly consistent results in the comparison.

-The last one by Moe et al. (2014) on “From offshore outsourcing to insourcing and partnerships: Four failed outsourcing attempts”

Most large software companies are involved in offshore development, now small and medium-sized companies are starting to undertake global sourcing too. Empirical research suggests that offshoring is not always successful; however, only a few comprehensive failure stories have been reported.

The objective of our study has been to understand why small and medium-sized companies terminate their offshore outsourcing relationships and what alternative arrangements they undertake afterwards. Therefore, we designed a multiple case study of four medium-sized Scandinavian software companies that have terminated their offshore outsourcing relationships. Our results are based on data collected through semi-structured interviews, informal dialogues and analysis of company documents.

We found that all companies terminated their offshore contracts because of low quality of the software being developed. This was caused by an inability to build the necessary human and social capital. The companies reported challenges with domain knowledge a lack of commitment of external developers, cultural clashes, poor communication and high turnover, which only amplified the problems.

2.4.7 Conclusion

An analysis of the use of the model by industry also would be beneficial. Examining how it is used across different industries and the most common type of relationship by industry would help identify any industry-specific bias either toward or against partnering as a form of business relationship. Partnership can be an important aspect of successful supply chain management. A well designed facilitation process for establishing the appropriate level of partnership with other members of the supply chain network can have substantial benefits. These benefits are especially relevant when addressing an organization’s critical supply chain linkages.

2.5 Related Research Literature

This section is devoted to review of foreign and Thai research reports related to this study, in order to learn what has already been studied and further extend this research to learn new and advanced knowledge on PSM and strategic fit for outsourcing of pharmaceutical manufacturing in Thailand. However, it turns out that there are only a few research reports in Thailand relevant to this study, as compared to plenty research reports in other countries especially the developed countries in Europe, America and Asia. Consequently, there seems to be so many issues needs to be study on Thai strategic fit for outsourcing, all of which must be studied using several research method, i.e. Scenario analysis. The researcher, therefore, plans to employ scenario analysis for this study, the matter of which must be clearly understood. As a result, the content of this section has two more additional topics on scenario analysis research, and related research using scenario analysis including keywords of ‘strategic fit’, ‘PSM’ and ‘outsourcing’, and/or ‘SCM’ as in the following two topics of research in Thailand and abroad. Research presented in both topics have been searched using keywords of ‘strategic fit’, ‘outsourcing’, ‘SCM’ and ‘pharmaceutical manufacturing’ with search engine ‘Google Scholar’, the researcher has acquired 20 Thai research reports conducted by either Thai or Foreign scholars, and 56 research reports abroad, plus 48 research reports on other business. After studying thoroughly, the researcher summarized those research reports into three sub-topics: 2.5.1) pharmaceutical research on strategic fit of outsourcing in SCM and the gaps between Thailand and foreign countries; 2.5.2) other business research on strategic fit of outsourcing in SCM; and the last, 2.5.3) Scenario analysis used in strategic fit of outsourcing in SCM as follows:

2.5.1 Pharmaceutical Research on Strategic fit of Outsourcing in SCM and gaps between Thai vs. Foreign Countries

Since there are two different types of research on strategic fit of outsourcing in SCM: Thai and foreign research, therefore, this topic is organized into 3 sub-topics: 1) Thai research, 2) foreign research, and 3) comparing Thai and foreign research to identify the research gaps as follows:

2.5.1.1 Thai Pharmaceutical Research

After studying thoroughly, the researcher summarized only screened 11 from those 20 research reports into 3 topics. The brief synopsis of those reports are presented in three topics of pharmaceutical situation, pharmaceutical strategic fit of outsourcing in SCM, and pharmaceutical scenario analysis and case study.

1) Thai Pharmaceutical Situation

Four research papers on Thai pharmaceutical situation ranged from a broad and extensive research to a narrow and specific research as follows:

-The first one by Saktontai (2007) on “Key determinant factors of pharmaceutical in Thailand under FTA Thai-USA”

The four objectives were 1) to explore the determinant factors that influence the pharmaceutical industry in under FTA Thailand- U.S.A. 2) to study future trends and directions of Thailand’s pharmaceutical industry, 3) to recommend the pharmaceutical industry in Thailand to improve itself to compete globally, and 4) to make future recommendations.

The research methods used were interviews and questionnaires. The study showed that there are several factors that influence on the pharmaceutical in Thailand under The FTA of TH- USA. They are demand conditions (security program, domestic customer’s quality requirement of pharmaceutical, domestic brand loyalty); strategy, structure and competition among domestic companies, and related and supporting industries (firm’s marketing strategy, firm’s pricing strategy, competition among domestic firms): the role of the government (cultivation management policy, trade relation with other countries, import management policies) external factors (competitors’ price, price sensitivity in Thailand, competition among pharmaceutical import countries) The study also identifies the trend of pharmaceutical industry in Thailand under the FTA of TH- USA..

The study recommends the government should plan the price’s drug control, import tariff. Government to government business management policies, production management, and reduce period time to registrations. The companies should focus on security program, brand identify, marketing strategies and domestic, imported medicine

instruments. The study also suggests the ideas for future study that focus on expanding the respondent, measuring the relations and demand forecasting.

-The second one by Kuanpoth (2006) on “Harmonization of TRIPS-Plus IPR policies & potential impacts on technology capacity”

Aimed at examining whether an agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS-Plus) rules on pharmaceutical patents generate benefits to developing countries by looking at the situation in Thailand. The TRIPS-Plus rules under the proposed Thailand-United States Free Trade Agreement (TUSFTA) are comprehensive, covering the following issues: restricting the grounds for exclusion of patentability; patents for any new uses or methods of using a known product; prohibiting pre-grant opposition and revocation of patents; limitations on the issuing of compulsory licenses; extension of patent term; data exclusivity; linkage of drug registration and the patent status of a drug; trade mark, and linkage of IPRs and investment.

This study used situation analysis, the study results found that Thailand did not have a functional technological base and this made the country industrially and technologically dependent on foreign interests. It consistently lost trade balance in the pharmaceutical sector to its trading partners. It was also evident that a stringent patent regime, as enshrined under TUSFTA, would have no impact whatsoever in promotion of R&D in the country. By contrast, the inherent monopoly privileges proposed in the form of TRIPS-Plus will hinder local R&D and impede inflow of technology. Patents would continue to be used by foreign drug companies as a mechanism for overpricing, transfer pricing and insertion of restrictive clauses in technology transfer agreements. The TUSFTA provisions would have a tremendous impact on technology prices. The rules on data exclusivity, extension of patent term, and extension of the scope of patentability will increase the ability of the patent holders to maintain high prices. The rules would reduce generic competition, prohibit the use of a compulsory license to make the patented drug available, and allowed the patent holder to maintain a longer monopoly position, charging a high price for its medicines. The TRIPS-Plus provisions that linked drug registration and the patent status of a drug would unnecessarily restrain the entry of generic medicines, threaten the existence of the Thai generic companies,

and inhibit the capacity of the Thai generic industry to expand its market. The prohibition of the pre-grant opposition would allow multinational companies to use invalid or spurious patents to increase prices and prevent the local manufacturers from producing the medicine.

-The third one by Strand (2014) on “TRIPS & medicines--prices, availability & health-effects on India, Thailand, S. Africa & Brazil”

This thesis investigated the TRIPS-agreement signed by all members of the World Trade Organization and how it has affected the price and availability of medicines, and its extension of overall effects on health. The researcher investigated by conducting four case studies of India, Thailand, South Africa and Brazil.

It was found that prices had been affected by TRIPS due to the extension of patent term in India and Brazil, delaying generic manufacturing and that compulsory licensing though permitted under the agreement held consequences, as seen in the cases of Thailand and South Africa. Availability in turn had not increased as indicated by studies of groups of essential medicines in any of the case studies, but appeared restricted by both high prices and other factors. In extension this meant added difficulties in affording and procuring medicines which meant negative effects on public health.

2) Thai Pharmaceutical Strategic Fit of Outsourcing in SCM

Five research papers on Thai pharmaceutical strategic fit of outsourcing in SCM ranged from a broad and extensive research to a narrow and specific research as follows:

-The first one by Pothitong & Charoensiriwath (2011) on “Improve supply chain efficiency through a web-based system: A case study on a pharmaceutical company”

The supply chain operation in pharmaceutical industry were one of the most complex operations to manage. To efficiently manage the supply chain in this industry, information technology (IT) played the crucial role. Over the last few decades, Electronic Data Interchange (EDI) had been employed in the pharmaceutical industry to synchronize information between business partners. However, an information standard was also needed to seamlessly exchange electronic documents between

business partners. XML-based information technology was a promising tool and was starting to gain popularity over EDI based technology.

In this research, we study a medium size multinational pharmaceutical company in Thailand, and how a web-based system and a business standard for information flow (Rosetta Net standard in this case) can be applied to improve efficiency in its supply chain operations. In particular, we examined the information flow during the process of order transactions between the pharmaceutical company, its customers (hospitals), and its distributors. We first examined the current business process and propose a new process with a web-based system. The new system was examined and the result was analyzed.

-The second one by Charoensiriwat & Pothitong (2008) on “Applying web-based system improving SCM in Thai pharmaceutical industry”

In order to successfully connect the whole supply chain, an information standard was needed to exchange electronic documents between business partners. The XML-based standard was starting to gain popularity over the EDI-based standard in many industries. There were two main standards being implemented by the industry. ebXML was supported by the United Nations and OASIS, while RosettaNet was supported by companies in electronics and high-tech industries.

The aim of these standards was to electronically connect companies within the same supply chain, regardless of their size.

-The third one by Baines (2010) on “Problems facing the pharmaceutical industry and approaches to ensure long term viability”

This paper examined the Pharmaceutical industry and the changes that have occurred particularly over the last 10 years as a result of the overall economic downturn, the rising cost of healthcare and the costs associated with the development and sales of pharmaceuticals. One response of Big Pharmaceuticals to this has been the recent spate of partnerships, mergers and acquisitions, consolidation, diversification, licensing agreements and downsizing in both human and capital resources. Four major challenges facing the complex pharmaceutical industry were highlighted and discussed. These include the decline in the discovery, approval and marketing of new chemical entities

(NCE) with fewer and fewer blockbuster drugs making it to the market, competition from generics drugs, regulatory pressures and the weak growth in the US market (the largest market), and therefore the need to explore other markets to name a few. In addition to the research driven aspect of the paper, a summary of the interviews conducted with executives and other industry practitioners (to get their personal views) was presented.

Finally referencing some of the strategies adapted by some companies, this thesis identified Organizational Dynamics areas of concentration and the role they could play within companies in their plans to ensure long term viability. The analysis focused on the commercial aspects of the industry and offers some steps that would be useful in changing the current business model and setting the stage for future success.

-The forth one by Pacific Bridge Medical (2014) on “Contract research organizations (CROs) in Asia 2014”

The majority of clinical trials in Thailand were Phase III studies. From 2010 to 2012, there were 215 Phase III trials of getting permission from FDA to import the drug for use in the clinical trial conducted, compared with 5 Phase I trials of selecting a research facility and researchers to conduct the study, 40 Phase II trials of getting ethical approval either from the independent ethics committee (IEC) of the research facility (usually a hospital or university) at which the trial will take place or from the MOPH's Ethical Review Committee (ERC) for Research in Human Subjects, g, and 26 Phase IV trials of getting a new import license because the license expires after a year.

-The fifth one by Piboonrunroj (2014) on “Measuring supply chain efficiency: A case of exporting Longan from Thailand to India”

Purpose of this paper: Logistics costs have a significant role in international trade (Behar & Venables, 2010). The aim of this paper is understand the structure of logistics cost and supply chain efficiency in the international trade in order to reduce such costs and therefore improve the international supply chain efficiency.

Design/methodology/approach: The structure of international logistics cost and supply chain efficiency was developed from the literature (Gunasekaran et al., 2001; Banomyong & Beresford, 2001) that propose the cost model. Then develop to fit with

the context of exporting Longan from Thailand to India by consulting the relevant document as well as interviews with Thai export and India import experts. The developed structure was then used to measure the logistics cost and supply chain efficiency of six agricultural co-ops in Thailand.

Findings: It was found that transports and warehousing have a significant contribution in the logistics cost. However the results show that there are several hidden costs such as costs related to the hygiene and quality control and assurance. Transaction costs in dealing with administration and document are also considered a burden in the logistics process in terms of both time and money. Moreover, costs related to supply chain risks (both process and environmental risks) are the key to supply chain efficiency.

3) Thai Pharmaceutical Scenario Analysis and Case Study

Three research papers on Thai pharmaceutical scenario analysis and case study ranged from a broad and extensive research to a narrow and specific research as follows:

-The first one by Suksawat & Boonsothonsatit (2015) on “Competitiveness enhancement of a biopharmaceutical plant in Thailand”

Purpose of this paper: This paper aims to analyze key success factors for enhancing competitiveness of a biopharmaceutical plant in Thailand along its supply chain. Eventually, it suggests decision makers the optimal ways to enhance such the competitiveness.

Methodology: The key success factors of biopharmaceutical industry are preliminarily studied along its supply chain by reviewing the related literatures and interviewing the related experts. Then, the preliminary study is analyzed on the basis of value chain. Finally, the key success factors are used for evaluating and enhancing the competitiveness of a biopharmaceutical plant in Thailand.

Findings: The key success factors of the biopharmaceutical supply chain consist of organizational factors (i.e. human resource, infrastructure, and technology) and external factors (i.e. regulations, government supports, collaboration, and partners). They contribute a biopharmaceutical plant to create more value with less cost, more quality and better lead time with sustainable competitiveness.

Value: There are a lot of significant ways to enhance the competitiveness of a biopharmaceutical plant in Thailand. However, it has not been studied, analyzed, evaluated, and suggested systematically. Such the gaps are bridged by this paper. Research limitations: This paper is studied using only one case of biopharmaceutical industry (a plant in Thailand). Its scopes may be limited and unable to be applied straightforwardly for other biopharmaceutical plants.

-The second one by Landau (2011) on “Leading a German subsidiary in Thailand: An experience report”

In this article, the author will share some of his experiences that he made while he was at the helm of Merck Ltd., Thailand from 1992 until 2008. Merck has a very long history in Thailand. Its roots can be traced back to the year 1899. Merck Ltd., Thailand is a company that is active in selling, marketing and distributing chemical and pharmaceutical products to its customers in Thailand. While its chemical products are all imported, the huge majority of its pharmaceutical products are contract-manufactured in Thailand. Merck Ltd., Thailand was strongly committed to the so-called 4 stakeholders-approach: Care for employees, customers, shareholders, and society. The current vision statement is fitting very well in today’s world: 2014 vision- We will be the first in customers’ minds to provide outstanding customer care through innovations created by talented, satisfied employees, while positively contributing to Thai society. As a further step towards implementing the vision statement of Merck Ltd., Thailand, the care-concept was developed. The core value “care” was at the heart of the organization and the operations. The care philosophy was holistically implemented across the company and showed high commitment by the employees. Decisions were not to compile a balanced scorecard for the whole company, but rather two scorecards for the pharmaceutical business and the chemical business, due to the different nature of the business.

The Pharmaceutical Division had outsourced the sales and the distribution function while the Chemical Division did sales, marketing and distribution all by itself. Therefore, the main difference between the two balanced scorecards came from the internal processes and the customer perspective, while the learning & growth perspective and the financial perspective were identical in both businesses. At Merck

Ltd., Thailand, we chose the following approaches that proved to be very successful: a) Management and the Finance Department helped to develop key performance indicators for every department and for every main process. In this way the department managers or the process owners were able to go for a self-controlling approach where the KPIs gave them a thorough overview where they stood regarding the effectiveness and efficiency of their department or that process; b) A few flagship controlling tools were developed and implemented (as described above) where the focus was always on a team approach in terms of a joint evaluation and a joint action plan. So the strong team bonding contributed immensely to the successful application of such corporate controlling tools.

-The third one by Kongrerak (2013) on "Study of the competitive advantage of Thai traditional medicines and herbal products"

Purpose: The main objective of this study is to derive competitive advantage of Thai Traditional Medicine and herbal products industry by analyzing from SWOT and Porter's Diamond model and finding out the relevancy of government policies in this industry.

Design/Methodology and Approach: Qualitative approaches have been used in this research by depth interview business owners.

Research result: Strengths and opportunities in this industry are derived from internal and external factors of their companies which indicated the competitive advantage over potential competitors. The result showed that strengths are the accessibility to raw materials, wide acceptance among overseas consumers, and the accreditation by international organizations. The opportunities of Thai traditional medicine (TTM) and herbal products composed of the increasing demand in both domestic and international market and the integration of ASEAN Economic Corporation. Weaknesses are explained as high cost of production, quality of raw materials, and strong dependency on overseas distributors. Threats in this industry related to the intense competition from both local and international markets. With regard to Porter model, Thai traditional medicine manufacturers have benefitted from favorable demand conditions particularly the size of home market. Nonetheless, this industry has also gained substantial market shares in Asia, EU & USA as well.

However, in terms of structure and rivalry, this industry faces high competition. Adding to this, government policies, such as marketing and financial support, regulate/deregulate are most relevant to this industry.

2.5.1.2 Foreign Pharmaceutical Research

Upon searching research report using Google Scholar and Google, 56 papers on pharmaceutical strategic fit, outsourcing, and/or supply chain management were acquired. After skimming and screening for the relevant papers, only 15 papers were recruited and studied thoroughly. The brief synopsis of those reports are presented in three topics of pharmaceutical situation, pharmaceutical strategic fit of outsourcing in SCM, and pharmaceutical scenario analysis and case study.

1) Foreign Research on Pharmaceutical Situation

The synthesis results of 4 papers on foreign pharmaceutical situation, as presented below, indicated different research questions and methods.

-The first one by Teng et al. (2014) on "An analysis of supply chain strategies in the regenerative medicine industry-Implications for future development"

The pharmaceutical, biotechnology and life sciences industry was worth approx. US\$1 trillion in 2010, of which 73.2% was attributed to pharmaceuticals, 25% to biotechnology and the remainder to life sciences. Regenerative medicines, which use live cells to cure previously incurable diseases, are a small, but growing sector of the life sciences industry. Product development here was long, the industry highly regulated and scaling up from lab to volume oriented dispersed production has many challenges. In contrast to most manufacturing environments, it was not possible to change manufacturing processes or supply chains ad hoc, as the entire supply process was specified as part of regulatory approval. It was therefore prudent to plan for the integration of production processes and supply chains during development, as the cost ramifications will seal the success or failure of a therapy at start up.

This paper presented a taxonomy, which decomposed regenerative medicine into exemplar cellular therapies that then enables the characterization of their supply chain strategies and structures. By a qualitative research, using a case study methodology, we

explore the supply chains of five cellular therapies to provide insight into how regenerative medicine supply chains could be configured and managed to get cell therapies to more markets faster, and within an acceptable cost regime.

With four research questions as follows: RQ1. What is the generic starting point for the development of regenerative medicine supply chains? RQ2. What is the structure of supply chains associated with current (core) regenerative medicine therapies? RQ3. What are the comparative supply chain uncertainties? RQ4. How might these supply chain uncertainties be resolved (to reduce therapy developmental risk)?

-The second one by Ganesh & Ghadially (2013) on "Optimization of supply chain management in pharmaceutical industry"

Supply chain optimization to channel management in pharmaceutical industry can transform the organization to better utilize assets and resources, generate profits, enhance shareholder value, and positively respond to customer demand. As the cost and efficiency level are very significant in channel management, this study focuses on incorporating the use of electronic means in distribution. The research was exploratory and structured questionnaire was administered to 46 chosen respondents from 30 pharmaceutical companies and 16 distributors in Karnataka. The analysis was in done two stages. In the first stage, Factor analysis was done to find predominantly used factors towards introducing E channels. In the second stage, Regression was used to find the elements contributed to shift from legacy systems to digital technology.

The study concludes that adoption of digital technology in channel management is no more an option, but a necessity to the success and growth of the industry. The benefits not only confined to monetary aspects but also to better channel relationships, lower attrition levels, employee and channel satisfaction.

-The third one by Rossetti et al. (2011) on "Forces, trends, and decisions in pharmaceutical supply chain management"

The purpose of this paper is to identify and examine the major forces that are changing the way biopharmaceutical medications are purchased, distributed, and sold throughout the supply chain. This will become important as healthcare reform moves forward, and logistics will be transformed in this industry.

Multiple interviews with key informants at each level of the value chain were combined with manifest text analysis from practitioner articles to derive key insights into the primary change drivers influencing the future of the biopharmaceutical supply chain.

The research discovered radical shifts in the structure of the biopharmaceutical supply chain. Future research into biopharmaceutical supply chain practices will need to explore three primary issues: How will supply chain member compensation influence the power of parties within the network? How will the role of supply chain intermediaries change the landscape of medication delivery to the end customer? What impact will the role of regulatory constraints on product pedigree and proliferation have on this network? The relationship between these forces is mediated by operations strategy concerning inventory policy, supply chain visibility, and desired service levels.

-The forth one by Kaplan & Laing (2005) on “Local production: Industrial policy and access to medicines-An overview of key concepts, issues, and opportunities for future research”

Local production of pharmaceuticals in developing countries may be seen as helping to stimulate industrial policy and/or as stimulating pharmaceutical “access” to needed medicines. However, if a developing country with manufacturing facilities is able to finish off bulk active ingredients sourced from developed or other countries at high costs, such manufacture may have no impact whatever on patient access to needed medicines. There has been some critical thinking in the past regarding whether or not small developing countries should make their own pharmaceuticals, but no recent comprehensive summary of the issues and policy options. This paper summarizes the issues surrounding “local production” from a policy and public health viewpoint.

It provides four brief country-level case studies, and reviews the evidence supporting the industrial policy assumptions underlying the goal of local production. In brief, in many parts of the world, producing medicines domestically makes little economic sense. If many countries begin local production, the result may be less access to medicines, since economies of scale may be lost if there are production facilities in many countries. The document concludes by providing a research agenda specifically designed to test assumptions about local production of pharmaceuticals.

2) Foreign Pharmaceutical Strategic Fit of Outsourcing in SCM

The synthesis results of 8 papers on Foreign Pharmaceutical Strategic Fit of Outsourcing in SCM, as presented below, indicated different research questions and methods.

-The first one by Raja & Sambandan (2015) on “Open innovation in pharmaceutical industry: A case study of Eli Lilly.”

Open Innovation paradigm has been a phenomenon of increasing interest in the last two decades, especially since Henry Chesbrough coined this term in 2003, triggering the creation of a new whole body of knowledge. However, all this research work could not come up with a standardized, all-in-one theory. Instead, we find a heterogeneous series of models that cope with different aspects and fit into specific contexts and industries. Among these empirical experiences of Open Innovation, we find the pharmaceutical industry. The shift to Open Innovation in this industry presents several particularities, like the need to overcome the current productivity crisis as driver for change, or the R&D-intensive nature of the industry. In this scenario of urgency, the lack of a well-established theoretical model on Open Innovation makes difficult the task of implementing this paradigm.

In this research work, we explore in detail the process of adoption of Open Innovation in the pharmaceutical industry through a case study, and analyze the empirical findings by framing it inside the current theoretical framework. Through this analysis, we aim to highlight generalizable patterns, and specific elements from the current body of knowledge. These highlights might serve as input for the creation of a unified model of Open Innovation.

-The second one by Haakonsson et al. (2013) on “A co-evolutionary perspective on the drivers of international sourcing of pharmaceutical R&D to India”

The attractiveness of the Indian pharmaceutical industry as a destination for R&D sourcing by multinational corporations (MNCs) has evolved over the past decades. This evolution has coincided with changes in MNC strategies regarding sourcing location and governance modes. We propose a co-evolutionary theory

perspective embracing both firm-internal and firm-environmental factors for location attractiveness, along with institutional and industry changes.

The framework integrates constructs from past research in economic geography, international business, and R&D internationalization. The Indian case illustrates how host-country institutional evolution, notably regarding intellectual property rights and education, plays a significant role for international sourcing of pharmaceutical R&D.

-The third one by Bals et al. (2013) on "Toward a flexible breathing organization: R&D outsourcing at Bayer"

Although R&D is at the core of knowledge-intensive industries like Pharmaceutical, outsourcing parts of its activities hold considerable efficiency and effectiveness potentials. That means managers must understand, which R&D activities can be outsourced and which need to stay in-house in order to ensure competitiveness. Nevertheless, systematic approaches for understanding the finer details of the decision-making process on R&D outsourcing are lacking. To address this gap, we present a framework developed in the context of a multinational company, Bayer.

The combination of literature studies and the study of the decision process in the pharmaceutical division at Bayer HealthCare allows us to unfold an outsourcing process model-the filter approach-that includes appropriate decision phases and proper tools.

The underlying logic of the model is that outsourcing decisions are rather a learning process with different stages than a rational one-off decision.

-The forth one by Abuhamad (2014) on "Applied to strategic for pharmaceutical outsourcing"

The paper examined why and how some firms embedded in weak National Systems of Innovation out-perform others in their innovation performance. It investigated how strategic practices associated with participation in international collaboration, specifically strategic search, contribute to different types and degrees of innovation.

The research was an exploratory study. It was based upon an innovation survey of 17 local pharmaceutical firms in Jordan, and detailed case studies of the four leading

firms. It identified how the firms perform strategic search for international collaboration, and how this influences the innovation performance. A key factor influencing the degree of participation in international collaboration is management pro-activeness in the search and sense making process. Informal and direct sense-making appear to be more important than formal sense-making in explaining differences in terms of the firms' participation in international collaboration. Informal and direct sense-making facilitate firms to participate in highly integrated deals such as joint ventures and R&D acquisition, which were associated with higher innovation performance.

In addition, the research identifies specific organizational practices that support greater senior employee involvement and integration during strategy decision-making contribute to improved international collaboration and innovation performance. There were 2 research questions: RQ1. How the firms' management practices in scanning process were associated with the different levels of participation in IC and the different types of innovation a firm performed? RQ2. How participating in different levels of International collaboration were associated with the type and degree of innovation performed by a firm?

The research employed a mixed methods approach (i.e., quantitative and qualitative), based on the findings of previous research and in depth interviews with the four case studies from the survey was conducted across 17 generic locally owned firms.

-The fifth one by Angwin & Meadows (2015) on "Applied to strategic for pharmaceutical industry"

The post-acquisition integration phase is widely recognized as critical to the M&A process. However post-acquisition typologies suffer from inadequate empirical support or lack of comprehensiveness.

This empirical paper responds to calls for methodological pluralism in M&A research, and uses a mixed method to assess the robustness of a leading post-acquisition integration typology. Through multiple cluster analyses, different post-acquisition strategies are identified and qualitative techniques allow them to be further explored.

This approach overcomes some limitations of single method research in M&A and results in a more robust, fine-grained and extended post acquisition typology. It

enables a more nuanced perspective on the coexistence of exploration and exploitation gains with implications for practitioners and researchers.

-The sixth one by JSB Intelligence (2005) on “Strategic analysis of pharmaceutical industries”

JSB Intelligence (2005) conducted a report providing an overview and analysis of the latest trends and strategies adopted by the main players of pharmaceutical industries. After literature overview, they analyzed the short and long term strategies of 50 big pharmaceutical and biotech companies using primary and secondary information, based on revenues, about the key market developments. Key market developments in the pharmaceutical industries had been classified into boosters and suppressants, and then the “Company Profile” drawn to highlight portfolios of big pharmaceutical companies in terms of revenues and strategies, including their benchmarks against their operational and business facts and figures.

The reports revealed that none of them covered all the market developments and their direct and indirect impact on the new revenue models of the pharmaceutical industry. A hypothetical revenue model had been used to provide a comprehensive evaluation of the net total effect on revenues of suppressants and boosters in the Pharmaceutical market. Moreover the JSB Intelligence intended to launch in February 2005, the “Pharmaceutical Monitor” which would offer a month-by-month strategic analysis of all key competitive developments in the pharmaceutical industries in a short and easy to ready view, but top pharmaceutical analysts and experts.

-The seventh one by Armstrong-Hough (2006) on “Applied to Good fit in Biotechnology Value Chain”

The biotechnology industry had been identified by cities and states across the country as an attractive, up-and-coming industry to be fostered by an array of economic development plans. The industry had the distinction of being among the most research-intensive, the most productive, and the most highly paid sectors in the US economy. North Carolina stands out from other states in pursuit of a lucrative piece of the biotechnology industry as having targeted biotechnology for development long before most. As early as 1981 the North Carolina legislature recognized and acted on the

potential of this industry by creating the North Carolina Biotechnology Center. Two decades later the North Carolina Biotech Center, which became a private, nonpartisan, nonprofit corporation in 1984, remains unique and North Carolina's biotechnology cluster is among the most highly regarded in North America.

The purpose of this working paper is to show how North Carolina fits into the global biotechnology sector by describing what elements of the value chain North Carolina plays a major role in, and what elements of that same chain North Carolina experiences differently from other important clusters.

We will review some of the literature defining and analyzing the biotech industry using the two fundamental concepts of industrial clusters and global value chains. We will then review the biotechnology global value chain and North Carolina's place in it, followed by a discussion of some of the unique characteristics of North Carolina's cluster. Finally, we will look ahead with a brief discussion of the NC biotech cluster's major challenges and opportunities for the future.

-The eighth one by Danese et al. (2006) on "Applied to External fit"

This study refines current literature on the sequences of improvement in supply networks, by demonstrating that the state of supply network configuration and integration is not enough to explain the decisional process that leads a company to follow a well-defined sequence.

The paper also explores how the external fit affects the adoption of the following SCM initiatives, thus proving that SCM sequences cannot be considered context-free.

The aim of the current study is to develop an understanding of the decisional process that leads a company, at a given point in time, to choose the subsequent SCM initiative to be implemented. This research adopts the descriptive case study research design, as defined by Four supply networks, whose central firms are leading pharmaceutical companies, have been investigated. At a given time when deciding the SCM initiative(s) to be implemented, external fit and the state of supply network configuration and integration are both important, but for different reasons. In particular, lack of external fit triggers the implementation of SCM initiatives.

Sequences of SCM initiatives are the result of a series of successive decisional situations, where the external fit and state of supply network configuration and integration vary each time a new SCM initiative is implemented.

3) Foreign Pharmaceutical Scenario Analysis

The synthesis results of 3 papers on foreign pharmaceutical scenario analysis, as presented below, indicated different research questions and methods.

-The first one by van Vierssen Trip (2013) on “R&D Productivity in the pharmaceutical industry: Scenario simulations using a Bayesian belief network”

For many decades the pharmaceutical industry was known for its value creation by producing life-saving therapies. Currently, pharmaceutical companies face rapidly increasing development costs, decreasing profitability of new medical entities (NMEs) and missing breakthrough innovations. It seems that this R&D driven industry is having a complex multifaceted problem. As the low hanging fruits are picked, R&D attrition rates are increasing and industrial competition is rising in decreasing markets; the gigantic pharmaceutical companies' R&D productivity is falling fast. R&D budgets are rising while new medical entities are declining. The pharmaceutical industry is in a R&D productivity crisis. In this thesis research we explore the causes of this crisis by understanding the system of the pharmaceutical R&D productivity and to locate any critical leverage points. If successful, the next step should be how these leverage points potentially favor pharmaceutical R&D productivity. Therefore, this thesis primarily ought to answer the following research question: ***How to identify the critical leverage points in the pharmaceutical R&D productivity system via a Bayesian belief network?***

Due to the complexity of the problem, a reductionist approach would not be suitable. In order to answer this research question, a Systems Thinking approach is chosen in the form of a Bayesian belief network. Bayesian belief network are useful when physical probabilities are not available and more subjective probabilities, or evidential probabilities are available. To realize a representative pharmaceutical R&D productivity system, the data for the construction of the literature based Bayesian belief network is supported on a collective mental model of pharmaceutical academics, not-

for profit and industrial R&D employees via an online questionnaire and an intensive qualitative verification.

This paper presents the Bayesian belief network as a management tool that allows decisions makers to identify leverage points that can improve the R&D productivity in different future scenarios. The scenarios analyze the focus points for the improvement of pharmaceutical R&D productivity. Besides the back casting of the system, this study contains three future scenarios: (1) **the blockbuster drug scenario** in which high sales are achieved with low number of profitable drugs. In this scenario, value reimbursement and R&D effectiveness are crucial for achieving R&D productivity; (2) **the generic drug scenario** in which copied drugs achieve high sales with a high number of low profitable drugs. In this scenario, a high number of NMEs is most important; and (3) **the personalized drug scenario** in which a high number of drugs fulfill a high number of small markets. In this scenario, a high number of NMEs through efficiency is most important.

As a result of these simulations, the leverage points (and thus the focus points for future research) are scenario dependent. The future scenario of the industry is still uncertain. However, in most of the scenarios except the generic drug scenario, the influence of the quality of a NME seems to be more important than the quantity of the NMEs. To achieve this goal, according to the simulations, the costs should be lowered via a decrease of ‘works in progress.’ In more pharmaceutical terms, by focusing on the ‘best in class drugs’ instead of ‘first in class drugs’ pharmaceutical R&D should increase according to this Bayesian belief network based on an industrial mental model.

-The second one by Festel et al. (2014) on “Outsourcing of pharmaceutical manufacturing -A strategic partner selection process”

The pharmaceutical industry is a growing industry, but companies struggle to capitalize on this growth because of a variety of challenges: shortening patent lives, strong pressure on prices, strict regulations, and the shifting of growth to emerging countries. Outsourcing of manufacturing is increasingly seen as a way to reduce operating costs and improve competitiveness. But external manufacturing is moving away from a purely opportunistic approach of transferring overcapacity to external partners or outsourcing of manufacturing to low-cost countries to reduce costs towards

a more strategic approach, where external service providers are seen as partners. The ability to establish and manage strategic partnerships is seen as a key competence.

This paper addresses this aspect and focuses on strategic partnerships to increase competitiveness of large pharmaceutical companies by outsourcing activities from chemical production through partly finished products to finished goods packaging.

An action research approach was used based on a single case study of a global leading pharmaceutical company. A partner selection process consisting of seven consecutive steps, including the criteria for the partner selection, was developed for pharmaceutical companies with their highly regulated, quality focused manufacturing processes and history of vertically integrated production. It was also shown that, besides having the right process in place, the appropriate organizational structure has to be established. The research questions are: RQ1. How can a strategic partner selection process for pharmaceutical manufacturing be defined and implemented? RQ2. What are criteria for the partner selection within such a process?

-The third one by Bradfielda & El-Sayedb (2009) on “Applied to strategic for pharmaceutical companies”

Pharmaceutical companies were facing several major interrelated challenges, the most strategic being the decline in R&D productivity resulting in empty product pipelines to replace products nearing patent expiry.

A common response had been mergers and acquisition of competitors and biotechnology firms, but rather than resolving the problems, this had created new ones. While biotechnology promises to reshape the pharmaceutical industry, it too faces challenges: the industry as a whole was unprofitable and there was uncertainty regarding market acceptance of its products.

This paper examined the current issues in the two industries, and described a scenario process resulting in the development of a set of scenarios depicting four possible future paths along which the pharmaceutical industry may develop over the next 15 years.

2.5.1.3 Pharmaceutical Research Gaps between Thai & foreign Countries

Upon searching research report using Google Scholar and Google, the researcher had acquired 5 and 15 pharmaceutical papers on Thai and other countries. As an initial set of evidences, these papers had been thoroughly studied to identify the pharmaceutical industry and outsourcing gaps between Thai and foreign countries, in terms of development and growth of pharmaceutical industry; strategic management in outsourcing; determinants of Thai pharmaceutical industry (e.g. the government regulations, the international factors, and the competition among Asian countries). After skimming and screening for the relevant papers, only 4 papers were recruited and studied thoroughly. The synthesis research results on comparing Thai and foreign research to identify the research gaps as follows:

-The first one by Yoongthong et al. (2012) on “National drug policies to local formulary decisions in Thailand, China, and Australia: Drug listing changes and opportunities”

This commentary is aimed at summarizing the second plenary session, presented at the ISPOR 4th Asia-Pacific Conference held in 2010, and compare the issues on drug listing of Thailand, China, and Australia. These countries have substantially different demographic and economic characteristics and health-care financing structures and are in different phases of development of health technology assessment (HTA).

In 2008, government expenditure on health per capita in Australia was approximately 60 times that of China and 20 times that of Thailand. The percentage of gross domestic product spent on health care in Australia is twice that of China and Thailand, and the percentage of government-funded health care of total health care is considerably low for China. The proportion of private expenditure on pharmaceuticals in both China and Australia is similar and reflects those of established market economies; in Asia, almost half of all pharmaceutical expenditure is privately funded. Each of the three countries has its own unique challenges and opportunities. These issues are presented for each country following an overview of the policy and drug listing of the three countries.

-The second one by Kaplan et al. (2013) on “The market dynamics of generic medicines in the private sector of 19 low and middle income countries between 2001 and 2011: A descriptive time series analysis”

This observational study investigates the private sector, retail pharmaceutical market of 19 low and middle income countries (LMICs) in Latin America, Asia and the Middle East/South Africa analyzing the relationships between volume market share of generic and originator medicines over a time series from 2001 to 2011. Over 5000 individual pharmaceutical substances were divided into generic (unbranded generic, branded generic medicines) and originator categories for each country, including the United States as a comparator.

In 9 selected LMICs, the market share of those originator substances with the largest decrease over time was compared to the market share of their counterpart generic versions. Generic medicines (branded generic plus unbranded generic) represent between 70 and 80% of market share in the private sector of these LMICs which exceeds that of most European countries. Branded generic medicine market share is higher than that of unbranded generics in all three regions and this is in contrast to the US. Although switching from an originator to its generic counterpart can save money, this narrative in reality is complex at the level of individual medicines. In some countries, the market behavior of some originator medicines that showed the most temporal decrease, showed switching to their generic counterpart. In other countries such as in the Middle East/South Africa and Asia, the loss of these originators was not accompanied by any change at all in market share of the equivalent generic version.

For those countries with a significant increase in generic medicines market share and/or with evidence of comprehensive “switching” to generic versions, notably in Latin America, it would be worthwhile to establish cause-effect relationships between pharmaceutical policies and uptake of generic medicines. The absence of change in the generic medicines market share in other countries suggests that, at a minimum, generic medicines have not been strongly promoted.

-The third one by Kaplan et al. (2012) on “Policies to promote use of generic medicines in low and middle income countries: A review of published literature, 2000–2010”

Objective: Review the literature on the impact of policies designed to enhance uptake of generic medicines in LMICs. **Methods:** We searched for publications related to generic medicines policies (January 2000–March 2010) and did a bibliometric, descriptive analysis of the dataset in addition to an analysis of studies evaluating the impact of pro-generic policies. We repeated a subset of this larger search in January 2012.

Results: Of the 4994 articles screened, 315 (6.3%) full-text publications were related to generic medicines policies. Of these 315, 236 (75%) dealt with generic medicine policies in high-income countries, and 79 (25%) with policies in LMICs. In total, we found only 10 evaluation studies looking at the impact of competition, trade, pricing and prescribing policies on generic medicine price and/or volume. Key barriers to implementing generic medicine policies in LMICs are negative perceptions of stakeholders (e.g., generics are of lower quality) plus perverse private sector financial incentives to sell products with the highest profit margin. Other relevant barriers are legal/ regulatory, such as the absence of generic substitution regulations. There also exists a general difficulty in promoting generics due to a lack of transparency in the pharmaceutical supply and distribution system, for example, a lack of price information provided by health care provider organizations to physicians.

Conclusion: There is little policy evaluation to determine which pro-generic policies increase generic medicines utilization in LMICs. Ensuring a functioning medicine regulation authority, creating a reasonably robust market of generic medicines and aligning incentives for physicians, consumers and drug sellers are necessary prerequisites for increasing the uptake and use of generic medicines.

-The forth one by Guennif & Ramani (2008) on “Catching up in pharmaceutical sector-lessons from India, Thailand & Brazil”

Catching-up in the pharmaceutical sector cannot be considered uniquely in terms of the development of industrial capabilities, but must be defined as a vector with at least two components: (i) industrial competence and (ii) availability of and accessibility to essential medicines. Since a little more than a decade the task of healthcare systems to ensure access to medicines has been made more complex by the international homogenization of IPR regimes. This refers to the signing of the TRIPS convention by

the member countries of the WTO. In the above context, the present paper focuses on the first component of the catch-up vector (industrial competence) and attempts to answer two central questions: (1) what are the determinants of catching up in terms of industrial capabilities in the pharmaceutical sector? (2) What is the role of IPRs on the catching up process?

We use the case study method to answer these questions through an examination of the evolution of the pharmaceutical sector in three emerging economies: India, Brazil and Thailand.

The research findings are 1) a comparison of industrial capabilities: India: Becoming global, Brazil: with industrial capabilities but still technically dependent, Thailand: a strong public sector but still technically dependent; 2) a comparison of innovation capabilities: India: R&D only for big firms and behind Western firms, Brazil: a committed public sector, Thailand: Technology transfer not much of a help; 3) the role of IPR: India: Vive re-engineering, Brazil: overdoing it with TRIPS, Thailand IPR: Boosting quality rather than quantity; and 4) the determinants of catching up in terms of industrial competence: In the light of the above, one can clearly conclude, that in terms of catching-up as given by development of industrial competence, India is clearly in the lead, followed by Brazil, and finally by Thailand. Creation of industrial capabilities and ensuring healthcare for all, are two different faces of the same coin of catching-up. The degree of catching-up on one aspect is not automatically correlated to the degree of catching up on the other. Moreover, policies which promote one part of catching-up need not promote the other and this applies especially to IPR.

In conclusion, the first research paper focused on the determinants of Thai pharmaceutical capacity development under the FTA, the next two papers shed light on harmonization of TRIPS -Plus IPR policies and the TRIPS-agreement affecting the price and availability of medicines, and its extension of overall effects on health, whereas the last paper focused on the determinants of catching up, and the role of intellectual property rights on the catching up process. The results of those four papers are rather related to international situation in pharmaceutical industry, all of which would be useful as background for this study. However, the researcher has to formulate the research questions on Thai pharmaceutical situation based on literature review rather than research review.

Based on analysis of the current status and international norms & standards, the gaps & issues in the Thai Pharmaceutical industry can be summarized as Table 2.4

Table 2.4: Summary of determinants/characteristics gaps between Thai & foreign

Author/ Yr published	China	India	Brazil	Thailand	Gap
Pricewater house Cooper, 2008	China is the leading	Be the second, followed closely to China			Outsourcing destination
IMS ,2011	18-21%	11-14%	8-11%		Global Pharma Market Growth to 2012
Kuanpoth, 2006		80% is formulation + 20% in bulk drug form.	Local firms have developed competencies in formulation. >90% API are imported from India or China	The dominant of local firms is simply formulations, and to a modest in the packaging of imported drugs. Few API	industrial capability (primary/ secondary manufacturing)
Kuanpoth, 2006		R&D targeted only to lower costs of production of selected drugs.	R&D with foreign firms remains marginal. Most are carried out by public laboratories	GPO & local firms do not invest much in R&D	Innovation Capability (R&D)
Wogart et al., 2006;		The new IPR regime began to recognize only process patents.	Overdoing it with TRIPS	Boosting quality rather than quantity	Role of IPR
Guennif & Ramani, 2008		Government invests in higher education and research	Use of, "Compulsory licensing" to strengthen local firms.	Promote safety (e.g. GMP, SMP) forced local firms to exit the market and fortified the market shares of foreign multinationals.	Role of the State (Government)
Guennif & Ramani, 2008		The Indian council of Medical Research	The public sector organizations were either	The public sector organizations were either	Role of public sector and public-private cooperation

Author/ Yr published	China	India	Brazil	Thailand	Gap
		hardly played any role either in helping Indian firms or the Indian healthcare system.	production or distribution units or both	production or distribution units or both	
Yoongthong et al.,2012	Establishing a rational use system of EDs, formulating clinical guideline and EDs formulary			Promoting the rational use of drugs by doctors, health professionals, and the public.	National Drug Policy (Rational use)
Yoongthong et al.,2012	Full implement of the new quality std. & safety for EDs; electronic monitoring of whole process from manufacturer to distribution			Development of a control system to ensure the quality, efficacy, and safety of drugs	National Drug Policy (Quality)
Yoongthong et al.,2012	92% of Chinese population at the end of 2010			99.4% of Thai population at the end of 2010	Population coverage of National Health Insurance
Nguyen et al., 2014		Cost plus pricing	Pharmaco economic evaluation for value based purchasing	Internal reference pricing	Pricing techniques
Siddiqui, 2014		Capital inflows rise by 8% in Y2011	Capital inflow rise by 31% in Y2011		FDI (foreign direct investment)

2.5.2 Other Business Research on Strategic fit of Outsourcing in SCM

Upon searching research report using Google Scholar and Google, 42 papers on other businesses than pharmaceutical strategic fit, outsourcing, and/or SCM were

acquired. After skimming and screening for the relevant papers, only 12 papers were recruited and studied thoroughly. The synthesis research results on strategic fit of outsourcing in SCM for other business are presented in three topics of business situation, business strategic fit of outsourcing in SCM, and business scenario analysis and case study.

1) Business Research on Situation

The synthesis results of 2 papers on other business situation, as presented below, indicated different research questions and methods.

-The first one by Bredenl w (2003) on "Strategic alliance: Synergies and challenges"

The researcher employed a free approach with little structure of the data collection, like case studies and interviews, aiming to handle high flexibility and enable to find interesting tracks along an explorative research journey. Starting from theories and known facts in literature, qualitative data generated by interviews and case studies are utilized to gain a better direction for the deep explorative study.

The case study methodology was to generate in-depth knowledge of the research problem. The interviewees consist of 25 Swedish manufacturing companies, mainly in the business of heavy equipment production. The analysis results could be used for suggestive purposes for other companies and as a foundation for further studies.

-The second one by Mckelvey (2014) on "Scenario planning in an uncertain world"

The researcher used scenario planning for both its process and its outcomes. The process of imagining the future through discreet scenarios forced executives to acknowledge that the recent past was rarely a reliable guide to the future; it minimized the risk of group think by providing a safe setting in which assumptions could be called into doubt; and it sharpened strategic decision-making in general by illuminating the major forces likely to affect an industry in the future.

Moreover, when scenario planning was backed with systematic research and analysis, the outcome was usually a set of scenarios that provided a surprisingly informative foundation for executives as they face an uncertain future.

2) Business Research on Strategic Fit of Outsourcing in SCM

The synthesis results of 6 papers on other business research on strategic fit of outsourcing in SCM, as presented below, indicated different research questions and methods.

-The first one by Brewer et al. (2013) on “Understanding the supply chain outsourcing cascade: When does procurement follow manufacturing out the door?”

Does the outsourcing of manufacturing trigger a cascade of follow-on outsourcing, wherein related procurement activities are subsequently entrusted to one’s outsourcing partner? We explored this question in a survey of US-based electronics original equipment manufacturers (OEMs) who have outsourced production to a CM (CM). Transaction-cost economics and the resource-based view were used as theoretical lenses to assess six potential drivers of this decision, utilizing direct and indirect-effects structural models across five phases of procurement activity. Results suggest that some sets of conditions appear to lend themselves to a wholesale outsourcing approach, wherein the CM is entrusted to both manufacture a product and engage in various procurement activities. Other conditions foster a more retail approach to procurement outsourcing, with limited or no follow-on outsourcing of procurement activities. In general, firms seem more comfortable outsourcing tactical procurement activities, entrusting strategic activities to CMs only when the product is highly commoditized or when the CM controls access to international resources the OEM is unable to leverage on its own. Overall, the relationship between manufacturing and procurement outsourcing is complex and contingent on a variety of factors.

-The second one by Langley (2014) on “Third-party logistics study: The state of logistics outsourcing, results and findings of the 18th annual study”

A distinguishing feature of the *Annual 3PL Study* is the multiple streams of research the study team undertakes to validate and illuminate the findings in this report. The team solicits survey topic ideas throughout the year from key industry participants and through desk research conducted by the team and by Capgemini’s Strategic Research Group, which also helps to vet potential topics of interest.

Survey topics and questions attempt to reflect key issues and trends facing both users and providers of logistics services. Following the survey, the team conducts intensive, one-day facilitated shipper workshops that enable the team to work side by side with shippers to explore survey results in the context of overall industry trends to discover deeper implications.

The survey instrument is typically well received by members and affiliates of the *Annual 3PL Study's* partner organizations, attracting 1,393 respondents. But this year's survey participation fell off significantly. This year's survey circulated in mid-2013, garnering 812 usable responses, from both users and non-users of 3PL services, as well as responses to a separate, related version of the survey by 581 respondents from the 3PL sector. The study report and additional materials are also presented via its own Web site, www.3PLstudy.com. This year's topics include Big Data, preferential sourcing, smart growth leaderships, and shipper-3PL relationships.

Big Data

One of the most exciting and talked-about trends in supply chain management is 'Big Data' and their potential to shed new light on supply chain problems and solutions. IDC and other analysts declared 2013 to be the start of the 'Big Data' era in supply chain, but concede that some organizations will 'get it' more quickly than others, and use that early adopter mentality for competitive advantage (Langley, 2014).

'Big Data' is high-volume, -velocity and -variety information assets that demand cost-effective, innovative forms of information processing for enhanced insight and decision making.' 'Big Data' represents a potential new source of competitive advantage for business industries by harvesting data for enhanced insight into market trends, cost structures and demand and capacity fluctuations, service providers can operate more efficiently and improve the scalability of their enterprises (Biederman, 2013)."

Supply chain activities may be generating 'Big Data', but internal IT departments are its curators. Succeeding with 'Big Data' initiatives that benefit the supply chain will require collaboration between supply chain and IT organizations within the companies (Langley, Jr., 2014).

-The third one by Walker et al. (2009) on “Outsourced marketing: It’s the communication that matters”

The researchers considered that outsourcing had been promoted as one of the most powerful trends in the modernization of marketing operations. The rationale for such an undertaking included a variety of factors but was generally predicated on fiduciary considerations.

They, therefore, examined the issues of outsourcing, specifically related to the Communication employee, commitment relationship, within the intercollegiate marketing context with an exploratory mixed-methods study incorporating qualitative and quantitative empirical data and the consequences.

Their finding from study 1 revealed that marketing directors perceive outsourcing as critical but also experienced dissatisfaction with the level, frequency, and direction of communication. Results from study 2 indicated that an explicit and positive relationship existed between employee satisfaction with communication and their resultant commitment to the organization. Even of its exploratory nature with relatively small sample, the research focuses on several temporary aspects of the communication-commitment framework not previously examined.

The researchers recommended firstly that managing the “right commitment” was essential for marketing departments when working with an outsourcing agency; and secondly, they called attention to the importance of certain contextual factors (e.g. shared knowledge, mutual dependency, and organizational linkage) that may serve to improve the outsourcing partnership.

-The forth one by Zaman & Mavondo (2008) on “Measuring alliance success: The role of strategic fit”

Strategic fit or co-alignment was a notion that asserts that the environment and organizational strategy interact in a dynamic co-alignment process and a match between them has significant and positive implications on performance.

With respect to alliances, the concept of strategic fit or co-alignment has not previously been empirically examined. It is a major and continuing challenge for alliance managers and firms to align alliance attributes with organizational capabilities. Based on a sample of alliances drawn from the Australian manufacturing and service

sectors, this study empirically tests strategic fit as co-alignment or co-variation and its implications on alliance performance.

The results suggest that co-aligning or reconciling the alliance attributes such as partner characteristics, relationship management and organizational capabilities have considerable influence on alliance success and that the co-alignment model is significantly superior to a direct effect model.

-The fifth one by Vorontsova & Rusu (2014) on "Fit for IT outsourcing relationships: A recipient-provider perspective"

Even though there is a big established IT outsourcing market, one can witness considerable amount of failed projects there. It is proven that good relationships between an outsourcing recipient and a provider contribute to the outsourcing success whereas less successful relationships increase the cost of outsourcing. The research in this area is mostly focused on either an outsourcing provider or more often on an outsourcing recipient, hardly considering both sides of the outsourcing relationships simultaneously. Moreover, there is no study on the importance of the determinants of the IT outsourcing relationships which takes into consideration both parties. In this research we are presenting the determinants of the IT outsourcing relationships.

Moreover, we are evaluating the importance of the IT relationship determinants in the case study of the relationships between one outsourcing provider and one outsourcing recipient by using interviews as a data collection method and a content analysis as a data analysis method.

The new findings can be used for the enhancement of the relationships between the outsourcing recipient and the provider, to improve the service deliveries to the end users and ultimately to contribute to the outsourcing success.

-The sixth one by Lee (2001) on "A SFM for IT outsourcing success: An exploratory approach"

Lee finished his first attempt to explore and identify major four dimensions for outsourcing strategy: degree of outsourcing, relationship type, period of outsourcing, and number of vendor, that could affect outsourcing success. His contribution differed

from the past research papers, all of which studied only one or two outsourcing strategies.

Using quantitative survey, he sent 1,000 CIO's of the firms by questionnaire and collected the data using an interview with 311 CIO's.

3) Business Scenario Analysis and Case Study

The synthesis results of 4 papers on other business scenario analysis and case study, as presented below, indicated different research questions and methods.

-The first one by Silva, et al. (2015) on "A framework of performance indicators used in the governance of logistics platforms: The multiple-case study"

The use of a logistics platform may be a source of competitive advantage by integrating activities within a specific supply chain scenario, which is seen as a key factor for the success of many companies. A logistics platform includes concepts of integrated logistics regarding physical structure, processes and operational activities, as well as information systems needed for the development of operations and reporting.

The objective of this research was to elaborate a framework of performance indicators that could be used in the governance of logistics platforms based on bibliographical research on performance indicators in the business environment and logistics indicators.

To achieve the proposed objective, a multiple cases study with leaders of logistic platforms located in Zaragoza, Valencia, and Barcelona in Spain was carried out. As a result a set of twenty seven performance indicators were identified. That presented a high degree of importance and can contribute to the governance of logistics platforms.

-The second one by Klibi & Martel (2012) on "Scenario-based supply chain network risk modeling"

The research provided a methodology for supply chain network design under uncertainty. The problem was initially casted as a two-level organizational decision process: the design decisions must be made here and now, but the reengineered supply chain network could be used for daily operations only after an implementation period. The network structure could also be adapted during the planning horizon considered.

When making the design decisions, the operational response and structural adaptation decisions taking place during the planning horizon must be anticipated.

The methodology recognizes three event types to characterize the future SCN environment: random, hazardous, and deep uncertainty events. At the design time, plausible futures are anticipated through a scenario planning approach. Several Monte Carlo scenario samples are generated and corresponding sample average approximation programs are solved in order to produce a set of alternative designs. A multi-criteria design evaluation approach was then applied to select the most effective and robust design among candidate solutions. An illustrative case, based on the location---transportation problem, was finally introduced to illustrate the approach, and computational experiments were performed to demonstrate its feasibility.

-The third one by Terbeck (2014) on “E-commerce 2025: Delphi-based scenarios and trend analysis for the future of digital commerce”

E-commerce is growing globally and an end to positive growth rates was not yet in sight. However, a high level of changes and risks through innovative startups and disruptive technologies is an inherent characteristic of the online retail industry. As consumer demand shifts constantly and new technological possibilities as well as an ongoing digitization foster the transformation of commerce, retail managers are confronted with great uncertainty.

Nevertheless, academic foresight studies for e-commerce technologies were missing. This thesis closes this prevailing research gap. The central research question is: What are plausible scenarios for the development of business-to consumer e-commerce by 2025 focusing on technologies? Four distinct, plausible, and innovative scenarios were developed on the basis of desk research, nine qualitative expert interviews, and two quantitative Delphi-survey rounds with 61 industry experts. The scenarios differ along two bipolar dimensions of uncertainty, i.e. the changes in lifestyles and the pervasiveness of technologies. The scenarios for B2C commerce in 2025 and its main traits are presented and derived for the strategic implications.

This study is very practice-oriented and provides five clear implications to retail managers. First, the results of this study shall be used to rehearse the future. Second, retailers have to monitor changes in the local and macro environments. Third, retail

businesses ought to be transformed to technology businesses. Fourth, customer centricity should be established as the core value. And fifth, multiple shopping experiences have to be served across different channels.

-The forth one by Mazzarino (2012) on “Strategic scenarios of global logistics: what lies ahead for Europe?”

The researcher found that most of the qualitative and strategic approaches in the building of future scenarios are mostly developed for sectors other than logistics and transportation (e.g., manufacturing), therefore there is the need to address the issue of scenario building in the field of global logistics through an efficient strategic method.

He had seek to fill this gap by employing a qualitative - quantitative methodology based on the strategic planning approach to provide a number of macro medium term scenarios in the field of global logistics and assessing the impacts on the European area. His research method consisted of a focus group analyses to derive a preliminary grid of main drivers of change, and a semi-structured interviews to build a number of strategic scenarios for global logistics are built – each scenario defined in terms of a combination of strategic drivers.

The research finding, in particular, showed how a specific model at the macro level – Symmetric Global Logistics Model – would be likely to prevail on a global scale, in which two fundamental sub-components (local/global) will play a determinant role. The impact of the Symmetric Global Logistics Model was then strategically assessed with regards to European logistics systems.

Each research has different research contexts, objectives and questions, and each of which will be conducted by same or different methods as shown in the following table 2.5

Table 2.5: Summary of related research literature review

Research Context	Research Reference	Research Objective/ Question	Research Method	Research Results
<i>Thai Pharma</i>				
Thai Pharma situation	Kuanpoth, 2006	- To examine whether TRIPS-Plus rules on pharmaceutical patents generate benefits to developing countries	-Situation analysis	Thailand did not have a functional technological base and this made the country industrially and technologically

Research Context	Research Reference	Research Objective/ Question	Research Method	Research Results
				dependent on foreign interests.
Pharmaceutical sector	Guennif & Ramani, 2008	-To examine the information flow during the process of order transactions between the pharmaceutical company. -To compare of industrial capabilities, a comparison of innovation capabilities, the role of IPR, the determinants of catching up in terms of industrial competence between three countries.	-Case study method	It showed that while IPR plays an important role, other factors like State policy in terms of investment in public research, regulation, nature of market competition, public-private cooperation and consumer preferences modulate the final impact.
Pharmaceutical supply chain	Pothitong & Charoensiriwath, 2011	-To study how a web-based system and business standard for information flow can be applied to improve efficiency in its supply chain.	-Case study method	It can be applied to improve efficiency in its supply chain operations of a web-based system and a business standard for information flow of medium size multinational pharma company in TH.
Pharmaceutical supply chain	Charoensiriwath & Pothitong, 2008	-To find the electronic connection companies standard within the same supply chain.	-Scenario research	Successful connect the whole supply chain, an information standard was needed to exchange electronic documents between business partners.
Supply chain efficiency	Piboonrungsri, 2014	- To understand the structure of logistics cost and supply chain efficiency in the international trade	- interview experts	Transports and warehousing have a significant contribution in the logistics cost. However the results show that there are several hidden costs such as costs related to the hygiene and quality control and assurance.
Pharmaceutical Merging	Baines, 2010	-To examine the Pharmaceutical industry and the changes that have occurred particularly over the last 10 years.	-In-depth interview	The analysis focused on the commercial aspects of the industry and offers some steps that would be useful in changing the current business model and setting the stage for future success.
Pharmaceutical outsourcing	Pacific Bridge Medical, 2014	- To examine the factors that differentiate one country from another, in order to determine which country is best suited for a particular clinical trial.	-Factor analysis	Each country has different factors for a particular clinical trial.

Research Context	Research Reference	Research Objective/ Question	Research Method	Research Results
Business competitive advantage	Kongrerk, 2013	- To derive competitive advantage of Thai Traditional Medicine and herbal products industry by analyzing from SWOT and Porter's Diamond model	-Depth interview (business owners)	Strengths and opportunities in this industry are derived from internal and external factors of their companies which indicated the competitive advantage over potential competitors
Pharmaceutical future trends	Landau, 2011	- To establish controlling tools will make a significant contribution to the success of Merck Ltd.	-Self-controlling approach	Management and the Finance Department helped to develop key performance indicators for every department and for every main process, and a few flagship controlling tools were developed and implemented
Key success factors	Suksawat & Boonsothonsatit (2015)	-To analyze key success factors for enhancing competitiveness of a bio pharma plant in Thailand along its supply chain	-Scenario research	The key success factors of the biopharmaceutical supply chain consist of organizational factors and external factors
Key determinant factors of pharmaceuticals	Saktontai, 2007	-1) To explore the determinant factors influencing the pharmaceutical industry in under FTA Thailand-U.S.A.; 2) to study future trends and directions of Thailand's pharmaceutical industry; 3) to recommend the pharmaceutical industry in Thailand to improve itself to compete globally; and 4) to make future recommendations	-Interviews & questionnaires	There are several factors that influence on the pharmaceutical in Thailand under The FTA Thailand- U.S.A. They are demand conditions, strategy, structure and competition among domestic companies, and related and supporting industries, the role of the government, external factors.
The factors effect on health	Strand, 2014	-To investigate the TRIPS-agreement signed by all members of the World Trade Organization -1) What are the determinants of catching up in terms of industrial capabilities in the pharmaceutical sector? 2) What is the role of intellectual property rights on the catching up process?	-Case study method	Prices had been affected by TRIPS due to the extension of patent term in India and Brazil, delaying generic manufacturing and that compulsory licensing though permitted under the agreement held consequences, as seen in the cases of Thailand and South Africa.
Foreign Pharma				
Pharmaceutical Supply chain strategies	Teng et al., 2014	-Four research questions: RQ1. What is the generic starting point for the	- case study methodology	-The generic supply chain shown describes all the possible steps

Research Context	Research Reference	Research Objective/ Question	Research Method	Research Results
		development of regenerative medicine supply chains? RQ2. What is the structure of supply chains associated with current (core) regenerative medicine therapies? RQ3. What are the comparative supply chain uncertainties? RQ4. How might these supply chain uncertainties be resolved (to reduce therapy developmental risk)?		in the production and supply of a cell therapy, the associated issues and potential links to the regenerative medicine industry. -It is made up of 12 discrete steps. The process of cell differentiation could then play a crucial role in developing supply chains as a key competitive advantage and in shifting the regenerative medicine industry into a more procedurally based services & industry.
Pharmaceutical Supply chain management	Ganesh et al., 2013	- To focus on incorporating the use of electronic means in distribution.	- Exploratory and structured questionnaire	The study concludes that adoption of digital technology in channel management is a necessity to the success and growth of the industry.
Pharmaceutical Supply chain management	Rossetti et al., 2011	-To identify and examine the major forces that are changing the way biopharmaceutical medications are purchased, distributed, and sold throughout the supply chain.	- Multiple interviews	The relationship between major forces is mediated by operations strategy concerning inventory policy, supply chain visibility, desired service levels.
Pharmaceutical outsourcing	Bals et al., 2013	- To find which R&D activities can be outsourced and which need to stay in-house in order to ensure competitiveness	- Scenarios analysis	R&D is the core of knowledge-intensive industries like Pharmaceutical, outsourcing parts of its activities hold considerable efficiency and effectiveness potentials
Pharmaceutical outsourcing	van Vierssen, 2013	-To explore the causes of this crisis by understanding the system of the pharmaceutical R&D productivity and to locate any critical leverage points. Research question is: <i>How to identify the critical leverage points in the pharmaceutical R&D productivity system via a Bayesian belief network?</i>	-Scenarios analysis	As a result of these simulations, the leverage points (and thus the focus points for future research) are scenario dependent. The future scenario of the industry is still uncertain.
Pharma outsourcing manufacturing	Festel et al., 2014	- The research questions are:	-An action research approach	The paper addresses this aspect and focuses on

Research Context	Research Reference	Research Objective/ Question	Research Method	Research Results
		RQ1. How can a strategic partner selection process for pharmaceutical manufacturing be defined and implemented? RQ2. What are criteria for the partner selection within such a process?		partnerships to increase competitiveness of large pharmaceutical companies by outsourcing activities from chemical production through partly finished products to finished goods packaging
Pharma outsourcing manufacturing	Kaplan et al., 2005	-To summarize the issues surrounding "local production" from a policy and public health viewpoint.	- Case study methodology	In many parts of the world, producing medicines domestically makes little economic sense. If many countries begin local production, the result may be less access to medicines, since economies of scale may be lost if there are production facilities in many countries.
Pharmaceutical outsourcing	Abuhamad, 2014	-To investigate how strategic practices associated with participation in international collaboration. With 2 RQs: RQ1. How the companies' management practices in scanning process are associated with the different levels of participation in IC and the different types of innovation a company performed? RQ2. How participating in different levels of International collaboration are associated with the type and degree of innovation performed by a company?	- An exploratory study	It identified how the firms perform strategic search for international collaboration, and how this influences the innovation performance. A key factor influencing the degree of participation in international collaboration is management proactiveness in the search and sense making process.
Pharmaceutical strategic management	Angwin & Meadows, 2015	-To call for methodological pluralism in M&A research, and uses a mixed method to assess the robustness of a leading post-acquisition integration typology.	-Multiple cluster analyses	This approach overcomes some limitations of single method research in M&A and results in a more robust, fine-grained and extended post acquisition typology.
Pharmaceutical strategic management	Bradielda & El- Sayedb, 2009	-To examine the current issues in the	-Scenario analysis	This paper examined the current issues in the two industries, and described a

Research Context	Research Reference	Research Objective/ Question	Research Method	Research Results
		Pharma & Biopharma industries, and scenario for next 15 years		scenario process resulting in the development of a set of scenarios depicting 4 possible future paths along which the pharmaceutical industry may develop over the next 15 yrs.
Pharmaceutical strategic management	JSB Intelligence, 2005	- To conduct a report providing an overview and analysis of the latest trends and strategies adopted by the main players of pharmaceutical industries.	- Using primary and secondary data	None of strategies covered all the market developments and their direct and indirect impact on the new revenue models of the pharmaceutical industry.
Pharmaceutical strategic fit	Armstrong, 2006	- To show how North Carolina fits into the global biotechnology sector by describing what elements of the value chain North Carolina plays a major role in, and what elements of that same chain North Carolina experiences differently from other important clusters.	- review the literature defining and analyzing	The biotechnology industry had been identified by cities and states across the country as an attractive, up-and-coming industry to be fostered by an array of economic development plans. The industry had the distinction of being among the most research-intensive, the most productive, and the most highly paid sectors in the US economy.
Pharmaceutical strategic fit	Danese et al., 2006	- To explore how the external fit affects the adoption of the following SCM initiatives, thus proving that SCM sequences cannot be considered context-free.	- Case study research	Sequences of SCM initiatives are the result of a series of successive decision situations, where the external fit and state of supply network configuration and integration vary each time a new SCM initiative is implemented.
Pharmaceutical open innovation	Raja & Sambandan, 2015	- To explore in detail the process of adoption of Open Innovation in the pharmaceutical industry through a case study.	- Case study research	We find a heterogeneous series of models that cope with different aspects and fit into specific contexts and industries like pharmaceuticals.
Pharmaceutical international sourcing	Haakonsson et al., 2013	- To identify and analyze the drivers and dynamics of the international sourcing of pharmaceutical research and development (R&D).	-In-depth interview	The research illustrates how host-country institutional evolution, notably regarding IP rights & education, plays a

Research Context	Research Reference	Research Objective/ Question	Research Method	Research Results
				significant role for international sourcing of pharma R&D.
<i>Other Business</i>				
Supply chain network	Klibi & Martel, 2012	- To provide a methodology for supply chain network (SCN) design under uncertainty.	- A multi-criteria design evaluation approach	The methodology recognizes three event types to characterize future SCN environment: random, hazardous, & deep uncertainty events.
Logistics outsourcing	Langley, 2014	- To survey topics and questions attempt to reflect key issues and trends facing both users and providers of logistics services.	-Desk research (Big Data)	'Succeeding with 'Big Data' initiatives that benefit the supply chain will require collaboration between supply chain and IT organizations within the companies
Outsourced marketing	Walker et al., 2009	- To examined the issues of outsourcing, specifically related to the Communication - employee, commitment relationship, within the intercollegiate marketing context.	-An exploratory mixed-methods study	Marketing directors perceive outsourcing as critical but also experienced dissatisfaction with the level, frequency, and direction of communication. And an explicit and positive relationship existed between employee satisfaction with communication and their resultant commitment to the organization.
Logistics platforms	Silva et al., 2015	-To elaborate a framework of performance indicators that could be used in the governance of logistics platforms based on bibliographical research on performance indicators in the business environment and logistics indicators.	-Multiple-case study	A multiple cases study with leaders of logistic platforms located (in Zaragoza, Valencia, and Barcelona in Spain) was carried out. As a result a set of twenty seven performance indicators were identified. That presented a high degree of importance and can contribute to the governance of logistics platforms.
E-commerce	Terbeck, 2014	- What are plausible scenarios for the development of business-to consumer e-commerce by 2025 focusing on technologies?	-Nine qualitative expert interviews, and two quantitative Delphi-survey	The results of this study shall be used to 1) rehearse the future, 2) retailers have to monitor changes in the local and macro environments, 3) retail businesses ought to be transform

Research Context	Research Reference	Research Objective/ Question	Research Method	Research Results
				ed to technology businesses, 4) customer-centricity should be established as the core value. And 5) multiple shopping experiences have to be served across different channels
Scenario planning	Mckelvey, 2014	-To imagine the future through discreet scenarios forced executives to acknowledge that the recent past was rarely a reliable guide to the future.	-Scenario analysis	The outcome was usually a set of scenario provided a surprisingly informative foundation for executives as they face an uncertain future.
Strategic alliance	Bredenlow, 2003	-To handle high flexibility and enable to find interesting tracks along an explorative research journey.	- Case studies and interviews	The case study methodology was to generate in-depth knowledge of the research problem. And the analysis results could be used for suggestive purposes for other companies and as a foundation for further studies.
Global Logistics	Mazzarino, 2012	-To found the most of qualitative and strategic approaches in the building of future scenarios are mostly developed for sectors other than logistics and transportation (e.g., manufacturing).	- A focus group analysis	A specific model at the macro level – Symmetric Global Logistics Model (SGLM) – would be likely to prevail on a global scale, in which two fundamental sub-components (local/global) will play a determinant role. The impact of the SGLM was then strategically assessed with regards to European logistics systems.
Strategic fit	Zaman & Mavondo, 2008	- To study empirically tests strategic fit as coalignment or covariation and its implications on alliance performance.	-Matching method	The coaligning or reconciling the alliance attributes such as partner characteristics, relationship and organizational capabilities have considerable influence on alliance success and that the coalignment model is significantly superior to a direct effect model.

Research Context	Research Reference	Research Objective/ Question	Research Method	Research Results
Outsourcing relationship	Vorontsova & Rusu, 2014	- To evaluate the importance of the IT relationship determinants in the relationships between one outsourcing provider and one outsourcing recipient.	-Case study and interviews	We are evaluating the importance of the IT relationship determinants in the case study of the relationships between one outsourcing provider and one outsourcing recipient by using interviews as a data collection method and a content analysis as a data analysis method.
Strategic fit	Lee, 2001	- To explore and identify major four dimensions for outsourcing strategy: degree of outsourcing, relationship type, period of outsourcing, and number of vendor, that could affect outsourcing success.	-Using questionnaire and collected the data using an interview.	All of the major four dimensions for outsourcing strategy: degree of outsourcing, relationship type, period of outsourcing, and number of vendor, can affect outsourcing success.

The conclusion of the above topics on review of related research, both in text and the Table 2.4 and 2.5, gives the researcher a guideline to construct a conceptual framework, even of most research papers are rather out of date, as they are published before 2010.

Firstly, research on Thai pharmaceuticals can be grouped into 4 topics. *a) Thai pharmaceutical situation:* past research published in 2006 indicated that Thailand industrially and technologically dependent on foreign interests because of functional technological base shortage; however, research in 2013 indicated that Thai pharmaceutical industry has strength and opportunity from the companies' internal and external factors over potential competitor companies. *b) Factors affecting pharmaceutical industry;* research in 2007 showed that factors influencing pharmaceutical industry are demand conditions, strategy, structure, competition among domestic companies, related and supporting industries, the government role, and the external factors; luckily research in 2011 indicated the future trends that the active role of the Management and the Finance Department helped developing key performance indicators for every main process, and a flagship tools, which would enhance the quality of pharmaceutical industry. *c) Thai pharmaceutical supply chain:* A research in 2008 and four research papers in 2014 indicated that supply chain management could be used

to improve operation efficiency, and the successful connection among business partners would be available only through using the documents with information standard. Moreover, one recent case study research in 2015 indicated that both organizational and external factors were key success factors of the pharmaceutical supply chain management. And *d) Thai pharmaceutical outsourcing*: only two research papers studied in 2010, and 2014, one showing the future trend in outsourcing in clinical trials and proposing some steps on commercial aspects to change the current business model; and the other just compared some countries to find only that each had different factors for a particular clinical trial.

Secondly, research on foreign pharmaceuticals can be grouped into 2 topics. *a) Pharmaceutical supply chain and strategic management*: six research papers published between 2005 -2015 indicated that the research problems called for ***mixed method research and scenario*** rather than single method, and found that the study factors necessary for the industry growth and success were digital technology, shifts in purchased, distributed, and sold throughout the supply chain. And *b) pharmaceutical outsourcing and strategic fit*: one paper in 2005 gave the summary of local production; five papers in 2013-2014 indicated the critical leverage points; identified which type of R&D activities could be outsourced or stayed in-house to ensure competitiveness; investigated the scanning process and the relationship between participation and innovation type and degree; and defined the criteria for selection and implemented strategic partner selection process; and two papers in 2006 indicated the sequences of SCM initiatives as a result of external fit and states of varying supply network configuration and integration; and reviewed literature to identify elements of the value chain North Carolina showing fits into biotechnology sectors, and elements North Carolina experienced differently from other cluster.

Thirdly, research on other business can be grouped into 2 topics. *a) outsourcing and strategic fit research*: seven papers in 2003-2014 indicated that Big data initiatives benefited logistic outsourcing and required collaboration; marketing directors perceived outsourcing as critical but dissatisfied with the level, frequency and direction of communication, and concluded the significance of communication and resultant commitment; focused the importance of IT relationship as the determinant of the relationship between the outsource provider and outsourcing recipients; identified four

dimensions of outsourcing strategy as outsourcing degree, relationship type, number of vendor, and outsourcing period; indicated that partner characteristics, relationship management, and organization capabilities are significant attributes affecting alliance success, and the coalignment model was significantly superior to a direct effect model; and the outsource provider should handle alliance with flexibility and matching interesting tracks along an alliance journey. And *b) other issues not related to strategic fit and outsourcing*: the other four research paper studied ,are on creating framework and scenarios on business issues other than strategic fit and outsourcing.

2.5.3 Scenario Research

From the aforementioned conclusions, it appears to the researcher that the scenario analysis may be an appropriate research method for this study couple with a dearth of knowledge, the researcher has on this topic, it is necessary to review literature briefly on scenario research and then review the related research using scenario analysis in pharmaceutical industry

Most strategic planning approaches concern with the future-focused description of a desired future, or organizational vision, because external forces shape the future environment in many ways that are beyond the organization's influence and result in uncertainty (Gate, 2010). Uncertainty is a situation of inadequate information, which can be of three sorts: inexactness, unreliability, and border with ignorance. Therefore, uncertainty can prevail in situations in which ample information is available. However, if new available information illuminates one's more understanding, then it can decrease uncertainty. On the contrary, if it produces more complex than previously thought, then it can increase uncertainty (Agusdinata, 2008; Walker, Lempert & Hwakkel, 2012), and one must paid attention to more strategic management (McKelvey, 2014). Consequently, several research methods greatly increase the value of future analysis and research in social sciences including business (Glenn & Gordon, 2009), especially in present and future planning, strategic planning and management approaches (Mckelvey, 2014). Those methods consisted of a) a quite practical and well-known scenario analysis which is appropriate for the multiple future analyses and strategic planning management in the uncertain world (Glenn & Gordon, 2009; Mandel & Wilson, 1993; Mckelvey, 2014; Vargas et al., 2014; Walker et al., 2012) including

strategic scenario analysis for studying strategic planning management, using qualitative and strategic approaches (JSB Intelligence, 2005; Mandel & Wilson, 1993; Mazzarino, 2012); b) an explorative and descriptive approach in a small or large scale (Langley, 2014; Lee, 2001) or even in a “Big Data” scale (Biiedrman, 2013) including Delphi techniques (Terbeck, 2014); and c) multiple case study (Silva et al., 2015).

Due to the significant role of scenario analysis in strategic planning and management as mentioned above, and the nature of scenario research that includes several other research methods as exploratory, descriptive and multiple case study research; couple with the appropriate approach in studying strategic planning in an uncertain world, the researcher intends to employ scenario analysis in this study. Therefore, the aims of this section of related research review are to shed some lights on the scenario analysis and the application of scenario analysis as follows:

Scenario Analysis

In order to understand and deeply learn how to conduct a scenario analysis, the researcher has study and presented the basic concepts, purposes and construction of scenario analysis as follows:

1) Basic Concept of Scenario Analysis

The term “scenario” comes from the dramatic arts. A scenario in the theater refers to an outline of the plot and in movies it is a summary or set of directions for the sequence of action (Glenn & Gordon, 2009). Scenarios were first used as a military planning tool in World War II. At that time Herman Kahn helped scenario planning take root in the civil domain shortly after the war (Gates, 2010). In their millennium Project of future research the editors: Glenn & Gordon (2009) claimed that Herman Kahn was the father of scenario construction for futures research and policy analysis, because he introduced the term “scenario” into planning in connection with military and strategic studies conducted by the RAND Corporation in the 1950s. He further popularized the concept in the 1960s as director of the Hudson Institute, a private nonprofit research center devoted to issues related to U.S. public policy, international development, and defense. *On Escalation: Metaphors and Scenarios* by Herman Kahn first published in 1965 by the Hudson Institute introduced the idea of distilling scenarios into an escalation ladder.

From then on, the scenario concept spread throughout the world, especially in the future research and research areas required planning for the future and monitoring. The meanings of scenario and scenario analysis also change with their evolution. For example in the business areas, Schwartz (1996, cited in Gates, 2010) defined a scenario as a tool for ordering one's perceptions about alternative future environments in which one's decisions might play out. Mandel & Wilson (1993) defined scenarios as "signposts" for possible changes in an organization's environment and can be described by the concept of "scenario monitoring" in which lists of indicators, qualitative as well as quantitative, serve as guidelines in monitoring and assessment of change in the environment. Wilkinson (2004, cited in Gates, 2010) asserted that future scenarios are inherently linked to planning and decision-making, and facilitate the identification of large-scale uncertainties that push the future in different directions. A robust strategy from one or a small number of precise futures is one that will play out well across several possible futures, the scenarios of which can still be pursued for early warning signs that indicate whether a particular future is or is not unfolding. Glenn & Gordon (2009) regards scenario analysis as one among several tools for future research, and defines a scenario as a story with plausible cause and effect links that connects a future condition with the present, while illustrating key decisions, events, and consequences throughout the narrative. What usually passes for a scenario today is a discussion about a range of future possibilities with data and analysis. Such a discussion of futures research is perfectly fine and should be done, but does not constitute a scenario. It is like confusing the text of a play's newspaper review with the text of the play written by the playwright. Whereas Mckelvey (2014) explained that scenarios forced executives to acknowledge that the recent past was rarely a reliable guide to the future; it minimized the risk by providing a safe setting in which assumptions could be called into doubt; and it sharpened strategic decision-making in general by illuminating the major forces likely to affect an industry in the future. Moreover, when scenario planning was backed with systematic research and analysis, the outcome was usually a set of scenarios that provided a surprisingly informative foundation for executives as they face an uncertain future.

In this study, the researcher intends to use the meaning given by Mckelvey (2014) and Glenn & Gordon (2009) because in strategic management research, one needs to

derive both the existing scenario and the target of future possible scenarios backing with research and exploratory analyses, in order to generate policies, strategies, and plans, which help bring desired and likely future circumstances in alignment. Having made this decision, the researcher then further present the purpose and constructing process of scenarios as follows:

2) Purposes of Scenarios

From the future research, the three purposes of scenarios are 1) to acquire future scenarios from the process of systematically exploration, creation, and testing consistent alternative future environments that encompass the broadest set of future operating conditions that the user might plausibly face; 2) to generate long-term policies, strategies, and plans, which help bring desired and likely future circumstances in closer alignment, including to serve bringing assumptions about the field they cover to the foreground and use as a tool to discuss, test and maybe re-evaluate these assumptions; and 3) to use for innovation development, when scenarios describing, for example future living conditions and specific fields of consumption, are used to generate new product ideas.

In general, there are two types of scenarios: 1) exploratory scenarios describe events and trends as they could evolve based on alternative assumptions on how these events and trends may influence the future, and 2) normative scenarios describe how a desirable future can emerge from the present. Consequently, the term scenario has been used in two different ways: 1) to describe a snapshot in time or the conditions of important variables/indicators/issues at some particular time, and 2) to describe a future history or the evolution from present conditions to one of several futures. The latter approach is generally preferred because it can lay out the causal chain of decisions and circumstances that lead from the present (Glenn & Gordon, 2009).

Based on Vargas et al. (2014), scenarios are “*an internally consistent view of what the future might turn out to be - not a forecast, but one possible future outcome*”. The key point is contained in the notion of “*internal consistency*”. Therefore, more specific purposes of scenarios application to management, states that scenarios used in scientific approaches can perform two fundamentally different representational functions: 1) a scenario can be a representation of a selected part of the world (the target system).

Those are called the "*models of data*", and 2) a scenario can represent a theory or a decision making support in the sense that it interprets the laws and axioms of that theory. Those scenarios are called "*models of theory*". In their research paper only the "model of data" is employed to obtain the scenario corresponds to the occurrence of an earthquake of a given intensity in a given region, and the establishment of its consequences on both human and logistics factors.

For lack of precise knowledge in Thai pharmaceutical outsourcing in this study, the researcher, therefore, intends to employ only exploratory scenarios using qualitative and quantitative data to construct the 'model of data' in order to use as a ground for the analyses of the consequence in order to acquire strategies for strategic fit of a selected pharmaceutical company. This intention has been confirmed by Walker et al. (2009), who considered that outsourcing had been promoted as one of the most powerful trends in the modernization of marketing operations and examined the issues of outsourcing in the intercollegiate marketing context with an exploratory mixed-methods study incorporating qualitative and quantitative empirical data and the consequences.

3) Construction Process of Scenarios

In futures research, Glenn & Gordon (2009) concluded that numerous methods have been developed to create scenarios, ranging from simplistic to complex, qualitative to quantitative. Most approaches recognize the need to understand the system under study and identify the trends, issues, driving forces, and potential events that are critical to this system. Its' large-scale participatory processes of the Futures Group to construct a global normative scenario for futures research in 2050, consisted of hundreds of futurists, scholars, business planners, scientists, and policy makers who work for international organizations, governments, corporations, NGOs, and universities. The Futures Group identified and rated norms that formed the core of the normative scenario and develop the three-step process of scenarios construction as follows:

Step 1: Preparation - Define the scenario space. A scenario study begins by defining the domain of interest. Given a clear statement of the domain, analysts list key driving forces thought to be important to the future of the domain. These driving forces should be independent "axes" in a scenario space. If three such forces were defined, the space would be three-dimensional. With two forces, scenario space is two-dimensional.

Instead of defining a large number of alternative worlds which is often neither necessary nor desirable, a smaller set of choices of four to five worlds that encompass the range of major challenges and opportunities usually suffices. The final selection of worlds should be sufficient to present a range of opportunities and challenges, but should be small enough in number to handle.

Step 2: Development. There are four-step sub-process to complete this step:

1) Define the key measures. Within each scenario, certain key measures are described. These measures need to be selected with care in order to have the potential for great impact on the outcome of the scenario. Every scenario in the set will include projections of the same measures.

2) Define the events. This list of events will also appear in each scenario. These events shape the scenarios in several different ways: they can impact the key measures, change the chains of causality that lead from the present to the future, and/or make certain policies more or less likely to work. The probabilities of the events are different in each scenario and depend on their position in the scenario space.

3) Project the key measures. Trend Impact Analysis (TIA) is a useful technique for projecting the key measures. (A methodology paper in this series describes this technique.) Briefly, the historical data for each of the measures is projected using time-series methods. The events, expressed probabilistically, are combined with the extrapolation using Monte Carlo methods to produce a new median forecast and a range of uncertainty. Since events within a scenario impact several measures wherever they are used, they have the same probability; thus, internal consistency is promoted.

4) Prepare descriptions. Now, given the quantitative forecasts of the measures based on the probabilistic description of the impacting events, many chains of causality become apparent, and cohesive narratives describing the future histories can be prepared.

Step 3: Reporting and Utilization. There are three-step sub-process to complete this step as follows:

1) Document. In most cases, the best documentation is a simple series of charts and narratives describing the future history represented by each scenario. As thinking surrounding the scenarios is driven further down in the organization, several

levels of documentation for each of the scenarios is often useful. A top-line summary gives readers a quick, intuitive feel for the characteristics of a world from the perspective of a selected future time, how it developed, and what the decisive events were that caused the world to develop as it did.

2) Contrast the implications of the alternative worlds. How different are the business decisions and planning goals you would pursue considering each alternative world? What actions and commitments offer your organization the most resilience in the face of these uncertainties?

3) Testing policies. The range of scenarios can be used to test policies. In any study, a list of alternative actions is prepared from the decision makers after reading the scenarios. Each is defined as precisely as possible. Then, using quantitative techniques if possible, the policies are “tested” in each of the scenarios. When a particular policy produces desirable results in all cases, it is clearly a good bet. The other scenarios may give rise to contingent policies that can be called on if the circumstances develop that the scenarios depict.

The key point in writing scenarios is during writing scenarios, the story might develop in a direction different from the original expectation. The cause and effects links can emerge and yield a new future condition even outside of the original scenario space. Do not force the scenario back into the preconceived direction, otherwise the insights that could be very important can be lost.

In contrast to the futures scenarios approach mentioned above, the scenarios approach by Vargas et al. (2014) defined five steps required to define relevant and complete scenarios as follows:

Step 1: Understanding existing outcomes or events of interest. This step consists in determining the required characteristics from the existing situation or events using field survey, observation or interview.

Step 2: Determining probabilities of occurrence of the outcomes or events. The aim of this step is to build a list a scenario, with an estimation of its probability of occurrence using information from experts, research or literature review.

Step 3: Delimiting the derived scenarios. At the end of this step, the most critical scenarios are identified.

Step 4: Estimating & assessing the impact of scenarios. This step defines the impact as well as vulnerability of results taken into account. The outcome is an estimation of the amount of precise impact.

Step 5: Assessing the impact on the organizations. An estimation of available capacity, together with an estimation of the impacts of the scenarios is therefore needed to evaluate the difficulty and to build decision trees on potential strategy.

Even of its concrete and clear construction process of scenario analysis or scenario research, there seems to be plenty methods that scenario research can be applied in order to gain more information for policy development in strategic planning and management. Some significant methods are SWOT analysis, PEST analysis and situation analysis (Bredenl w, 2003). The Business Dictionary (2015) had defined those methods as follows:

SWOT analysis: A situation analysis in which internal strengths and weaknesses of an organization, and external opportunities and the threats faced by it are closely examined to chart a strategy. SWOT stands for strengths, weaknesses, opportunities, and the threats.

PEST analysis: A type of situation analysis in which political-legal (government stability, spending, taxation), economic (inflation, interest rates, unemployment), socio-cultural (demographics, education, income distribution), and technological knowledge generation, conversion of discoveries into products, rates of obsolescence factors are examined to chart an organization's long-term plans.

Situation analysis: A systematic collection and evaluation of past and present economic, political, social, and technological data, aimed at 1) identification of internal and external forces that may influence the organization's performance and choice of strategies; and 2) assessment of the organization's current and future strengths, weaknesses, opportunities, and threats.

Aiming to study strategic fit of pharmaceutical outsourcing in Thailand, this study requires a scenario approach to construct the existing scenario of the select pharmaceutical company, and to construct all possible future scenarios based upon the organization's demand and supply in order to acquire strategy for strategic fit. Hence, the next topic presents an application review of scenario analyses in order to learn the research objectives, the research methods and the concluding research outcome.

4) Related Research Using Scenario Analysis

Aiming to get guidelines for formulating the research questions and objectives, the research framework and hypotheses, and research method for this study in such a way not to replicate the past research on pharmaceutical outsourcing, the researcher, therefore, has searched, studied, and synthesized related researches that using scenario analysis as follows:

Scenario & Multiple Cases study

Silva et al. (2015)

The use of a logistics platform may be a source of competitive advantage by integrating activities within a specific supply chain scenario, which is seen as a key factor for the success of many companies. A logistics platform includes concepts of integrated logistics regarding physical structure, processes and operational activities, as well as information systems needed for the development of operations and reporting.

The objective of this research was to elaborate a framework of performance indicators that could be used in the governance of logistics platforms based on bibliographical research on performance indicators in the business environment and logistics indicators. To achieve the proposed objective, a multiple cases study with leaders of logistic platforms located in Zaragoza, Valencia, and Barcelona in Spain was carried out. As a result a set of twenty seven performance indicators were identified. That presented a high degree of importance and can contribute to the governance of logistics platforms.

Instruments

Silva et al. (2015) employed 2 type of data collection. They were

1. In-depth interview

This research was carried out by means of in-depth interviews with four managers of logistics platforms, which are in the top management in the companies visited. Individual in-depth interviews allow greater analysis and understanding of the purpose of research, because researchers make use of inductive strategies, raising and checking information that can be translated into concepts and practices that build a more

consistent approach to research. The sample of survey respondents is presented in Table 2.6

Table 2.6: Sample of survey respondents

Respondent	Job position	Company	Time with company	Equity
R1	Commercial Director	LP - Zaragoza	12 years	Public-Private
R2	General Director	LP - Zaragoza	9 years	Public-Private
R3	General Manager	LP - Valencia	4 years	Public-Private
R4	General Director	*Saba Parques Logísticos	5 years	Private

* *Saba Parques Logísticos* – Owner of 9 logistics platforms in Europe. LP- Logistics Platform / LPs – Logistics Platform

A set script of questions was used by the researchers, which was the basis for the overall direction and conduct of interviews. It is important to stress that additional questions during the interviews were asked, since the instrument above mentioned served as a script, thus allowing a greater degree of flexibility with the interviewees. With the script in hand, the interviews were conducted in Spanish, the respondents' native language. The possibility to conduct the interview in the respondents' native language allowed them to get more comfortable to expose their ideas and opinions.

2. Survey

A survey instrument was prepared based on the conceptual framework of usable indicators on governance of logistics platforms (Table 2.5) that contained 41 performance indicators (resulting from the literature review), distributed in 8 dimensions. The indicators were described in the survey form, and the respondents attributed the degree of importance for each indicator, according to its relevance when used in the governance of the logistical platforms, being ranked: 1-not important, 2-Low importance, 3-somewhat important, 4-Indifferent, 5-Important 6-Very Important and 7- Extremely important. While developing the scales, the response patterns among multiple items are weighed. Two control questions were used in the data collection instrument: i) taking into consideration the performance indicator structure proposed, in your opinion, what is the degree of importance of each indicator in governance of logistics platform?; and ii) Is there any other performance indicators on governance of

logistics platform which are not part of the proposed structure? If yes, what are those indicators?

Applied to Disaster Management such as Earthquake

Vargas et al. (2014)

One of the main issues is that the scenarios used to design and validate the proposals are often not accurate and/or too simple compared to the complexity of real situations. Designing realistic scenarios is of prime importance to be able to propose relevant quantitative models which could be implemented by practitioners. This paper tackles this problem by proposing a structured methodology which aims at defining realistic disaster scenarios. The case of earthquakes management in Peru is used to illustrate the consistency of our proposal.

Scenarios are “an internally consistent view of what the future might turn out to be not a forecast, but one possible future outcome”. The key point is contained in the notion of “internal consistency”. Scenarios used in scientific approaches can perform two fundamentally different representational functions. On one hand, a scenario can be a representation of a selected part of the world (the ‘target system’). Those are called "models of data". On the other hand, a scenario can represent a theory or a decision making support in the sense that it interprets the laws and axioms of that theory. Those scenarios are called "models of theory". In this paper only the “model of data” is employed.

Method: For lack of precise knowledge on locations, intensity and impact of future earthquakes, the approach proposed in this paper is based on the analysis of a set of plausible scenarios. One scenario corresponds to the occurrence of an earthquake of a given intensity in a given region, and the establishment of its consequences on both human and logistics factors (number of impacted population and partial or total destruction of warehouses and roads).

Depending on the availability of the information needed, the uncertainties are treated differently. Discrete probability distributions are calculated directly when data is available and pre-specified intervals are used otherwise. In our approach, five steps are required to define relevant and complete scenarios which describe the impact of a disaster on relief supply chains.

Step 1: Understanding trigger events. This step consists in determining earthquake characteristics (location and intensity). To achieve this, a review of historical databases of earthquakes is done. After having selected the area, which will be the target of the study, regions are identified. For each regions past disasters are listed. The data needed here is usually provided by the national institution in charge of the registration of seismic activity, or by the OFDA/CRED International Disaster Database (EM-DAT, <http://www.emdat.be/database>). The core target of our approach concerns the "recurrent disasters" and not "chaotic disasters" (big ones) that are inherently impossible to predict. The result of the survey of past earthquakes in Peru showed date, hour, latitude, Longitude, depth, magnitude in richer unit, and maximum intensity.

Step 2: Determining probabilities of occurrence. The aim of this step is to build a list a scenario, with an estimation of its probability of occurrence. For this purpose, we use as criteria the fact that there is a quasi-periodical value of earthquakes per fixed times. To determine the region where the epicenter of the earthquake is located, we calculate the percentage of earthquake in each region. To determine the intensity of this earthquake in our scenario, we use pre-specified intervals. Those have been defined by experts at the Geophysical Institute of Peru, who agreed on 5 classes of intensity (magnitude below 5,5 ; between 5,5 and 6 ; between 6 and 7 ; between 7 and 8 and above 8). Then we calculate the percentage of earthquakes belonging in each class. The objective being to define a consistent list of scenarios, we select the most representative earthquakes among those which are sufficiently severe to induce a humanitarian response (see the application on Peruvian earthquake for more details). The combination of these scenarios must represent at least 75% of the data recorded. At the end 27 scenarios are built with their magnitude and probability of occurrence.

Step 3: Delimiting the affected areas. At the end of this step, the most critical geographical areas are identified. For this identification, national maps and information on the types of soil, the territorial geography and their seismic activity is required. Indeed, locating the epicenter is not sufficient to estimate the perimeter of the region affected by a given earthquake. Local geography and geology factors are instrumental in the definition of the affected area.

Step 4: Estimating & assessing the impact on the population. This step defines the impact of the disaster on the population of each region. Urban densities as well as vulnerability of populations are here taken into account. The outcome is, for each region, an estimation of the amount of post-disaster victims.

Step 5: Assessing the impact on infrastructures. To help those who need assistance after the disaster, humanitarian workers use available infrastructures. Local storage and transportation capacities may have suffered from the disaster. An estimation of available capacity, together with an estimation of the impacts of the crisis on local infrastructures is therefore needed to evaluate the difficulty of aid delivery. For those estimations, a review of the information on available infrastructures is combined with interviews of experts. The knowledge acquired with those interviews is used to build decision trees on potential destructions.

At the end of these five steps, a plausible scenario is defined. This scenario provides figures on the number of affected families and on the state of warehouses and transportation aspects. The two main advantages of the method are that the probabilities are obtained through the elaboration of a proper historical record of seismic parameters, and the values of capacity reduction use practitioners' experience. Those two keystones of our approach enable the construction of reliable scenarios. This approach has also its limits. Indeed, good scenarios usually need a knowledgeable group to develop them.

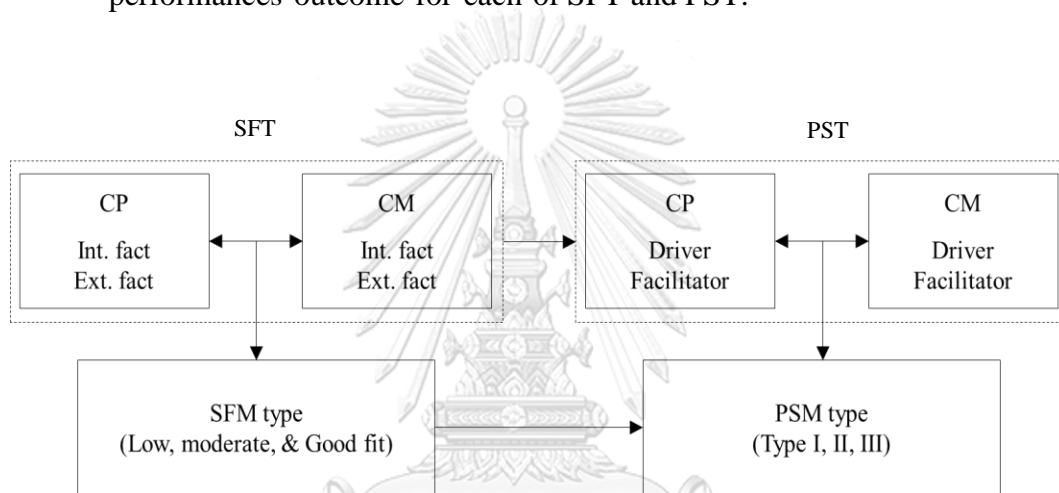
2.6 Research Framework and Hypotheses

Based upon the literature review on 2.1 overview and nature of pharmaceutical industry, 2.2 outsourcing manufacturing in pharmaceutical industry, 2.3 strategic fit for outsourcing manufacturing in pharmaceutical industry, 2.4 the outsourcing PSM, and 2.5 related research literature, the researcher organizes the ideas from those literature and draw a research framework, to survey and find out the results based on the research question no. 2

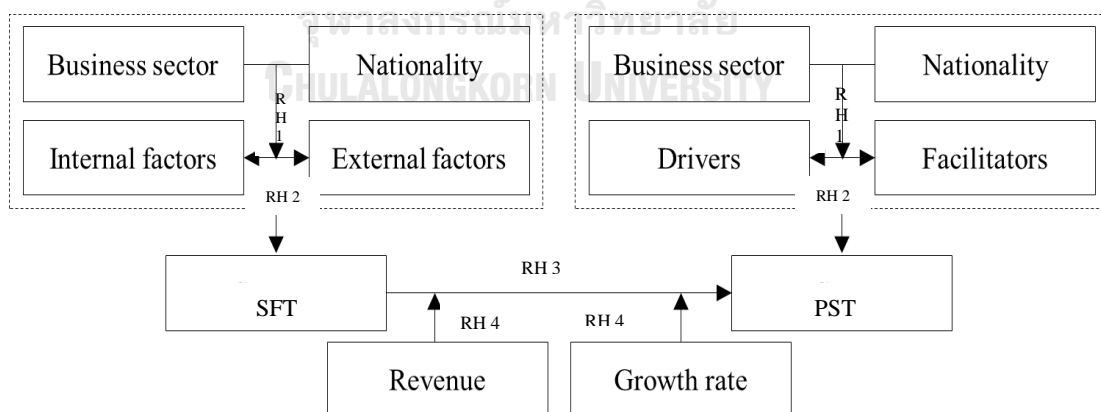
The research framework, Figure 2.11, propose the overview of relationships between SFM and PSM, with separate in to two parts: Part a) the matching of two key factors in each of model, the conversion of SFM to PSM and SFT to PST; and Part b) indicating moderating effects of business sector, nationality, and company

characteristics between key factors of two models and types of two models, with four hypotheses, as follows:

- RH 1:** Each of two key factors of SFM and PSM are similar between business sectors and nationalities.
- RH 2:** The relationship between two of strategic fit’s key factors and two of partnership’s key factors are strong.
- RH 3:** There are strong relationships between SFT and PST.
- RH 4:** Company revenue and growth rate are the predictors of the companies’ performances outcome for each of SFT and PST.



Part a: The conversion of SFM to PSM



Part b: Moderating effects in two outsourcing models

Figure 2.11: Research Framework

CHARTER 3

RESEARCH METHOD

The purposes of the research are 1) to study the pharmaceutical outsourcing trends and strategic fit management in outsourcing manufacturing between Thai and foreign countries from documentary review. 2) To study, analyze, compare, and summarize the associations and/or correlations of key factors of PSM and SFM between the business sectors, nationalities, and the outsourcing performance outcomes based on the PSM and the SFM, in order to identify the PST and SFT, using empirical study of both Thai & foreign CPs and CMs in Thailand. And 3) the post-evaluation for finding the appropriate policies, and strategic goals from Thai Government in outsourcing pharmaceutical industry.

This chapter described three studies employed in the research, firstly, documentary review study for answering the research objective no.1. Then, researcher presented a survey study for explore the research objective no.2. And lastly, a post-evaluation survey of the research finding in order to achieve the research objective no.3.

3.1 Documentary Review Study

3.1.1 Aims of Study: The study aims were to study the pharmaceutical outsourcing trends and strategic fit management in outsourcing manufacturing between Thai and foreign countries from literature search.

3.1.2 Data Collection: The designed methods were searching, retrieving, studying, reviewing and summarizing the research studies on pharmaceutical outsourcing trends and strategic fit management in outsourcing manufacturing between Thai and foreign countries. The searching process started from a) scope of content review from the papers must be linked or significantly related to the two topics of the first research objective: e.g. future trend of outsourcing in Thai and foreign countries, especially on government regulations; extended outsourcing industry of foreign pharmaceutical companies to Thailand in the next decade; and readiness of Thai pharmaceutical companies to accommodate outsourcing from abroad; b) sources of data were current

and publishing research papers, including official documents, theses and dissertations, books and monographs, published in 2011-2017; c) all papers, searching from scholar and popular search engines such as “Google Scholar”, “Pub Med”, “Research Gate”, “Science Direct”, must be published officially or distributed by peered-review journal; and d) each of which consisted of at least approximately 25 papers, with a total number of approximately 50 papers. Those papers can be classified based upon the following keyword as “pharmaceutical industry” (15 papers), “outsourcing” (10 papers), “partnership” (8 papers), “strategic fit” (6 papers), “trend and evolution” (5 papers), and “research of pharmaceutical industry paper in Thai” (5 papers). Using the exclusion criteria of a) unsatisfactory qualitative and quantitative content credibility, b) irrelevant papers, and c) incredible reports, approximately 30 papers were included in the study no.1.

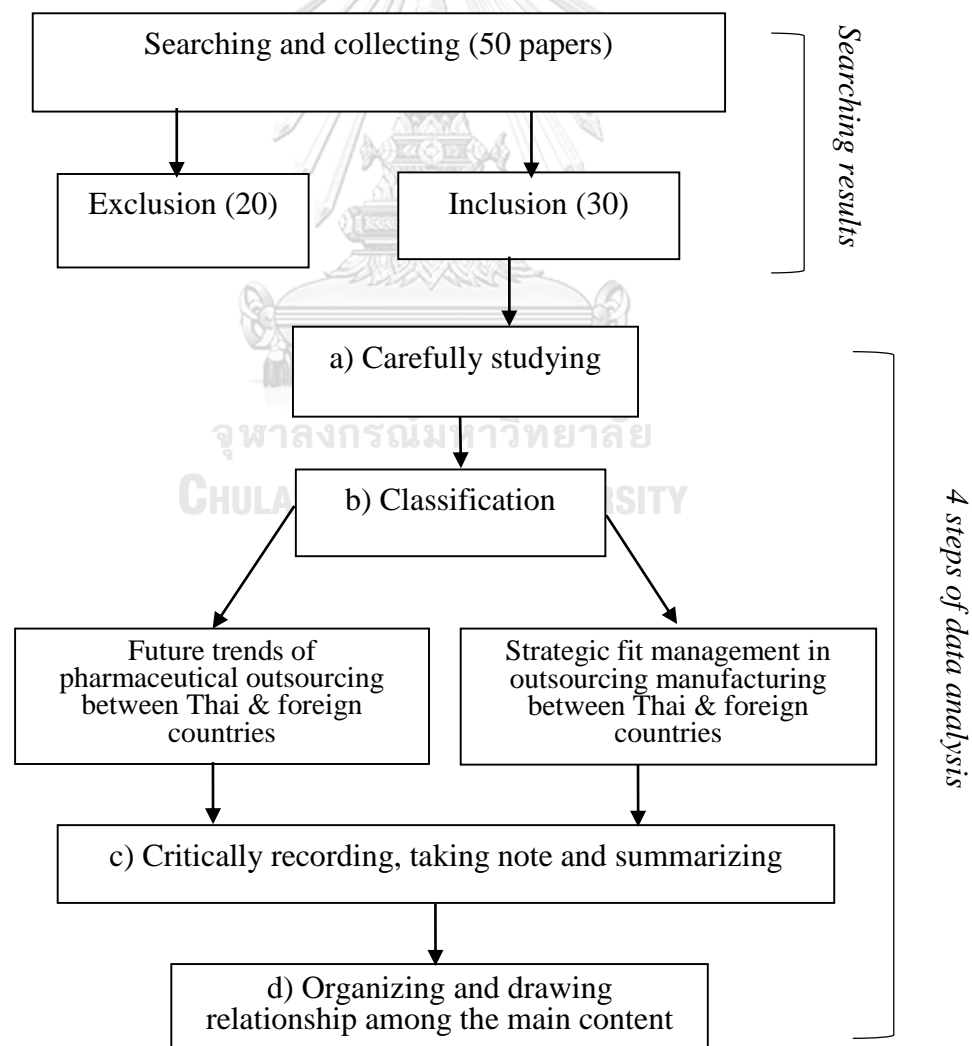


Figure 3.1: Documentary review process

3.1.3 Data Analysis: after excluding undesirable papers consisted of a) carefully studying all 30 papers to get clearer understanding; b) classifying the selected papers into two categories: 1) future trends of pharmaceutical outsourcing, and 2) strategic fit management in outsourcing manufacturing between Thai and foreign countries; c) critically reading the paper, taking a note and summarizing the important statements (gist) for each paper; and d) organizing and drawing relationship among the gist or the main content, in order to lay out future trend as required, as shown in figure 3.1

3.2 Survey Study

3.2.1 Aims of Study: The main aim of the survey study was to investigate the key factors of partnership and outsourcing SFTs for summarize the associations and/or correlations between the business sectors, nationalities, and the outsourcing performance outcomes based on the PSM and the SFM of Thai and foreign pharmaceutical companies, using the structured interviewed questionnaire and the telephone interview schedule. The respondents from qualified representatives worked at local and foreign pharmaceutical companies in Thailand. Two types of analyses were conducted: firstly, the survey data were compared between outsourcing business sectors and nationalities; and, secondly, the data were explored to obtain the relationship between PSTs and SFTs of those alliance companies. The survey results were expected to shed some light on similarities, associations and/or correlations between PSTs and outsourcing SFTs in Thai pharmaceutical outsourcing manufacturing.

3.2.2 Survey Design

- **Survey Method:** Ex Post Facto research survey was designed to summarize the associations and/or correlations of the key factors of partnership and SFTs between the business sectors and nationalities, include outsourcing performance outcomes based on the PSM and the outsourcing SFM, in order to identify the PST (by using 3x3 driver-facilitator matrix) and SFT (by 3x3 internal–external fit matrix), using empirical study (as details in Table 3.5) of both Thai and foreign CPs and CMs in Thailand.

- **Survey Population and sample:** The research population of Thai pharmaceutical outsourcing manufacturing in this study are 95 companies (63 of CPs

and 32 of CMs), which match with our specification and following criteria: 1) only private sector, Thai and foreign pharmaceutical companies in Thailand; 2) the pharmaceutical companies must conduct outsourcing business, either CPs or CMs; 3) both partner companies must have either a branch office or factory located in Bangkok Metropolitan area, 4) All CMs are modern medicine GMP compliance manufacturers under TH- FDA approval. Finally, there are only 43 companies (=45.263% of 95) that be willing and consent to participate in this research survey, all of which were 31- CPs and 12-CMs, and classification based on the nationality of the surveyed companies revealed 15 Thai companies and 28 foreign companies consisting of: 8 JP- companies, 10 USA-companies, and 10 EU-companies.

All of the surveyed pharmaceutical companies agreed to respond to the questionnaires given their choice of choosing only one of their best Thai and/or foreign outsourcing partners. Consequently, as the surveyed companies could choose either one (TH or F) or two (TH and F) outsourcing partners, there were 67 pairs of outsourcing partners, all of which were classified into 4 relationship types of 1. CP-TH vs. CM-TH (n = 13), 2. CP-F vs. CM-TH (n = 18), 3. CP-TH vs. CM-F (n = 9), and 4. CP-F vs. CM-F (n = 27), as shown in Table 3.1, where the data from all 67 pairs were analyzed using both the PSM and the SFM.

Table 3.1: The outsourcing partnership pairs

Type-Nationality (CP,CM) - (T, F, All)	CM-T (n = 9)	CM-F (n = 3)	CM-All (n = 12)
CP-TH (n = 6)	1. CP-TH vs. CM-TH (n = 13)	3. CP-TH vs. CM-F (n = 9)	CP-TH vs. CM-All (n = 22)
CP-F (n = 25)	2. CP-F vs. CM-TH (n = 18)	4. CP-F vs. CM-F (n = 27)	CP-F vs. CM-All (n = 45)
CP-All (n = 31)	CP-All vs. CM-TH (n = 31)	CP-All vs. CM-F (n = 36)	CP-All vs. CM-All (n = 67)

During our survey data collection, another concern arrived as almost all of the alliance CP & CM pairs decline to provide an interview from both alliance companies, and willing to offer their perceived data of their alliances with a guarantee of data reliability. As a result, *the researcher obtained only 2 pairs of real data and 65 pairs of perceived alliance data*. Although, the above data analysis indicated highly reliable data from measuring CPs or CMs data with their perceived alliance data, the researchers recognized that the data still have limitations as compared to the real data collection from each of the alliance companies. Therefore, the research findings should be confident under this limitation as well, and further analysis should be done in the future.

Table 3.2: Comparison of the strategic fit and partnership's key factors and type means of the real CPs or CMs with their alliances using t-test (matched pair)

Pair no.	Variable pair	Mean	Std. dev.	Std. error	Corr.	Sig.	Paired differences					
							Mean	S.D.	Std. error mean	t	d.f.	Sig. (2-
1	SumIn	14.143	1.994	0.533	0.853	0.00	0.071	1.14	0.3	0.2	13	0.818
	pSumIn	14.071	2.165	0.579								
2	SumEX	13.786	1.626	0.434	0.760	0.00	-0.143	1.29	0.3	-	13	0.686
	pSumEx	13.929	1.979	0.529								
3	STFtype	3.214	0.579	0.155	The correlation and t cannot be computed because the standard error of the							
	pSTFtype	3.214	0.579	0.155								
4	SumDri	14.071	2.269	0.606	0.802	0.00	-0.071	1.49	0.3	-	13	0.861
	pSumDri	14.143	2.445	0.653								
5	SumFac	15.357	1.906	0.509	0.879	0.00	-0.286	1.06	0.2	-	13	0.336
	pSumFac	15.643	2.240	0.599								
6	PNStype	3.214	0.426	0.114	The correlation and t cannot be computed because the standard error of the difference is 0.							
	pPNStype	3.214	0.426	0.114								

The researcher, therefore, has attempted to collect real data from the CPs or CMs alliances, the available results of which consisted of only 14 pairs. The perceived data from the initial data file, thus can be consequently compared with the real data from each pair alliance using *t-test (match paired)*. The analysis results shown in Table 3.2, as have indicated that the four comparisons (pairs number 1, 2, 4, and 5) of the internal, external, driver and facilitator factors, between the real data vs. their perceived data, has no significant difference between the alliance pairs with the t-values of 0.234, -0.414, -0.179 and -1.000 with the associated p-values of 0.818, 0.686, 0.861, and 0.336 respectively. Whereas the analysis results comparing the SFT and PST between the real data vs. their perceived data (pairs number 3 and 6), indicated that the pair different means are equal, and consequently the correlation and the matched pair t-tests cannot be computed.

In the further analysis, the researcher estimates the correlation between the four key factors of SFM and PSM, from both the real and perceived data set, then estimate the correlation matrix to test the significance of all pairs of real data and perceived data. The researcher expects that all correlation coefficients between the real and perceived data should be highly correlated which support that the 14 pairs of collected data, even of the single source, are reliable. The analysis results are in accordance with expectation as can be seen in Table 3.3. It is noteworthy to indicate that the real data and the perceived data of the 4 factors in SFM and PSM are highly significantly correlated at

0.760 – 0.879; whereas the real data and the perceived data of the SFT and PST are perfectly correlated.

Table 3.3: Means, standard deviations, and correlation coefficient between the strategic fit and partnership factors and types of SFM and PSM

	1	2	3	4	5	6	7	8	9	10	11	12
1 SumIn	1.000											
2 SumEX	0.888	1.000										
3 STFtype	0.837	0.788	1.000									
4 SumDri	0.592	0.526	0.690	1.000								
5 SumFac	0.795	0.722	0.762	0.776	1.000							
6 PNStype	0.776	0.738	0.736	0.699	0.846	1.000						
7 pSumIn	0.853	0.748	0.846	0.563	0.702	0.817	1.000					
8 pSumEx	0.724	0.760	0.820	0.515	0.578	0.750	0.881	1.000				
9 pSTFtype	0.837	0.788	1.000	0.690	0.762	0.736	0.846	0.820	1.000			
10 pSumDri	0.532	0.511	0.738	0.802	0.830	0.707	0.536	0.495	0.738	1.000		
11 pSumFac	0.684	0.611	0.775	0.792	0.879	0.893	0.720	0.618	0.775	0.853	1.000	
12 pPNStype	0.776	0.738	0.736	0.699	0.846	1.000	0.817	0.750	0.736	0.707	0.893	1.000
Mean	14.143	13.786	3.214	14.071	15.357	3.214	14.071	13.929	3.214	14.143	15.643	3.214
Std. Dev.	1.994	1.626	0.579	2.269	1.906	0.426	2.165	1.979	0.579	2.445	2.240	0.426

Note: $r \geq .792$, $p < .001$; $r \leq .530$, $p > .05$

3.2.3 Research Instrument

In order to summarize the associations and/or correlations of the key factors of PST and outsourcing SFT between the business sectors, nationalities, and the outsourcing manufacturing outcomes based on the PSM and the SFM, and identify the PST and SFT using empirical study, the structure interviewed questionnaire and the telephone interview schedule were designed. Firstly, the interviewed questionnaire was chosen in this study because it was a better choice in terms of measuring attitudes, perceptions and understandings of the participants in a limited period of time (Cohen et al., 2013). Modifications to the original survey instruments measuring the two factors for the PSM (Lambert et al. 2004) and other two factors for the outsourcing SFM (Saxton, 1997) were made to meet the purposes of this present study. The questionnaire was comprised of thirty items altogether. The first part consisted of six questions which were designed to collect background information of the respondents and their companies. The second part consists of twenty-one Likert-scale scenarios which were designed to examine PST and SFT understanding of outsourcing in pharmaceutical business. The third part of the questionnaire was comprised of three open-ended questions that were intended to collect more comments and/or environment impacted to the research. The modified questionnaire was approved by three pharmaceutical

experts (inter-rater agreement or Cohen's kappa = 0.867 %) and had Cronbach's alpha reliability of 0.831 (Table 3.3) as compared to 0.960 of the Lambert's original one. And secondly, the telephone interview schedule was constructed asking for the companies' revenue, annual growth rate, new investment and profit/ loss of Y2015 in range, one month after the interview questionnaire, in order to obtain the valid information without the contaminating effect of the questionnaire responses. However, most respondents declined to give all information, but finally, we got only 2 variables, company revenue and annual growth rate, to be used in this study.

Table 3.4: Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	No. of Items
.831	.825	21

3.2.4 Questionnaire Design: The questionnaire (see Appendix A) consisted of three parts of questions: 1) demographic; 2) Likert-scale; and 3) open-ended questions, as follows:

• **Part I: Demographic Questions**

This part consisted of six multiple-choice questions; these questions were aimed to collect the respondents and their companies' information, such as: job title, working years in pharmaceutical business, type of business sector, number and nationality of their partner companies, main outsourcing manufacturing dosage forms, and company performance outcomes in Y 2015. This information helped the researcher group the data based on business sectors, nationalities, outsourcing types and outsourcing performance outcomes in term of PSM and SFM in the analysis. Also positioning the demographic questions at the beginning, help the respondents know better the purpose of the research.

• **Part II: Likert-Scale Questions**

The second part of the questionnaire comprised of twenty-one Likert-scale questions. They were divided into three parts, which were (1) the co-benefit of each driver form their partner companies, (2) the consistency of each below facilitator form their partner company that support together, and (3) the strategic fit of internal and external factors with their partner companies in outsourcing performance, as follows:

(1) *The co-benefit of each driver from their partner companies:* The question in this part was worded as “What do you think about the co-benefit of each below driver from your partner company (CP or CM) that work together in outsourcing of Thai pharmaceutical manufacturing industry?” Click on the best response from scale 5 = certain benefit, scale 1 = no benefit”. This part was designed to uncover the diver determinants’ benefit between the outsourcing partner companies. In order to achieve this purpose, 4 key determinants; Asset/Cost Efficiencies, Customer service, Market advantage, and Profit Stability/Growth, were provided for rating from “certain benefit =5” to “no benefit =1”. These 4 key determinants altogether were aimed to uncover the driver score from interviewed company. In case the respondents rated efficiencies in each of determinant with scale 3-5, and considered its advantage was either a sustainable competitive advantage or it allow matching benchmark standard in industry, one more point will be add on.

(2) *The consistency of each below facilitator form your partner company that support together:* The question in this part was worded as “What do you think about the consistency of each below facilitator form your partner company (CP or CM) that support together in outsourcing of Thai pharmaceutical manufacturing industry?” Click on the best response from scale 5 =certain supportive, scale 1 = no supportive”. This part was designed to uncover the support of facilitator determinants between the outsourcing partner companies. In order to achieve this purpose, 4 key determinants were called primary facilitators; Corporate compatibility, Management philosophy, Mutuality, and Symmetry, were provided for rating from “certain supportive =5” to “no supportive”=1”. For this part, also had 5 additional facilitators; exclusivity, shared competitors, close proximity, prior history, and shared end user, normally support the chance of success of partnership as well. But the additional facilitators were provided for rating only as “yes =1” to “no =0”. These all determinants altogether was aimed to uncover the facilitator score from interviewed company.

(3) *The strategic fit of internal and external factors with your partner companies in outsourcing performance:* The question of this part was worded as “What do you think about the strategic fit of internal and external factors with your partner companies in outsourcing performance of Thai pharmaceutical manufacturing industry?” Click the best scale in the column on the right based on your understanding from scale “5 = best

fit to scale 1= no fit”. This part was designed to find out respondents’ consideration of the impacts from internal and external factors. In this regard, 4 key factors of internal fit; Trust and commitment, Innovation transfer, Winning relationship, and financial investment, and other 4 key factors of external fit; Market uncertainty, Dynamic shifts, Patent/Tax/ Regulation, and Risk control/ management, were provided for rating from “best fit =5” to “no fit was not nearly as bad =1”. These 8 determinants were developed to uncover respondents’ understanding on the outsourcing SFTs.

• ***Part III: Open-ended Questions***

This part included three open-ended questions. These questions were designed to solicit respondents’ original and in-depth feeling, to explore the expectations of PST and SFT with their partner companies. The three questions were designed as follows: (1) what are the expectations of PST between your company and your partners? (2) What are the expectations of SFT between your company and your partners? And the last, (3) any other comments or suggestions from each respondent, for some improvement guild line to this survey.

3.2.5 Pretest and Pilot Study

In order to ensure the comprehensibility and validity of the questionnaire, figure out the time it takes to complete the questionnaire, the practicability of the questionnaire was necessary to be ensured before using that questionnaire in the real experiment, so focus group interview method was applied. The focus group interview with 3 experts (1-Professor in Logistics and Supply chain field, 1-Plant manager of foreign pharmaceutical company, and 1-MD from local pharmaceutical company) was conducted as a pretest. The main reasons for conducting the focus group interview before conducting experimental studies were as follows. First, all of the key factors of PSM and SFM needed to be ensured by the focus group interview that they were able to select properly before conducting the experiments. Second, the measurement items in the questionnaire were developed based on the opinion of western subjects, some of the items might not appropriate to directly apply to Thai environment. Thus, some measurement items might need to be adjusted to make them clearer or more suitable to apply with the Thai outsourcing alliances. Last, another reason was that the measurement items must be translated from English to Thai language, so the focus

group interview could help the researcher to know subjects' opinion about the translated items, whether the translated words were proper or not.

After adjusted the questionnaire and research instruments according to the result from focus group interview, the questionnaire was back translated to check the similarity again. Then, another in-depth interview was conducted to finalize the understandable of the questionnaire before conducting pilot study.

Regarding to pilot study, during May 1-15, 2016, researcher conducted a pilot study with other 3 experts (one from key customers, one from academic, and the last one from experience practitioners), as below name lists:

- 1) Mr. Treetouch Viriyasumon – Director of Board, Aesthetic Plus Co., Ltd.
- 2) Mr. Cheocharn Ratanamahatana - President of Alpha Management Consultant Co., Ltd.
- 3) Dr. Satit Puttipipatkajorn - Head of Department of Manufacturing Pharmacy, Mahidol University.

Table 3.5: Reliability Statistics Item-Total Statistics

	Scale Mean	Scale Variance	Corrected Item-Total Correlation	Cronbach's Alpha
Asset /cost efficiency	54.66	37.047	.262	.831
Customer service	54.75	37.313	.311	.828
Market advantage	55.15	34.250	.563	.815
Profit / sustainable growth	55.22	35.328	.561	.817
Corporate compatibility	54.72	34.873	.606	.814
Management philosophy	55.06	35.330	.607	.815
Mutuality	54.87	35.785	.450	.822
Symmetry	55.22	34.873	.531	.817
Trust/Commitment	54.49	34.860	.435	.823
Innovation transfer	55.16	35.321	.454	.821
Winning relationship	54.37	36.601	.312	.829
Financial investment	55.04	35.862	.449	.822
Market uncertainty	54.88	36.622	.374	.825
Dynamic shifts	55.30	35.970	.440	.822
Patent/Tax/Regulation	55.10	37.095	.244	.832
Risk control/ management	54.70	34.031	.568	.815

The pilot study among these three experts, 26 from 30 subjects were approved, and 4 subjects need to adjust and correct. Furthermore, pilot study helped researcher and experimental assistants to have a real experience of conducting the survey study according to the mentioned research design. Hence, the problems which might happen from all phases in the experimental procedure had been solved before conducting the real experiment. Moreover, the reliability test of all constructs from pilot study (Table 3.5) showed that all constructs had acceptable reliability (0.814-0.832). Therefore, the researcher was confident to use all of the measurement items in the real experimental study.

3.2.6 Research Variable

The variables in this research were followed and applied from PSM (Lambert et al. 2004) and SFM (Ekwutosi 2014), as shown in Table 3.6. The principle variables consisted of 4-indicator internal and 4-indicator external factors measuring strategic fit outsourcing model; and other two set of 4-indicator factors measuring the driver, and facilitator factor with one additional indicator for each factor in the PSM. The two sets of the total summated scale scores can be interpreted as the types of partnership and strategic fit results, which will be compared with expected PST, expected SFT and each outsourcing performance outcome as well.

Table 3.6: Variables and operational definitions

Variables & Definitions	
SFM	PSM
<p>1. Internal factor: The strategic factor focuses on the organizational and HRM systems resources and capabilities, which helps to determine the appropriate level of a business outsourcing strategic partner. It consists of 4 variables, all of which are measured using 4-item, Likert's 5-point rating scale. The factor scores range between 4-20 points, and have been grouped into four categories of 4-7, 8-11, 12-15, and 16-20. The definitions of those 4 variables are as follows:</p>	<p>1. Driver: The strategic factor identifies the compelling reasons to partner and influence outcome; resulting in a competitive advantage, which helps to determine the appropriate level of a business relationship. It consists of 4+1 variables, all of which are measured using 4-item, 5-point Likert's rating scale questionnaire. The driver scores range between 4-24 points, and have been grouped into four categories of 4-7, 8-11, 12-15, and 16-24 (a combed categories of 16-19, and 20-24). The definitions of those 5 variables are as follows:</p>

Variables & Definitions	
SFM	PSM
<i>1.1 Trust / Commitment:</i> Loyalty to each other, loyalty to the partnership, and a long-term focus are all the elements.	<i>1.1 Asset/cost efficiency:</i> Potential management for better utilization of asset and/or for cost reductions in e.g. transportation, packaging, or product cost.
<i>1.2 Innovation Transfer:</i> The new know-how or technology sharing or passing through to the partners.	<i>1.2 Customer service:</i> Integrating activities leading to customer's service improvement: e.g. reduced inventory.
<i>1.3 Winning Relationship:</i> A win-win proposition for both sides: e.g. buyer & seller, outsourcer & outsourcing company.	<i>1.3 Market Advantage:</i> A stronger integration between two organizations to enhance the organization's marketing mix, or to ease entry into new markets, etc.
<i>1.4 Financial Investment:</i> Firm's sharing financial resource across the relationship can strengthen a partnership.	<i>1.4 Profit stability/growth:</i> Strengthening of relationship which improve or enhance profitability: e.g. long-term volume & price commitments, reduce sales variability.
	<i>1.5 Motivation strength to partners:</i> The advantage is either sustainable competitive advantage or it allow matching benchmark standard.
2. External factor: The strategic factor relate to programs, activities and strategies that the organization develops to respond to the external environment. External factor consists of 4 variables, all of which are measured using 4-items Likert's 5-point scale questionnaire. The external score computed a summation of 4 variables, ranging from 4-20 points, which have been grouped into four categories of 4-7, 8-11, 12-15, and 16-20, in order to construct the internal-external fit's matrix. The definitions of those 4 variables are as follows:	2. Facilitator: The strategic supporting environmental factors that enhance partnership growth and relationship maintenance of the two firms that will help or hinder the partnership development process. There are 4 major + 5 additional variables, all of which are measured using 4-items Likert's 5-point scale questionnaire. The facilitator score computed a summation of 4+5 variables, ranging from 4-25 points, which have been grouped into four categories of 4-7, 8-11, 12-15, and 16-25 (notice that this category is a combined score of the last two categories). The definitions of those 5 variables are as follows:
<i>2.1 Market Uncertainty:</i> The lack of market certainty. A state of having limited knowledge where it is impossible to exactly describe the existing state, a future outcome, or more than one possible outcome.	<i>2.1 Corporate compatibility:</i> The cultures and business objectives of the two firms must mesh. They do not have to identical, but they cannot clash.
<i>2.2 Dynamic Shifts:</i> The external factors or environment that fast changing and impacted to business.	<i>2.2 Managerial philosophy:</i> Such things as organizational structure, attitude toward employee empowerment. The relative importance of teamwork and the commitment to continuous improvement.
<i>2.3 Patent/Tax/Regulation:</i> Number and expiration drug patents, government tax and	<i>2.3 Mutuality:</i> A willingness to develop joint goals, share sensitive information, and take a long-term perspective.

Variables & Definitions	
SFM	PSM
other regulations ex: GMP, PIC/s that impacted to industry.	
2.4 Risk Control/ Management: The risk is the possibility that an event will occur and adversely affect the achievement of an objective. Therefore, risk itself has the uncertainty	2.4 Symmetry: The probability for success is enhanced when the partners are demographically similar.
	2.5 Additional facilitator: The five situation-specific factors that enhance and strengthen the relationship between CPs and CMs, namely: a) Shared competitor, b) Close proximity, c) Exclusivity, d) Prior history, and e) Shared supplier. Each of the five factors is measured as a bonus points using two choices (yes or no) question.
3. SFT: The organization's matching degree level in its <u>resources</u> and capabilities with the opportunities in the external environment. A calibration of the strategic fit using 3x3 internal-external fit matrix (as modified from the partnership relation calibration). Notice that the lowest category is omitted because it combination identifies "no fit" which cannot be treated as SFT. Consequently, the 3X3 internal and external factor matrix yields three types of strategic fit as the following description:	3. PST: A calibration result of the partnership components using 3x3 driver-facilitator matrix. Notice that the lowest category of driver and facilitator (4-7) are omitted, because the combination of the lowest categories is identified as "an arm's-length relationship" which cannot be treated as a PST; whereas the highest category of driver (20-24) and facilitator (20-25) are included in the category next to the highest one. Consequently, the 3x3 driver-facilitator matrix, resulted in three types of partnership as the following description:
<i>3.1 Low Fit</i> –The strategic fit with moderate level of either internal or external scores, indicating limited basis of both or either organization's resources and capabilities as well as its external environment factors.	<i>3.1 Type I partnership</i> – The partnership with limited basis, coordination and joint planning are low and rare, or shot-term focus. Most of the time, this type involves with single department or function in each party.
<i>3.2 Moderate Fit</i> -The strategic fit of two alliance companies which have both or either the internal and external factors above moderate to high level. The type of fit indicates quite big efforts in the organization's internal functions, to obtain similar agreement.	<i>3.2 Type II partnership</i> – The relationships between parties involve more than just coordination. The relationships are rather long-term. And multiple departments, divisions, or functions in each party are engaged in the partnership.

Variables & Definitions

SFM				PSM			
3.3 <i>Good Fit</i> - The strategic fit relation of two companies with either one or both of them have approximately equality of internal and/or external factors at high level.				3.3 <i>Type III partnership</i> – The parties share “substantial level of operational integration” and whole organization were included. Typically, there is no end date for this type.			
External Fit Points	Internal Fit Points			Facilitator Points	Driver Points		
	8-11 Points	12-15 Points	16-20 Points		8-11 Points	12-15 Point	16-24 Point
8-11 Points	No Fit	Low Fit	Moderate	8-11 Points	Arm's length	Type I	Type II
12-15 Points	Low Fit	Moderate	Good Fit	12-15 Points	Type I	Type II	Type III
16-20 Points	Moderate Fit	Good Fit	Good Fit	16-25 Points	Type II	Type III	Type III
4. Expected SFT: The overview or the whole picture of SFT relation that respondent expected from their outsourcing partners.				4. Expected PST: The overview or the whole picture of PST relation that respondent expected from their outsourcing partners.			
5. Outsourcing outcomes: Outcomes measure the extent to which each firm achieves its target. Appropriately established and effectively managed, should improve performance for both parties, ex: Revenue, % Growth rate, etc.				5. Outsourcing outcomes: Outcomes measure the extent to which each firm achieves its driver. Appropriately established and effectively managed, should improve performance for both parties, ex: Revenue, % Growth rate, etc.			

3.2.7 Data Collection

Firstly, the researcher had collected data using questionnaires and interviews as planned in September, 2016 with 43 surveyed companies, as follow activities: a) contact and ask for participation as were key person in this study; b) after receiving consent agreement, asking for the interview appointment during July-September, 2016; c) organizing and administrating the interview regarding the set schedule; d) checking for any missing information and further collecting additional data to impute those missing information. Secondly, the telephone interview schedule was constructed asking for the companies' revenue, annual growth rate, investment and profit/ loss in range, one month after the interview questionnaire, in order to obtain the valid information without the contaminating effect of the questionnaire responses. However, most respondents declined to give the company financial information. So, the researcher got only 2 variables, company revenue and growth rate, in range to be used in this study. And finally, create data file to be ready for data analysis (close sheet, key-in data, double check the file, and examination for any typing error).

3.2.8 Data Analysis

After coding and creating the SPSS data file, the researcher processed three steps for analysis as followed: (1) derivation the raw data collection for PST and SFT, ran a set of frequency distributions and cross tabulation analyses to clean the data, compute and recode the variables in order to create variables based on the analysis in accordance with the research objectives; (2) Data analysis of Likert-scale questions, and (3) Data analysis of the open-ended questions, as follows:

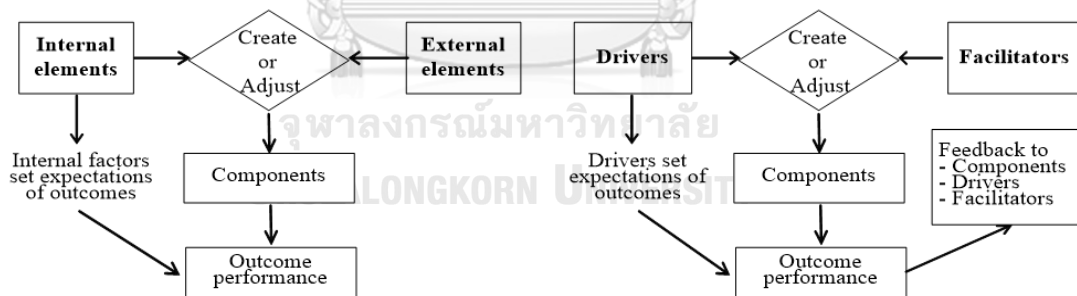
(1) Derivation of PST and SFT: Drivers are “the compelling reasons to partner” with many determinants, include asset and cost efficiency, customer service, marketing advantage, and profit stability & growth. They must be examined first when approaching a potential partner. Facilitators are “supporting environmental factors that enhance partnership development process and growth”. There are several facilitators in PSM, including corporate compatibility, managerial philosophy and techniques, mutuality, and symmetry. Those four elements are called primary facilitators. Absences of them may result in partnership’s failure. The additional facilitators normally support the chance of success of partnership. However, absence of these facilitators does not mean failure. The additional facilitators are exclusivity, shared competitors, close proximity, prior history, and shared end user.

To determine type of partnership (Figure 3.3) needed to meet expected outcomes, drivers and primary facilitators are assessed by using five-scale rating semi-structured interview questions. The questions in the assessment form will ask respondents to give probability of success, improvement, or substantially encourage by specific drivers and facilitators. The additional facilitators are assessed by using yes/no (1 or 0 score) semi-structured interview questions. The PST is the combination of facilitators and drivers that prescribes the appropriate type of partnership (Figure 3.5), as propensity to partner matrix.

Regarding the strategic fit process, Dess & Lumpkin (2013) asserted that the process involved management of all other internal factors within an organization to ensure that the implementation process was successful. Strategic fit had been conceptualized in various ways. The relationships here were causal ones in which the strategies must match with the external conditions if the company was to survive and gain a competitive advantage (Porter 1980, 1985). The SFM could present as Figure

3.2. Therefore, strategic fit could be one of the major key successful factors for a company's success. Waterman (1982) argued that the possibility of successfully executing a strategy depends on the interaction among elements in the McKinsey 7-S framework: strategy, structure, systems, skills, staff, style and shared values. In addition, the congruence among internal organizational elements should be reached if the organization was to achieve competitive advantage (Bae & Lee, 2015; D'Aveni et al., 2004). Hitt et al. (2000), proposed the notion of strategic fit, based on many studies in examining the co-alignment of (a) partner characteristics, (b) alliance relationship management, (c) organizational capabilities and their relationship to (d) alliance success, in selection of an appropriate partner which had been a very critical decision in an alliance engagement.

The SFM (Figure 3.2) modified from Lambert's PSM (1996), using a three by three matrix to prescribe SFT and therefore is subject to the difficulties present with any grid approach. The MPF (Meeting Process Facilitator) needs to be sensitive to the fact that a single point change on either internal or external factors can move a relationship from a moderate fit to a good fit or to a low fit (Figure 3.4).



Source: Lambert, Emmethainz, and Gardner (1996)

Figure 3.2: Strategic Fit Model (SFM)

Figure 3.3: Partnership Model (PSM)

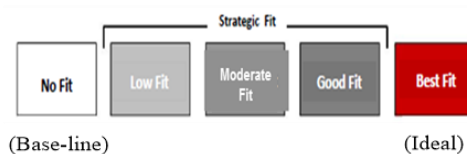
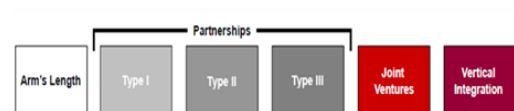


Figure 3.4: Strategic Fit Type (SFT)



Source: Lambert, Emmethainz, and Gardner (1996)

Figure 3.5: Partnership Type (PST)

(2) Data analysis of business sectors, nationality, outsourcing types and performance predictors

The research data were analyzed by SPSS version 17, using frequency distribution and descriptive statistics of all principle variables, then the data were further analyzed in order to compare the differences in means of those factors measuring PST, and SFT, using t-test, between business sector (CMs vs. CPs) and nationality (TH vs. F). Next the PST and the SFT were calibrated and analyzed to clarify the associations between business sector and nationality, using correlation analysis and testing their moderating effects as well. Then, cross-tabulation analysis between PST and the SFT were obtained. The cross-tabulations between two predictors (company revenue and % growth rate) and the PST & the SFT were conducted in order to clarify which one was the best predictor. The reason underlining the analysis choice was due to the categorical measure of both two predictors and the partnership and strategic fit outcomes.

(3) Data analysis of expected outsourcing types and other comments

In order to analyze the responses from the open-ended questions, first of all, the researcher copied these answers from the file, and grouped them together based on the questions. Then, reading the answers carefully from each question and categorized the answers based on the meanings.

3.3 Post Evaluation Survey

3.3.1 Aims of Study: The study aims were post-evaluating two aforementioned studies and findings, for the appropriate policies, and strategic goals from Thai government, for the successful outsourcing manufacturing in the future of Thai pharmaceutical industry by summative evaluation survey.

3.3.2 Questionnaire Design: The questionnaire (see Appendix B) consisted of two parts of questions: 1) Obstacles/ problems of Thai pharmaceutical outsourcing industry, and 2) Thai Government policies, and strategic goals should be applied.

3.3.3 Data Collection: Researcher had collected data using questionnaires and interviews in September, 2017 with 8 managers from private pharmaceutical companies, and 4 officers from government sector.

3.3.4 Data Analysis: By using post-evaluation survey the sample respondents (Agree or Disagree with, and conclude in % of total agree), for find out the appropriated policies and strategic goals from Thai Government, for each of obstacle or problem in Thai pharmaceutical outsourcing industry.



CHAPTER 4

RESEARCH FINDINGS AND DISCUSSION

In this chapter, the researcher reported the finding results based on the three objectives of the research: firstly, to study the pharmaceutical outsourcing trends and strategic fit management in outsourcing manufacturing between Thai and foreign countries from literature review; secondly, to study, analyze, compare, and summarize the associations and/or correlations of key factors of partnership type and strategic fit type between the business sectors, nationalities, and the outsourcing performance outcomes based on the partnership model and the strategic fit model, in order to identify the partnership type and strategic fit type, using empirical study of both Thai & foreign CPs and CMs in Thailand; and lastly, the post-evaluation for finding the appropriate policies, and strategic goals from Thai Government in outsourcing pharmaceutical industry. Researcher presented the research findings separately in three sections: 4.1) Preliminary analysis: Respondents and their companies' characteristics, 4.2) Data analysis results, and lastly, 4.3) Research discussions, as follows:

4.1 Preliminary analysis: Respondents and Companies' characteristics

Data were collected during July-September 2016 through 43 pharmaceutical companies and individual interviews. Table 4.1 presents the respondents' working company, job title, and working experiences, with the company data of outsourcing partners, outsourcing dosage forms, and performance outcomes in Y 2015.

Table 4.1: Frequency distribution of respondents' characteristics

<i>Respondents (n=43)</i>	Frequency	Percentage
<i>1. Working company (nationality/ business sector)</i>	43	100.00%
- TH	15	34.88%
- Foreign	28	65.12%
- CP	31	72.09%
CP-TH	6	13.95%
CP-F	25	58.14%
- CP-JP	6	13.95%
- CP-USA	10	23.26%
- CP-EU	9	20.93%

- CM	12	27.91%
CM-TH	9	20.93%
CM-F	3	6.98%
- CM-JP	2	4.65%
- CM-EU	1	2.33%
2. Job Title	43	100.00%
- MD	2	4.65%
- Director	11	25.58%
- Manager	30	69.77%
3. Working experience in pharma business	43	100.00%
- 6-10 years	4	9.30%
- 11-20 years	25	58.14%
- >20 years	14	32.56%
4. Nationality of partner company(s)	43	100.00%
- Thai only	3	6.98%
- Foreign only	16	37.21%
- Both Thai and foreign	24	55.81%
5. Outsourcing dosage forms		
- With Thai partners	38	100.00%
Tablet/ Capsule	19	50.00%
Liquid/ Syrup	8	21.05%
Cream/ Ointment	5	13.16%
Powder	4	10.53%
Sterile injection	1	2.63%
Others (Lozenges)	1	2.63%
- With Foreign partners	54	100.00%
Tablet/ Capsule	27	50.00%
Liquid/ Syrup	14	25.93%
Cream/ Ointment	4	7.41%
Powder	1	1.85%
Sterile injection	7	12.96%
Others (Lozenges)	1	1.85%
6. Company performance outcome in Y 2015		
- Revenue (MB)	43	100.00%
< 1000	23	53.49%
≥ 1000	20	46.51%
- Growth rate (%)	43	100.00%
< 8.2%	22	51.16%
≥ 8.2%	21	48.84%

4.2 Data Analysis Results

To answer the three research questions, researcher presented and reported the research findings separately in four sections: 4.2.1) the outsourcing trends and strategic management in outsourcing manufacturing between Thai and foreign countries; 4.2.2)

The outsourcing manufacturing associations, and/or correlations based on the PSM & SFM, and the outsourcing PST & SFT between Thai and foreign countries; 4.2.3) The predictors of the companies' performance outcomes; and lastly, 4.2.4) The post-evaluation for finding the appropriate policies, and strategic goals from Thai Government in outsourcing pharmaceutical industry as follows:

4.2.1 The outsourcing trends and strategic management in outsourcing manufacturing between Thai vs. foreign countries

The researcher summarized 30 current research papers, including official documents, theses and dissertations, books and monographs, which published in 2011-2017 as "scope of data", for studying and analysis related to the research objective #1. This topic consisted of two sub-topics: 4.2.1.1) the pharmaceutical outsourcing trends between Thai vs. foreign countries, and 4.2.1.2) strategic management in outsourcing manufacturing between Thai and foreign countries, as follows:

4.2.1.1 The pharmaceutical outsourcing trends between Thai vs. foreign

According to World Bank statistics, health expenditure represented 9.9% of GDP in 2014 and about a seventh of this was pharmaceutical sales. In 2015, the global pharmaceutical market reached \$1.1 trillion and was expected to continue growing at approx.5.5% per annum (Newrzella, 2017). The overall pharmaceutical market growth normally supports the contract manufacturing industry, if outsourcing trends are continue. The global pharmaceutical contract manufacturing market will grow at a CAGR of 6.91% during the period 2016-2020 (Wood, 2017).

The big challenges for global pharmaceutical outsourcing companies are: (1) the contract manufacturing sector is faster grow than the pharmaceutical industry, and the greater growth is expected in the generics' API segment. The major part of CMO revenues come from small molecule in commercial manufacture forms, approx. were \$59.1bn and expected CAGR of 6.4%. Whereas, the Biologics CMO market, is estimated at \$5.3bn, even starting from a lower base but is expected to grow faster at 8.3% of CAGR (Newrzella, 2017). (2) The CMO industry remains fragmented, lead many CMOs are acquiring one another with several reasons, such as: to gain a more global footprint to meet client needs for global partners and large-scale capabilities; to

expand into many service areas (drug development, drug formulation, etc.); and to gain access to advanced technologies (Zhang, 2011). (3) The CMO opportunity growth from new geographic markets, with increased competition, EU & USA- CMOs are trying to differentiate in response to low cost competition. In the last decades, the cost base has been specially shaken by India and China (Miller, 2015). (4) New outsourcing strategies and types of services are developing almost in every stage of the pharmaceutical manufacturing and R&D process. Currently, the R&D are more and more critical in the industry, especially in biotech companies. (5) The CROs and CMOs each presently make roughly equal contributions (CRO: CMO = 48:52) to the total global pharmaceutical outsourcing market value. Of the total CRO market value, which is about \$40.5bn, chemistry-based drug discovery research service accounts for about 25%, whereas the biology-related services account for 75% (Miller, 2015).

The global outsourcing trends are continuously developed due to the high competition and adjust for survive from market uncertainty, as: 1) Big Pharma companies have started experimenting outsourcing formulation development to emerging markets. 2) Increment of “Branded generics” in market (branded companies work with a generic company to produce generic drug products after patent expiration). 3) CROs lead the way in providing outsourcing services in formulation development and manufacturing. 4) Biological products would play the increasingly important role in drug development process. 5) Both biopharmaceutical companies and CROs need highly collaborative models (He et al., 2011; Jantzi et al., 2013).

The global pharmaceutical outsourcing business are changed and refocused, USA is particular interest of given that it is the largest pharmaceutical market in the world, but because of the saturation in the North American market, has led most of pharma company move to focus on the EU and Emerging market instead.

The outsourcing trends in foreign countries; Japanese pharma companies are heavy spenders on R&D and much of the spending goes abroad. Since then, many Japanese drug makers have gone global, buying biotech and other companies abroad and establishing international networks of R&D centers. Eisai, for example, has research operations in the USA, UK, India and Singapore as well as Japan. This has allowed Japanese companies to tap foreign scientific knowledge and experience.

The Chinese pharmaceutical services has been developing extraordinarily fast in the past decade, it has attracted a large number of pharmaceutical and biopharmaceutical companies from all the world for a variety of outsourcing opportunities (Zhang, 2012). Among the low cost regions, China has become one of the primary choices for Big Pharma. China, currently, is world leader in the manufacture of APIs and bulk drug materials (Mueller & Mintz, 2013), and becoming the R&D center of Asia and the world as well. The Chinese pharmaceutical market is believed to experience healthy growth in the near future (Zhang, 2012).

India is one of the largest and lowest cost producers of globally generic drugs (*PricewaterhouseCoopers, 2013; Shukla, 2007*). Indian contract manufacturing is a strong segment of the domestic market, and finished generics supplied from India account for nearly 20% of the global generic marketplace (*PricewaterhouseCoopers, 2013*). India also contributes expertise in the production of a variety of complex dosage forms. Recently, the priority of drug research has been refocused from the reverse engineering of generics to research involving NCEs (Ryan & Sancilio, 2013). The availability of a large number of potential study subjects has attracted pharmaceutical companies such as GlaxoSmithKline and Eli-Lilly to conduct clinical trials in India (*Shukla, 2007*). Typically, it is 40-50% less expensive to conduct clinical trials in India compared to western countries. According to the Indian Government, by 2020 India would be one of the top five pharmaceutical innovation hubs with one out of every five to ten drugs discovered in India (Reddy & Gupta, 2013).

In Thailand, the contract manufacturing looks good and in uptrends situation, there is a big opportunity since the ASEAN market is opening up. It means much more investment will flow into Thailand, as from here they can export throughout ASEAN. So, now it is not the only local pharmaceutical industry that is interested in being CMs but the multinationals also re-consider make their own investments as well. Thai Government should make a big move to invite global pharmaceutical companies to invest in Thailand. Regarding the GMP standards, the Thai local industry has learned and improved a lot in the last 5 years, now many local factories readied to be a CM for multinationals. Thai's FDA already got approval for PIC/S membership in 2016, the local industry gained much more awareness and those which did not join the program are now starting to build up the standard already. This has been a big change occurring

in the last five years, Nowadays, more and more large research-based pharmaceutical companies are entering the generics business, for example through the acquisition of local players. In light of the ASEAN integration, Thai pharmaceutical products have been exported to neighboring countries for decades. The market for Thai products are now being challenged more by the emerging countries like Indonesia and Malaysia. Despite the rising number of players haring the market, we will keep exporting (Pharmaboardroom, 2012). Thai pharmaceutical market has been growing in every year compared to the neighboring countries, which does not apply the universal healthcare scheme. Particularly for pharmaceuticals, Thailand is the best location for investment, and the government should take this opportunity to invite more investors (Pharmaboardroom, 2012), and specially by more establish and develop of Thai R & D academic institution and CROs, the collaboration from both government and private sectors to develop Thai CROs & CDMO are need and important for the key success factors of Thai Pharmaceutical outsourcing industry.

4.2.1.2 Strategic management in outsourcing manufacturing between Thai vs. foreign

The strategic outsourcing is a necessary action for pharmaceutical organizations, Boulaksil & Fransoo (2007) found that in the last few years, a number of researchers have analyzed and explored outsourcing in various industries including pharmaceuticals. Strategic outsourcing also has assumed an increasingly important role in the operations of established as well as emerging pharmaceutical companies (Lowman et al., 2012). Several outsourcing research outcomes indicated that the alliance or partner selection is also a very critical decision in an alliance engagement (Hitt et al., 2000). In conclusion, researcher recognizes that the strategic fit is a core concept in normative models of strategy formulation (Hofer & Schendel, 1978; Zajac et al., 2000). While, Zaman & Mavondo (2008) also believed that there must be a certain degree of 'fit' between the alliances or partners, which in turn increases the probability of achieving positive alliance outcomes performance.

Collaborative relationships beyond organizational boundaries are an essential part of current's business. They usually are in the form of joint ventures, strategic alliances, or partnerships (Ali & Khan, 2016). For outsourcing, have received increased

attention in management practice around the world over recent decades (Bhattacharya et al., 2013; La Londe & Cooper, 1989). The outsourcing partnership is a business associations between two or more organizations founded upon, openness, mutual trust, shared rewards and risks that produce a competitive benefits, resulting from performing in this association more than that might be attained by the either organization individualistically (Lambert et al., 2004; Lambert & Enz, 2016). Research by Kedia & Lahiri (2007) suggested that despite an increase in international outsourcing of services (IOS) to survive in today's highly competitive business, they thus seek to elaborate type of outsourcing partnership model and classified 3 types: tactical, strategic, and transformational using the value propositions and nature of involvement with providers in different ways. In brief, partnership, being a consequence of outsourcing strategic fit, is a flexible, long term relationship established based on sharing of benefits, risks, future goals and visions. In practice only a fruitful outsourcing relationship is eligible to promote to outsourcing partnership where the parties share confidential information about future plans, work together, combine resources, share ownership, risks and benefits, and take joint decisions to undertake mutually beneficial (Khan & Ali, 2015; Ali & Khan, 2016).

The conversion from an outsourcing relationship to the partnership relationship has been further investigated and made clearer by Ali and Khan (2016) who identify and analyze factors that are important for vendors in conversion of their existing outsourcing relationship to partnership, using a systematic literature review process for the identification of critical success factors (CSFs) from a sample of 111 articles. They further categorized the identified CSFs into five partnership levels based on Capability Maturity Model Integration (CMMI) and the Outsourcing Vendors' Readiness Model. The 5 partnership levels are as follows: 1) Initial contract; 2) Successful contract; 3) Partnership; 4) Conversion to partnership; and 5) Maturing partnership.

So, the strategic management in pharmaceutical outsourcing for moving up the value chain by converse from an outsourcing relationship to the partnership relationship, selecting issues for consideration as below:

1. Establish strategic partnerships with client companies. The powerful customers may attempt to minimize their risks with a highly-valued supplier by

proposing a merger or acquisition or developing the requisite expertise in-house. (Javalgi et al., 2013).

2. Create global business partners. The public policy, may make advantage provide incentives to target key high-value, knowledge-intensive multinational companies services, will invite and attract foreign direct investment (FDI) from service providers of high-end, knowledge-based services to invest and partner with local suppliers.

3. Serve strategic niches with value-added solutions. Strategic niches can become profitable if outsourcing suppliers can progress from offering piece-meal projects to high value-added solutions.

4. Building R&D MegaclustersThe companies such as AstraZeneca and Glaxo-Smith-Kline, have established and expanded significant R&D operations in India which offer significant cost advantages in the areas of contract research and clinical trials (Pandey et al., 2004).

5. Creating a culture of ethical behavior. With the outsourcing of business operations, new pressures have emerged for parent corporations that are trying to transfer their corporate values and practices to offshore suppliers who contribute to the design and manufacture of the final product. The growth of outsourcing with low cost regions of the world, many with different or uneven standards of ethical conduct, it becomes imperative for parent corporations to include ethical oversight as one of the many critical performance values in managing their relationships with outsourcing partners (Javalgi et al., 2013).

In conclusion, pharmaceutical outsourcing manufacturing business, most foreign companies, even in USA or EU, including China & India, the outsourcing relationship are outsourcing partnership. Whereas, in Thailand, mostly of outsourcing relationships are contractual outsourcing with strategic management, the stress is given on the obligation of formally written contract agreement between CPs vs. CMs, and on achieving specific business goals, except two foreign CMOs (Fuji pharma & Interthai Pharmaceutical) which mainly manufacture serving portfolio of foreign clients, are partnership relationship (Kinnula, 2006; Lane & Lum, 2011). However, currently, most Thai local companies are conversing to outsourcing partnership trends.

4.2.2 The outsourcing manufacturing associations, and/or correlations based on the PSM & SFM and PST & SFT

To answer the second research question concerning the associations and/or correlations between the CPs vs. CMs, Thai vs. foreign companies, PSM vs. SFM, and PST vs. SFT in Thai outsourcing pharmaceutical manufacturing industry, researcher presents the data analysis results in five parts: 4.2.2.1) Outsourcing associations between business sectors and nationalities; 4.2.2.2) Correlations between key factors of the PST & SFT and moderating effect; 4.2.2.3) Cross-tabulation of PST & SFT between TH vs. F countries; 4.2.2.4) Cross-tabulation of PST & SFT between the surveyed results vs. the expected results of TH and F countries; and 4.2.2.5) Fisher's exact test of PST & SFT, as follows:

4.2.2.1 Outsourcing associations between business sectors and nationalities

The analysis results, aiming to study matching of the two factors means of each of the two factors of SFM and PSM, in Table 4.2 revealed that four mean difference pairs were not rejected as expected, indicating that there were no significant differences in the four factors means of PSM & SFM between CPs vs. CMs (t-statistics = 1.392, .531, 1.211, 1.364, at degrees of freedom = 65). On the contrary, the analysis results, study of TH & F countries, indicated that all four null hypothesis were rejected (t-statistics = -2.568, -2.070, -4.555, -4.257, at degrees of freedom = 65).

Table 4.2: Independent samples *t*-test results

Variable	Studied	Results of the four factors- means differences between CP and CM								
		n	Mean	S.D.	Levene's test for equality of	t	d.f.	P	Conclusion	
Driver	CP	45	15.760	2.38	F	0.458	1.392	65.000	0.169	No different
	CM	22	14.820	2.97	Sig	0.501				
Facilitator	CP	45	16.360	2.37	F	0.442	0.531	65.000	0.597	No different
	CM	22	16.000	2.94	Sig	0.509				
Internal factor	CP	45	14.800	1.96	F	0.285	1.211	65.000	0.230	No different
	CM	22	14.180	1.96	Sig	0.595				
External factor	CP	45	13.910	1.90	F	0.053	1.364	65.000	0.177	No different
	CM	22	13.230	1.97	Sig	0.819				
Results of the four factors- means differences between Thai and foreign										
Variable	Studied	n	Mean	S.D.	Levene's test for equality of	t	d.f.	p	Conclusion	
Driver	Thai	26	14.460	2.518	F	0.770	-2.568	65.000	0.013	Significant different
	Foreign	41	16.070	2.494	Sig	0.384				
Facilitator	Thai	26	15.460	2.353	F	3.994	-2.070	57.080	0.043	Significant different
	Foreign	41	16.730	2.589	Sig	0.050				
Internal factor	Thai	26	13.460	1.363	F	6.856	-4.555	64.419	0.000	Significant different
	Foreign	41	15.320	1.968	Sig	0.011				
External factor	Thailand	26	12.650	1.198	F	19.22	-4.257	64.696	0.000	Significant different
	Foreign	41	14.340	2.045	Sig	0.000				

4.2.2.2 Correlations between key factors of the PST & SFT and moderating effect

In order to clarify the relationship between business sectors and nationalities using correlation analysis between the two of partnership factors (driver vs. facilitator) and two of strategic fit factors (internal vs. external factors), the correlation matrix, with the factor means and standard deviations, was obtained as shown in Table 4.3. The analysis results indicated that the overall means and standard deviations (in part of total correlation) of the internal factor (14.600 and 1.970) and external factor (13.690 and 1.940) were lower than those of driver (15.400 and 2.680) and facilitator (16.240 and 2.559) as our expectation. Five correlation coefficients were highly significant at .01 with the two largest ones between drivers vs. facilitators (0.863), and internal vs. external factors (0.716). The remaining coefficients indicated the low relationship between partnership factors and strategic fit factors (0.290 and -0.356). The analysis result thus implied the similarity between the outsourcing partnership and the strategic fit of pharmaceutical companies, and further indicated that the pharmaceutical companies must improve the strategic fit scores in order to transform the outsourcing alliances to the outsourcing partnership. In sum, the analysis results supported the second research hypothesis (RH 2), and consequently require further analysis for testing our third research hypothesis.

For more studies, by testing company nationality (Thai vs. foreign), and business sector (CP vs. CM) as the moderators, whether there are any effects on the correlations between key factors of partnership and SFTs, or not? Testing differences between two independent correlations, given $\rho \neq 0$, using **Fisher's transformation of r into r'** , based on $r' = (0.5) \log_e \left[\frac{1+r}{1-r} \right]$, and standard error of $r' = 1/\sqrt{n-3}$; we can test the null

hypotheses that $\rho_1 = \rho_2$ using the formula as
$$z = \frac{r'_1 - r'_2}{\sqrt{\frac{1}{n_1-3} + \frac{1}{n_2-3}}}$$
.

Table 4.3: The correlation matrix between key factors of the PST and SFT

n = 67	Classified on nationality (Foreign, Thai, Total)											
	F				T				Total			
	1	2	3	4	1	2	3	4	1	2	3	4
1. Driver	1.000	-	-	-	1.000	-	-	-	1.000	-	-	-
2. Facilitator	0.855 ^{**}	1.000	-	-	0.859 ^{**}	1.000	-	-	0.863 ^{**}	1.000	-	-
3. Internal F	0.408 ^{**}	0.424 ^{**}	1.000	-	0.123	0.069	1.000	-	0.344 [*]	0.356 ^{**}	1.000	-
4. External F	0.284	0.301	0.656 ^{**}	1.000	0.061	0.087	0.616 ^{**}	1.000	0.290 [*]	0.317 ^{**}	0.716 ^{**}	1.000
Mean	16.070	16.730	15.320	14.340	14.350	15.460	13.460	12.650	15.400	16.240	14.600	13.690
S.D.	2.494	2.589	1.968	2.045	2.667	2.353	1.363	1.198	2.680	2.559	1.970	1.940
$r_t^2(\text{dri, fac})=1.293$, $r_t^2(\text{dri, ex})=1.274$, $z=1.075$, $p=.142$ $r_t^2(\text{in, ex})=.717$, $r_t^2(\text{in, ex})=.784$, $z=.388$, $p=.348$												
n = 67	Classified on business sector (CP, CM, Total)											
	C				C				T			
	1	2	3	4	1	2	3	4	1	2	3	4
1. Driver	1.000	-	-	-	1.000	-	-	-	1.000	-	-	-
2. Facilitator	0.826	1.000	-	-	0.923 ^{**}	1.000	-	-	0.863	1.000	-	-
3. Internal F	0.261	0.318 [*]	1.000	-	0.434 [*]	0.411	1.000	-	0.344	0.356	1.000	-
4. External	0.120	0.163	0.652 [*]	1.000	0.496 [*]	0.557 [*]	0.823 [*]	1.000	0.290	0.317	0.716	1.000
Mean	15.760	16.36	14.800	13.91	14.680	16.000	14.180	13.23	15.400	16.240	14.600	13.69
S.D.	2.385	2.376	1.961	1.905	3.138	2.944	1.967	1.974	2.680	2.559	1.970	1.940
$r_{cp}^2(\text{dri, fac})=1.172$, $r_{cm}^2(\text{dri, fac})=1.683$, $z=2.551$, $p=.005$ $r_{cp}^2(\text{in, ex})=.775$, $r_{cm}^2(\text{in, ex})=1.172$, $z=2.245$, $p=.012$												

Note: *p < 0.05; ** p < 0.01

The researcher tested for the difference between two independent, calculated for the z-value, and find for p-value for decision. The analysis results, Table 4.3, separated in 2 groups: a) classified on nationality (Foreign, Thai, Total) revealed that all two null hypotheses of the correlation difference tests are not rejected as expected, indicating that there were no significant effects from nationality to the correlation between PSM and SFM (z & p-statistics for driver/ facilitator = 1.075, .142, and z & p-statistics for internal f / external f = .388, .348). And, b) classified on business sector (CP, CM, Total), the analysis results indicated that two null hypothesis are rejected (z & p-statistics for driver/ facilitator = 2.551, .005, and z & p-statistics for internal f / external f = .2.245, .012), indicating that there were have significant of moderating effects from business sector to the correlation between PSM and SFM.

4.2.2.3 Cross tabulation of PST and SFT

This analysis focused on the cross classification of the PST and the SFT using cross-tabulation, because the measurement levels of the two model types were ordinal level. The researcher used SFT as the column variable with the PST or the future aim in outsourcing as the row variables, with percentage down calculation and cross comparison. Based on our third research hypothesis, we expected to get the majority outsourcing pairs currently being in a moderate and good fit strategic type, but they

should be, in the future, in type II and III PST respectively. The two analysis results: 1) Overall relationship between pharmaceutical outsourcing types in TH. 2) The relationship between two outsourcing types with nationality, and business sector together with nationality, as follows.

(1) Overall relationship between pharmaceutical outsourcing types in TH

Table 4.4 showed that the statistically significant analysis results, using the 2-way cross-tabulation for all 67 pairs' pharmaceutical outsourcing types were in accord with our expectation. All of the 5 (100.000%) low SFT companies could struggle to be in type II PST, whereas the majority 37 (92.500% of 40) moderate SFT companies would still be in type II PST, and the failure 3 (13.836 % of 22) good fit strategic type failed to reach their target type III PST, the results of which contrasting to the majority 19 (86.364 % of 22) of good SFT companies that could maintain or made progress in the type III PST. Hence, it could be possible to conclude that the majority of outsourcing relations of pharmaceutical companies in Thailand are PST II, as well as moderate SFT. However, this analysis result could be further clarified in the next analysis using 3-way cross-tabulation.

Table 4.4: The cross tabulation of PST and SFT

PST	SFT			Total
	Low Fit	Moderate Fit	Good fit	
Type II Count (% of SFT)	5 (100.000 %)	37 (92.500 %)	3 (13.836 %)	45 (67.164%)
Type III Count (% of SFT)		3 (7.500 %)	19 (86.364 %)	22 (32.836 %)
Total Count (% of Total)	5 (7.463 %)	40 (59.701 %)	22 (32.836 %)	67(100.000 %)

a. 2 cells (33.3%) have expected count less than 5. The minimum expected count is 1.64.

(2) The relationship between two outsourcing types with nationality, and business sector together with nationality

Table 4.5 showed the cross-tabulation analysis results of four nationalities were in accord with our expectation. (1) **JP**: the majority 7 (87.500% of 8) good SFT companies would still be in type III PST, and the failure 1 (12.500 % of 8) good fit strategic type failed to reach their target type III PST, whereas 4 (100.000%) moderate SFT companies would still be in type II PST. (2) **USA**: the majority 5(62.500% of 8) moderate SFT companies would still be in type II PST, and the rest 3(37.500% of 8) of moderate SFT companies could made progress in the type III PST, whereas 4 (80.000

% of 5) good SFT companies would still be in type III partnership, and the failure 1 (20.000 % of 5) good fit strategic type failed to reach their target type III PST. (3) **EU**: all of 8 (100.000%) good SFT companies would still be in type III PST, and all of 8 (100.000%) moderate SFT companies also would still be in type II partnership as well. And (4) **TH**: the majority 20 (76.923% of 26) moderate SFT ones would still be in type II PST, the failure 1 (3.846 % of 26) good fit type failed to reach their target type III partnership, whereas 5 (19.231% of 26) of low SFT companies could made progress in the type II partnership.

Table 4.5: The cross tabulation of PST and SFT with nationality

Nationality	PST	SFT			Total
		Low fit	Moderate fit	Good fit	
JP	Type II		4(100.000%)	1(12.500%)	5(41.667%)
	Type III			7(87.500%)	7(58.333%)
	% of Total		4(33.333%)	8(66.667%)	12(100.000%)
USA	Type II		5(62.500%)	1(20.000%)	6(46.154%)
	Type III		3(37.500%)	4(80.000%)	7(53.846%)
	% of Total		8(61.538%)	5(38.462%)	13(100.000%)
EU	Type II		8(100.000%)		8(50.000%)
	Type III			8(100.000%)	8(50.000%)
	% of Total		8(50.000%)	8(50.000%)	16(100.000%)
TH	Type II	5(100.000%)	20(100.000%)	1(100.000%)	26(100.000%)
	Type III				0 (0.000%)
	% of Total	5(19.231%)	20(76.923%)	1(3.846%)	26(100.000%)

Hence, the comparison of two outsourcing relationship between PST vs. SFT among 4 nationalities, based on % of total of the best types (% of total PST- III and % of total SFT-good fit). It could be concluded that **JP** had the highest % of these two outsourcing types ((% of total PST- III =58.333% and % of total SFT-good fit = 66.667% respectively) that had better chance to move up to higher PST as compared with the rest of 3 countries, **EU** were the second (50.000 %; 50.000%), **USA** were the third (53.846%; 38.462%), while, **TH** local companies were the worst (0.000%; 3.846%) that had only PST II outsourcing relationship.

Table 4.6 showed the cross-tabulation analysis results of two outsourcing relationships between two business sectors together with nationality were in accord with our expectation. (1) **CPs group**, with four nationalities: (1.1) **CP-JN**, the majority 5 (83.333% of 6) good SFT companies would still be in type III PST, and the failure 1 (16.667 % of 6) good fit type failed to reach their target PST III, whereas 2 (100.000%)

moderate fit type companies would still be in type II PST. (1.2) **CP-USA**: the majority 5(62.500% of 8) moderate SFT companies would still be in type II PST, and the rest 3(37.500% of 8) moderate fit type companies could made progress in PST III, whereas, 4 (80.000 % of 5) good fit type companies would still be in type III partnership, and the failure 1 (20.000 % of 5) good fit strategic type failed to reach their target type III partnership. (1.3) **CP-EU**: all of 7 (100.000%) moderate SFT companies would still be in PST II, same as all of 7 (100.000%) good SFT companies also would still be in PST III as well. And the last (1.4) **CP-TH**: the majority 8(80.000% of 10) moderate SFT ones would still be in type II PST, whereas 2 (20.000% of 10) of low SFT companies could made progress in the type II partnership. (2) **CMs group**, with three nationalities: (2.1) **CM-JN**, all of 2 (100.000%) moderate fit type companies would still be in PST II, same as all of 2 (100.000%) good SFT companies would still be in type III partnership as well. (2.2) **CM-EU**: all of 1 (100.000%) moderate fit type companies would still be in type II partnership, same as all of 1 (100.000%) good SFT company would still be in PST III as well. And the last group (2.3) **CM-TH**: the majority 12 (75.000% of 16) moderate fit type ones would still be in type II partnership, the failure 1 (6.250 % of 16) good fit strategic type failed to reach their target type III partnership, whereas, 3 (18.750% of 16) low fit type companies could made progress in PST II.

Table 4.6: The cross tabulation of PST & SFT with business sector together with nationality

B. Sector	Nationality	PST	SFT			Total
			Low fit	Moderate fit	Good fit	
CPs	JP	Type II		2(100.000%)	1(16.667%)	3(37.500%)
		Type III			5(83.333%)	5(62.500%)
		% of Total		2(25.000%)	6(75.000%)	8(100.000%)
	USA	Type II		5(62.500%)	1(20.000%)	6(46.154%)
		Type III		3(37.500%)	4(80.000%)	7(53.846%)
		% of Total		8(61.538%)	5(38.461%)	13(100.000%)
	EU	Type II		7(100.000%)		7(50.000%)
		Type III			7(100.000%)	7(50.000%)
		% of Total		7(50.000%)	7(50.000%)	14(100.00%)
	TH	Type II	2(100.000%)	8(100.000%)		10(100.000%)
		Type III				0(0.000%)
		% of Total	2(20.000%)	8(80.000%)	0(0.000%)	10(100.000%)
CMs	JP	Type II		2(100.000%)		2(50.000%)
		Type III			2(100.000%)	2(50.000%)
		% of Total		2(50.000%)	2(50.000%)	4(100.00%)
	EU	Type II		1(100.000%)		1(50.000%)
		Type III			1(100.000%)	1(50.000%)
		% of Total		1(50.000%)	1(50.000%)	2(100.000%)
	TH	Type II	3(100.000%)	12(100.000%)	1(100.000%)	16(100.000%)
		Type III				0(0.000%)
		% of Total	3 (18.750%)	12 (75.000%)	1 (6.250%)	16(100.000%)

Hence, the outsourcing relationship between PST vs. SFT with business sector together with nationality (Table 4.6), the analysis results showed that 4 nationalities of CPs group had the relations between PST vs. SFT same and align with the results with 4 nationalities (in Table 4.5), *JP* had the best of two outsourcing types and *TH* companies still were the worst outsourcing types. Whereas, the relationship types of CMs group with 3 nationalities, showed some differences from CPs group that *JP&EU* had the same structure of outsourcing models and types, however, *TH* local companies still were the worst of both two outsourcing types as well.

4.2.2.4 Cross tabulation of expected SFT & PST and between the surveyed results vs. the expected results of Thai and foreign countries

This analysis results presented three tables of the cross classification: 1) the expected SFT vs. expected PST (from part III of questionnaire: open-end questions), 2) the surveyed SFT vs. the expected SFT, and 3) the surveyed PST vs. the expected PST, to explore the respondents' expectation of the outsourcing relationship with their partner companies, using cross-tabulation to compare the relationships between Thai and foreign companies as well.

Table 4.7: The cross tabulation of expected SFT and expected PST

Exp. PST	Exp. SFT			Total
	Low Fit	Moderate Fit	Good fit	
Type II Count (% of Total)	2(100.000 %)	30 (85.714 %)	10(33.333 %)	42 (62.637%)
Type III Count (% of Total)		5 (14.236 %)	20 (66.667 %)	25 (37.313 %)
Total Count (% of Total)	2(2.935 %)	35 (52.239 %)	30 (44.776 %)	67(100.000 %)

Table 4.7 showed that the statistically significant analysis results, using the 2-way cross-tabulation for all 67 pairs' pharmaceutical outsourcing expected types. All of the 2 (100.000%) low exp. SFT companies could struggle to be in exp. PST II, whereas the majority 30 (85.714% of 35) moderate exp. SFT's companies would still be in exp. PST type II, and the failure 10 (13.836 % of 22) good fit type failed to reach the exp. PST III target, the results of which contrasting to the majority 20 (66.667 % of 30) of good SFT companies that could maintain or made progress in the type III PST. Hence, it could be possible to conclude that the majority of outsourcing relations expectation of pharmaceutical companies in Thailand are PST II, as well as moderate

SFT. However, the analysis result showed that most of respondents expected the higher (better) of PST and SFT than the surveyed results (in Table 4.4, PST III = 32.836% and good SFT = 32.836%).

Table 4.8: The cross tabulation of SFT vs. expected SFT with nationality

Nationality	PST	SFT			Total
		Low fit	Moderate fit	Good fit	
JP	Exp. Moderate fit		2(50.000%)		2(16.667%)
	Exp. Good fit		2(50.000%)	8(100.000%)	10(83.333%)
	% of Total		4(33.333%)	8(66.667%)	12(100.000%)
USA	Exp. Moderate fit		6(75.000%)		6(46.154%)
	Exp. Good fit		2(25.000%)	5(100.000%)	7(53.846%)
	% of Total		8(61.538%)	5(38.462%)	13(100.000%)
EU	Exp. Moderate fit		8(100.000%)	1(12.500%)	9(56.250%)
	Exp. Good fit			7(87.500%)	7(43.750%)
	% of Total		8(50.000%)	8(50.000%)	16(100.000%)
TH	Exp. Low fit	2(40.000%)			2(7.692%)
	Exp. Moderate fit	3(60.000%)	15(75.000%)		18(69.231%)
	Exp. Good fit		5(25.000%)	1(100.000%)	6(23.077%)
	% of Total		20(76.923%)	1(3.846%)	26(100.000%)

Table 4.9: The cross tabulation of PST vs. expected PST of with nationality

Nationality	Expected PST	PST		Total
		Type II	Type III	
JP	Exp. Type II	5(100.000%)	1(14.286%)	6(50.000%)
	Exp. Type III		6(85.714%)	6(50.000%)
	% of Total	5(41.667%)	7(58.333%)	12(100.000%)
USA	Exp. Type II	6(100.000%)		6(46.154%)
	Exp. Type III		7(100.000%)	7(53.846%)
	% of Total	6(46.154%)	7(53.846%)	13(100.000%)
EU	Exp. Type II	7(87.500%)	1(12.500%)	8(50.000%)
	Exp. Type III	1(12.500%)	7(87.500%)	8(50.000%)
	% of Total	8(50.000%)	8(50.000%)	16(100.000%)
TH	Exp. Type II	22(84.615%)		22(84.615%)
	Exp. Type III	4(15.385%)		4(15.385%)
	% of Total	26(100.000%)	0(0.000%)	26(100.000%)

The research findings showed that the comparison between surveyed SFT vs. expected SFT of 4 nationalities (Table 4.8), considering based on the best of SFT (good fit), almost of respondents' (*JP*, *USA*, & *TH*) expectation were higher (better) than the surveyed results, except *EU*, a little bit lower than the surveyed results. Whereas, the comparison between surveyed PST vs. expected PST of 4 nationalities (Table 4.9), considering based on the best of PST (type III), showed the surveyed vs. the expected results from both *USA* & *EU* were equal; while *JP*, the surveyed results were higher (better) than the expectation; only *TH* companies, that the surveyed results were lower than their expectation.

4.2.2.5 Fisher's exact test of PST and SFT

During the research analysis, the researcher found another problem arrived from the small sample size, which consequently showed that some cells of the previous findings have expected frequencies less than 5 and chi-square tests were not available. So, the further research, the researcher change to use Fisher's exact test that is valid test in this case (using 2X2 contingency table by combine the data of low fit (small quantity) and moderate fit (bigger quantity) together as the moderate fit type data.

Table 4.10 showed that the statistically significant analysis results of all 67 pairs' pharmaceutical outsourcing types were in in accord with our expectation. The majority 42 (93.333% of 45) are moderate SFT which would still be in type II partnership, and the failure 3 (13.636 % of 22) good fit strategic type failed to reach their target type III partnership, the results of which contrasting to the majority 19 (86.364 % of 22) of good SFT that could maintain or made progress in type III partnership. This analysis results supported the third research hypothesis (RH 3).

Table 4.10: Fisher's exact test of PST and SFT

PST	SFT			Analysis results	Value	d.f.	Sig.
	Moderate	Good fit	Total				
Type II	42 (93.333 %)	3 (13.636 %)	45 (67.164 %)	Pearson	42.556a	1	0.000
Type III	3 (6.667 %)	19 (86.364 %)	22 (32.836 %)	Fisher's	-	-	0.000
Count (% of total)	45 (100.000 %)	22 (100.000%)	67 (100.000%)	Somers' d	0.797	-	0.000

a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 7.22.

b. Computed only for a 2x2 table

4.2.3 The Predictors of the Companies' Performance Outcomes

These analysis results had answered the second research question concerning the predictors of the companies' performances outcome form each of PST and SFT. Using the cross tabulations between two predictors: 4.2.3.1) company revenue in Y 2015 (separated in two groups: < 1000 MB, and \geq 1000 MB); and 4.2.3.2) % growth rate of Y 2015 (separated in two groups: < 8.2%, and \geq 8.2%), and the PST & SFT were conducted in order to clarify which one was the best predictor. The reason underlining the analysis choice was depend on the categorical measure of both two predictors and the partnership and strategic fit outcomes. The analysis results were presented as follows:

4.2.3.1 Revenue performance evaluation between PST and SFT

Table 4.11 showed the analysis results comparing the outsourcing type relation between 2 groups of revenue as follows: (1) The low revenue companies (< 1000 MB in Y2015), there were 27 (96.429% of 28) moderate fit type ones would still be in PST II, and the failure 3 (33.333 % of 9) good fit type failed to reach their target PST III. The result of which contrasting to the rest 6 (66.667 % of 9) good fit type ones that could maintain or made progress in the PST III. (2) The high revenue companies (\geq 1000 MB), there were 15 (88.235% of 17) moderate fit ones would still be in PST II, the result of which contrasting to 13 (100.000 % of 13) of good fit ones that could maintain or made progress in the type III partnership.

Table 4.11: The cross tabulation between PST vs. SFT classified based on two groups of Revenue

Predictor		SFT		Total	Analysis results			
		Moderate fit	Good fit		Value	d.f.	Sig.	
Revenue < 1000, n = 37	Type II	27(96.429%)	3 (33.333%)	30(81.081%)	Pearson	17.676 ^a	1	0.000
	Type III	1 (3.571%)	6 (66.667%)	7(18.919%)	Fisher's	-	-	0.000
		28(100.000%)	9 (100.000%)	37(100.000%)	Somers' d	0.631	-	0.002
Revenue \geq 1000, n = 30	Type II	15(88.235%)	0 (0.000%)	15(50.000%)	Pearson	22.941 ^b	1	0.000
	Type III	2 (11.765%)	13 (100.000%)	15(50.000%)	Fisher's	-	-	0.000
		17(100.000%)	13 (100.000%)	30(100.000%)	Somers' d	0.882	-	0.002

a. 1 cells (25.0%) have expected count less than 5. The minimum expected count is 1.70.

b. 1 cells (25.0%) have expected count less than 5. The minimum expected count is 6.50.

The analysis results also aiming to study whether company revenue is a moderator having effect on the relationship between SFT and PST, indicated of the group#1 (Revenue <1000 MB), there are 96.429% of company which are moderate fit type could transform to be in partnership-type II, only 3.571% of companies can't ship to good fit type. 66.667% of good fit type are in PNS-type III. Pearson value = 17.676, d.f. =1, sig. =.000, Fisher's exact Sig. = .000, and Somers'd value (with PST dependent) is .631, we can interpret that the relationship of these two models are moderately significant with the first group of revenue. For the group#2 (Revenue \geq 1000 MB), also same concept to analyze, with Pearson value = 22.941, d.f. =1, sig. =.000, Fisher's exact Sig. = .000, and Somers'd value (with PST dependent) is .882, we can interpret that the relationship of these two models are highly significant with the second group of revenue. This

analysis results supported the fourth research hypothesis (RH 4). However, this analysis result ought to be further analyzed with several predictors in order to clarify this study.

4.2.3.2 Growth rate performance evaluation between PST and SFT

Table 4.12 showed the analysis results comparing the outsourcing type relation between two groups of company growth rate as follows: (1) The low % growth rate companies (< 8.2% in Y2015), there were 25 (96.154% of 26) moderate fit type ones would still be in PST II, and no failure of good fit failed to reach their target PST III. The result of which contrasting to the rest 8(100.000 % of 8) good fit ones that could maintain or made progress in the PST III. (2) The high % growth rate companies (\geq 8.2% MB), there were 17 (89.474% of 19) moderate fit ones would still be in PST II, and the failure 3 (21.429% of 14) of good fit type failed to reach their target PST III. The result of which contrasting to 11 (78.571 % of 14) of good fit ones that could maintain or made progress in the PST III.

Table 4.12: The cross tabulation between PST and SFT classified based on two groups of Growth rate

Predictor		SFT		Total	Analysis results			
		Moderate fit	Good fit		Value	d.f.	Sig.	
Growth R < 8.2% n = 34	Type II	25(96.154%)	0(0.000%)	25(73.529%)	Pearson	29.060 ^a	1	0.000
	Type III	1 (3.846%)	8(100.000%)	9(26.471%)				
			26(100.000%)	8(100.000%)	34(100.000%)	Somers' d	0.962	
Growth R \geq 8.2% n = 33	Type II	17(89.474%)	3(21.429%)	20(60.606%)	Pearson	15.632 ^b	1	0.000
	Type III	2 (10.526%)	11(78.571%)	13(39.394%)				
			19(100.000%)	14(100.000%)	33(100.000%)	Somers' d	0.680	

a. 1 cells (25.0%) have expected count less than 5. The minimum expected count is 2.12.

b. 1 cells (25.0%) have expected count less than 5. The minimum expected count is 5.52.

The analysis results also aiming to study whether company growth rate is a moderator having effect on the relationship between SFT and PST, indicated of the group#1 (% Growth rate < 8.2), there are 96.154% of company which are moderate fit type could transform to be in partnership-type II, only 3.846% of companies can't ship to good fit type, and 100.000 % of good fit type are in partnership-type III. Pearson value = 29.060, d.f. =1, sig. =.000, Fisher's exact Sig. = .000, and Somers'd value (with PST dependent) is .962, we can interpret that the relationship of these two models are highly significant with the first group of growth rate. For the group#2 (%Growth rate \geq 8.2), also same concept to analyze, with Pearson value =15.632, d.f. =1, sig. =.000,

Fisher's exact Sig. = .000, and Somers'd value (with PST dependent) is .680, we can interpret that the relationship of these two models are moderately significant with the second group of growth rate. This analysis results also supported the fourth research hypothesis (RH 4) as well. However, this analysis result ought to be further analyzed with several predictors in order to clarify this study.

Our brief analysis results on testing regarding the second research question supported almost of our expected research results. Firstly, there were both associations and correlations between the CPs vs. CMs alliance companies, between Thai vs. foreign companies, and between PST and SFT in pharmaceutical companies in Thailand, the results of which strongly support the relationship between the two models, especially the transfer from outsourcing strategic pair to the expected partnership alliance in the future. And secondly, both of the companies' revenue and growth rate could predict the companies' performances outcome for each of PST and SFT. It was quit noteworthy that only the pharmaceutical companies with the highest revenue and growth rate could have good SFT and transfer to the PST III in the future, whereas only the companies with high revenue and growth rate could have moderate type and only a few of them could transfer to the type III partnership. Our analysis results had thus shed some light on the prediction of the outsourcing SFM and PSM.

4.2.4 The post evaluation for finding the appropriate policies, strategic goals from Thai government in outsourcing pharmaceutical industry

To answer the third research question concerning the appropriated policies, and strategic goals from Thai Government, for the successful of outsourcing manufacturing in the future of Thai pharmaceutical industry. Researcher surveyed by summative evaluation, using post-evaluation questionnaire (see Appendix B), with two concerned topics: (1)The obstacles/ problems of Thai pharmaceutical outsourcing manufacturing Industry, and (2) The suggestion of appropriate policies and strategic goals of Thai government in this industry. The characteristics and research results from eight private (P), and four government (G) respondents are shown in Table 4.13 and 4.14, as follows:

Table 4.13: Characteristics of respondents in post-evaluation survey

Respondent	Business S./Nationality	Job Level	Working experiences (years)
P1	CP-J	Manager	16
P2	CP-U	Manager	8
P3	CP-U	Director	18
P4	CP-E	Manager	20
P5	CM-J	Manager	15
P6	CM-E	Director	12
P7	CM-T	Manager	10
P8	CM-T	Director	23
G1	FDA	Supervisor	9
G2	FDA	Officer	3
G3	DITP	Supervisor	10
G4	BOI	Supervisor	12

Table 4.14: Post- evaluation survey results

(1)The obstacles/ problems of Thai outsourcing pharmaceutical manufacturing Industry	% of respondent agree with		
	Private	Government	Total
	n ₁ =8	n ₂ =4	n=12
1.1 The delay in drug /formulation registrations of Thai manufacturers with FDA	8 (100.0%)	3 (75.0%)	11 (91.7%)
1.2 The GPO, manufacturer government sectors, produce and sell their own drugs to compete with private companies, and have the privilege that not require to register the medical list	8 (100.0%)	1 (25.0%)	9 (75.0%)
1.3 There are few of Thai drug factories that pass EU- GMP PIC/S standard (only 10-20%)	6 (75.0%)	4 (100.0%)	10 (83.3%)
1.4 Need to have drug registrations again when export.	6 (75.0%)	4 (100.0%)	10 (83.3%)
1.5 Thai local drugs can't compete with imported drugs from China and India. Because of the higher cost from imported APIs (can't produce in Thai)	8 (100.0%)	4 (100.0%)	12(100.0%)
1.6 Thai government still does not enforce the Patent Law by international standard, leads to some multinational companies postpone or reduce their drug expansion projects in Thailand	6 (75.0%)	1 (25.0%)	7 (58.3%)
Total % of respondent agree with Topic (1)	42 (87.5%)	17 (70.8%)	59 (81.9%)
(2) The suggestion of policies and strategic goals for Thai government should be applied	Private	Government	Total
	n ₁ =8	n ₂ =4	n=12
2.1 Thai government should speed up the registration process by reducing lead time or procedure for various types of drug registration, for Thai pharmaceutical manufacturers can compete with other countries, as follow: (a) New drugs reduce from the actual average of 380-480 to 280 working days. ¹ (b) Export drugs from 45 to 20 working days. ² (c) Reduce the time that academics use to examine from 120-180 to 20 working days. ³ (d) Reduced drug registration time to be sent to experts, from 540 to 120 working days. ³	a. 8(100.0%)	4 (100.0%)	12(100.0%)
	b. 8(100.0%)	1 (25.0%)	9 (75.0%)
	c. 8(100.0%)	0 (0.0%)	8 (66.7%)
	d. 8(100.0%)	2 (50.0%)	10 (83.3%)
2.2 The Ministry of Public Health has developed a five-year action plan in line with the National Drug			

Policy and Strategy for the Development of the National Drug Administration (MDT), 2000-2021, with projects related to the development of the domestic pharmaceutical industry, for production efficiency and highly competitiveness.	8 (100.0%)	4 (100.0%)	12(100.0%)
2.3 The government should set GPO as the leader in upgrading for Thai local factories, instead of private rivals in the manufacture of drugs.	8 (100.0%)	3 (75.0%)	11(91.7%)
2.4 Thai-FDA has been accepted as a PIC/S member country since Aug.1, 2016. So, Thai export drugs can sell and will be short cut for drug registration in member countries.	6 (75.0%)	4 (100.0%)	10 (83.3%)
2.5 The government should promote and increase number of Thai pharmaceutical companies to be certified EU-GMP PIC/S standard, for more opportunity to increase export drugs to PIC/S member.	8 (100.0%)	4 (100.0%)	12(100.0%)
2.6 Thailand now are in ASEAN Listed Inspection Service Member, so Thai drugs are accepted for export to neighboring countries in AEC.	8 (100.0%)	4 (100.0%)	12(100.0%)
2.7 The government encourages Thai private companies to produce new patented generic drugs, with strategic goal that Thailand will be a center for generic drugs production in ASEAN.	8(100.0%)	4 (100.0%)	12(100.0%)
2.8 The Board of Investment (BOI) of Thailand is considering upgrading the investment promotion in Thai pharmaceutical industry from B1 (except for machinery, raw materials and other non-tax benefits) to A3 (5 years corporate income tax exemption) for entrepreneurs applying the investment promotion from 2018 onwards. And A2 (exemption from corporate income tax for 8 years) for entrepreneurs applying the investment incentives by 2016.	8 (100.0%)	4 (100.0%)	12(100.0%)
2.9 The government, by coordinating with Department of Export Promotion (DEP), by providing tax support to promote the export of Thai pharmaceutical manufacturers	8 (100.0%)	3 (75.0%)	11(91.7%)
2.10 The government should strengthen and contribute to the research and development of the pharmaceutical industry, by establish Thai Pharmaceutical Research and Development Committee)	8 (100.0%)	4 (100.0%)	12(100.0%)
2.11 The government should provide a sourcing directory of APIs, which quality specification and cheaper price, for Thai manufacturers can easily buy with cost reduction, and can compete with imported drugs include export markets as well.	8 (100.0%)	4 (100.0%)	12(100.0%)
2.12 The public should joint with Thai private companies, to build APIs factory and/or biological plants, with a focus on highly competitive in ASEAN region.	7 (87.5%)	4 (100.0%)	11 (91.7%)
Total % of respondent agree with Topic (2)	113(94.2%)	49 (81.7%)	162(90.0%)

1. Summarized from PReMA

2. According to Thai FDA announcement on Jul. 27, 2015

3. Regulatory reform and relaxation Study on new drug registrations

The post-survey results from twelve respondents in topic **(1) “The obstacles/problems of Thai pharmaceutical outsourcing manufacturing Industry”** revealed that 81.9% of total respondents agree with six obstacles/problems of Thai pharmaceutical outsourcing manufacturing Industry, 87.5% from private and 70.8% from government respondents. Most of obstacles/problems (4 from 6 issues); 1.1, 1.3, 1.4 & 1.5; the surveyed results from private respondents are quite similar as government respondents, only two issues; 1.2 & 1.6; are significant differences between both sectors, and will be discussed later. Considering the results from % of total respondents (both private & government respondents), the sequence of obstacles/problems from high % of total agree (100.0%) to low % of total agree (58.3%), as follows:

- Thai local drugs can't compete with imported drugs from China and India. Because of the higher cost from imported APIs (can't produce in Thai). (100%)
- The delay in drug /formulation registrations of Thai manufacturers with FDA (91.7%)
- There are few of Thai drug factories that pass EU- GMP PIC/S standard (only 10-20%). (83.3%)
- Need to have drug registrations again when export. (83.3%)
- The GPO, manufacturer government sectors, produce and sell their own drugs to compete with private companies, and have the privilege that not require to register the medical list. (75.0%)
- Thai government still does not enforce the Patent Law by international standard, leads to some multinational companies postpone or reduce their drug expansion projects in Thailand. (58.3%)

And the surveyed results in topic **(2) “The suggestion of policies and strategic goals for Thai government should be applied”** showed that 90.0% of total respondents agree with twelve of suggestion policies and strategic goals from Thai government should be applied, 94.2% of private and 81.7% from government respondents. Almost of policies and strategic goals (11 from 12 policies), the surveyed results from private are quite similar as government respondents, except only policy 2.1 that both sectors' results are significant difference, and will be discussed later.

Considering the results from % of total respondents (both private & government respondents), the sequence of Thai government policies and strategic goals that should be applied from high % of total agree (100.0%) to low % of total agree (66.7%), as follows:

- The Ministry of Public Health has developed a five-year action plan in line with the National Drug Policy and Strategy for the Development of the National Drug Administration (MDT), 2000-2021, with projects related to the development of the domestic pharmaceutical industry, for production efficiency and highly competitiveness. (100.0%)
- The government should promote and increase number of Thai pharmaceutical factories to be certified EU-GMP PIC/S standard, for more opportunity to increase export drugs to PIC/S member. (100.0%)
- Thailand is in ASEAN Listed Inspection Service Member, so now Thai drugs are easy and accepted for export to neighboring countries in AEC. (100.0%)
- The Board of Investment (BOI) of Thailand is considering upgrading the investment promotion in Thai pharmaceutical industry from **B1** (except for machinery, raw materials and other non-tax benefits) to **A3** (5 years corporate income tax exemption) for entrepreneurs applying the investment promotion from 2018 onwards. And **A2** (exemption from corporate income tax for 8 years) for entrepreneurs applying the investment incentives by 2016. (100.0%)
- The government should strengthen and contribute to the research and development of the pharmaceutical industry, by establish Thai Pharmaceutical Research and Development Committee). (100.0%)
- The government should provide a sourcing directory of APIs, which qualified specification and cheaper price, for Thai manufacturers can easily buy with cost reduction, and can compete with both imported drugs and export markets as well. (100.0%)
- The government encourages Thai private companies to produce new patented generic drugs, with strategic goal that Thailand will be a center for generic drugs production in ASEAN. (100.0%)
- The government should set GPO as the leader in upgrading for Thai local factories, instead of private rivals in the manufacture of drugs. (91.7%)

- The government, by coordinating with Department of Export Promotion (DEP), by providing tax support to promote the export of Thai pharmaceutical manufacturers. (91.7%)
- The public should joint with Thai private companies, to build APIs factory and/or biological plants, with a focus on highly competitive in ASEAN region. (91.7%)
- Thai-FDA has been accepted as a PIC/S member country since Aug.1, 2016. So, Thai export drugs can sell and will be short cut for drug registration in member countries. (83.3%)
- Thai government should speed up the registration process by reducing the time or procedure for various types of drug registration, to be tight and fast for Thai pharmaceutical manufacturers can compete with other countries, as follow: (1) New drugs reduce from the actual average of 380-480 to 280 working days.¹ (2) Drugs produced for export from 45 to 20 working days.² (3) Reduce the time that academics use to examine from 120-180 to 20 working days.³ (4) Reduced drug registration time to be sent to experts, from 540 to 120 working days.³(81.3%)

In conclusion, both public and private sectors are the important sectors in Thai pharmaceutical outsourcing manufacturing industry, the appropriate policies, strategic goals from Thai government include public-private partnership are the key success factors for sustainable growth in this industry.

4.3 Research Discussions

This study, an empirical survey of the Thai outsourcing between CPs and CMs pharmaceutical companies regarding the partnership and strategic fit models based supply chain management, and their outcomes performance had confirmed our expectations.

(1) There was no significant difference in the four factor means (driver, facilitator, internal and external factors) of the PSM and SFM between business sectors (CPs vs. CMs). On the contrary, there were significant differences between nationalities (Thai vs. foreign companies).

(2) The significantly high correlations between the two factors measuring the partnership success (drivers & facilitators) and the strategic fit success (internal & external factors), whereas the partnership correlations were higher than the strategic fit correlations, indicated a better congruencies in the partnership than the strategic fit success.

(3) The results showed that strategic fit was strongly associated with the partnership, signifying the great efforts had been made by the CPs and CMs toward their agreements in strategic management in order to accomplish their targeting outsourcing success, and the expected partnership success (Festel et al., 2014; Lambert et al., 1996; Piltan & Sowlati, 2016; Schwarz, 2014).

(4) The big differences in means across the Thai and foreign pharmaceutical companies revealed significance higher alliance performance for the foreign companies as compared to those of the Thai companies which already known from the past research. For example, Javalgi et al. (2013); Kedia & Lahiri (2007) had shown that the long-term nature of strategic partnership provided the CMs for gradually learning to be able to utilize their deep involvement with their CPs in developing their best resources and capabilities, and drivers which had indeed spurred the adoption of transferring the outsourcing strategic to partnership alliance. Therefore, in order to achieve successful transformation through outsourcing, the pharmaceutical company executives must “go beyond ‘making deals’ and instead design their active business models that would work for their expected target,” in other words, those executives could not achieve their expected sustaining outsourcing services without a continuous development of their strategic management.

(5) The foreign companies’ advantages over the Thai companies reflects the Thai companies’ inability to strengthen their key outsourcing factors led to subsequent inability to compete with the foreign companies. As three of the four factors consist of the companies’ internal factors, their drivers and facilitators, whereas the fourth factor concerns with the external elements such as the strict government drug regulation and time consuming process of getting permission, cultural clashes, poor communication and high turnover, therefore, without the extensive government support for the fourth factor, the Thai companies could not achieve their target partnership alliance with their upgrade of the other three factors.

(6) The cross-tabulation between PST vs. SFT, revealed that the 43 pharmaceutical companies in Thailand, the strategic fit relations; SFT; were classified: 7.5% as the low fit; 59.7% as moderate fit; and 32.8% as good fit. And the partnership relations; PST; were classified as: 67.2% of type II, and 32.8% of type III. Comparing across the two outsourcing relation types showed that most of the moderate fit type companies (92.8%) were likely remain into the type II partnership, and most of those good fit companies (86.36 %) would be expected to be into the type III partnership. It could be conclude that the most of Thai pharmaceutical outsourcing manufacturing are classified as the partnership type II, as well as the moderate strategic fit type.

(7) The comparison of two outsourcing relationship between PST vs. SFT among four nationality of pharmaceutical companies in Thailand, it could be concluded that Japan had the best of both two outsourcing types, this may be caused from the outsourcing manufacturing types, because most of Japan's outsourcing manufacturing category in Thailand was packaging products, they use Thailand both for re-export the drugs to sell in Japan, and export to ASEAN countries as well. While, most of EU & USA outsourcing companies in Thailand were outsourced their products as drug formulation type. Lastly, Thai local companies were the worst of two outsourcing relationship among these four nationalities.

(8) Considering the outsourcing relationship with business sector together with nationality, the results showed that *four nationalities of CPs group* had the outsourcing relations between PST vs. SFT same and align with the results with four nationalities, that Japan companies were the best ,and Thai companies still were the worst ones. Whereas, the relationship types of *CMs group with three nationalities*, showed some differences from CPs group that Japan and Europe had the same pattern of outsourcing relationship, however, Thai local companies still were the worst of these two outsourcing types among these four nationalities.

(9) The research findings also showed that almost of surveyed companies requested for the better types of outsourcing relationship from their outsourcing partners than the current relationship types, especially Thai companies. The survey results, thus confirmed the findings of quite a big differences between the available target-aimed partnership factors and the existing strategic fit factors which the companies must working hard to achieve. Considering the feasibility of the

transformation into the partnership alliance, Thai pharmaceutical companies seemed, not only to be handicapped, comparing with other Asian countries, because of partly the Government strict regulations and time consuming process to get the official permission (TIR, 2015), but also their transformation ability from internal factors to both drivers and facilitators to achieve their transformation target (Khan & Ali, 2015; Lee, 2013; Moe et al., 2014). The solutions of these arguments thus require further research in terms of in depth cases study.

(10) Both of the outsourcing partnership and strategic fit efforts and success could be predicted by two and existing factors of the companies' open characteristics data, with company revenue as a better predictor as compared to the growth rate. These results were quite obvious because of the great variation in revenue as compared to the growth rate. However, the findings just confirmed the limitation concerning difficulty in acquiring open data source from the pharmaceutical companies in Thailand, the content of which further suggested the case study design from a specific company instead of the survey as in the research conducted by Kinnula (2005).

(11) The post-evaluation survey from both private and government respondents agreed that Thai pharmaceutical contract manufacturing industry is in uptrend situation, and believed that most of the obstacles /problems can be solved and fit by public-private partnership, and the appropriate policies, strategic goals from government sector.

(12) The Government Pharmaceutical Organization (GPO), one of the crucial state enterprises for Thailand's national development, especially regarding to national public health system, should be role as research and development of new medicine for international competitiveness and producing raw material, initial substance or vaccine for national health security and stability as well as emergency assessment. However, GPO still need to produce the basic or essential drugs for national health security, but will not compete with private companies to manufacture in other groups of drugs.

(13) In case of "Compulsory licensing", government allows someone else to produce the patented product or process without the consent of the patent owner, this leads to some multinational companies postpone or reduce their drug expansion projects in Thailand. So, Thai government should be more concerns and enforce the Patent Law by international standard, and strictly control of compulsory licensing.

(14) For speed up the drug registration process by reducing lead time or procedure for various types of drug registration, even 100% of private respondents agree to reduce the process lead time as much as FDA can, but most of government sector disagree with the proposed lead time, because they believed that it doesn't practical, and need to improve some concerned resource as well, such as: increase number of Academics and Experts; increase compensation fee for Experts; prepare public guide for pharmaceutical companies to reduce the incomplete documents and request forms; etc. The suggested lead time should be:

- (a) New drugs reduce from the actual average of 380-480 to *280 working days*.
- (b) Export drugs from 45 to *30 working days*.
- (c) Reduce the time that academics use to examine from 120-180 to *60 working days*.
- (d) Reduced drug registration time to be sent to experts, from 540 to *120 working days*.

CHARTER 5

CONCLUSION

5.1 Conclusion

This study shed some light on the significant relationships both partnership type and strategic fit type, including outsourcing performance and yielded, with some valuable recommendation, such as the appropriate policies, and strategic goals from government, as follows: firstly, the pharmaceutical outsourcing manufacturing in Thailand still are the uptrend situation, especially for Thai local companies, but they need urgent to transform the current outsourcing relationship to the higher and suitable partnership type. Secondly, the Thai Government should announce the policies and extend their supports under the establishment of an ASEAN Community by 2015 in every field of economic industry, especially the pharmaceutical industry for Thai company to compete with the ASEAN neighbor nations, on the feasible relaxed regulations and laws in addition to improving the time consuming process to get the official permission. Thailand now also has been accepted as a PIC/S member since Aug.1, 2016. This causes a big opportunity for Thai export markets to many PIC/S member countries, but Thai factories have to be certified EU-GMP PIC/S standard before. And lastly, Thai pharmaceutical companies will be able to effectively compete with the foreign companies provided that the Government helps supporting the cooperation between the Thai research Universities and the pharmaceutical companies to develop their capacities on R&D for pharmaceutical drug development.

5.2 Limitations and Further Research

Similarly to most empirical research study, this study had at least three limitations. Firstly, the notion of confidential data: most of the pharmaceutical companies in Thailand were reluctant to participate and share their strategic outsourcing data because of high competition, and consequently, our empirical data obtained from each company were only the data from only one of their chosen alliance without identification. Although we had tried to prove that our data were reliable by examine

the relationship between the available perceived data from CPs & CMs, and the real data from each of the alliance companies, we still had a limitation that was not possible to study how they decided to choose their best alliance partners. Secondly, this study was only from private sector, the further research should include public sector as well, for show the whole picture of industry. And lastly, there were only 2 public available predictors for our predictions of the strategic fit and partnership success, which were not possible to yield any complete fact of prediction in this study. These limitations should be aware for any researchers who would like to carry on their further research along this line.

5.3 Recommendation

The recommendations, firstly, for further research are an ex-post facto, comparative case study research of the success and failure companies in order to trace longitudinally the partnership model and strategic fit model based supply chain management, and the comparative case study, using scenarios, between the successful and the failure companies. Researcher is confident that these further research papers will clarify and help extending the guideline for the pharmaceutical companies in Thailand transforming their outsourcing strategic fit model to their expected partnership model. Secondly, there should be a continuing research similar to our survey using AHP analysis (Ersan & Hayder, 2012; Saaty & Tran, 2007) to get the weight mean of the four key multi-indicators factors, in order to obtain more accurate result. Finally, as this paper revealed roughly the fact concerning with the partnership model and strategic fit model based supply chain management, and their outcomes performance.

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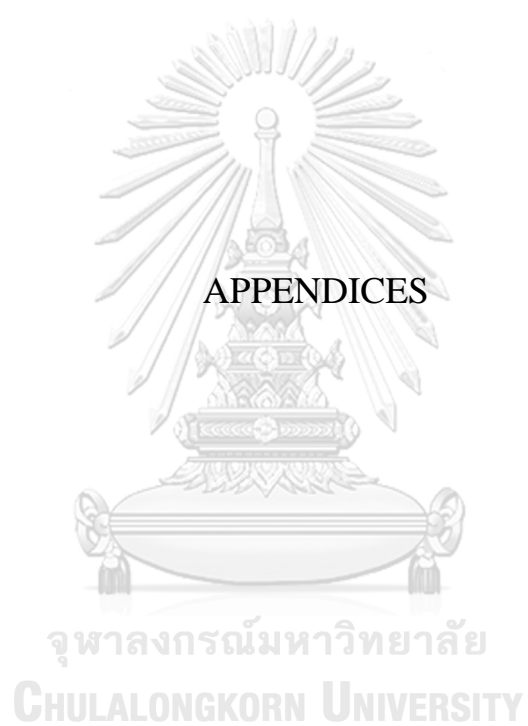
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APPENDIX: A

จุฬาลงกรณ์มหาวิทยาลัย
CHULALONGKORN UNIVERSITY

แบบสอบถามโดยการสัมภาษณ์
**“กลยุทธ์ที่เหมาะสมสำหรับการจัดจ้างบริษัทภายนอกในการผลิตยา การศึกษาสถานการณ์ใน
 ประเทศไทย”**

แบบสอบถามนี้เป็นส่วนหนึ่งของวิทยานิพนธ์ปริญญาเอกตามข้อกำหนดของหลักสูตรสาขาวิชาโลจิสติกส์ บัณฑิตวิทยาลัย จุฬาลงกรณ์มหาวิทยาลัย มีวัตถุประสงค์เพื่อศึกษาและสำรวจสถานการณ์ปัจจุบันของการจัดจ้างบริษัทภายนอกในการผลิตยาของประเทศไทย และประเภทความสัมพันธ์ระหว่างบริษัทจ้างผลิต (Contract Providers-CPs) และบริษัทรับจ้างผลิต (Contract Manufacturers-CMs) ด้านรูปแบบความร่วมมือแบบพันธมิตรและรูปแบบกลยุทธ์ที่เหมาะสม ทั้งบริษัทของไทยและต่างชาติ ทั้งนี้ ประโยชน์ที่คาดว่าจะได้รับจากการทำวิจัยในครั้งนี้ เมื่อได้รับข้อมูลจากท่าน ได้แก่

- บริษัทจ้างผลิตและบริษัทรับจ้างผลิตสามารถจัดหาผู้ค้าได้อย่างเหมาะสมและตรงกับความต้องการ
- บริษัทสามารถเรียนรู้ สังเคราะห์ และนำเสนอนโยบาย ทางเลือกและการตัดสินใจเชิงกลยุทธ์ที่เหมาะสมในการจัดจ้างบริษัทภายนอกในการผลิตยา อันจะเป็นประโยชน์ต่อวงการสาธารณสุข และช่วยสร้างเสริมผลสำเร็จทางธุรกิจต่ออุตสาหกรรมยาของไทยในอนาคต
- ได้แนวทางการขยายผลและต่อยอดให้เกิดงานวิจัยในวงกว้างและเชิงลึกมากยิ่งขึ้น อันเป็นประโยชน์ต่อการขยายขอบเขตความรู้ในการวิจัย

ข้อความถามในแบบสอบถามแบ่งเป็น 2 ตอน คือ ข้อมูลภูมิหลัง และ ความสัมพันธ์ระหว่างบริษัทจ้างผลิตและบริษัทรับจ้างผลิต ในรูปของความร่วมมือแบบพันธมิตรและรูปแบบกลยุทธ์ที่เหมาะสม โดยมีปัจจัยหลักในการวิจัยรวม 3 ปัจจัย ได้แก่ ปัจจัยที่ก่อให้เกิดประโยชน์ร่วมกัน ปัจจัยสนับสนุนต่อกัน และปัจจัยด้านธุรกิจที่เหมาะสมและสอดคล้องกัน

ข้อมูลตามความเป็นจริง และครบถ้วน รวมถึงความจริงใจที่ได้รับจากการสัมภาษณ์ท่านอย่างจริงจัง จะทำให้งานวิจัยนี้ได้ผลลัพธ์และแนวโน้มสถานการณ์ที่มีคุณค่าและเป็นประโยชน์ต่อการจัดจ้างบริษัทภายนอกผลิตยา ทั้งต่อประชาชนซึ่งเป็นผู้บริโภค และต่ออุตสาหกรรมการผลิตยาของไทยเป็นอย่างยิ่ง

อนึ่ง ข้อมูลทั้งโดยส่วนตัวของท่าน และบริษัทของท่าน จะถูกเก็บเป็นความลับ การเผยแพร่ข้อมูลในงานวิจัยนี้จะเสนอเป็นภาพรวม โดยไม่ปรากฏแหล่งที่มาที่ระบุถึงตัวท่านหรือบริษัทของท่าน

ขอขอบคุณล่วงหน้าในความกรุณาและความร่วมมือจากท่านมา ณ ที่นี้เป็นอย่างสูง

นายสมพงษ์ อภิธรรมสุนทร

หลักสูตรการจัดการ โลจิสติกส์ (หลักสูตรนานาชาติ)

บัณฑิตวิทยาลัย จุฬาลงกรณ์มหาวิทยาลัย

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วันที่ สัมภาษณ์ ___ / ___ / ___ เวลา _____ - _____

บริษัทที่สัมภาษณ์.....(รหัสบริษัท.....)

ตอนที่1 ข้อมูลภูมิหลังของผู้ตอบแบบสอบถามและบริษัท

คำชี้แจง: โปรดทำเครื่องหมาย ✓ ในช่อง และให้ข้อมูลในช่องว่างที่เกี่ยวข้องกับตัวท่านและบริษัทของท่าน โดยโปรดตอบทุกข้อ

1. ตำแหน่งงาน:	<input type="checkbox"/> ประธานบริษัท	<input type="checkbox"/> รองประธาน	<input type="checkbox"/> กรรมการผู้จัดการ										
	<input type="checkbox"/> ผู้จัดการทั่วไป	<input type="checkbox"/> ผู้อำนวยการ	<input type="checkbox"/> ผู้จัดการ										
2. จำนวน(ปี)ที่ทำงานในภาคธุรกิจ:	<input type="checkbox"/> น้อยกว่า 1	<input type="checkbox"/> 1- 5	<input type="checkbox"/> 6- 10										
	<input type="checkbox"/> 11- 20	<input type="checkbox"/> มากกว่า 20											
3. ประเภทและสัญชาติของบริษัทท่าน:	<input type="checkbox"/> จ้างผลิต (CP)	<input type="checkbox"/> ไทย	<input type="checkbox"/> ต่างชาติ										
	<input type="checkbox"/> รับจ้างผลิต (CM)	<input type="checkbox"/> ไทย	<input type="checkbox"/> ต่างชาติ										
4. ประเภท,สัญชาติและจำนวนบริษัทคู่ค้าหลักของท่าน:	<input type="checkbox"/> รับจ้างผลิต (CMs) <table border="0" style="width: 100%;"> <tr> <td><input type="checkbox"/> ไทย</td> <td>รวม.....บริษัท</td> </tr> <tr> <td><input type="checkbox"/> ต่างชาติ...ญี่ปุ่น...</td> <td>รวม.....บริษัท</td> </tr> <tr> <td><input type="checkbox"/> ต่างชาติ...อเมริกา...</td> <td>รวม.....บริษัท</td> </tr> <tr> <td><input type="checkbox"/> ต่างชาติ...ยุโรป...</td> <td>รวม.....บริษัท</td> </tr> <tr> <td><input type="checkbox"/> ต่างชาติอื่น(ระบุ).....</td> <td>รวม.....บริษัท</td> </tr> </table>			<input type="checkbox"/> ไทย	รวม.....บริษัท	<input type="checkbox"/> ต่างชาติ...ญี่ปุ่น...	รวม.....บริษัท	<input type="checkbox"/> ต่างชาติ...อเมริกา...	รวม.....บริษัท	<input type="checkbox"/> ต่างชาติ...ยุโรป...	รวม.....บริษัท	<input type="checkbox"/> ต่างชาติอื่น(ระบุ).....	รวม.....บริษัท
<input type="checkbox"/> ไทย	รวม.....บริษัท												
<input type="checkbox"/> ต่างชาติ...ญี่ปุ่น...	รวม.....บริษัท												
<input type="checkbox"/> ต่างชาติ...อเมริกา...	รวม.....บริษัท												
<input type="checkbox"/> ต่างชาติ...ยุโรป...	รวม.....บริษัท												
<input type="checkbox"/> ต่างชาติอื่น(ระบุ).....	รวม.....บริษัท												
	<input type="checkbox"/> จ้างผลิต (CPs) <table border="0" style="width: 100%;"> <tr> <td><input type="checkbox"/> ไทย</td> <td>รวม.....บริษัท</td> </tr> <tr> <td><input type="checkbox"/> ต่างชาติ...ญี่ปุ่น...</td> <td>รวม.....บริษัท</td> </tr> <tr> <td><input type="checkbox"/> ต่างชาติ...อเมริกา...</td> <td>รวม.....บริษัท</td> </tr> <tr> <td><input type="checkbox"/> ต่างชาติ...ยุโรป.....</td> <td>รวม.....บริษัท</td> </tr> <tr> <td><input type="checkbox"/> ต่างชาติอื่น(ระบุ).....</td> <td>รวม.....บริษัท</td> </tr> </table>			<input type="checkbox"/> ไทย	รวม.....บริษัท	<input type="checkbox"/> ต่างชาติ...ญี่ปุ่น...	รวม.....บริษัท	<input type="checkbox"/> ต่างชาติ...อเมริกา...	รวม.....บริษัท	<input type="checkbox"/> ต่างชาติ...ยุโรป.....	รวม.....บริษัท	<input type="checkbox"/> ต่างชาติอื่น(ระบุ).....	รวม.....บริษัท
<input type="checkbox"/> ไทย	รวม.....บริษัท												
<input type="checkbox"/> ต่างชาติ...ญี่ปุ่น...	รวม.....บริษัท												
<input type="checkbox"/> ต่างชาติ...อเมริกา...	รวม.....บริษัท												
<input type="checkbox"/> ต่างชาติ...ยุโรป.....	รวม.....บริษัท												
<input type="checkbox"/> ต่างชาติอื่น(ระบุ).....	รวม.....บริษัท												
5. ประเภทของยาหลักที่ท่านจ้างผลิต (หรือรับจ้างผลิต) เลือกตอบได้มากกว่า 1 คำตอบ:	5.1 กับคู่ค้าสัญชาติไทย <table border="0" style="width: 100%;"> <tr> <td><input type="checkbox"/> ยาเม็ด/ ยาแคปซูล</td> <td><input type="checkbox"/> ยาผง</td> </tr> <tr> <td><input type="checkbox"/> ยาฉีด</td> <td><input type="checkbox"/> ยาฉีด</td> </tr> <tr> <td><input type="checkbox"/> ยาครีม</td> <td><input type="checkbox"/> อื่นๆ.....</td> </tr> </table>			<input type="checkbox"/> ยาเม็ด/ ยาแคปซูล	<input type="checkbox"/> ยาผง	<input type="checkbox"/> ยาฉีด	<input type="checkbox"/> ยาฉีด	<input type="checkbox"/> ยาครีม	<input type="checkbox"/> อื่นๆ.....				
<input type="checkbox"/> ยาเม็ด/ ยาแคปซูล	<input type="checkbox"/> ยาผง												
<input type="checkbox"/> ยาฉีด	<input type="checkbox"/> ยาฉีด												
<input type="checkbox"/> ยาครีม	<input type="checkbox"/> อื่นๆ.....												
	5.2 กับคู่ค้าต่างชาติ <table border="0" style="width: 100%;"> <tr> <td><input type="checkbox"/> ยาเม็ด/ ยาแคปซูล</td> <td><input type="checkbox"/> ยาผง</td> </tr> <tr> <td><input type="checkbox"/> ยาฉีด</td> <td><input type="checkbox"/> ยาฉีด</td> </tr> <tr> <td><input type="checkbox"/> ยาครีม</td> <td><input type="checkbox"/> อื่นๆ.....</td> </tr> </table>			<input type="checkbox"/> ยาเม็ด/ ยาแคปซูล	<input type="checkbox"/> ยาผง	<input type="checkbox"/> ยาฉีด	<input type="checkbox"/> ยาฉีด	<input type="checkbox"/> ยาครีม	<input type="checkbox"/> อื่นๆ.....				
<input type="checkbox"/> ยาเม็ด/ ยาแคปซูล	<input type="checkbox"/> ยาผง												
<input type="checkbox"/> ยาฉีด	<input type="checkbox"/> ยาฉีด												
<input type="checkbox"/> ยาครีม	<input type="checkbox"/> อื่นๆ.....												
6. ผลประกอบการและการลงทุนเพิ่มของบริษัทฯในปี 2015 (หัวข้อนี้สอบถามเพิ่มเติมภายหลังทางโทรศัพท์)													
6.1 ยอดรายได้ (ล้านบาท)	<input type="checkbox"/> ≤500	<input type="checkbox"/> -999	<input type="checkbox"/> ≥1000										
	<input type="checkbox"/> ระบุ.....												
6.2 อัตราการเติบโต (%)	<input type="checkbox"/> ≤2.0	<input type="checkbox"/> -8.1	<input type="checkbox"/> ≥8.2										
	<input type="checkbox"/> ระบุ.....												
6.3 ผลกำไร/ขาดทุน (ล้านบาท)	<input type="checkbox"/> กำไร(ระบุ).....	<input type="checkbox"/> ขาดทุน(ระบุ).....	<input type="checkbox"/> ไม่ทราบ										
6.4 ยอดการลงทุนเพิ่ม(ล้านบาท)	<input type="checkbox"/> เพิ่ม(ระบุ).....	<input type="checkbox"/> ไม่เพิ่ม	<input type="checkbox"/> ไม่ทราบ										

ตอนที่ 2 แบบสอบถามงานวิจัย ความสัมพันธ์ระหว่างบริษัทจ้างผลิต และ บริษัทรับจ้างผลิต

คำชี้แจง: โปรดทำเครื่องหมาย ✓ ในช่องคะแนน ที่ตรงกับคำตอบของท่าน โดยใช้เกณฑ์ "%ความน่าจะเป็นในการตอบคำถาม" ดังตัวอย่างต่อไปนี้

1. ความคิดเห็นต่อการจ้างบริษัทภายนอกในการผลิต	สัญชาติ คู่ค้า	น้อยมาก	น้อย	ปานกลาง	มาก	มากที่สุด
		0.0-20.0%	20.1-40.0%	40.1-60.0%	60.1-80.0%	80.1-100.0%
1.1 การจ้างบริษัทภายนอกช่วยผลิต มีคุณภาพสูง ในด้าน	ไทย			✓		
	ต่างชาติ				✓	
- ลดค่าใช้จ่ายด้านการผลิต						
- มีพันธมิตรที่พึ่งพกัน ได้						
1.2 การจ้างบริษัทภายนอกผลิตเป็น กลยุทธ์ที่จำเป็นต้องทำ เพราะ	ไทย			✓		
	ต่างชาติ			✓		
- กลยุทธ์นี้ช่วยเพิ่มความสามารถในการแข่งขันของบริษัท						
- อื่นๆ(โปรดระบุ) สามารถ สนองตอบตลาด ได้รวดเร็ว						

บริษัทคู่ค้าสัญชาติไทย..... (รหัสบริษัท.....): บริษัทคู่ค้าต่างชาติ..... (รหัสบริษัท.....)

1. ความคิดเห็นต่อความน่าจะเป็นของ ผลประโยชน์ที่ได้รับร่วมกันในด้าน ต่อไปนี้ อันก่อให้เกิดความสำเร็จใน การสร้างพันธมิตร	ความน่าจะเป็นของประโยชน์ที่ได้รับร่วมกัน					
	สัญชาติ คู่ ค้า	น้อยมาก 0.0-20.0%	น้อย 20.1-40.0%	ปานกลาง 40.1-60.0%	มาก 60.1-80.0%	มากที่สุด 80.1-100.0%
1.1 การบริหารสินทรัพย์และต้นทุน อย่างมีประสิทธิภาพ มีผลดีในประเด็น	ไทย					
	ต่างชาติ					
- ต้นทุนลดลง/ประหยัด						
- การบริหารงานมีประสิทธิภาพ						
- การบริหารจัดการสินทรัพย์ดี						
- อื่นๆ (โปรดระบุ).....						
ไทย: ถ้าคำตอบของท่านอยู่ในช่วง40.1-100.0% และยืนยันว่าปัจจัยนี้ช่วยให้เกิดความได้เปรียบในการแข่งขันอย่างยั่งยืน โปรดทำ เครื่องหมาย ✓ ในช่อง <input type="checkbox"/>						
ต่างชาติ: ถ้าคำตอบของท่านอยู่ในช่วง40.1-100.0% และยืนยันว่าปัจจัยนี้ช่วยให้เกิดความได้เปรียบในการแข่งขันอย่างยั่งยืน โปรด ทำเครื่องหมาย ✓ ในช่อง <input type="checkbox"/>						
1.2 การให้บริการลูกค้า มีประโยชน์ ในประเด็น	ไทย					
	ต่างชาติ					
-ปรับปรุงการจัดส่งสินค้าได้ตรงเวลา						
- ลดระยะเวลาการรอของลูกค้า						
- มีประสิทธิภาพในกระบวนการ บริการอย่างเหมาะสม						
- อื่นๆ (โปรดระบุ).....						
ไทย: ถ้าคำตอบของท่านอยู่ในช่วง40.1-100.0% และยืนยันว่าปัจจัยนี้ช่วยให้เกิดความได้เปรียบในการแข่งขันอย่างยั่งยืน โปรดทำ เครื่องหมาย ✓ ในช่อง <input type="checkbox"/>						
ต่างชาติ: ถ้าคำตอบของท่านอยู่ในช่วง40.1-100.0% และยืนยันว่าปัจจัยนี้ช่วยให้เกิดความได้เปรียบในการแข่งขันอย่างยั่งยืน โปรด ทำเครื่องหมาย ✓ ในช่อง <input type="checkbox"/>						

1.3 ความได้เปรียบทางการตลาด ได้ประโยชน์ในประเด็น	ไทย					
	ต่างชาติ					
- ศักยภาพด้านนวัตกรรมที่เข้มแข็ง						
- การเข้าถึงเทคโนโลยีใหม่ๆรวดเร็วและได้ผลดี						
- การเข้าสู่ตลาดใหม่ถูกจังหวะและทันเวลา						
- อื่นๆ (โปรดระบุ).....						
ไทย: ถ้าคำตอบของท่านอยู่ในช่วง40.1-100.0% และยืนยันว่าปัจจัยนี้ช่วยให้เกิดความได้เปรียบในการแข่งขันอย่างยั่งยืน โปรดทำเครื่องหมาย ✓ ในช่อง <input type="checkbox"/>						
ต่างชาติ: ถ้าคำตอบของท่านอยู่ในช่วง40.1-100.0% และยืนยันว่าปัจจัยนี้ช่วยให้เกิดความได้เปรียบในการแข่งขันอย่างยั่งยืน โปรดทำเครื่องหมาย ✓ ในช่อง <input type="checkbox"/>						
1.4 ผลกำไรมีเสถียรภาพและ/หรือเติบโตแบบยั่งยืน	ไทย					
	ต่างชาติ					
- ยอดขายเพิ่มขึ้น						
- สัดส่วนทางการตลาดเพิ่ม						
- การเติบโตแบบยั่งยืน						
- อื่นๆ (โปรดระบุ).....						
ไทย: ถ้าคำตอบของท่านอยู่ในช่วง40.1-100.0% และยืนยันว่าปัจจัยนี้ช่วยให้เกิดความได้เปรียบในการแข่งขันอย่างยั่งยืน โปรดทำเครื่องหมาย ✓ ในช่อง <input type="checkbox"/>						
ต่างชาติ: ถ้าคำตอบของท่านอยู่ในช่วง40.1-100.0% และยืนยันว่าปัจจัยนี้ช่วยให้เกิดความได้เปรียบในการแข่งขันอย่างยั่งยืน โปรดทำเครื่องหมาย ✓ ในช่อง <input type="checkbox"/>						

2. ความคิดเห็นต่อความน่าจะเป็นของการสนับสนุนต่อกันของปัจจัยในด้านต่อไปนี้ อันก่อให้เกิดความสำเร็จในการสร้างพันธมิตร	ความน่าจะเป็นของการสนับสนุนต่อกัน					
	สัญชาติ คู่ค้า	น้อยมาก 0.0-20.0%	น้อย 20.1-40.0%	ปานกลาง 40.1-60.0%	มาก 60.1-80.0%	มากที่สุด 80.1-100.0%
2.1 ความเข้ากันได้ระหว่างบริษัทคู่ค้าในด้าน	ไทย					
	ต่างชาติ					
- พนักงานเป็นสินทรัพย์ระยะยาวตรงกัน						
- การยึดมั่นในการเป็นพันธมิตรหุ้นส่วนสอดคล้องกัน						
- แผนกลยุทธ์สนองจุดหมายร่วมกัน						
- อื่นๆ (โปรดระบุ).....						
2.2 ความสอดคล้องของปรัชญาการบริหารจัดการ ในประเด็น	ไทย					
	ต่างชาติ					
- โครงสร้างบริษัทคล้ายกัน						
- ให้ความสำคัญด้านการทำงานเป็นทีมเหมือนกัน						
- ผู้บริหารระดับสูงให้การสนับสนุนเท่าเทียมกัน						
- อื่นๆ (โปรดระบุ).....						
2.3 ความร่วมมือเพื่อประโยชน์ร่วมกันในประเด็น	ไทย					
	ต่างชาติ					

- ความร่วมมือกันในระยะยาว						
- มีเป้าหมายและแลกเปลี่ยนความคาดหวังร่วมกัน						
- การแลกเปลี่ยนข้อมูลการดำเนินงานอย่างโปร่งใส						
- อื่นๆ (โปรดระบุ).....						
2.4. ความสมดุลใกล้เคียงกัน ในด้าน	ไทย					
	ต่างชาติ					
- ขนาดสัมพันธภาพขององค์กรด้านยอดขาย						
- ภาพลักษณ์และชื่อเสียงของแบรนด์						
- ความเข้มแข็งทางการเงิน						
- อื่นๆ (โปรดระบุ).....						

บริษัทท่านและบริษัทคู่ค้ามีปัจจัยที่ส่งเสริมความเป็นพันธมิตร ในด้านต่อไปนี้ด้วยใช่หรือไม่

ปัจจัยเสริม		ใช่	ไม่ใช่
3.1 ที่ตั้งของบริษัททั้งคู่อยู่ในถิ่นฐานเดียวกัน	ไทย		
	ต่างชาติ		
3.2 บริษัททั้งคู่มีคู่แข่งทางธุรกิจร่วมกัน	ไทย		
	ต่างชาติ		
3.3 บริษัทคู่ค้าเต็มใจในการทำงานร่วมกันและให้สิทธิพิเศษแก่กัน	ไทย		
	ต่างชาติ		
3.4 บริษัททั้งคู่มีประวัติการเป็นพันธมิตรที่เคยทำงานร่วมกันมาก่อน	ไทย		
	ต่างชาติ		
3.5 บริษัททั้งคู่มีลูกค้า (ผู้รับบริการปลายทาง) เดียวกัน	ไทย		
	ต่างชาติ		

จุฬาลงกรณ์มหาวิทยาลัย

4. ความคิดเห็นต่อความน่าจะเป็นด้านความสอดคล้องของปัจจัยธุรกิจ ดังต่อไปนี้	ความน่าจะเป็นของความสอดคล้องกัน					
	สัญชาติคู่ค้า	น้อยมาก 0.0-20.0%	น้อย 20.1-40.0%	ปานกลาง 40.1-60.0%	มาก 60.1-80.0%	มากที่สุด 80.1-100.0%
4.1 ความไว้วางใจและซื่อสัตย์ ในด้าน	ไทย					
	ต่างชาติ					
- การกำหนดกลยุทธ์การทำงานร่วมกันอย่างไว้วางใจ						
- การทำงานร่วมกันอย่างโปร่งใส						
- การแลกเปลี่ยนข้อมูลกันโดยไม่ปิดบัง						
- อื่นๆ (โปรดระบุ).....						
4.2 การถ่ายโอนนวัตกรรม ในด้าน	ไทย					
	ต่างชาติ					
- ความรู้ทางวิชาการ						
- ความเตรียมความพร้อมด้านการพัฒนาผลิตภัณฑ์						
- ความรู้ใหม่ๆ ด้านงานวิจัยเพื่อการพัฒนาผลิตภัณฑ์						
- อื่นๆ (โปรดระบุ).....						

4.3 ความสัมพันธ์แบบชนะทั้งสองฝ่าย (win-win) ในด้าน	ไทย					
	ต่างชาติ					
- มีความเข้าใจความต้องการของแต่ละฝ่าย						
- พยายามสนองความต้องการของแต่ละฝ่าย						
- บูรณาการในระดับกลยุทธ์และปฏิบัติการอย่างมีนัยสำคัญ						
- อื่นๆ (โปรดระบุ).....						
4.4 ความพร้อมด้านการเงินในการลงทุน ในด้าน	ไทย					
	ต่างชาติ					
- การเตรียมจัดหางบประมาณตามแผนงบประมาณของตน						
- การบริหารกระแสเงินสดโดยไม่ติดขัด						
- ความพร้อมในการลงทุนร่วมกัน						
- อื่นๆ (โปรดระบุ).....						
4.5 ความไม่แน่นอนทางการตลาด ในประเด็น	ไทย					
	ต่างชาติ					
- ความไม่แน่นอนของอุปสงค์						
- ความกดดันจากการเปลี่ยนแปลงของราคาสินค้า						
- มีคู่แข่งขึ้นใหม่เพิ่มขึ้น						
- อื่นๆ (โปรดระบุ).....						
4.6 การเปลี่ยนแปลงเชิงพลวัต ในประเด็น	ไทย					
	ต่างชาติ					
- ประชากรสูงอายุเพิ่มขึ้น						
- อำนาจการตัดสินใจเปลี่ยนจากแพทย์ไปสู่ผู้บริโภค/คนไข้						
- การควบรวมกิจการ (M&A) เพิ่มขึ้น						
- อื่นๆ (โปรดระบุ).....						
4.7 สิทธิบัตรยา, ภาษีและกฎหมาย ในประเด็น	ไทย					
	ต่างชาติ					
- การหมดอายุของสิทธิบัตรยาเพิ่มมากขึ้น						
- สิทธิประโยชน์ทางภาษีจากการสนับสนุนของภาครัฐ						
- กฎหมายยาเข้มงวดมากขึ้น โดยเพิ่มข้อกำหนดมากขึ้น						
- อื่นๆ (โปรดระบุ).....						
4.8 การควบคุม/บริหารปัจจัยเสี่ยง โดย	ไทย					
	ต่างชาติ					
- การมีแผนจัดการและรองรับความเสี่ยงที่อาจเกิดขึ้น (BCP)						
- การให้ข้อมูลของปัจจุบัน เมื่อมีภาวะความเสี่ยงเกิดขึ้น						
- ความพร้อมบริหารแผนจัดการความเสี่ยงเมื่อเกิดวิกฤต						
- อื่นๆ (โปรดระบุ).....						

ระดับความเป็นพันธมิตร (Partnership type) เมื่อพิจารณาจากผลประโยชน์ร่วมกันและปัจจัยสนับสนุนต่อกันของ บริษัทจ้างผลิต และบริษัทรับจ้างผลิต จะสามารถแบ่งเป็นประเภทได้ ดังนี้



ภาพแสดงระดับความเป็นพันธมิตร ที่มา Lambert (1996)

ความสัมพันธ์แบบพื้นฐาน (Arm's Length) หมายถึง ความสัมพันธ์ของบริษัทคู่ค้าทั่วไป มีสัญญาเป็นรายครั้ง ไม่มีสัญญาระยะยาว

ความสัมพันธ์ระดับที่หนึ่ง (Type I) หมายถึง การที่บริษัทคู่ค้าฝ่ายใดฝ่ายหนึ่งเพียงฝ่ายเดียว ตระหนักถึงความสำคัญในการสร้างร่วมมือระหว่างกัน

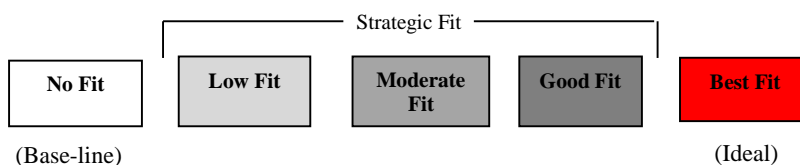
ความสัมพันธ์ระดับที่สอง (Type II) หมายถึง การที่บริษัทคู่ค้าทั้งสองฝ่ายมีความร่วมมือในกิจกรรมต่างๆ ร่วมกัน เป็นความสัมพันธ์ในระยะยาว มีการบูรณ การความร่วมมือกัน

ความสัมพันธ์ระดับที่สาม (Type III) หมายถึง การที่บริษัทคู่ค้าทั้งสองฝ่ายมีการบูรณาการความร่วมมือในระดับยุทธศาสตร์และในระดับปฏิบัติการอย่างมีนัยสำคัญ โดยทั้งสองฝ่ายมองแต่ละฝ่ายเป็นเสมือนหนึ่งเป็นบริษัทของตนเอง

ความสัมพันธ์แบบกิจการร่วมค้า (Joint Ventures) หมายถึง การร่วมธุรกิจของบริษัทคู่ค้า ทำสัญญาที่จะร่วมทุนภายใต้ข้อตกลงหรือสัญญาร่วมค้า โดยมีการกำหนดวัตถุประสงค์และเป้าหมายในการดำเนินงานไว้อย่างชัดเจน มีการกำหนดสัดส่วนผู้ถือหุ้น สิทธิความเป็นเจ้าของ หน้าที่ความรับผิดชอบต่างๆ รวมถึงการแบ่งผลประโยชน์และความเสียหายที่อาจจะได้รับจากการดำเนินงาน

5. โดยภาพรวม ท่านเห็นว่า บริษัทของท่านและบริษัทคู่ค้ามีระดับความเป็นพันธมิตร (Partnership type) เป็นแบบใด	สัญชาติ คู่ค้า	พื้นฐาน (Arm's Length)	ระดับที่1 (Type I)	ระดับที่2 (Type II)	ระดับที่3 (Type III)	กิจการร่วมค้า (Joint Ventures)
	ไทย					
	ต่างชาติ					

ระดับความเหมาะสมเชิงกลยุทธ์ (Strategic Fit type) เมื่อพิจารณาจากของปัจจัยธุรกิจ(ปัจจัยภายในและปัจจัยภายนอก) ที่สอดคล้องกันระหว่างบริษัทจ้างผลิตและบริษัทรับจ้างผลิต จะสามารถแบ่งเป็นประเภทได้ ดังนี้



ความสัมพันธ์แบบพื้นฐาน (No Fit) หมายถึง ความสัมพันธ์ของบริษัทคู่ค้าทั่วไป โดยไม่มีหรือมีน้อยใน ความสอดคล้องกันของปัจจัยภายในและปัจจัยภายนอก ทำให้ไม่เกิดความเหมาะสมเชิงกลยุทธ์ระหว่างกัน

ความสัมพันธ์ระดับที่หนึ่ง (Low Fit) หมายถึง การที่บริษัทคู่ค้า มีความสอดคล้องกันของปัจจัยภายใน หรือปัจจัยภายนอกเพียงปัจจัยเดียว ทำให้มีความเหมาะสมเชิงกลยุทธ์ระหว่างกันในระดับต่ำ

ความสัมพันธ์ระดับที่สอง (Moderate Fit) หมายถึง การที่บริษัทคู่ค้าทั้งสองฝ่ายมีความสอดคล้องกัน ของปัจจัยภายในและปัจจัยภายนอกในระดับปานกลาง หรือมีความสอดคล้องกันของปัจจัยใดปัจจัยหนึ่งมาก ทำให้เกิดความเหมาะสมเชิงกลยุทธ์ระหว่างกันในระดับปานกลาง

ความสัมพันธ์ระดับที่สาม (Good Fit) หมายถึง การที่บริษัทคู่ค้าทั้งสองฝ่าย มีความสอดคล้องกันในระดับปานกลางถึงมากของปัจจัยภายในและปัจจัยภายนอกทางธุรกิจ ทำให้เกิดความเหมาะสมเชิงกลยุทธ์ระหว่างกันในระดับสูง

ความสัมพันธ์แบบอุดมคติ (Best Fit) หมายถึง การที่บริษัทคู่ค้าทั้งสองฝ่าย มีความสอดคล้องกันมาก ของทั้งปัจจัยภายในและปัจจัยภายนอกทางธุรกิจ ทำให้เกิดความเหมาะสมเชิงกลยุทธ์ระหว่างกันในขั้นสูงสุด และเป็นผลให้เกิดประโยชน์สูงสุดต่อกันและมีการเติบโตอย่างยั่งยืนในธุรกิจร่วมกัน

6. โดยภาพรวม ท่านเห็นว่าบริษัทของท่านและบริษัทคู่ค้ามีระดับความเหมาะสมเชิงกลยุทธ์ (Strategic Fit type) เป็นแบบใด	สัญชาติ	พื้นฐาน	ระดับที่1	ระดับที่2	ระดับที่3	อุดมคติ
	คู่ค้า	(No Fit)	(Low Fit)	(Moderate Fit)	(Good Fit)	(Best Fit)
	ไทย					
ต่างชาติ						

7.ข้อเสนอแนะอื่นๆ

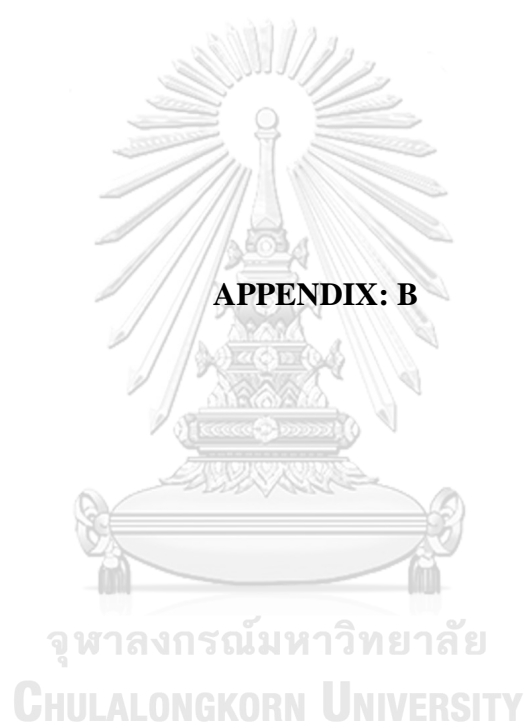
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จบแบบสอบถาม

ขอขอบคุณในความกรุณาและความร่วมมือจากท่านมา ณ ที่นี้เป็นอย่างสูง



การประเมินผลเพื่อตรวจสอบนโยบายและการกำหนดเป้าหมายเชิงกลยุทธ์ของภาครัฐต่อการ พัฒนาการจัดจ้างบริษัทภายนอกในอุตสาหกรรมการผลิตของไทย

แบบสำรวจนี้เป็นส่วนหนึ่งของงานวิจัยเรื่อง “กลยุทธ์ที่เหมาะสมสำหรับการจัดจ้างบริษัทภายนอกในการผลิต การศึกษาสถานการณ์ในประเทศไทย” เพื่อตรวจสอบนโยบายและการกำหนดเป้าหมายเชิงกลยุทธ์ของภาครัฐ ต่อการลดอุปสรรคปัญหาของการจัดจ้างบริษัทภายนอกในอุตสาหกรรมการผลิตของไทย เพื่อส่งเสริมและพัฒนาให้ธุรกิจและเวชภัณฑ์ของไทยสามารถแข่งขันได้ในตลาดระดับประเทศและภูมิภาค โดยมีหน่วยงานและองค์กรที่เกี่ยวข้อง ดังนี้ คือ

ภาครัฐ

- สำนักงานคณะกรรมการอาหารและยา (อย.)- กระทรวงสาธารณสุข
- กรมส่งเสริมการส่งออก (ดีอีพี) - กระทรวงพาณิชย์
- คณะกรรมการส่งเสริมการลงทุน (สกท)- สำนักนายกรัฐมนตรี

ภาคเอกชน

- บริษัทในกลุ่มสมาคมพรีม่า (สมาคมผู้วิจัยและผลิตเภสัชภัณฑ์) เป็นกลุ่มบริษัทจากต่างประเทศที่มาเปิดสำนักงานขายในประเทศไทย
- บริษัทในกลุ่มสมาคมไทยอุตสาหกรรมผลิตยาแผนปัจจุบัน
- บริษัทฯที่ไม่ได้สังกัดสมาคมใดๆ ส่วนใหญ่เป็นผู้ผลิตรายเล็กๆ

ทั้งนี้ ผลการประเมินของท่านต่อนโยบายและการกำหนดเป้าหมายเชิงกลยุทธ์ของภาครัฐนี้ จะเป็นประโยชน์ต่องานวิจัย ในการนำเสนอเพื่อพัฒนาการจัดจ้าง บริษัทภายนอกในอุตสาหกรรมการผลิตของไทยต่อไป

จุฬาลงกรณ์มหาวิทยาลัย
CHULALONGKORN UNIVERSITY

ผู้วิจัยขอขอบคุณสำหรับความร่วมมือของท่านมา ณ โอกาสนี้

การประเมินผลเพื่อตรวจสอบนโยบายและการกำหนดเป้าหมายเชิงกลยุทธ์ของภาครัฐต่อการ
พัฒนาการจัดจ้างบริษัทภายนอกในอุตสาหกรรมการผลิตยาของไทย

ท่านเห็นด้วยหรือ ไม่กับ (1) อุปสรรค-ปัญหา (2)นโยบายและการกำหนดเป้าหมายเชิงกลยุทธ์รัฐดังต่อไปนี้

(1) อุปสรรค-ปัญหาของอุตสาหกรรมการจัดจ้างผลิตยาของไทย	เห็นด้วย	ไม่เห็นด้วย
1.1 ความล่าช้าในการขอขึ้นทะเบียนยา/สูตรการผลิตของผู้ผลิตไทยกับอย.		
1.2 องค์กรเภสัชกรรมในฐานะผู้ผลิตหลักของภาครัฐผลิตยาแข่งกับบริษัทเอกชน โดยได้สิทธิพิเศษที่ไม่ต้องขอขึ้นทะเบียนยาด้วย		
1.3 โรงงานผลิตยาของไทยที่ได้ตามมาตรฐานของยุโรป (EU GMP-PIC/S) มีน้อย (เพียง 10-20% เท่านั้น)		
1.4 การต้องขอขึ้นทะเบียนยาอีกในแต่ละประเทศที่จะส่งออก		
1.5 บริษัทยาของไทยไม่สามารถแข่งขันกับยานำเข้าจากจีนและอินเดีย เพราะมีต้นทุนที่สูงกว่า เนื่องจากไทยไม่สามารถผลิตวัตถุดิบตัวยา(API)ได้เอง		
1.6 ภาครัฐยังไม่บังคับใช้กฎหมายสิทธิบัตรตามมาตรฐานสากล ทำให้บริษัทข้ามชาติบางบริษัทตัดสินใจชะลอหรือลดการลงทุนผลิตยาในไทย		
1.7 อื่นๆ (เพิ่มเติม).....		
1.8 อื่นๆ (เพิ่มเติม).....		
1.9 อื่นๆ (เพิ่มเติม).....		
(2).นโยบายและการกำหนดเป้าหมายเชิงกลยุทธ์ของภาครัฐที่นำมาปรับใช้	เห็นด้วย	ไม่เห็นด้วย
2.1 รัฐควรเร่งปรับปรุงโดยพิจารณาเวลาหรือขั้นตอนในการขอขึ้นทะเบียนตำรับยาประเภทต่างๆกับอย.ให้รวดเร็วขึ้น เพื่อให้ผู้ผลิตยาไทยสามารถแข่งขันกับประเทศอื่นๆ ได้ ดังนี้ ก) ยาใหม่ลดจากค่าเฉลี่ยจริง 380-480 วันทำการให้เหลือเพียง 280 วันทำการ ¹		
ข) ยาที่ผลิตเพื่อการส่งออก จากเดิม 45 วันทำการ ให้เหลือเพียง 20 วันทำการ ²		
ค) ลดเวลาที่นักวิชาการใช้ในการพิจารณาตรวจสอบจาก 120-180 วันทำการ ให้เหลือเพียง 20วันทำการ ³		
ง) ลดเวลาทะเบียนตำรับยาที่ต้องส่งผู้เชี่ยวชาญพิจารณาจาก 540 วันทำการให้เหลือเพียง 120 วันทำการ ³		
2.2 กระทรวงสาธารณสุขได้จัดทำแผนปฏิบัติการระยะ 5 ปี ตามนโยบายแห่งชาติด้านยาและยุทธศาสตร์การพัฒนาระบบยาแห่งชาติ พ.ศ. 2560-2564 โดยมีโครงการที่เกี่ยวข้องกับการพัฒนาอุตสาหกรรมการผลิตยาในประเทศ ในด้านการเพิ่มประสิทธิภาพการผลิตให้สามารถแข่งขันได้		

2.3 รัฐควรมีนโยบายให้ห้องค์การสาธารณสุขซึ่งเป็นหน่วยงานของรัฐ เป็นผู้นำในการช่วยยกระดับโรงงานในประเทศ แทนที่จะเป็นคู่แข่งของภาคเอกชนในการผลิตยา		
2.4 ปัจจุบันน้อย.ไทยได้รับการอนุมัติให้เข้าเป็นสมาชิกการตรวจประเมินยาแห่งสหภาพยุโรป (PIC/S Member) แล้วตั้งแต่ 1 สิงหาคม 2559 ทำให้บริษัทยาของไทยมีความสะดวกรวดเร็วในการขอขึ้นทะเบียนตำรับยาเพื่อส่งออก		
2.5 รัฐควรส่งเสริมให้บริษัทยาของไทยผ่านการเกณฑ์มาตรฐาน GMP-PIC/S เพิ่มมากขึ้น เพื่อเพิ่มโอกาสในการส่งออกยาไปยังกลุ่มประเทศที่เป็นสมาชิก PIC/S ได้มากขึ้น		
2.6 ประเทศไทยได้รับการรับรองเป็นหน่วยประเมินการตรวจสอบคุณภาพของอาเซียน ทำให้ยาที่ผลิตในไทยสามารถส่งออกไปขายในประเทศอาเซียน สะดวกและเพิ่มมากขึ้น โดยไม่ต้องผ่านการตรวจสอบคุณภาพซ้ำที่ปลายทางอื่น		
2.7 รัฐควรสนับสนุนให้ ภาคเอกชนมุ่งเป้าไปยังการผลิตยาชื่อสามัญชนิดใหม่ๆที่หมดสิทธิบัตรแล้ว โดยวางกลยุทธ์ให้ไทยเป็นศูนย์กลางการผลิตยาชื่อสามัญของอาเซียน		
2.8 สำนักงานคณะกรรมการส่งเสริมการลงทุนพิจารณาปรับระดับการส่งเสริมการลงทุนในอุตสาหกรรมการผลิตยา จาก B1 (ยกเว้นอาคาร เครื่องจักร วัสดุคืบ และสิทธิประโยชน์อื่นที่มีจำกัด) เป็น A3 (ยกเว้นภาษีเงินได้นิติบุคคล 5 ปี) สำหรับผู้ประกอบการที่ยื่นขอรับส่งเสริมการลงทุน ตั้งแต่ปี 2561 เป็นต้นไป และ A2 (ยกเว้นภาษีเงินได้นิติบุคคล 8 ปี) สำหรับผู้ประกอบการที่ยื่นขอรับส่งเสริมการลงทุนภายในปี 2560		
2.9 รัฐควรตั้งหน่วยงานเฉพาะเพื่อส่งเสริมการส่งออกของผู้ผลิตยาไทย โดยการประสานกับกรมส่งเสริมการส่งออก โดยให้การสนับสนุนด้านภาษี เช่น ยกเว้นภาษีเงินได้นิติบุคคล		
2.10 รัฐเร่งสร้างจุดแข็งและสนับสนุนการวิจัยและพัฒนาอุตสาหกรรมยา โดยมีการจัดตั้งคณะกรรมการวิจัยและพัฒนาด้านเภสัชกรรมขึ้น (Pharmaceutical Research and Development Committee)		
2.11 รัฐควรจัดให้มีทำเนียบแหล่งวัตถุดิบตัวยาที่มีคุณภาพและราคาถูก เพื่อให้ผู้ประกอบการไทยสามารถจัดซื้อได้ง่ายและเป็นการลดต้นทุน เพื่อสามารถแข่งขันกับยานำเข้าราคาถูก และในตลาดส่งออกด้วย		
2.12 รัฐควรร่วมทุนกับบริษัทยาเอกชนในการจัดตั้ง โรงงานผลิตวัตถุดิบตัวยา และ/หรือ โรงงานผลิตยาชีวภาพของไทย โดยมุ่งเป้าไปสู่ระดับภูมิภาคอาเซียนให้ไทยมีความสามารถในการแข่งขันสูง		

2.13 อื่นๆ (เพิ่มเติม).....		
2.14 อื่นๆ (เพิ่มเติม).....		
2.15 อื่นๆ (เพิ่มเติม).....		

1.สรุปข้อมูลจาก PRoMA

2.ตามประกาศสำนักงานอย.เมื่อวันที่27 กค.2558

3.การปฏิรูปแบบการลดและผ่อนคลายกฎระเบียบ ศึกษากรณีการขึ้นทะเบียนตำรับยาใหม่

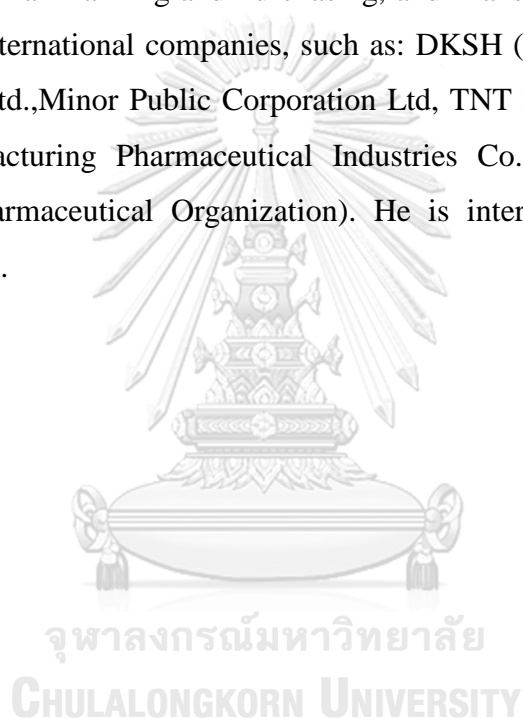
ขอขอบคุณ



จุฬาลงกรณ์มหาวิทยาลัย
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VITA

Mr. Sompong Apithamsoonthorn was born in September, 1961 in Bangkok, Thailand. He received Bachelor of Science in Pharmacy from Mahidol University in 1985. He then earned a Master Degree, Business Administration from the Thammasart University, in 1997. His professional experiences in pharmacy and many industries, includes in Logistics management, disciplined in Production, Operations, Material Planning and Purchasing, and Transportation management in both Thai and international companies, such as: DKSH (Thailand) Ltd, Wilsonart (Thailand) Co.,Ltd.,Minor Public Corporation Ltd, TNT Logistics (Thailand) Ltd, Interthai Manufacturing Pharmaceutical Industries Co., Ltd., and GPO (Thai Government Pharmaceutical Organization). He is interested in operations and logistics research.





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