Framework for Managing an Efficient and Effective Pharmaceutical Supply Chain in Malaysia

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Declaration

I hereby declare that:

1. I have not been enrolled for another award of the University, or other academic or professional organisation, whilst undertaking my research degree.

2. None of the material contained in the thesis has been used in any other submission for an academic award.

3. I am aware of and understand the University's policy on plagiarism and certify that this thesis is my own work. The use of all published or other sources of material consulted have been properly and fully acknowledged.

4. The work undertaken towards the thesis has been conducted in accordance with the SHU Principles of Integrity in Research and the SHU Research Ethics Policy.

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Abstract

The pressure in pharmaceutical sectors in Malaysia is increasing as the country new policy, in regards to medical care, is to standardise the existing Good Manufacturing Practise (GMP) and Good Distribution Practise (GDP) guidelines, disseminate the medical information and evaluate the pharmaceutical products, implement knowledge transfer when it comes to public service. In line with this effort, Ministry of Health (MOH) Malaysia is investing into efficient implementation of GMP and GDP to assure the impact of drug quality are contemplated. However, it is unclear if all the partners/stakeholders within this process are aware about the appropriate indications and possible limitations.

In addition, many organisations uses a wide variety of metrics to measure their performance, typically in two broad categories efficiency and effectiveness to improve its customer service which is crucial in the pharmaceutical industry. Efficiency metrics such as inventory costs, operations cost, and utilisation of resources are broader in scope but not linked to the strategic objectives of the organisations. Effectiveness metrics such as customer satisfaction and total supply chain costs represent significant leap in integration, visibility and alignment with overall supply chain performance.

Therefore, main aim of this research are to design and develop an integrated framework involving efficiency, effectiveness, optimisation, and GDP dimensions to support the design of pharmaceutical cold supply chain in Malaysia.

In addition, the philosophical approach used in this study and process of developing a supply chain management framework will be justified. Then the potential supply chain frameworks and models available and are widely implemented in the industry will be evaluated.

This framework has been developed by integrating six models that are widely implemented by companies in various industry namely, Strategic Fit model to explain the strategic role and objective of the framework, Good Distribution Practise (GDP) model to clarify the supply chain specifications and requirements, Total Quality Management (TQM) and Quality Risk Management to establish all processes that are designed encompass quality assurance and continuous improvements, Supply Chain Network Optimisation model to ensure the optimal distribution pattern has been achieved, and lastly performance indicator model to measure efficiency and effectiveness.

The framework has been validated and refined through the feedback received from industry.

To conclude, effective GDP implementation in its operations may improve their efficiency, effectiveness and optimisation, and may experience reduction in costs and increase in customer and employee satisfaction.

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Abbreviations

3PL	Third Party Logistics
AHP	Analytic Hierarchy Process
ATO	Assemble to Order
B2C	Business to Customer
BOM	Bill of Materials
BPR	Business Process Reengineering
CLPD	Capacitated-Location/Production/Distribution
CoA	Certificate of Analysis
COA	Certificate of Authenticity
CPFR	Collaborative Planning, Forecasting and Replenishment
CRS	Constant Returns to Scale
CS	Competitive Strategy
DC	Distribution Centres
DCA	Drug Control Authority
DIFOT	Delivery in Full, On Time
EFQM	European Foundation for Quality Management
EMA	European Medicines Agency
ERP	Enterprise Resource Planning
ETA	Estimated Time of Arrival
FDA	Food and Drug Administration
FEI	Fast-Evolving Industries
GDP	Good Distribution Practise
GDPMD	Good Distribution Practice in Medical Devise
GMP	Good Manufacturing Practise

IFLP	International Facilities Location Problem
JIT	Just In Time
KPI	Key Performance Indicator
LTL	Less Than Truckload
MA	Marketing Authorisation
MHRA	Medicinal Health and Regulatory Agency
MIP	Mixed-Integer Programming
MOH	Ministry of Health
MTO	Make-To-Order
MTS	Make-To-Stock
NPCB	National Pharmaceutical Control Bureau
OTD	On Time Delivery
OTIF	On Time In Full
QC	Quality Control
QDA	Qualitative Data Analysis
QMS	Quality Management System
QRM	Quality Risk Management
RDL	Right Day Late
RFID	Radio Frequency Identification
RMP	Risk Management Programs
ROA	Return on Assets
SCC	Supply Chain Council
SCD	Supply Chain Design
SCI	Supply Chain Integration
SCM	Supply Chain Management

SCOR	Supply Chain Operations Reference
SCS	Supply Chain Strategy
SKU	Stock Keeping Unit
SOP	Standard Operating Procedures
TCO	Total Cost of Ownership
TQM	Total Quality Management
VRS	Variable Returns to Scale
WDL	Wrong Day Late
WHO	World Health Organisation

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Chapter 1: Introduction

1.1: Background

Over the last decade, many organisations have set great emphases on their logistics and supply chain performances and it has been recognised as the backbone of every economy (Lu, 2011). With the accelerated growth of global sourcing and manufacturing over the last few decades, effective and efficient management of supply chains and the associated logistics have become a key priority (Sollish and Semanik, 2010). Businesses are continually making an effort to re-align their business models to ensure their customer needs are better served than their competitors.

In the effort to improve services for customers, organisations use a wide variety of metrics to measure their performances, typically in three broad categories i.e. efficiency, effectiveness, optimisation. Efficiency metrics such as inventory cost, operations cost, and utilisation of resources are broader in scope but are not linked to the strategic objectives of the organisations. Effectiveness metrics such as customer satisfaction and total supply chain cost represent a significant leap in integration, visibility and alignment with the overall supply chain performance. Optimisation metrics such as manufacturing cost, total cost of ownership (TCO), transportation cost, Collaborative Planning, Forecasting and Replenishment (CPFR), distribution cost to ensure optimal placement of product throughout the supply chain (Davis, 2016).

1.2: Pharmaceutical Industry in Malaysia

1.2.1: Overview of the Malaysian Health-care System and Pharmaceutical Expenditure

Malaysia lies on the Malay Peninsula (West Malaysia) in tropical Southeast Asia, bordering Thailand to the north, the Strait of Malacca to the west, the South China Sea to the east and the island of Singapore to the south. The country also occupies the northern one-third of the island of Borneo (East Malaysia), bordering Indonesia to the south, the South China Sea to the north, and the Sulu Sea and Celebes Sea to the east. Malaysia consists of 13 states and a federal territory covering an area of 330 252 square kilometres. The population of Malaysia in 2019 was estimated to be 32.58 million with an annual growth rate of 2.1 per cent. Sixty-two percent of the population lives in the urban areas. The population is relatively young with 32.2 per cent between the age of 0 and 14 years, 63.4 per cent between 15 and 64 years and only 4.4 per cent more than the age of 65 years (Department of Statistics, 2018).

A dual health-care system, with both public and private health services, coexists in Malaysia. The government through its Ministry of Health (MOH) is the major health-care provider in the country, providing primary care, secondary care and tertiary care through various types of health facilities such as general hospitals, district hospitals and health clinics (Yu et al, 2008). Private health providers complement the medical services provided by the government. However, the private health providers mainly focus on curative services through general practitioner clinics, medical centres to private hospitals. Public health services are heavily subsidised by the government and are financed mainly from taxes on earned income. Other sources of financing for health services are private voluntary insurance, social security and user fees (Yu et al, 2008). Private voluntary insurance is gaining popularity now because there is no compulsory insurance or National Health Insurance Scheme in Malaysia yet. It was estimated that the country spent 7.25 per cent of its gross domestic profit on health care (Malaysian Investment Development Authority, 2019). This figure is quite low compared to most developed nations. In ensuring welfare and quality of life, a sum of RM29 billion was allocated for the public healthcare sector for 2019, an increase of 7.8 percent from 2018. This is almost 10 percent of the total national budget. Out of that sum, RM10.8 billion is set aside for development, maintenance and upgrading work of existing public healthcare facilities, the procurement of medical equipment and medicine (International Trade Administration, 2019).

1.2.2: Malaysian Pharmaceutical Market

The Malaysian pharmaceutical market is dominated by prescription drugs that account for approximately 70 per cent of the pharmaceutical market share and the prescription drug dominance is likely to prevail in the future (Azmi and Alavi, 2001). There are three categories of prescription drugs in Malaysia, namely imported proprietary drugs, generics manufactured locally by Malaysian companies as well as imported generics (Ministry of Health, 2016). Proprietary drugs, being innovator products with a strong foothold in the Malaysian market, have the largest market share of approximately 70 per cent. Nevertheless, in recent years, the market share of the generics is steadily increasing to achieve the present 30 per cent (MIDA, 2018). Imported generics are also making inroads into the Malaysian pharmaceutical market in recent years due mainly to the ASEAN harmonisation initiatives as well as the unprecedented growth of the global generic pharmaceutical industry such as in India. The lack of entry barriers into the Malaysian pharmaceutical market itself has, in part, attracted many overseas generic players. Only recently, initiatives are in place to inspect foreign manufacturing facilities, particularly those that have not been audited by competent authorities, whereas local manufacturing facilities are subjected to periodic

audit all this while by our local regulatory authority including authorities from countries in which Malaysian companies are exporting.

1.2.3: Malaysian Pharmaceutical Industry

In Malaysia, pharmaceutical expenditures have increased over the years. For instance, in 2004, the government spent about RM 808 million to procure drugs, which has increased to more than RM 2.38 billion in 2014 (Ministry of Health, 2017). The Malaysian pharmaceutical industry was valued at approximately RM 12 billion in 2017 (Malaysian Investment Development Authority, 2018). It is expected that it will continue to register steady growth in the next few years, and the market value is anticipated to increase to over RM 75 billion by the year 2021 (Malaysian Investment Development Authority, 2018).

According to Malaysian Investment Development Authority (MIDA) (2019), as at 2017, a total of 251 facilities were licensed by the Drug Control Authority (DCA), Ministry of Health Malaysia. They are categorised into 158 (63%) facilities that produce traditional medicine, 83 (33%) facilities that produce pharmaceuticals and 10 (4%) facilities that produce veterinary products. A total of 23,650 pharmaceutical products are DCA-registered, including traditional products (51.6%), prescription medication (27.7%), non-prescription/over-the-counter medication (13%), health supplements (4.7%), and veterinary medicine (3%).

Major local companies in the industry include Pharmaniaga, CCM Pharmaceuticals, Kotra Pharma, Hovid and Xepa-Soul Pattinson. Some notable foreign-owned manufacturers, such as Oncogen Pharma, Y.S.P. Industries, GlaxoSmithKline (GSK), Ranbaxy, and Biocon, also have a presence in the country. Responding to the growing demand for such products in the South East Asia (SEA) region, leading Malaysian pharmaceutical companies are moving into the production of biologics, oncology drugs, and high value-added generic compounds (Malaysian Investment Development Authority, 2019).

The pharmaceutical industry in Malaysia may be divided into manufacturing, importation and distribution (MOPI, 1999). The importation and distribution are mainly dominated by the multinational pharmaceutical companies whereas the manufacturing sector consists of local generic pharmaceutical manufacturers. The products manufactured include prescription drug products, over-the-counter medications, traditional medicines as well as nutraceuticals or health supplements. The local generic manufacturers have the capability to produce almost all dosage forms, including sterile preparations such as eye preparations and injections, as well as soft gelatine capsules, controlled-release medications and granules for reconstitution. Currently, there are over

40 local generic manufacturers in Malaysia. The local industry is producing about 30 per cent of the domestic demand according to the Malaysian Industrial Development Authority (MIDA) (2019).

In Malaysia, the pressure in pharmaceutical sectors is increasing as the country new policy, in regards to medical care, is to standardise the existing Good Manufacturing Practise (GMP) and Good Distribution Practise (GDP) guidelines, disseminate the medical information and evaluate the pharmaceutical products, implement knowledge transfer when it comes to public service (Ahmed et al, 2016). The implementation of GMP and GDP is challenging in terms of how to centralise the patients benefit and overcome the burden between the manufacturers and institutional borders. The policy should review the conflict of interest and reveal the financial ties to pharmaceutical leaders and sponsors and oversight the outcome versus the costs (Ahmed et al, 2016).

To face the challenge, the Ministry of Health (MOH) Malaysia is investing into efficient implementation of GMP and GDP to assure the impact of drug quality are contemplated. Integrated strategies to address these aims are ongoing and the safety standards that are implemented is the third revised version (Good Distribution Practice in Medical Devise (GDPMD) Malaysia, 2015). However, it is unclear if all the partners/stakeholders within this process benefit equally from the available therapeutics roles and if they are aware about the appropriate indications and possible limitations. However, there is no updated studies of how close are the Malaysian practice to the global GMP and GDP standards. According to data published in 2012 by Ministry of Health (MOH), Planning and Development Division, Health Informatics Centre, that in 2011 the total population used the public health facilities was 33,379,603 (Ministry of Health, 2012).

Given the importance of the three key categories of metrics Efficient–Effectiveness–Optimisation along with the GDP policy, they should essentially be considered in parallel during the design of supply chains. Review on related literature indicates that there are no design frameworks where all three categories are considered concurrently. The emergence of powerful supply chain specific simulation systems may provide an opportunity to consider all three categories concurrently.

This research, therefore, aims to design and develop a framework that takes efficiency, effectiveness, optimisation, and GDP dimensions into account to support the design of pharmaceutical supply chain.

1.3: Research Aim and Objectives

1.3.1: Aim:

To design and develop an integrated framework in which efficiency, effectiveness, optimisation, and Good Distribution Practices (GDP) are concurrently considered in the design of pharmaceutical supply chains in Malaysia.

1.3.2: Objectives:

1. To perform a comprehensive literature review to establish the current knowledge and practices in the field pharmaceutical industry, in particular, supply chain design, supply chain planning, supply chain operations, and key performance indicators (KPIs).
2. To develop the proposed framework used for the management of an efficient and effective cold supply chain.
3. To verify and validate the proposed framework.
4. To conclude the overall work.

1.4: Thesis Structure

The objectives mentioned in the previous section will be addressed in six chapters in this thesis. This chapter introduces the aims and objectives of the research. Chapter Two presents a comprehensive literature review on previous researches and the methodologies employed by previous researchers in the design of supply chain, in addition to definitions of key terms related to this research.

Chapter Three discusses the methodology employed in the study. It describes the philosophical approach used in this study and process of developing a supply chain management framework. It will then appraise the potential supply chain frameworks and models available and are widely implemented in the industry.

Chapter Four presents the proposed integrated supply chain design framework, which integrates six different models, each of which performs a defined role within the overall supply chain design. Firstly, GDP policy is adapted in the process configuration stage. The strategic objective model sets out four different supply chain strategies to meet customer requirements in both certain and uncertain business environments, taking supply chain capabilities and target performance levels into account. The total quality management model (TQM) and quality risk management (QRM) model assists managers in implementing the right policies to maximise resource utilisation and achieve the supply chain strategic goals. The optimisation network model clarifies the way in which various entities in the supply chain network can achieve optimisation in

each process. Finally, the performance indicators model measures supply chain performance and defines the extent to which meets its objectives.

Chapter Five analyses the feedback from companies that was undertaken to implement and verify the proposed framework. This process was conducted using interviews. Chapter Six summarises the key findings from this research and discusses the future prospects of this study.

Chapter 2: Literature Review

2.1: Introduction

The literature review will be divided into two main sections, organised around key themes related to the topic. Sources from various authors will be used in order to identify relevant theories that will be useful further on in this research.

Section one will examine the definition of supply chain management and cold chain as previously defined by different authors. This section will also discuss the characteristics of supply chain efficiencies, the impact of supply chain effectiveness, the supply chain optimisation models and the correlation between supply chain design and supply chain performance. Evidence and review from previous studies at the international and national levels will be used to put into context the advantages and limitation of cold supply chain. More importantly, it will analyse the contradicting literature methods to improve the cold supply chain framework.

Section two will explore the process and requirements of goods distribution practices (GDP). This section will define GDP and its usage, study the reasons for GDP implementation in many counties and companies, and the impacts that follow. This section aims to gain an in-depth understanding on methods to improve the precision of GDP process.

2.2: Supply Chain Management:

Evolved over more than two decades, supply chains play a critical competitive role in today's increasingly turbulent marketplace (Melnyk et al., 2009). By harnessing the capabilities such as capacities and skill offered by supply chains and by building and fostering relationships with both customers and suppliers, businesses can reduce inventories, lower costs, enhance responsiveness, and improve strategic focus in terms of design, execution and capital investments (Lambert et al., 2005). The term "supply chain management" (SCM) was first coined in 1982 by Keith Oliver, a consultant at Booz Allen Hamilton, in an interview with the Financial Times (Kransdorff, 1982). Since then, it has developed as a discipline, occurred primarily in the industrial sector. Melnyk (2014) argues that:

"Supply chain management is a concept that has been born of practice, grown through need, and changed in response to various challenges, threats and opportunities. Consequently, until recently, it has largely not been theoretically grounded. Rather, attention has been devoted to understanding what supply chain management is (and is

not), how it is related to similar approaches such as logistics, operations management and purchasing/sourcing management and how it affects performance".

Figure 2.1 shows the core discipline of supply chain management. SCM includes all functional areas of business and several areas from outside of business. Supply chain may be described as a business entity in which two or more organisations are linked by a flow of goods, funds, and information and may be global in scope. This could include everything from the raw materials used in manufacturing to the delivery of the product to the final consumer, and all activities in between. SCM does not only include organisations, but also the suppliers, buyers, vendors, customers, and others with whom it interacts. As a result, this definition emphasises cross-functional links and seeks to manage those links to enhance a company's competitive advantage.

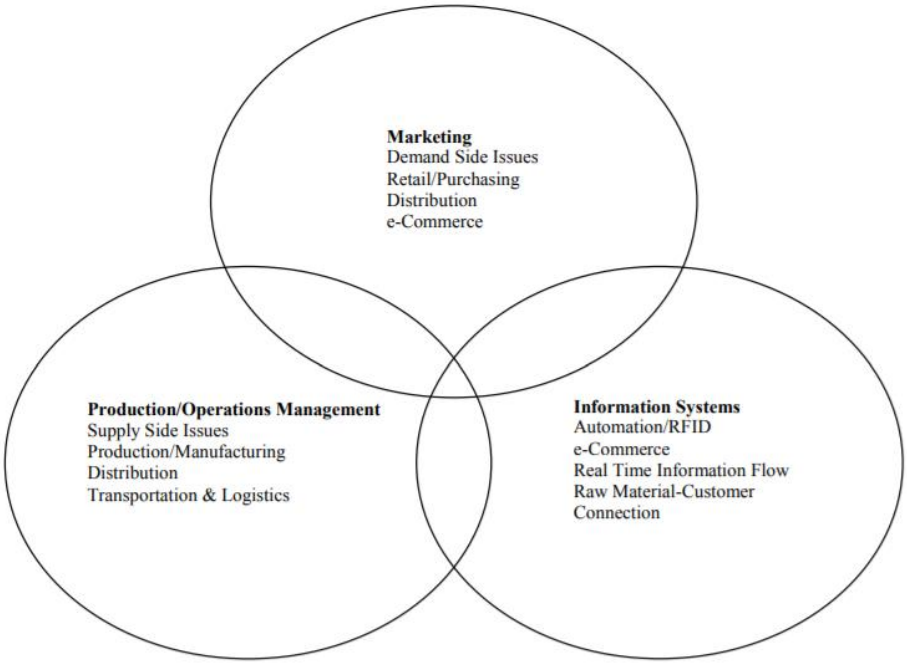

Figure 2.1: Core Discipline of Supply Chain Management

Source: Jones, Cope, & Budden, 2009

Lu (2011) argues that as the business environment changes, competition become less a matter of organisation versus organisation than supply chain versus supply chain. As a result, a business's survival no longer solely depends on its ability to compete but rather, on its ability to cooperate with others in the supply chain.

Wu, Melnyk and Flynn (2010) note that supply chains have changed from being

strategically decoupled and price-driven to strategically coupled and value- driven. They argue that: *"This transition is not simply a 'happy accident'. Rather, it is the result of deliberate management action and strategic corporate investments aimed to procure, develop and configure the appropriate supply chain resources that will allow the firm to compete successfully in the marketplace".* The concept of supply chain design lies at the very heart of these investment decisions.

Figure 2.2 shows the general concept of an integrated supply chain model. This figure illustrate the logical and logistical links from a firm and its distributor, and supplier network to the customers. The significance conveyed by this model is that the integrated value- creation process must be aligned and managed from material procurement to end-customer product/service delivery in order to achieve effectiveness, efficiency, relevancy, and sustainability.

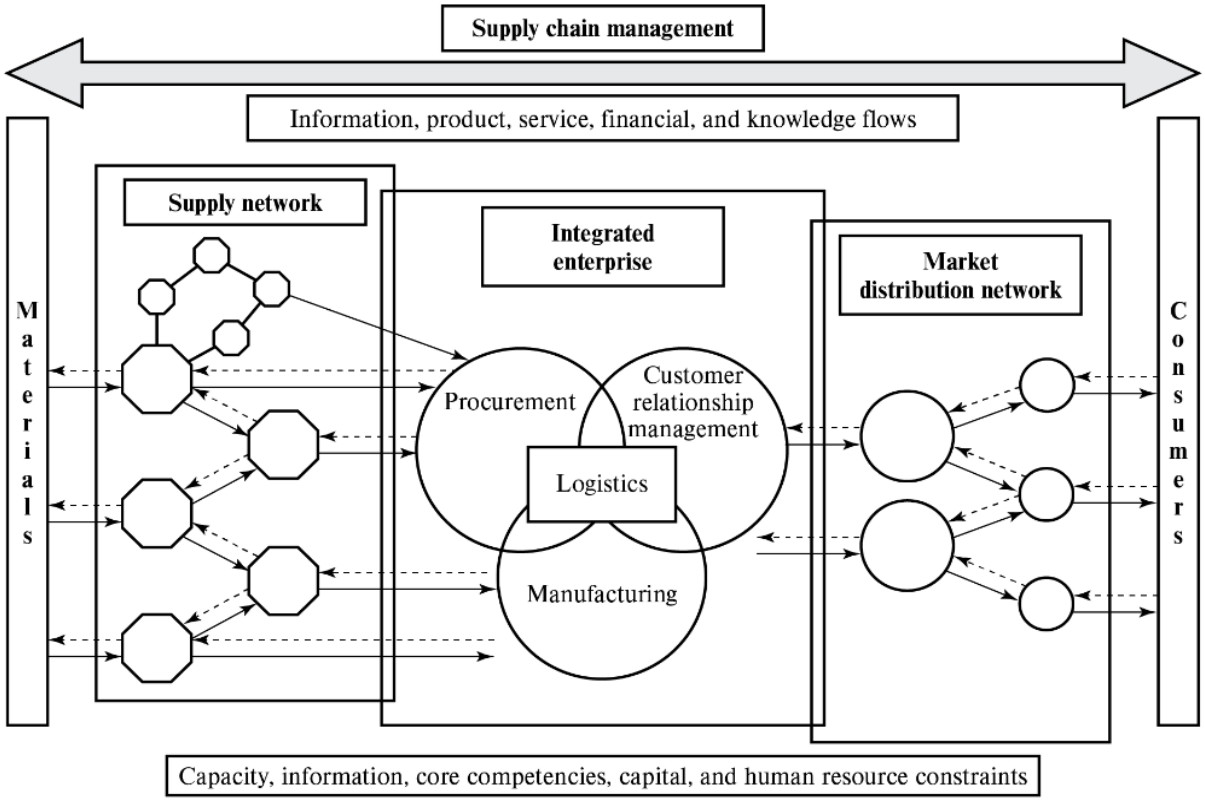

Figure 2.2: Integrated Supply Chain Management Model

Source: Bowersox, Closs, Cooper and Bowersox, 2013

2.3: General Supply Chain Management Framework:

Soni and Kodali (2013) reviewed a number of supply chain management framework articles and proposed a framework that possibly suggests a way to achieve coherence in the use of supply chain management frameworks. They noticed a massive use of sets of elements (or constructs) in supply chain management frameworks and tried to find out a possible set of standard constructs that make supply chain management by the aid of supply chain management professionals, the efforts were directed towards finding out the broad area, a particular construct may belong. This broad area is referred as a pillar of supply chain management and that leads to the emergence of a comprehensive supply chain management framework as shown in Figure 2.3.

At the top of the framework is the mission and vision of the company. This informs its competitive strategy, whether this is based on cost structure or product differentiation. Once the competitive strategy and its priorities have been established, the company then formulates a supply chain strategy that will promote supply chain efficiency and effectiveness.

Once the supply chain strategy is in place, the supply chain management pillars are used to build the capabilities of the chain and help the organisation to achieve its mission and vision. However, this will only true if a strategic fit is achieved between its competitive strategy and supply chain strategy.

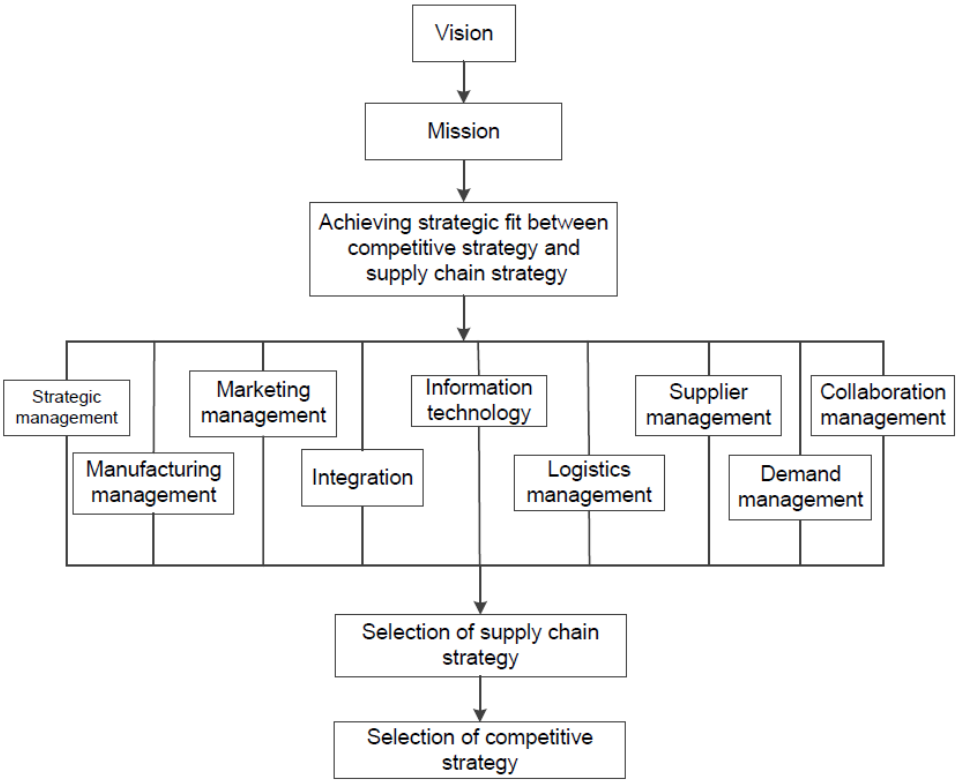

Figure 2.3: Supply Chain Management Framework

Source: Soni and Kodali (2013)

2.4: Supply Chain Design:

Fine (1998) was the first to recognise that supply chain design (SCD) goes beyond the issues of make/buy, buyer-supplier relationships or vertical integration to encompass investment decision making. How a firm decides to distribute its investment across its various supply chains will affect the capabilities of each of these chains (Wu, Melnyk and Flynn, 2010) and shape the types of relationship that emerge between supply chain partners and the degree of transparency that is achieved (Janvier-James, 2012). Researchers have focused on SCD from both theoretical and empirical perspectives, but as Melnyk (2014) points out, many have focused on issues such as process, investments and structure without offering an overall framework to tie these aspects together. The following two sections discuss what the concept of supply chain design actually means and the frameworks that have been put forward for understanding this concept.

2.3.1: Concept and Scope:

Broadly speaking, the business of supply chain design is to utilise resources efficiently in order to achieve defined outcomes. However, the literature review highlights that there is no general consensus among authors about how the concept should be defined. Baud-Lavigne et al. (2012) suggests that SCD may be considered at two different levels: the strategic level (e.g. the choice of production facilities, load/manufacturing capacities and technologies) and the tactical level (e.g. mid-term decision making on issues such as the choice of suppliers, the allocation of products to production facilities and the flow of each product and sub-assembly in the network) (Cordeau et al., 2006).

Mansoornejada, Pistikopoulosb and Stuart (2013) and Leukel and Sugumaran (2013) appear to take the strategic perspective with their argument that the supply chain has to be designed to support the strategic objectives of the firm, in which their suggestions involve making long-term decisions about products; process technologies; the number, location and capacity of supply chain nodes; production rates; and suppliers, markets and partners. Mallidis, Dekker and Vlachos (2012) also see SCD as encompassing decisions about the number, location, capacity and operation of distribution centres/production facilities, and the selection of intermediaries and partners (suppliers, freight forwarders etc.). Melnyk (2014), meanwhile, defines supply chain design as identifying the desired strategic outcomes for the firm and developing, implementing and managing the resources, processes and relationships within the firm and across the supply chain that will make the attainment of these outcomes inevitable over time.

At the tactical level, Metta and Badurdeen (2013) argue that supply chain design involves identifying product design criteria (e.g. materials, functionality, components and interfaces) and evaluating their impact on supply chain configuration (e.g. the number and location of supply chain partners, their capabilities and capacities) to achieve optimum supply chain performance. Melnyk (2014) defines supply chain design as identifying the desired strategic outcomes for the firm and developing, implementing and managing the resources, processes and relationships (within the firm and across the supply chain) that will make the attainment of the desired outcomes inevitable over time. Prasad, Subbaiah and Rao (2014) explain that the design should aim to maximise overall value in the supply chain by optimising transportation, inventory, operating facilities and information flow.

Further complicating the issue, the perceived scope of the supply chain design process seems to have changed over the years. Speier et al. (2011) argue that SCD decision makers have historically focused on how to minimise the total landed cost, for example by considering carefully where to locate facilities such as plants and

warehouses and by controlling materials acquisition, production, inventory and logistics costs. However, Closs and McGarrell (2004) claim that over time, SCD objectives have gone beyond cost, with chains now being expected not only to operate within designated cost parameters but also to meet the unique service requirements of different customer segments. Indeed, these objectives have recently extended even further to include consideration of the dimensions of security, risk and sustainability.

Govindan, Fattahi and Keyvanshokooh (2017) define three types of uncertain environments in which SCD decision makers must operate. First, the decision-making environment has random parameters whose probability distributions are known to the decision maker. These are called stochastic parameters and are described by either continuous or discrete scenarios. Second, there are again random parameters, but the decision maker has no information about their probability distributions. Under this setting, robust optimisation models are usually developed with the purpose of optimising the worst-case performance of the SC network. The third type of environment is the fuzzy decision-making environment. This is characterised by ambiguity and vagueness. In this context, fuzzy mathematical programming handles the planner's expectations about the level of an objective function, the uncertainty range of coefficients, and the satisfaction level of constraints.

2.3.2: Frameworks and Models:

Frameworks and models help researchers to see clearly the essential elements of their research of interest and guide them through the entire process of their research study to achieve the aims.

The framework developed by Du Toit and Vlok (2014) as shown in Figure 2.4, offers a simple graphical representation that divides SCD into different components, defined the components and shows the relationships between them to helps users to make sense of a complex concept in a practical manner. This framework starts with organisational strategy, highlighting the importance of the alignment between this and supply chain strategy. The next object in the framework is SCM, through whose plans the supply chain strategy is implemented. SCM has three main components: supply chain participants, supply chain life-cycle activities and supply chain support functions. Supply chain participants link to both SCM plans and life-cycle activities. Performance measurement acts as a feedback loop into continuous improvement, which impacts on both supply chain strategy and management. The different components within SCM are affected by enablers that act across functions, activities and participants.

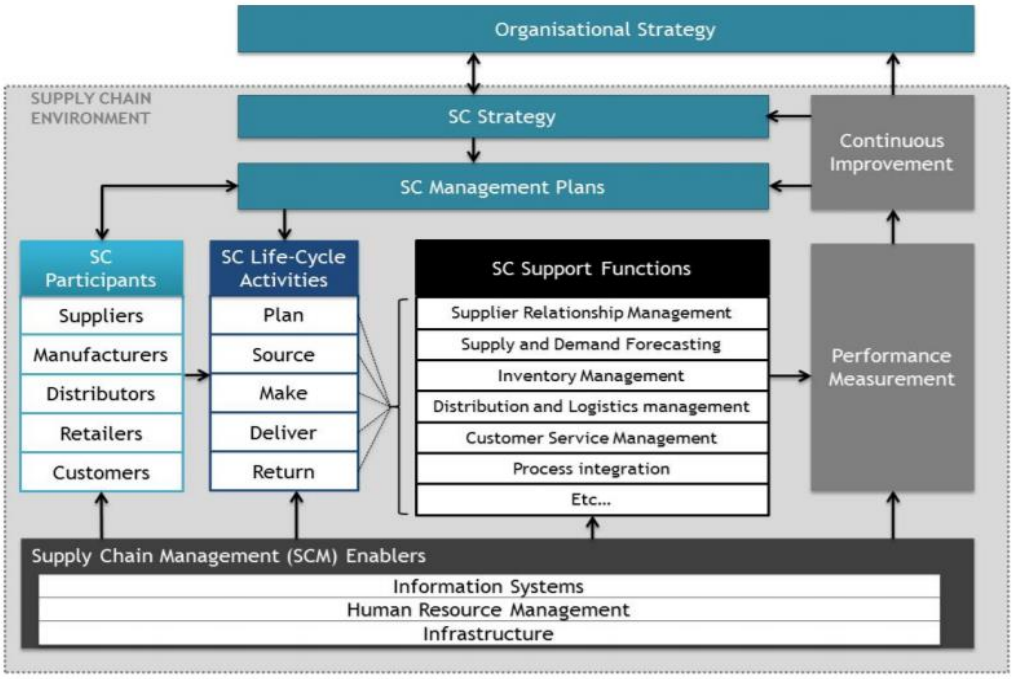

Figure 2.4: Supply Chain Management Framework

Source: Du Toit and Vlok, 2014

Naslund and Williamson (2010) presented the Supply Chain Operations Reference (SCOR) model, developed by the Supply Chain Council (SCC) and AMR Research in 1996. According to the SCC, the SCOR model may be used to identify, measure, reorganise and improve supply chain processes. They claim that: *"...(It) provides a unique framework that links business processes, metrics, best practices and technology features into a unified structure to support communication among supply chain partners and to improve the effectiveness of supply chain management and related supply chain improvement activities"* (Supply Chain Council, 2009).

The validity of the SCOR model has been confirmed by Zhou et al. (2011), whose empirical findings generally support the relationships it posits between supply chain processes (plan, source, make and deliver).

A number of authors have discussed the SCOR model including; Huan, Sheoran and Wang (2004) who, note its integration of BPR, benchmarking and process measurement within a cross-functional framework and employ the analytic hierarchy process (AHP) to demonstrate its strength as decision- making tool. However, they also

note that the model fails to consider change management or to supply quantifiable measurements of SC performance.

While Fronia, Wriggers and Nyhuis (2008), acknowledge that the SCOR model initially provides as universal as possible a description of the supply chain, they show how the SCOR model might be extended to offer a more detailed framework for supply chain design. The models they offer give a clearer explanation of each SCOR process. When Long (2014) developed a hierarchical framework for modelling supply chain networks based on an improved version of the SCOR model, he found that these networks generally consist of several entities, each of which may be composed of several departments or workshops. This led him to argue that any supply chain network can be divided into four levels namely; the supply chain network level, enterprise level, workshop level and production. He suggests that any element at any level can be modelled using the five core processes from the SCOR model.

Other attempts at a framework include that by Ivanov (2009), who employed software to develop and validate a complex mathematical model with the aim of increasing the efficiency, consistency, implacability and sustainability of SCD decision making and showing the links between the design, planning and implementation functions. Ivanov points out the need for further work to investigate the relationship between business processes and information systems, and suggests that researchers should consider the flow of financial data between departments alongside the flow of materials and information.

A number of authors have proposed five-step models. One of who is Hilletofth (2012), who stated the steps: develop a segmentation model, collect market information, then specify, select and implement supply chain solutions. As for Corominas et al. (2015), the steps are: define supply chain objectives and conduct environmental analysis; define supply chain macrostructure (activity blocks and the relationships between these blocks); define supply chain mesostructure (product structure and production process); define supply chain microstructure (demand, production activities and transportation); choose supply chain configuration and implement. Finally, Marchesini and Alcântara (2016) propose: identify logistics activities; characterise these activities according to need and their impact on customer value and logistics service; assign logistics activities to companies; identify any gaps in internal coordination and integration; measure the performance of logistics activities.

The framework proposed by Affonso, Liu and Zolghadri (2013) integrates product and supply chain design. It consists of identifying and evaluating product functions, defining relevant supply chain structures, identifying and evaluating potential suppliers, selecting suppliers, and finally defining the supply chain configuration.

Melnyk, Narasimhan and DeCampos (2014) claim that supply chain design is shaped by three dimensions that have a hierarchical relationship consisting the influencers, design decisions and building blocks as shown in Figure 2.5. Influencers are factors that impact on overall supply chain performance such as the desired supply chain outcomes and the global environment. Design decisions are the specific decisions that must be made with regards to the supply chain as a whole (e.g. network design, sourcing strategies), while building blocks are the investments that are required to implement these decisions and build the supply chain.

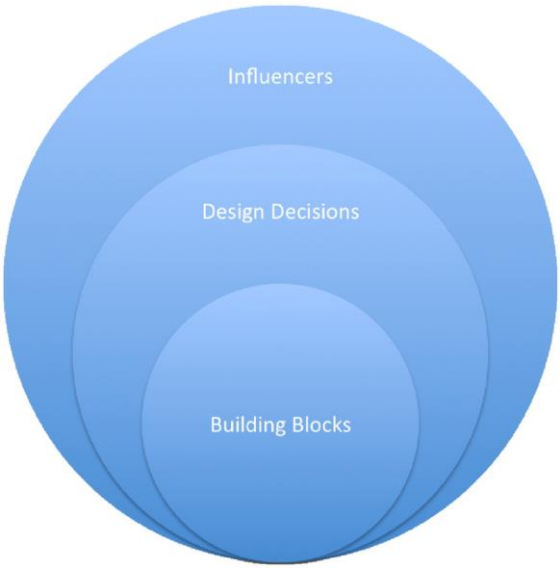

Figure 2.5: Three Levels of Factors Influencing Supply Chain Design

Source: Melnyk, Narasimhan and DeCampos, 2014

Sabet, Yazdani and De Leeuw (2016) developed a conceptual model specifically for SCM in fast-evolving industries (FEIs). Their model illustrates that the more important the supplied products/services are to a firm's core business, the more closely it must integrate with its suppliers to secure its value-creation processes and protect this core business. At the same time, if supply is associated with a high level of risk and uncertainty, the firm must aim for alignment, adaptability and agility within its supply chain.

It should be noted that whichever framework or model is applied, all SCD activities must be guided by the supply chain strategy to ensure that all decisions in the design stage contribute positively towards achieving the company's strategic objectives.

2.5: Supply Chain Strategy:

Successful companies understand the value of focusing their energies on those dimensions where they can compete most effectively. In a survey of 234 companies from 16 countries, Roland Berger Strategy Consultants (2009) found that companies with supply chain fit achieve a Return on Assets (ROA) of 4-6% higher on average than companies without supply chain fit. Companies without supply chain fit tend to have the wrong priorities when designing their supply chain; companies with standardised products do not focus enough on cost, inventory management or utilisation rates. On the other hand, companies with customised products often do not focus enough on flexibility, delivery reliability and service level improvement.

2.4.1: Strategic Fit:

Randall, Morgan and Morton (2003) examine the association between product demand characteristics and the initial investment in a supply chain at the time of market entry. Characterising supply chains as responsive or efficient, they conclude that responsive market entry is associated with lower industry growth rates, higher contribution margins and higher technological demand uncertainty.

Chaharsooghi and Heydari (2011) discuss the concept of strategic fit in supply chain management, concluding that in highly turbulent environments it is essential for the SC to focus on responsiveness to avoid losing customers. Soni and Kodali (2011) explore the strategic fit between competitive strategy (CS) and supply chain strategy (SCS) in the Indian manufacturing industry by investigating the mediating role of supply chain strategy between competitive strategy and company/supply chain performance. Their findings reveal a causal relationship between competitive strategy and supply chain strategy and that the choice of both affects both business and supply chain performance. Wagner, Gross-Ruyke and Erhun (2012) also investigate the relationship between supply chain fit and the financial performance of the firm. Their findings indicate that the higher the supply chain fit, the higher the ROA of the firm, and that firms with a negative misfit perform worse than firms with a positive misfit.

2.4.2: Strategic Supply Chain Management

Hwang (2010) discusses how to develop a supply chain's overall competitive strategic direction so as to optimise SC performance. His general strategic supply chain management framework comprises three stages, namely strategy formulation, strategy implementation and strategy evaluation. Alfalla-Luque, Medina-Lopez and Dey (2013)

identify information integration, coordination and resource sharing, and organisational relationship linkage as the three major dimensions of supply chain integration (SCI) and analyse how these affect overall supply chain performance in terms of efficiency and responsiveness. The authors offer an integrative model that blends together elements of supply chain configuration, stakeholder management and capability development. Their analysis reveals that the nature of stakeholder exposure determines how social/environmental, technical and relational capabilities impact on social and environmental outcomes. Their framework builds on Fisher's (1997) prototypical efficient and market responsive configurations, expanding them to include social and environmental issues. Taking Apple/Foxconn as an example, they suggest that capabilities based upon responsiveness, such as product improvement and collaboration, may need to be supplemented with efficiency-oriented capabilities, such as process improvement and monitoring, to satisfy the demand for economic, social and environmental outcomes.

Wieland (2012) proposes a model that enables companies to select a supply chain strategy based on risk probability and risk impact. He identifies four supply chain strategies – agility, robustness, resilience and rigidity, advising resilience where supply chain risk probability and impact are high, and rigidity where both values are low. When only risk impact is low, robustness is optimal, whereas agility is optimal when only risk probability is low.

Um et al. (2017), investigated the impact of product variety strategy on supply chain performance and, developed a conceptual model that links product variety management strategies with supply chain responsiveness, cost and customer service in high- and low-customisation environments. They found that product variety strategy influences supply chain cost and customer service performance only when mediated by internal and external responsiveness capabilities, and that its impact on performance depends on the level of product customisation. In a low-customisation environment, both supply chain flexibility and agility have a significant influence on cost efficiency, while in a high-customisation environment, these dynamic capabilities have a significant influence on customer service.

2.6: Supply Chain Performance:

The identification of appropriate performance metrics is crucial for monitoring and improving supply chain performance. These metrics play an important role in setting objectives and determining future trends. Attempts have been made to survey the main performance metrics currently used in supply chain management (Elrod, Murray and Bande, 2013; Gopal and Thakkar, 2012), and a number of authors have called for new

measures to be introduced in response to the evolving business environment. Akyuz and Erkan (2010), for example, suggest that new performance measurement systems are needed to take account of qualities such as agility, flexibility, information productivity, business excellence and collaborative/partnership capacity. Kim, Kumar and Kumar (2010) developed a framework for assessing the comprehensive performance of supply chain partnerships (SCP). Their framework is based on the self-assessment dimensions and approaches of the business excellence model developed by the European Foundation for Quality Management (EFQM).

Drawing on his review of the literature, Leończuk (2016) compiled a list of the various indicators that have been proposed for measuring supply chain performance as shown in Table 2.1.

As outlined in Chapter 1, this research aims to focus equally on the dimensions of efficiency, responsiveness and optimisation. The following sections therefore discuss these three dimensions and their metrics in more detail.

Source	Categories/Dimensions	Framework
Shepherd, Günter 2012; Chan *et al.* 2013	qualitative, quantitative	-
Gunasekaran *et al.* 2004	strategic, tactical, operational	Decision level
De Toni, Tonchia 2001	cost and non-cost; time, quality, flexibility	-
Neely et al. 1995; Elrod *et al*. 2013; Arif-UzZaman, Ahsan 2014; Bozarth, Handfield 2007	time, cost, flexibility, quality	-
Shepherd, Günter 2012	time, cost, flexibility, quality, innovativeness	
Chimhamhiwa *et al*. 2009	cost, time, quality, technological innovation, society, customer	-

	satisfaction	
Angerhofer, Angelides 2006; Beamon 1999	resources, output, flexibility	-
Cai *et al*. 2009	resource, output, flexibility, innovativeness, information	-
Cho *et al*. 2012	financial, competitiveness, quality of service, flexibility, resource utilisation, innovation	service supply chain
Ganga, Carpinetti 2011	reliability, flexibility, responsiveness, cost, assets	SCOR metrics focus on five performance attributes
Golrizgashti 2014; Rodriguez-Rodriguez *et al*. 2010	financial, internal processes, innovation and improvement, customers	balanced scorecard perspectives
Bullinger *et al*. 2002	financial, customer, organisational, innovation (for each supply chain perspective, customer perspective, function perspective)	balanced scorecard perspectives
Gunasekaran *et al*. 2004; Chae 2009	plan, source, make, deliver	SCOR model
Shepherd, Günter 2012; Arif-Uz-Zaman, Ahsan 2014	planning and product design (plan), supplier (source), production (make), delivery (deliver), customer (return)	SCOR model
Zailani *et al.* 2012	operations, economic, social, environment	the extent of implementation of sustainable supply chain
Raja Gopal 2009	customer orientation,	-

	distribution, internal operations, supply	
Kowalska 2011	quality, delivery, total cycle time, loss	-
Witkowski 2010	added value and customer satisfaction, cost of operations, financial results, added value of the chain	-
Kisperska-Moroń 2006	logistics, production, purchasing, new product development, customer order management, supply chain diagnostics	used in IBM
van Hoek 1998	cost effectiveness, integration, customer service	-
Otto, Kotzab 2003	system dynamics, operational research, logistics, marketing, organisation, strategy	-
Carvalho, Azevedo 2012	operational performance, economic performance	-
Anand, Grover 2015	transport optimisation, inventory optimisation, information technology optimisation, resource optimisation	retail supply chain
Wibowo *et al*. 2015	reliability, responsiveness, flexibility, costs, assets	SCOR model
Liu *et al.* 2016	Cost, wastage	-
Rezaei *et al.* 2017	reliability, responsiveness, flexibility, costs, assets	SCOR model

Schön *et al.* 2017	level of investment, improvement, self-reliance	-

Table 2.1: The Categories/Dimension of Supply Chain Performance Indicators

Source: Leończuk, 2016

2.6.1: Supply Chain Efficiency:

The measurement of supply chain efficiency is vital, not just to give an insight into how the chain is performing but also to identify any problems in a timely fashion. Lichocik and Sadowski (2013) attempt to explain the problem of supply chain management efficiency in the context of general theoretical considerations relating to supply chain management. The authors highlight the determinants and practical implications of supply chain management efficiency, concluding that efficiency means being cost-effective and streamlining processes while ensuring that service remains high quality. Mishra (2012) employed data envelopment analysis to measure SC efficiency in Indian pharmaceutical companies, using the constant returns to scale (CRS) assumption and variable returns to scale (VRS) assumption to calculate a technical efficiency score.

Danese and Romano (2011) analysed the impact of customer integration on efficiency and the moderating role of supplier integration by employing hierarchical regression analysis to test two hypotheses. The integration includes upstream and downstream operations in both suppliers and customer's sites. Their analysis revealed that supplier integration positively moderates the relationship between customer integration and efficiency, but did not support the hypothesis that in general, customer integration has a positive impact on efficiency. Where supplier integration is low, customer integration can even reduce efficiency.

2.6.2: Supply Chain Effectiveness:

The characterisation of the current business practices by variation in demands and differences in customer requirements has motivated many firms to be responsive (Somuyiwa and Adebayo, 2013). Therefore, the modern supply chains are expected to respond rapidly, effectively, and efficiently to changes in the marketplace to sustain, and furthermore create competitive advantage (Somuyiwa and Adebayo, 2013). Sukati et al (2012) investigated the impact of supply chain integration on competitive advantage and

assessed the impact of supply chain responsiveness on firm competitive advantage. The data were analysed using mean, standard deviation and correlation between independent and dependent variables. Their research findings supported the hypotheses that supply chain integration positively impact supply chain responsiveness and competitive advantage. Their finding also showed that supply chain responsiveness was positively associated with the competitive advantage of a firm.

Ghosh, Das and Deshpande (2014) presented an integrative framework relating to chain responsiveness, process integration, supply chain coordination and performance. The paper outlines how using information, responsiveness, process integration and coordination can be improved. The authors suggested future research to understand and explore the quantitative relationships among the constructs of the research framework.

Danese, Romano, and Formentini (2012) argue that in supply networks both external and internal integration practices have a significant and positive impact on responsiveness. It suggests to managers methods to properly tune the level of adoption of integration practices as per the degree of supplier network internationalisation. The authors found that the external integration effect on performance is amplified. Conversely, the impact of internal integration on responsiveness is not moderated using international suppliers. Yi, Ngai, and Moon (2011) illustrated and examined the different flexibility strategies adopted by supply chain participants because of different environmental uncertainties. In response to the various uncertainties, four types of flexibility strategy are identified in our case analysis: laggard, conservative, agile, and aggressive. It proposed that theoretical framework could assist managers to properly diagnose and deploy supply chain flexibility strategies. The authors suggested that better supply chain responsiveness can be achieved in two ways: by reducing uncertainties and by improving supply chain flexibility.

Singh and Sharma (2013) have tried to prioritise flexibility alternatives by analytical network process approach. Findings from the study report that organisations should prioritise improvements on manufacturing flexibility followed by customers' and suppliers' flexibility. Roh, Hong, and Min (2013) presented a research model that defines the drivers, strategy, and practices of a responsive supply chain and the performance outcomes. This study suggests that the key contextual factors that influence the extent of implementation of a responsive supply chain strategy are mostly the size of firms, industry characteristics, and customer and supplier bases, rather than the location of manufacturing firms. The study shows that the effective implementation of a responsive supply chain strategy involves the integration of inter organisational resources (i.e. socio-relational and techno process integration) across the global supply chain to enhance pull production capabilities.

2.6.3: Supply Chain Optimisation Model:

One of the first steps to run an effective supply chain is the strategic positioning of the manufacturing facilities, warehouses and distribution centres. Canel and Khumawala (1997) provide a review of the literature for the incapacitated multi-period international facilities location problem (IFLP). They formulate a mixed-integer programming (MIP) model and solve it using the branch and bound method. The decision variables include the countries to locate manufacturing facilities, and their production and shipping levels. They also provide a case study with an application of the solution procedure. The performance measurement criteria used here is the number of nodes needed to reach the optimal solution, and to verify the optimality. Computational time was also considered as another performance indicator. The research also identifies the scope for multi-stage problems wherein the location of manufacturing facilities would be accompanied by the optimal location of distribution centres (DC). Canel and Khumawala (2001) later develop heuristic procedures for solving the MIP model of a similar IFLP. The heuristic procedures are tested for their computational efficiency. The profit maximisation problem also considers the other important factors for international location problems, such as, exchange rates, export incentives, tariffs, taxes, and so on. The multi-period model also takes into account the time-dependent variations in prices, costs, and demands.

A number of quantitative models use mixed-integer programming (MIP) to solve the supply chain optimisation problems. One of the first attempts was done by Geoffrion and Graves (1974), where a MIP model was formulated for the multi-commodity location problem. This seminal research involved the determination of distribution centre (DC) locations, their capacities, customer zones and transportation flow patterns for all commodities. A solution to the location portion of the problem was presented, based on Bender's Decomposition (BD). The transportation portion of the problem is decoupled into a separate classical transportation problem for each commodity. Their approach shows a high degree of effectiveness and advantage of using BD over branch-and-bound. The technique has been applied on a real problem to test its performance. However, the computational requirements and technical resources required for its implementation make it a difficult choice.

Vidal and Goetschalckx (1997) provide a critical and comprehensive review of the production-distribution models in global supply chain systems. An explanation of the different optimisation models is presented with emphasis on MIP models, followed by a brief review of analytic approach. Further comments on some modelling issues include review of work done to explain the additional aspects of formulating the models such as aggregation of suppliers, qualitative aspects of inventory management, common errors

in aggregation of customers, and so on. Areas for future research are suggested, which include considering stochastic aspects of global supply chains, bill of materials (BOM) constraints, qualitative factors, exchange rates, taxes, duties, and other factors. The authors point to the lack of research in integrating the different components of a production-distribution system.

Sarmiento and Nagi (1999) review the research done in combined optimisation of the production-distribution functions. Only models with two echelons are considered and they are classified according to the production, distribution and the related inventory decisions taken at each echelon. The classification is also based on finite/infinite time horizons. Research in inventory/routing problems is also analysed followed by a comprehensive account of suggestions for future research. The areas that need to be considered in more details for inventory/distribution problems include constrained transportation systems, complex networks, multiple product systems, location of multiple customers and depots, emergency shipments, vehicle routing, and inventory level setting. Apart from searching for optimal solutions, more research could be done in the area of heuristic procedures and validation methods. Stochastic demands is another area that needs further exploration. For production/distribution problems, further research is proposed in minimum safety stock requirement for guaranteed reliability, analytical formulations, and study of interrelations between production and distribution. The authors also express the need for simultaneous integration of multiple functions along with considering non-linear transportation costs, variable travel times in the analysis of distribution systems.

Beamon (1998) presents a comprehensive review of the research in multi-stage supply chain modelling along with a direction for future research in this area. Multi-stage supply chain models have been categorised into deterministic, stochastic, economic and simulation models. The paper categorises supply chain performance measures into two categories- qualitative and quantitative. It also lists the decision variables usually used in supply chain modelling. Selecting the correct set of performance measures for the chosen decision variables is suggested to be an important area for future research. Various other modelling issues such as product postponement, demand distortion and supply chain classification schemes are also considered important for future research.

2.7: Cold Chain:

During the past five decades, drug development achieved notable successes. However, no single therapy so far can be prescribed as fully and entirely safe and effective (Syhakhang, 2004) . The pharmaceutical sectors globally are pressurised to afford medicines for the estimated ninety pillion population, while simultaneously

addressing the quality and safety (Furberg and Furberg, 2007). In Malaysia, the pressure is increasing as the country new policy, in regards to medical care, is to standardise the existing Good Manufacturing Practise (GMP) and Good Distribution Practise (GDP) guidelines, disseminate the medical information and evaluate the pharmaceutical products, implement knowledge transfer when it comes to public service.

The implementation of GMP and GDP is challenging in terms of how to centralise the patients benefit and overcome the burden between the manufacturers and institutional borders. The policy should review the conflict of interest and reveal the financial ties to pharmaceutical leaders and sponsors and oversight the outcome versus the costs. The total sale of locally manufactured medicines in 2006 in Malaysia was about 272 million USD. 65%- 80% of the Malaysian pharmaceutical needs are still imported from Germany, England and France, including the new generation of antibiotic, cholesterol lowering, diabetic, cardiovascular and anticancer medicines (Smith et al., 2009).

To face the challenge, the Malaysian regimen is investing into efficient implementation of GMP and GDP to assure the impact of drug quality are contemplated. Integrated strategies to address these aims are ongoing and the safety factors are revised. However, it is unclear if all the partners/stakeholders within this process benefit equally from the available therapeutics roles and if they are aware about the appropriate indications and possible limitations (MOH, 2011). One more interesting question, if the access to the entire related information is guaranteed and if the statistical records are actual figures or underestimate. Yet there is no updated studies of how close are the Malaysian practice to the global GMP and GDP standards. According to data published in 2012 by Ministry of Health (MOH), Planning and Development Division, Health Informatics Centre, that in 2011 the total population used the public health facilities was 33,379,603 (Ministry of Health, 2012).

According to Li Jie (2010), cold chain involves the process of the manufacture, storage, transport, and retail for chilled food. These processes should be controlled in low temperature. Food cold chain logistics use the cryogenic technology to protect the quality of the food. According to Smith and Sparks (2004), cold chains are more important compared to ordinary retail supply chains as they are more complex. In this context, he stated that the challenge is more formidable when the materials and products require temperature control. The shelf life is often shorter for such products, placing even greater importance on the speed and dependability of transportation and handling systems. Temperature controlled products also require specialised transportation equipments, storage facilities and closer monitoring of product integrity while they are in the logistics system. Figure 2.6 shows the elements of the cold chain that should be considered during the planning process.

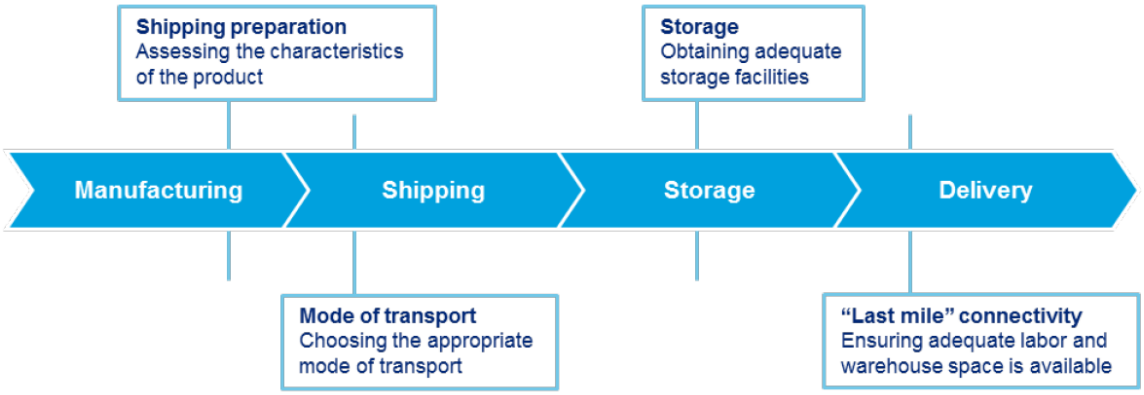

Figure 2.6: Cold Chain Planning Components

Source: Wong & Xie, 2007

Besides the food cold chain, the pharmaceutical industry also depend heavily on temperature controlled supply chain (Bishara 2006). Transportation of products along a supply chain must be maintained within a certain temperature range in order to uphold the integrity of the products and in the pharmaceutical industry, the emergence of bioscience has significantly increased the demand for cold chain infrastructure, since biologics, blood products, and vaccines require a stringent set of guidelines that must be followed in order to ensure product safety and viability (Okeke et al. 2000). Variations in temperature can partially or wholly void a shipment and lead to millions of dollars in lost sales for the company. Figure 2.7 provides a good example of potential points of exposure along a given supply chain.

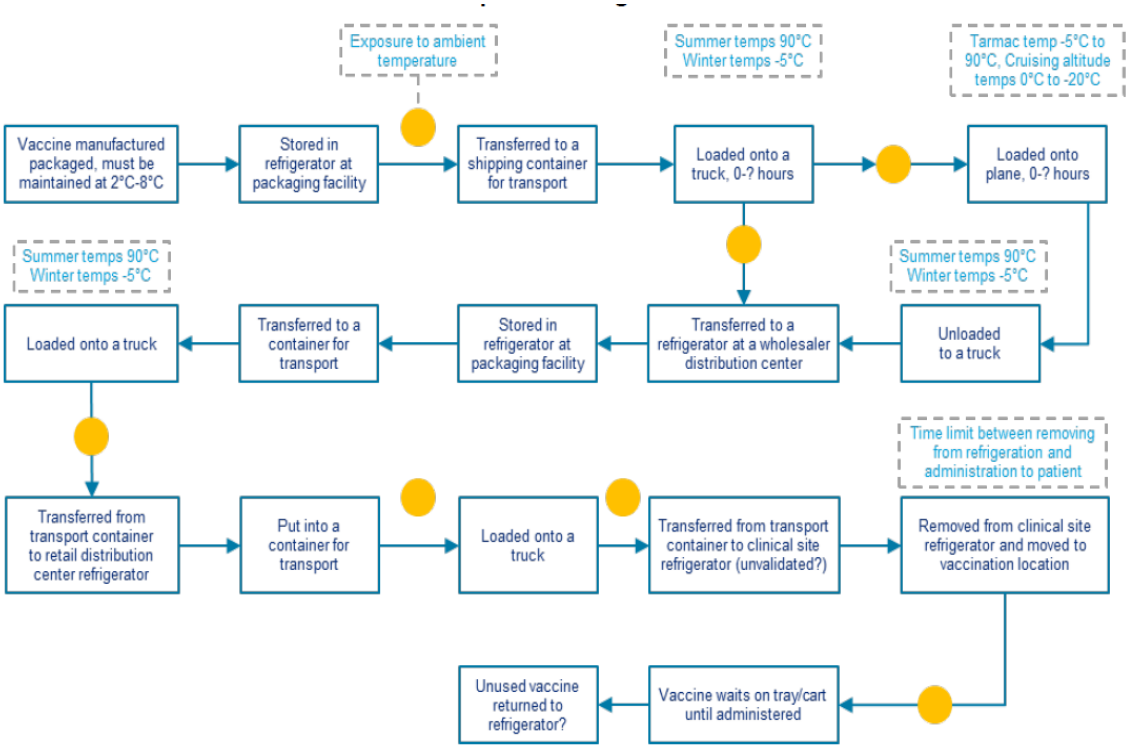

Figure 2.7: Points of Exposure along Cold Chain

Source: Bezawada-Joseph, 2010

2.8: Good Distribution Practice (GDP)

The World Health Organisation (WHO) (2011) described Good Distribution Practice (GDP) as a part of quality assurance which ensures that products are consistently stored, transported and handled under a suitable condition as required by the marketing authorisation (MA) or product specification. Alternatively, the National Pharmaceutical Control Bureau (NPCB), and Ministry of Health (MOH) Malaysia (2013) defined GDP as measures that need to be considered in the storage, transportation and distribution of any registered product or notified cosmetic and its related materials such that the nature and quality intended is preserved when it reaches the consumer. On the other hand, Good Distribution Practice in Medical Devise (GDPMD) Malaysia (2013) explained GDP as a part of quality assurance which ensures that products are consistently stored, transported and handled under suitable condition as required by the marketing authorisation or product specification. In order to provide such assurance, companies will require more than just a set of quality manuals, but also a comprehensive system to “give assurance”. This may include appropriate procedures, suitably trained and qualified personnel, correct processes/facilities/equipment as well

as clear and timely records and documentation, to credibly demonstrate the consistency of quality assurance. Figure 2.8 shows the pharmaceutical distribution process.

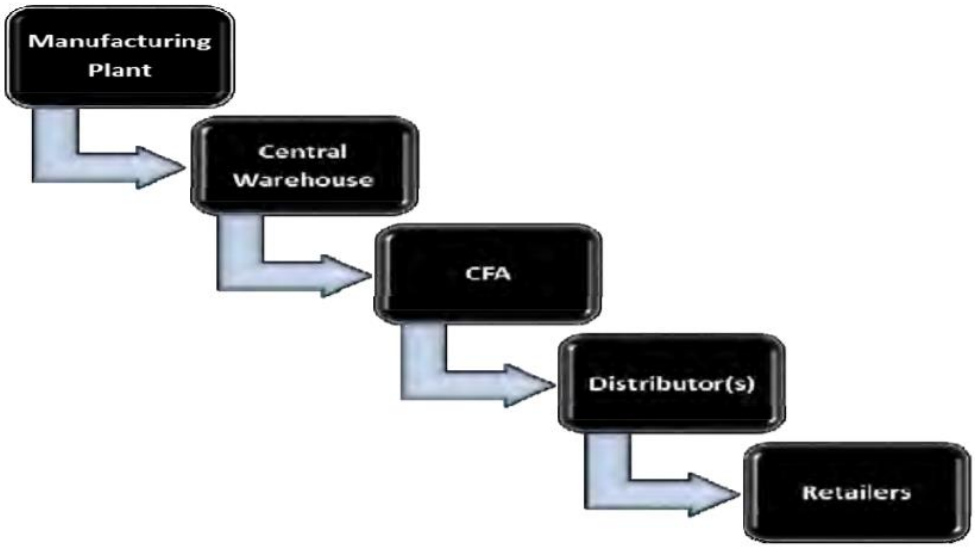

Figure 2.8: Pharmaceutical Distribution Process

Source: Brenken et al. 2009

A review availability on GDP literature on a worldwide level reveals that the GDP awareness is highest in United States of America (USA) followed by the United Kingdom and Europe as shown in Figure 2.9. The GDP guidelines are intended to be applicable to all persons and outlets involved in any aspect of the storage and distribution of pharmaceutical products from the premises of the manufacturer of the product to the person dispensing or providing pharmaceutical products directly to a patient or his or her agent (WHO, 2011). With increasing incidents of counterfeiting, theft and diversion, the industry needed to continuously evolve methods to control and rapidly manage these risks in addition to pre-emptively shift practices to avoid the incident.

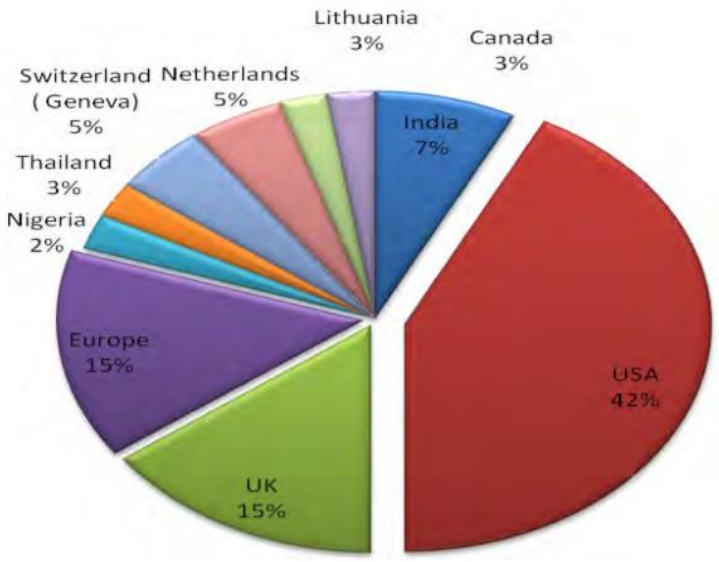

Figure 2.9: Survey of countrywide literature's availability on GDP

Source: Draksiene et al., 2003

2.7.1: EU GDP Initiatives/Challenges

In the United Kingdom (U.K), GDP implementation has significantly influenced the healthcare and pharmaceutical industry as the national body has been established to ensure the interest of common patients. However, the absence of a structured mechanism to address the overall problems faced by patients has been observed. The problem of counterfeit medications in the United Kingdom has been assessed by independent hospitals (Jackson et al., 2011). GDP Consultative committee meets at a regular quarterly interval under the aegis of national regulatory body Medicinal Health and Regulatory Agency (MHRA). The Consultative Committee is an informal committee established to provide a dialogue between the MHRA and other Governmental departments, the Devolved Administrations, and relevant trade associations on matters relating to the manufacture and wholesale distribution of medicinal products for human use (Department of Health, U.K., 2013).

This committee comprises of a group of experts drawn from government, regulators, British Association of Research Quality Assurance, industry, and the academic and third sector communities meet to discuss healthcare regulation issues, including the development of new initiatives and innovations (Department of Health, U.K., 2013). In September 2012, a meeting was held to discuss the various issues. The

MHRA, who attended the meeting, considered that the key objective is to establish a strategy for all stakeholders to work together (Department of Health, U.K., 2013). The drugs regulatory agency of U.K has quality noticed problems arising during the distribution of medicines. In U.K, the problem with medicine supply can occur for various reasons, such as manufacturing problems, difficulties in obtaining raw materials, regulatory issues, changes to manufacturers' distribution systems and fluctuations in parallel trade (Jackson et al., 2011).

On the other hand, in Europe, the European Medicines Agency (EMA) (2012), published a Reflection paper on medicinal product supply shortages caused by manufacturing/Good Manufacturing Practice Compliance problems. This Reflection Paper concerned public health crises that arise due to unforeseen disruptions within the manufacturing process, caused by manufacturing/GMP compliance problems and affects medicinal products for human use, independent of their route of authorisation, where a need for co-ordination of the assessment and risk reducing actions at a Community level has been identified (EMA, 2012).

While control and supervision of the national market remain a national responsibility, Member States may experience difficulties in acting in a purely national way when faced with a pan-European crisis during distribution network (EMA, 2010). The network is increasingly looking to the European Medicines Agency (EMA) by coordinating the development and communication of appropriate risk management measures arising from unexpected shortages in supply. This coordination may be through informal cooperation and information sharing or formally through the initiation of Community procedures as a result of identified public health concerns where supply is affected (EMA, 2010).

In member countries of the European Union, the wholesale distribution of medicinal products is an important activity in integrated supply chain management. Today's distribution network for medicinal products is increasingly complex and involves many players (EMA, 2012). These guidelines lay down appropriate tools to assist wholesale distributors in conducting their activities and to prevent falsified medicines from entering the legal supply chain. Compliance with these guidelines will ensure control of the distribution chain and consequently maintain the quality and the integrity of medicinal products (EMA, 2012).

2.7.2: Implementation Challenges in Developing Countries

The main challenges in implementing GDP includes the GDP regulations are not universally understood by international manufacturing companies (Kiyohito et al., 2009). For instance, Asian countries such as Thailand, Malaysia, and Indonesia may not have

fully implemented the GDP processes as shown in Figure 2.3 above. Manufacturers or transporters from these countries may not be able to comply with the stated regulations, or there could be missing agreements between parties (Kiyohito et al., 2009).

In addition, the complexity of the supply chain is one of the challenges faced by the pharmaceutical industry as well (Barlett et al., 2007). Increasing supply chain complexity makes it more difficult to maintain confidence in either the resilience or ethical nature of supply chain partners. Resilience is a key requirement to achieve continuity of supply and ethical sourcing is particularly important for GDP implementation (Barlett et al., 2007). Extending supply chains around the world accentuates the problem of developing confidence as it is difficult to build trust and confidence if the lower tier suppliers are not known.

Additionally, the lack of traceability, authentic and complete documentation is also the contributing factor (Holcomb et al., 2011). It is the duty of manufacturer to ensure that their distributors comply with the GDP requirements and other regulatory requirements (Holcomb et al., 2011). In some instances, miscommunication between the manufacturer and foreign distributors made it difficult to ascertain whether distributors were compliant with GDP guidelines and if their products met product specifications, defined in the approval documents (Hammervoll et al., 2014).

2.9: Review and Conclusion:

This chapter demonstrates that while numerous researchers have discussed supply chain design, there is no consensus on how the concept should be defined. Furthermore, although various frameworks have considered different aspects of cold supply chain strategy, structure, process and performance, a single framework that ties all of these functions together has yet to be presented (Melnyk, 2014). The review also indicates that despite the government's emphasis on GDP implementation for evaluating and improving supply chain outcomes, it has rarely been exploited in the field of strategic supply chain management.

A truly competitive supply chain strategy that seeks to improve efficiency and customer service across the entire chain while keeping negative environmental impacts to a minimum is required. Accordingly, Chapter 3 sets out the methodology that was employed to develop the framework, while Chapter 4 presents the results of the framework that was designed and Chapter 5 discussed the validation of framework.

Chapter 3: Methodology

3.1: Introduction

This chapter will firstly describe the philosophical approach used in this study. It will then appraise the potential supply chain frameworks and models available and are widely implemented in the industry. Next, justification will be provided for the selection of the chosen model.

3.2: Philosophical Approach

The research methodology is essentially the philosophy or general principle guising the research. Selecting a methodology requires understanding of the two major research paradigms: qualitative and quantitative approaches (Antwi and Kasim, 2015). Both approaches are fundamentally different in its theoretical rationale, each with their strengths and weaknesses. Quantitative approach seek to gain a large-scale, surface understanding about few variables while qualitative approaches aims to gain in-depth understanding of an array of variables (Roberts, 2004). Nevertheless, neither is better than the other and its suitability depends on the research questions at hand.

In this case, qualitative research approach will be adopted to answer the question posed. Qualitative research is a type of scientific research. In common terms, this method consists of an investigation that (Atkinson *et al, 1998)*:

- Seeks answers to a question
- Systematically uses a predefined set of procedures to answer the question
- Collect evidence
- Produces findings that were not determined in advance
- Produces findings that are applicable beyond the immediate boundaries of the study

Qualitative research shares these characteristics. Besides that, it seeks to understand a given research problems or topic from the organisation involved (Woods, 2006). Therefore, this method is particularly effective in obtaining specific information about the common problems of efficiency, effectiveness and Good Distribution Practise (GDP) implementation in the pharmaceutical industry.

3.3: Potential Methods for Data Collection and Validation

Upon deciding on the most suitable primary data collection methods for this research, a variety of potential methods were considered, including participant observation, interviews, and case study approach. This section evaluates the strengths and weaknesses of these methods with references of its usage in previous studies.

3.3.1: Participant Observation

Originating from ethnographic research, participant observation has been described by Matthews and Ross (2010) as the most basic, although not the simplest, way to collect data in that the researcher records what she/he observes. On the other hand, this method could also possibly involve immersing oneself into a particular community by participating in its routines and building relationship in order to understand how things work “from the inside” (Cook, 1997).

A thorough participant observation would take a long time, possibly months or years, as the researcher needs to build up a trusting and lasting relationship with those being studied (Dawson, 2009). Cook (1997) goes on to mention three other challenges relating to participant observation, which are the ability of gaining access into the community, the role of the research once inside the community and the kinds of data constructed during this period. However, successful practise of this method will lead to a deep and profound understanding of the particular community.

Participant observation also brings certain ethical issues, namely when researcher practises covert observation in which participants do not know they are being studied (Dawson, 2009). On the contrary, overt observation might not yield similarly accurate results if the participants behave differently when they know they are being observed (Matthews and Ross, 2010).

Among the previously reviewed literature, many researchers used this method to observe the forecasting process of the organisation (Hanke, 1995). They concluded that their findings are detailed and in-depth knowledge is gained in the studies.

It could also be argued that the researcher has inadvertently been conducting participant observation throughout her time as a student. Due to the time length required in conducting a proper observation, this method is not practical and will not be selected for this study. However, the researcher will be able to use some of the knowledge gathered during previous interaction with the pharmaceutical industry to inform the implementation of other, more feasible, research methods.

3.3.2: Interviews

Interviews are one of the main data collection methods used by researchers, providing the opportunity for direct interaction between the researchers and the participants (Matthews and Ross, 2010). The most common types of interviews are unstructured, structured or semi-structured (Dawson, 2009), each used under different circumstances.

A common criticism of interviews is that they are not representative of a community or group of people. However, Valentine (1997) points out that this is not the primary aim of this technique, but rather to understand an individual's experiences within their own life. Even so, interviews are still criticised by positivists as un-objective claiming that respondent's answers are biased by the interviewers. Humanists argue that there is no such thing as objectivity in research and those studies are explicitly or implicitly informed by the experiences, aims and interpretations of the research (Valentine, 1997). On this matter, O'Connell Davidson and Layder (1994) stated that interviews are not losing their objectivity and it is simply a tool to explore subjective values, beliefs, and thoughts of the responder rather than imposing a particular world view on them.

"*The expressive power of language provides the most important resource for accounts. A crucial feature of language is its capacity to present descriptions, explanations and evaluations an almost infinite variety about any aspect of the world."* (Hammersley and Atkinson, 1995 in Matthews and Ross, 2010)

Although it allows for obtaining in-depth data, the gathering process is time consuming (Matthews and Ross, 2010). Interviewing skills on the researcher's part is also needed to prevent the discussion from going off topic or not flowing at all. In this case, considering the researcher's lack of experience, structured or semi-structured interviews might be used to overcome this. Furthermore, there are ethical concerns which must be considered such as confidentiality, sensitive topics, conflict of interests, and so on (Valentine, 1997).

Interviews are increasingly used in researches in many areas. In order to gain more in-depth knowledge in this research, this method will be applied by the researcher to answer the question posed.

3.3.2(1): Steps in Conducting Interviews

These suggestions are designed to provide the researcher with the tools needed to conduct a well constructed, professional interview with their participants. Some of the most common information found within the literature relating to interviews, according to Creswell (2007) are as below:

I. Preparation for the Interview:

This process can help make or break the process and can either alleviate or exacerbate the problematic circumstances that could potentially occur once the research is implemented. McNamara (2009) suggests the importance of the preparation stage in order to maintain an unambiguous focus as to how the interviews will be erected in order to provide maximum benefit to the proposed research study. Along these lines Chenail (2011) provides a number of pre-interview exercises researchers can use to improve their instrumentality and address potential biases. McNamara (2009) applies eight principles to the preparation stage of interviewing which includes the following ingredients:

- choose a setting with little distraction
- explain the purpose of the interview
- address terms of confidentiality
- explain the format of the interview
- indicate how long the interview usually takes
- tell them how to get in touch with you later if they want to
- ask them if they have any questions before you both get started with the interview
- don't count on your memory to recall their answers

II. Selecting Participants

Creswell (2018) discusses the importance of selecting the appropriate candidates for interviews. He asserts that the researcher should utilise one of the various types of sampling strategies such as criterion based sampling or critical case sampling in order to obtain qualified candidates that will provide the most credible information to the study. Creswell also suggests the importance of acquiring participants who will be willing to openly and honestly share information or “their story”. It might be easier to conduct the interviews with participants in a comfortable environment where the participants do not feel restricted or uncomfortable to share information.

III. Pilot Testing

Another important element to the interview preparation is the implementation of a pilot test. The pilot test will assist the research in determining if there are flaws, l imitations, or other weaknesses within the interview design and will allow him or her to make necessary revisions prior to the implementation of the study (Kvale, 2007). A pilot test should be conducted with participants that have similar interests as those that will participate in the implemented study. The pilot test will also assist the researchers with the refinement of research questions, which will be discussed in the next section.

IV. Constructing Effective Research Questions

Creating effective research questions for the interview process is one of the most crucial components to interview design. Researchers desiring to conduct such an investigation should be careful that each of the questions will allow the examiner to dig dip into the experiences and/or knowledge of the participants in order to gain maximum data from the interviews. McNamara (2009) suggests several recommendations for creating effective research questions for interviews which includes the following elements: (a) wording should be open-ended (respondents should be able to choose their own terms when answering questions); (b) questions should be as neutral as possible; (c) questions should be asked one at a time; (d) questions should be worded clearly; and (e) be careful asking "why" questions.

V. Follow-up Questions

Creswell (2018) also makes the suggestion of being flexible with research questions being constructed. He makes the assertion that respondents in an interview will not necessarily answer the question being asked by the researcher and, in fact, may answer a question that is asked in another question later in the interview. Creswell believes that the researcher must construct questions in such a manner to keep participants on focus with their responses to the questions. In addition, the researcher must be prepared with follow-up questions or prompts in order to ensure that they obtain optimal responses from participants.

VI. Implementation of Interviews

As with other sections of interview design, McNamara (2009) makes some excellent recommendations for the implementation stage of the interview process. He includes the following tips for interview implementation:

- occasionally verify the audio recorder is working
- ask one question at a time
- attempt to remain as neutral as possible
- encourage responses with occasional nods of the head, "uh huh"s, etc.
- be careful about the appearance when note taking
- provide transition between major topics, e.g., "we've been talking about (some topic) and now I'd like to move on to (another topic);"
- don't lose control of the interview as this can occur when respondents stray to another topic, take so long to answer a question that times begins to run out, or even begin asking questions to the interviewer

VII. Interpreting Data

The final constituent in the interview design process is that of interpreting the data that was gathered during the interview process. During this phase, the researcher must make “sense” out of what was just uncovered and compile the data into sections or groups of information, also known as themes or codes (Creswell, 2018). These themes or codes are consistent phrases, expressions, or ideas that were common among research participants (Kvale, 2007). Many researchers suggest the need to employ a third party consultant who can review codes or themes in order to determine the quality and effectiveness based on their evaluation of the interview transcripts (Creswell, 2018). This helps alleviate researcher biases or potentially eliminate where over-analysing of data has occurred. Many researchers may choose to employ an iterative review process where a committee of non-participating researchers can provide constructive feedback and suggestions to the researcher primarily involved with the study

3.3.3: Audio Recording

Traditionally, interviewers have physically written or typed the responses provided. However, electronic recording is increasingly being utilised and it is believed to be more accurate, effective and transparent method of capturing information than traditional methods (CSR- Centre for Strategy Research Boston, 2006).

One of the primary benefits of recording an interview either audio or visual is that it allows the interviewer to concentrate on the interview rather than writing notes, which can act as a distraction to both the interviewee and the person asking the questions. This in turn often leads to a disjointed interview where key information can be overlooked, forgotten or missed (CSR- Centre for Strategy Research Boston, 2006).

Furthermore, studies have shown that recorded interviews allow the interviewee and interviewer to develop and foster a better relationship and rapport during the proceedings, which led to the interviewee disclosing more detailed and in-depth information (Mary, 2008). This finding is further supported by a 2003 study, which noted that, during recorded interviews, the body language, interview methods and behaviour of law enforcement officers improved and became more professional and cordial (Sullivan, 2010). It was observed that officers avoided threatening and antagonising behaviours and built a better rapport with interviewees, which, in turn, produced less confrontation and more productive interviews (Sullivan, 2010).

In addition to fostering a more positive, interactive and informative dialogue with interviewees, audio and visual recording also improves the quality and transparency of the information provided. With note taking, there is often an increased risk of the interviewer being more subjective or misinterpreting the information provided to him or her by the interviewee (Sullivan, 2010). An audio or visual record, therefore, provides an unbiased and true recitation of the interview, which provides greater context and a holistic picture of the situation (Sullivan, 2010).

Moreover, rather than simply relying on notes taken, the interviewer has the ability to review and replay the interview at a later date and potentially identify key information that may have been missed during the interview (Sullivan, 2010).

Recording interviews also offers a distinct advantage over simple note taking from a management and training perspective, as it allows for the interviewer's performance to be evaluated and used for further training (Sullivan, 2010). This then allows for the provision of feedback, improving the interviewer's technique and ensuring more informative and productive interviews in the future.

In summary, audio recording offers many benefits over the other methods, including accuracy, level of detail and the protection of the interests of all involved

3.3.4: Case Studies

There are multiple definitions and understandings of the case study. According to Bromley (1990), it is a "systematic inquiry into an event or a set of related events which aims to describe and explain the phenomenon of interest." The unit of analysis can vary from an individual to a corporation. While there is utility in applying this method retrospectively, it is most often used prospectively.

The terms "case study", "case review" and "case report" are used loosely in the scientific and professional literature (Zucker, 2009). The key features of a "case study" are its scientific credentials and its evidence base for professional applications. A "case review" might emphasise a critical reappraisal of a case. A "case report" might refer to a summary of a case or to the document reporting a case, as in case law or medicine. Case studies of individuals in health care research, for instance, often involve in-depth interviews with participants and key informants, review of the medical records, observation, and excerpts from patients' personal writings and diaries. Case studies in nursing, for example, have a practical function in that they can be immediately applicable to the participant's diagnosis or treatment.

Case study research excels at bringing researchers to an understanding of a complex issue or object and can extend experience or add strength to what is already known through previous research (Soy, 1997). Case studies emphasise detailed contextual analysis of a limited number of events or conditions and their relationship. Researchers have used the case study research method for many years across a variety of disciplines. Social scientists, in particular, have made wide use if this qualitative research method to examine contemporary real-life situations and provide the basis for the application of ideas and extension methods. Researcher Robert K. Yin (1984) defines the case study research method as an empirical inquiry that investigates a contemporary phenomenon within its real-life context, when the boundaries between phenomenon and context are not clearly evident, and in which multiple sources of evidence are used.

Nonetheless, case studies as a research method or strategy have traditionally been viewed as lacking rigor and objectivity when compared with other social research methods. This is one of the major reasons for being extra careful to articulate research design, and implementation. On the other hand, despite this scepticism about case studies, they are widely used because they may offer insights that might not be achieved with other approaches. Case studies have often been viewed as a useful tool for the preliminary, exploratory stage of a research project, as a basis for the development of the 'more structured' tools that are necessary in surveys and experiments. For example, Eisenhardt (1989) says that case studies are:

"Particularly well suited to new research areas or research areas for which existing theory seems inadequate. This type of work is highly complementary to incremental theory building from normal science research. The former is useful in early stages of research on a topic or when a fresh perspective is needed, whilst the latter is useful in later stages of knowledge"

Due to the limited resources of cases required in conducting a proper observation, this method is not practical and will not be selected for this study.

3.3.5: NVivo Software

NVivo, a Qualitative Data Analysis (QDA) computer software package produced by QSR International, has many advantages and may significantly improve the quality of research. The software reduces a great number of manual tasks and gives the researcher more time to discover tendencies, recognize themes and derive conclusions (Wong, 2008). In addition, NVivo is considered as an ideal technique for researchers working in a team since it facilitates combining the work of individuals to come up with one project together.

Bazeley (2007) mentions five important tasks in which NVivo ease analysis of qualitative data. These tasks include:

- Manage data: by organising a number of muddled data documents. That includes interview transcripts, surveys, notes of observations and published documents.
- Manage ideas: in order to understand the conceptual and theoretical issues generated in the course of the study.
- Query data: by posing several questions of the data and utilising the software in answering these queries. "Results of queries are saved to allow further interrogation and so querying or searching becomes part of an ongoing enquiry process" (Bazeley, 2007).
- Modelling visually: by creating graphs to demonstrate the relationships between the conceptual and theoretical data.
-Reporting: by utilising the data collected and the result found to formulate transcript reports about the study conducted.

3.3.5(1): Steps in Applying NVivo Software

The procedures of employing Nvivo software program are illustrated in Figure 3.1 below.

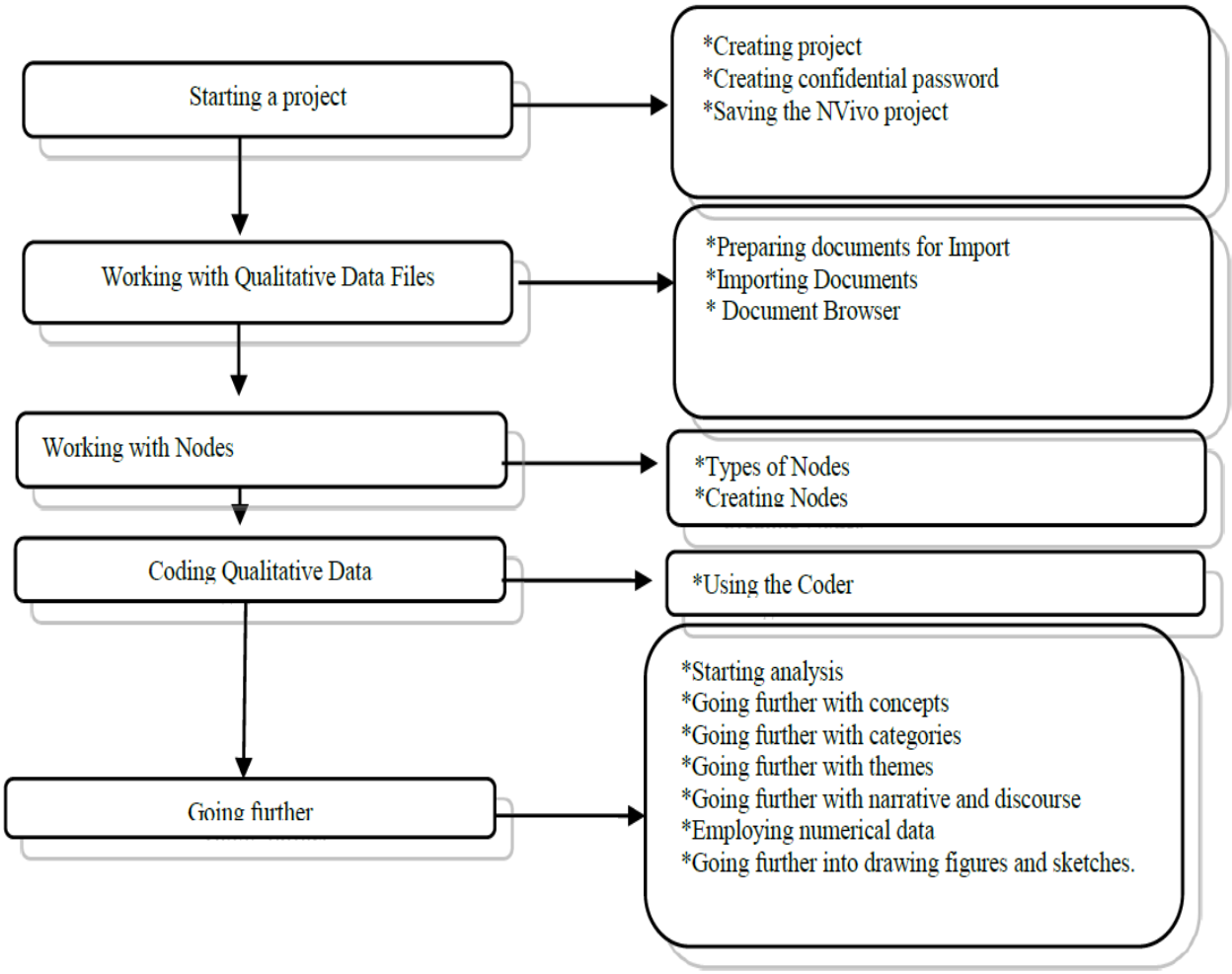

Figure 3.1: Procedure Followed in Applying NVivo Software
Source: Bazeley (2007)

The first step in this stage is to create a project comprised of all the documents, coding data and associated information that can assist during the analysis process. Seeking to restrict access to the data recorded the researcher may create a confidential password in the project (Bazeley, 2007).

Secondly, the researcher records interviews digitally to capture all the details revealed by the interviewee. It is recommended to store the electronic sound files under a name of each interviewee. These interviews have to be transcribed and stored in a

word processing application in order to make them text based. The next step is to import the files which the researcher intends to analyse. This procedure is basically done via steering to the location where the file has been stored, then picking the appropriate file extension (Bazeley, 2007). NVivo automatically imports the selected documents into the application. Also using the Document Browser allows the researcher to recognise all of the text in the imported document.

Next is working with nodes, the function of nodes is to store a place in NVivo for references to code text. The two common nodes available are tree nodes and free nodes, contain the all known information about a particular concept or category (Bazeley, 2007).

Subsequently, to code a chunk of data in a project document under a particular node, the researcher can highlight the text via the mouse and pull the highlighted text to the identified node. When the cursor is located over the node, the highlighted text changes colour and the relevant node linked with the text shows up on the Coding Stripe to the right of the browser. That allows assigning multiple codes to the same chunk of the text as well by going through the same process (Bazeley, 2007).

Lastly, in stage of "going further", the researcher can go forward to analyse the data. Bazeley (2007) suggests that further than just code and retrieve in the context of those basic principles of continues analysis, creativity tempered by rigor and care, through documentation and flexibility along with disciplinary awareness. At this stage, the researcher should focus on the techniques for utilising the available tools productively and analytically. These techniques facilitate the development of the concepts, categories and themes, as well as going further with the narrative and discourse pertaining to the study. Also, the researcher can employ several numerical data obtained during the study conducted. These numerical data can sometimes be demonstrated as figures and sketches to facilitate the reading of the findings.

3.4: Potential Models for Integrated Framework

3.4.1: Strategic Objective Model

The supply chain strategy is part of the company's overall business strategy, but unlike most company strategies, it requires the coordination and commitment of many different firms (Mentzer, Stank and Myers, 2007). Ambe and Badenhorst-Weiss (2011) suggest that developing a strategic SCM framework involves three steps: understanding the market and customer demand; defining the company's core competencies; and choosing the most appropriate strategy as shown in Figure 3.2.

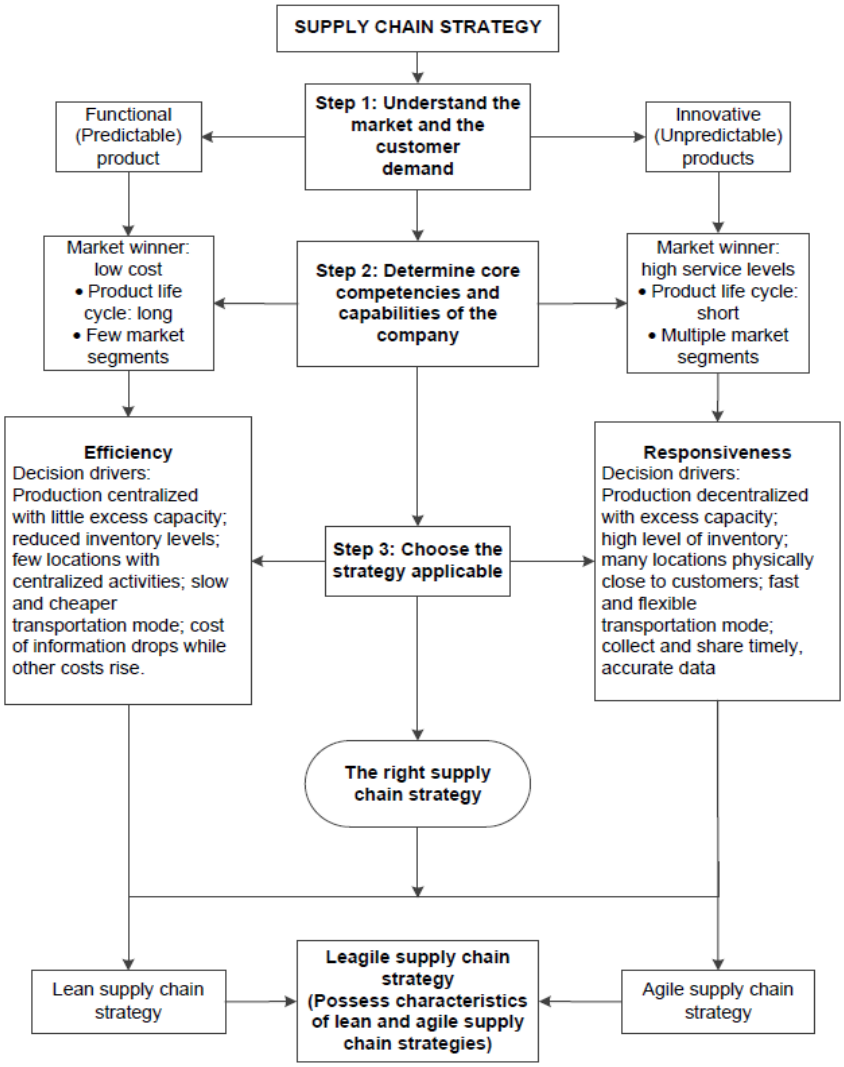

Figure 3.2: Development of Strategic Supply Chain Framework

Source: Ambe and Badenhorst-Weiss, 2011

- ***Step 1: Understand the market and the nature of customer demand:*** Six key market variables determine the attributes of a supply chain structure: volume, time, variety, service level required, price and rate of change, innovation and new product development (Zokaei and Hines, 2007). If it to choose the right type of supply chain strategy, an organisation must understand both its customers and supply chain uncertainty (Chopra and Meindl, 2018). Supply chain uncertainty is strongly affected by product life cycle (Fawcett et al., 2007); new products have higher supply uncertainty because design and production processes are still evolving, whereas mature products tend to have less supply uncertainty (Chopra and Meindl, 2018). Different market requirements demand different kinds of supply chain. Choosing the wrong strategy for a product may lead to mismatch in the supply chain (Lee, 2002). Mismatch is the root cause of supply chain problems (Fisher, 1997).

- ***Step 2: Define core competencies and capabilities of a supply chain:*** Supply chains have different characteristics, but all supply chains have two important attributes: cost and service (Christopher and Holweg, 2011). Zokaei and Hines (2007)) and Chopra and Meindl (2018) explain that supply chain capabilities include the ability to respond to a wide range of demanded quantities, meet short lead times, handle a large variety of products, build highly innovative products, meet a high service level and handle supply uncertainty. Where products are predictable, the ability to produce these products at low cost becomes the dominant consideration. The capabilities of a supply chain are determined by the trade-off its participants are prepared to make between responsiveness and cost (Christopher and Holweg, 2011). The so-called efficient frontier (Chopra and Meindl, 2018) marks the lowest possible cost that can be achieved for a given level of responsiveness (Chopra and Meindl, 2018).

- ***Step 3: Choose the applicable strategy:*** The level of responsiveness that can be achieved in the supply chain depends upon the level of cost incurred; raising costs lowers efficiency but increases responsiveness. To achieve complete strategic fit, an organisation must ensure that all its functions maintain consistent strategies that support the competitive strategy. All sub-strategies within the supply chain, such as manufacturing, inventory and purchasing, need to be consistent with the supply chain level of responsiveness to reduce uncertainties and cost while satisfying the end customer's needs (Zokaei and Hines, 2007).

  A supply chain can be lean (efficient), agile (responsive) or a combination of the two (leagile) (Nel and Badenhorst-Weiss, 2011). An organisation can achieve a competitive advantage by strategically employing a leagile supply chain model that minimises cost and maintains stability while still being flexible and

responsive to customer demand (Datta, 2017). This model will allow the organisation to compete on innovation, cost, service and quality (Datta, 2017).

This model will be applied in this study as it will allow the researcher to understand and decide the suitable strategise to be implemented in order to fulfil customers requirements.

3.4.2: Good Distribution Practise (GDP) Model

Good Distribution Practice (GDP) refers to the regulatory guidelines governing the wholesale distribution of medicinal products to ensure their quality and integrity is maintained throughout the entire supply chain, from the early delivery of raw materials to the manufacturing plants, to the final shipment of finished drugs to the end user. Good Distribution Practice extends beyond the distribution of the finished product and includes the sourcing, storage and transportation of APIs and other ingredients prior to manufacturing.

The implementation of Good Distribution Practice is of paramount importance to patient safety as the global supply chain is becoming complex and fragmented. The WHO (2010) defines Good Distribution Practice as "*an essential tool to secure the distribution system from counterfeits, unapproved, illegally imported, stolen, counterfeit, substandard, adulterated, and/or misbranded pharmaceutical products".*

GDP is regulated and controlled by numerous national and supranational guidelines. It is reliant on a series of inter-connecting quality systems operated by wholesalers or distributors of pharmaceutical drug products. The systems ensure the following: distributed products are authorised in accordance with the relevant legislation; appropriate storage conditions are maintained at all times, including movement of goods between various parts of the distribution network; contamination by other products is avoided; an appropriate turnover of stock takes place; and that products throughout the distribution chain are stored in safe and secure areas. In addition, to help combat counterfeiting, there should be a system to enable faulty products to be rapidly found and recalled. In parallel, an effective quality system is required to ensure that the right product is delivered to the right location within a designated time period.

The main challenges in implementing GDP includes the GDP regulations are not universally understood by international manufacturing companies (Kiyohito et al., 2009). For instance, Asian countries such as Thailand, Malaysia, and Indonesia may not have fully implemented the GDP processes as manufacturers or transporters from these countries may not be able to comply with the stated regulations, or there could be missing agreements between parties (Kiyohito et al., 2009).

Ministry of Health (MOH) in Malaysia emphasised that it is compulsory for all pharmaceutical companies to implement and GDP certified. In order to gain more in-depth knowledge of this model, this method will be applied by the researcher.

3.4.3: ISO 13845 Medical Devices- Quality Management System

ISO 13485 is a stand-alone Quality Management System (QMS) standard, derived from the internationally recognised and accepted ISO 9000 quality management standard series. ISO 13485 adapts the ISO 9000 process-based model for a regulated medical device manufacturing environment. While ISO 13485 is based on the ISO 9001 process model concepts of "Plan, Do, Check, Act" it is designed for regulatory compliance. It is more prescriptive in nature and requires a more thoroughly documented quality management system (ISO, 2016).

ISO 13485 was introduced to support medical device manufacturers in designing quality management systems that establish and maintain the effectiveness of their processes. It ensures the consistent design, development, production, installation, and delivery of medical devices that are safe for their intended purpose.

Oriel (2016) stated one of the challenges faced while implementing ISO13845 is making implicit requirements explicit. For instance, handling of customer feedback, handling of corrective actions and preventive actions, determination of personnel competency requirements, and many more requirements implicitly involved risk-based decision making as part of relevant activities conducted to meet those requirements. ISO 13485:2016 now explicitly calls for risk-based decision making and clearly expects risk to be considered for product performance (safety and effectiveness) and compliance with regulatory requirements.

Due to the indistinct requirements as well as the low demand for this certification, this method will not be considered in this research.

3.4.4: Total Quality Management (TQM)

Sadikoglu and Oclay (2014) mentioned that global competition requires greater levels of quality accomplishments by corporations. Total quality management is the forerunner of many quality management frameworks, such as Lean, ISO, and Six Sigma. Hallam, Valerdi and Contreras (2018) stated that, if a company disregards this methods, it is probably not going to succeed in current international rivalry for greater quality, quicker delivery and lower costs. TQM is an efficient plan of action that surround

a scope of instruments and techniques for the elimination of waste inside the manufacturing framework that comprises at all stages of supply chain.

The benefits of TQM originate in the elimination of waste at all stages. Seven core wastes were identified – faulty product, lead time, handling waste, overproduction, movement, stock, and transportation (Arunagiri and Gnanavelbabu 2016). Manufacturing facilities are structured to reduce the number of facilities movement, and a single-piece flow minimise the lead time between the processes in production. Besides, TQM also improved response time to customer demand.

The challenges of implementing TQM is change management (Ismail, 2012). TQM needed an organisation to redefine its focus on continuous process improvement and customer satisfaction. TQM also requires long-term management commitment and ongoing employee engagement. Denning (2018) believes that changing the culture of an organisation is a formidable challenge because culture incorporates a range of interrelated values, processes, attitudes, communication practices, roles, goals and assumptions, and is often resisted by employees who believe this is a threat to them.

TQM are widely practised by many organisations and has proven to improve many elements of the supply chain. Therefore, this model will be applied in this research.

3.4.5: Quality Risk Management

Quality Risk Management (QMR) is defined as a method for the assessment, control, communication and review of risks to the quality of the drug (medicinal) product through the product lifecycle where decisions can occur at any point in the process (ICH Q9, 2003).

All products and all processes have an inherent element of risk (Griffith, 2004). In an organisation that is intending to apply an effective quality risk management approach, a clear definition of what is considered ''risk'' should be agreed upon because of the too many stakeholders in the pharmaceutical industry and their corresponding diverse interests (ICH Q9, 2003).

The Food and Drug Administration (FDA) has noticed that it needs to reorganise its procedures and processes to merge the use of risk management programs (RMP) within the agency and within the industries it regulates. Consequently, the FDA has started publishing position papers and guidelines on what it expects to see in an RMP (Griffith, 2004).

Risk management plans should be used to identify risk (Griffith 2004). An effective QRM approach can further ensure the high quality of the drug product to the patient by identify and control potential quality issues during development and manufacturing. Use of QRM can improve the decision making if a quality problem arises. Effective QRM implementation can facilitate better and well versed decisions which can provide regulators with greater assurance of a company's ability to deal with possible risks (ICH Q9, 2010). Table 3.1 shows the common risk management tools that are implemented by firms from various industry.

Risk Management Tool	Description/Attributes	Potential applications
Basic Tools		
- Diagram analysis - Flowcharts - Check sheets - Process mapping - Cause/effect diagrams	Simple techniques that are commonly used to gather and organise data, structure risk management processes and facilitate decision making	Compilation of observations, trends or other empirical information to support a variety of less complex deviations, complaints, defaults or other circumstances
Risk ranking and filtering	- Method to compare and rank risks - Typically involves evaluation of multiple diverse quantitative and qualitative factors for each risk, and weighting factors and risk scores	- Prioritise operating areas or sites for audit/assessment - Useful for situations when the risks and underlying consequences are diverse and difficult to compare using a single tool
Advanced Tools		

Fault Tree Analysis (FTA)	- Method used to identify all root causes of an assumed failure or problem - Used to evaluate system or sub-system failures one at a time, but can combine multiple causes of failure by identifying causal chains - Relies heavily on full process understanding to identify causal factors	- Investigate product complaints - Evaluate deviations
Hazard Operability Analysis (HAZOP)	- Tool assumes that risk events are caused by deviations from the design and operating intentions - Uses a systematic technique to help identify potential deviations from normal use or design intentions	- Access manufacturing processes, facilities and equipment - Commonly used to evaluate process safety hazards
Hazards Analysis and Critical Control Points (HACCP)	- Identify and implement process controls that consistently and effectively prevent hazard conditions from occurring - Bottom-up approach that considers how to prevent hazards from occurring and/or propagating - Emphasises strength of preventative controls rather than ability to detect - Assumes comprehensive understanding of the process and that critical process parameters (CPPs) have been defined prior to initiating the assessment. Tool ensures that CPPs will be met.	- Better for preventative applications rather than reactive - Great precursor or complement to process validation - Assessment of the efficacy of CPPs and the ability to consistently execute them for any process

Failure Modes Effects Analysis (FMEA)	- Assesses potential failure modes for processes and the probable effect on outcomes and/or product performance - Once failure modes are known, risk reduction actions can be applied to eliminate, reduce, or control potential failures - Highly dependent upon strong understanding of product, process and/or facility under evaluation - Output is a relative "risk score" for each failure mode	Evaluate equipment and facilities; analyse a manufacturing process to identify high risk steps and/or critical parameters

Table 3.1: Common Risk Management Tools

Source: Vijayakumar Reddy et al, 2014

As mentioned above, risk plays an important role in the pharmaceutical industry. Thus, this model will be applied in this research.

3.4.6: Supply Chain Network Optimisation Model

Supply Chain Network design is a process to determine the unique network configuration for the supply chain that offers the lowest total cost/ highest total profit considering operational and financial risk while achieving targeted Service Levels (Shukla and Thomas, 2012). Figure 3.3 below provide an illustration of how network design implementation helps in finalising Zone of indifference/Range of indifference where supply chain cost is minimal basis various tradeoffs involved. In supply chain network design exercise, performance simulation can be created to validate the feasibility of supply chain strategies.

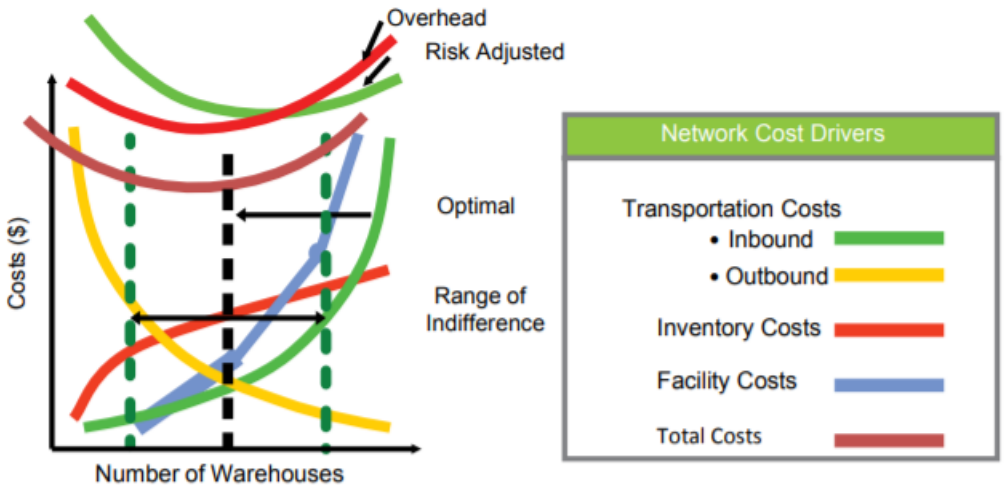

Figure 3.3: Finalising zone/range with minimum cost

Source: Shukla and Thomas, 2012

In the context "supply chain" implies that there is only one player at each stage of the chain, but in practice, manufacturers may source materials from a range of suppliers and work with several different distributors. In other words, most supply chains are more accurately described as networks (Chopra and Meindl, 2018). A supply chain network is made up of suppliers, manufacturers, distribution centres and retailers (Shapiro, 2001), it comprises a series of processes and stages, which starts with the material/information supplier and ends with the customer. Mid-stage participants play a dual role as the customer of the next stage and supplier of the previous stage.

Wang (2009) claims that supply chain network design is one of the company's biggest strategic tasks and central to the long-term efficiency of the whole supply chain. It involves working out the optimal number, capacity, layout and type of factories, warehouses and distribution centres required, setting up distribution channels and calculating the quantity of materials which will be consumed in the production process, the quantity of materials which will be transported from suppliers to customers, and the quantity of materials which will be produced. Figure 3.4 shows the different stages that make up a typical supply chain.

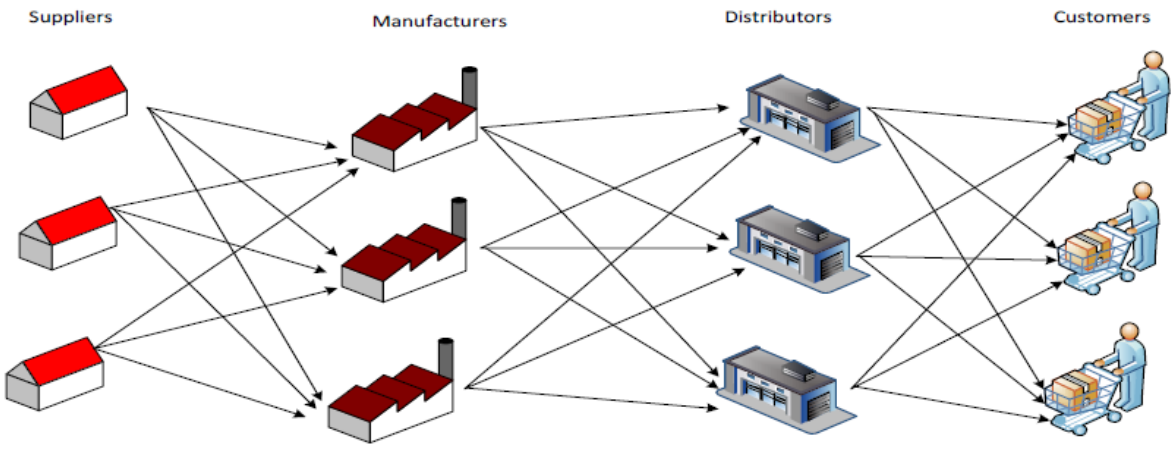

Figure 3.4: Multi-echelon Supply Chain Network

Source: Chopra & Meindl, 2018

Hence, with the implementation of Supply Chain Network Optimisation, organisations are "narrowing their choices to the very best when there are virtually innumerable feasible options and comparing them is difficult" (Institute of Operations Management and Management Science). An important component of this model is determining how to achieve an effective design, given a performance measure or a set of performance measures (Beamon, 1998). Optimisation models answer questions about plant location, product mix, choice of technology, distribution methods, inventory planning and control, choice of suppliers, configuration and reverse logistics (El-Aal et al., 2008). Thus, this model will be applied in this study.

3.4.7: Key Performance Indicator (KPI) Model

A key performance indicator *(KPI)* is a quantifiable measure a company uses to determine how well it's meeting its operational and strategic goals (Parmenter, 2015). Different businesses have different KPIs depending on their individual performance criteria or priorities. That said, the indicators usually follow industry-wide standards.

The three main characteristics of KPIs are as follows:

- **Quantitative-** KPIs can be presented in the form of numbers. For example, delivery in full, on time (DIFOT) rate can be used to measure well the company fulfil orders and meet customer expectations (Marr,2014).
- **Practical-** KPIs integrate well with existing company processes. For example, response time. Reducing response times from generated inbound leads is vital

for maximising return on marketing investment. This indicator ensures that response time are optimised and is a great indicator where reduction means revenue (Marr, 2014).

- **Actionable-** KPIs can be put into practical application to effect the desired change. For example, conversion rate that looks at the success rate of turning leads or potential customers into actual customers. Understanding the conversion rate will give companies an insight into how well their marketing and sales strategies and their operations are aligned.

In order to have an accurate and reliable data, a key performance indicator must be based on legitimate data and must provide context that echoes business objectives. KPIs must also be defined in such a way that external factors, beyond the control of a company, cannot interfere with them (Marr, 2014). Another key issue is that KPIs should have a specific time frame that is divided into key checkpoints for accuracy. This model will be adopted in this study to measures the efficiency and effectiveness of the framework.

3.5: Conclusion

To summarise, this research will apply the interview method to analyse the data collected from various companies. For the development of an integrated framework for supply chain design, Strategic Fit concept will be applied to explain the strategic role and objective of the framework. Then, Good Distribution Practise (GDP) model will be used to clarify the supply chain specifications and requirements, Total Quality Management (TQM) and Quality Risk Management to establish all processes that are designed encompass quality assurance and continuous improvements. Also, Supply Chain Network Optimisation model will be applied to ensure the optimal distribution pattern has been achieved, and lastly performance indicator model to measure efficiency and effectiveness. The proposed integrated framework will be further discussed in Chapter 4.

Chapter 4: Design & Development

4.1: Introduction

This chapter analyses the development of an integrated framework for pharmacuetical supply chain. To present the proposed framework, the theoretical fundamentals related to its parts are introduced; the researcher will discuss Strategic Fit concept to explain the strategic role and objective of the framework, Good Distribution Practise (GDP) model to clarify the supply chain specifications and requirements, Total Quality Management (TQM) and Quality Risk Management to establish all processes that are designed encompass quality assurance and continuous improvements, Supply Chain Network Optimisation model to ensure the optimal distribution pattern has been achieved, and lastly performance indicator model to measure efficiency and effectiveness. The proposed framework which defines the proposed process framework composed of six different models, each of which performs a defined role, as shown in Figure 4.1 and Figure 4.2

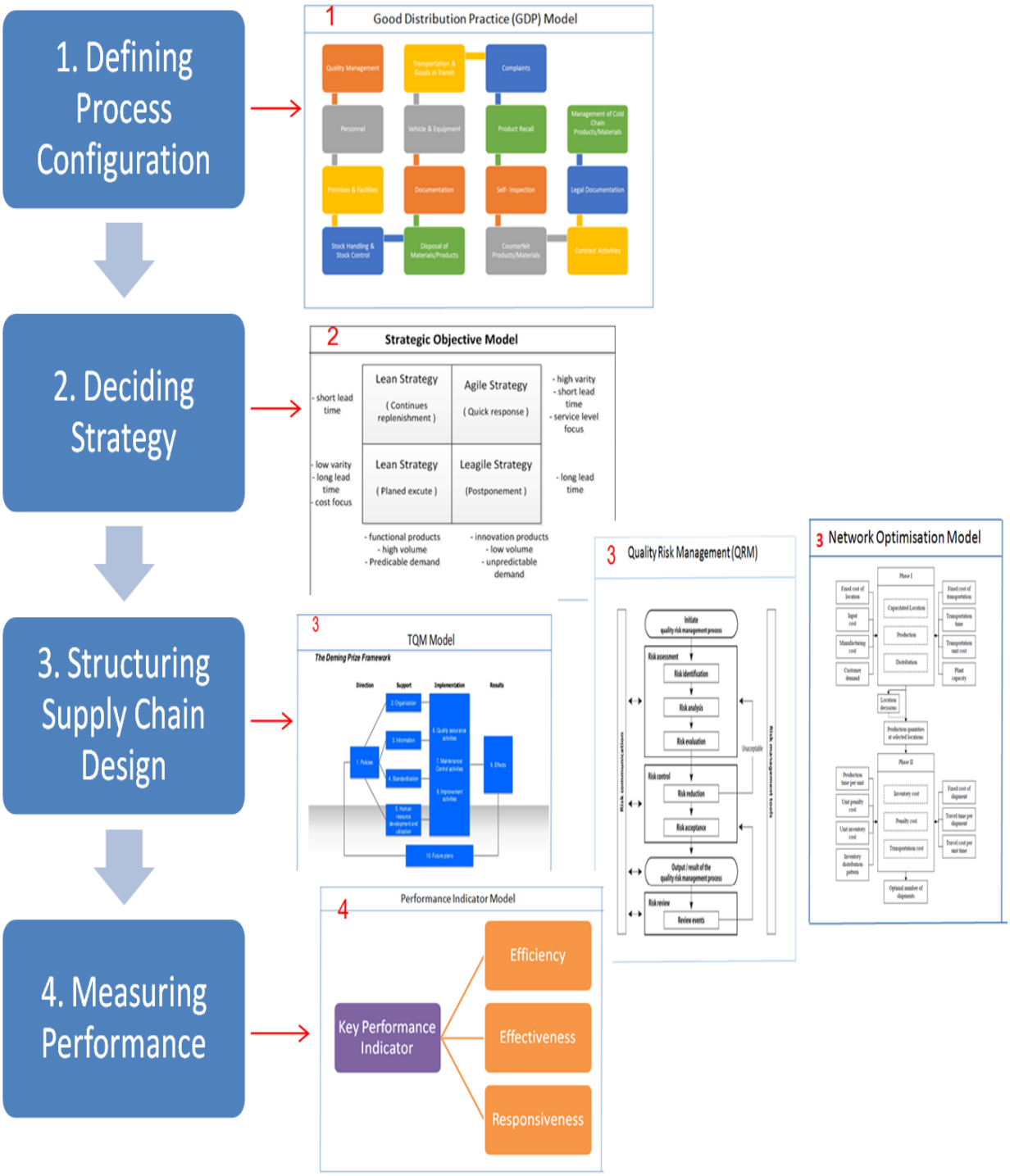

Figure 4.1: Integrated Framework

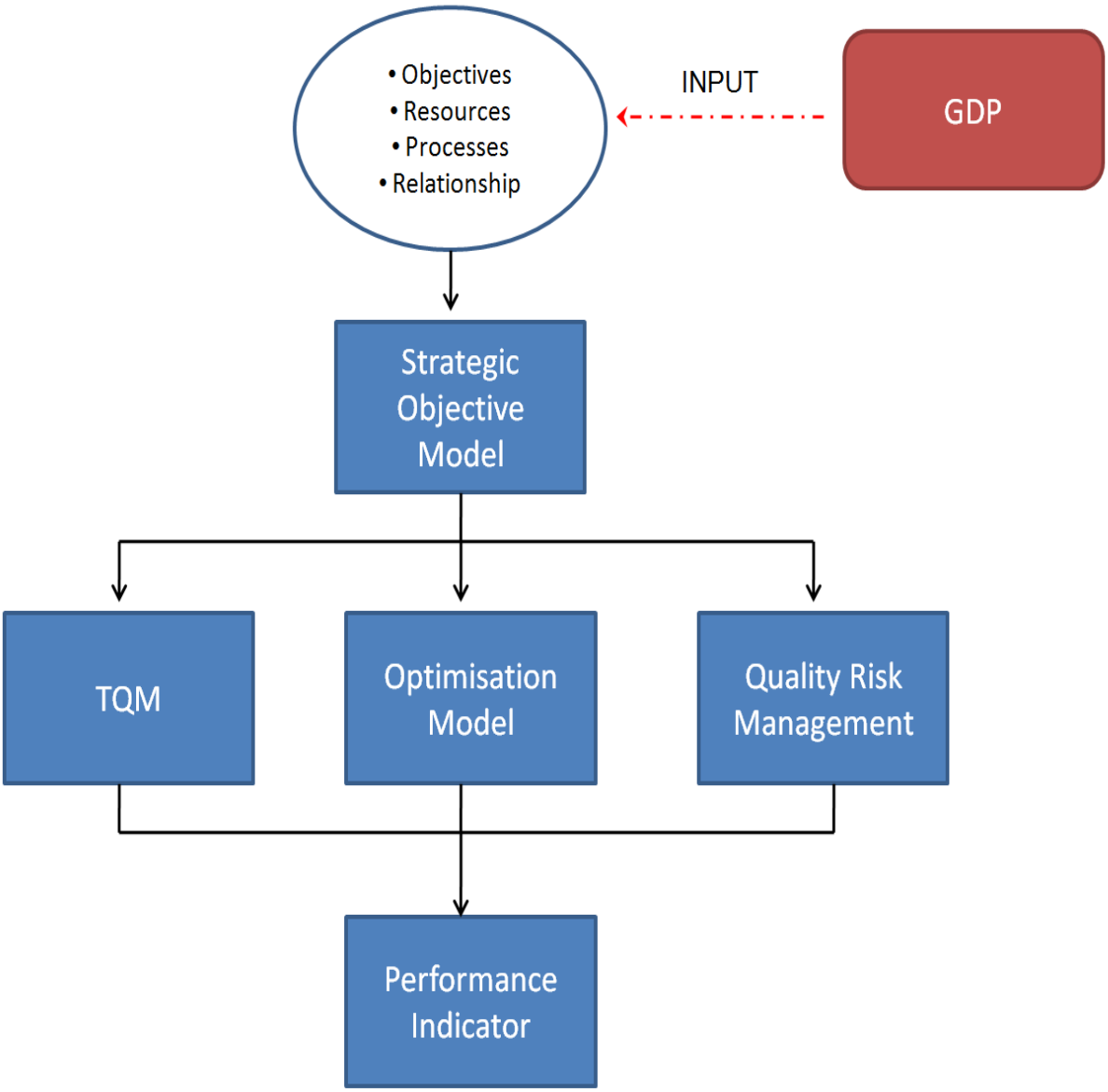

Figure 4.2: Proposed Process Framework

4.2: Development of Supply Chain Management Frameworks:

Although the term "framework" is frequently used in the supply chain management literature, there seems to be a lack of consensus about what a framework actually is. Since this chapter presents a proposed framework, it is essential to discuss the general concept and how they are developed.

A framework structure which the researcher believes can best explain the natural progression of the phenomenon to be studied (Camp, 2001). It is linked with the concepts, empirical research and important theories used in promoting and systemising the knowledge supported by the researcher (Grant & Osanloo, 2014). Very often, the terms model and framework are used interchangeably, but for the purpose of this research, the two terms will be regarded as distinct concepts. The framework is made up of six models; these answer “what is” questions, while the overall framework answers “how to” questions. Soni and Kodali (2013) suggest that a framework should depict the complete structure of relationships between elements of the system under study (not only to identify the elements that make up the system) describe the steps/stages/sequence of activities that need to be undertaken to achieve the designated purpose; and describe the activities connecting the various elements within the framework.

4.3: Integrated Supply Chain Design

Published literature revealed that there is no standard methodology for designing supply chains; some researchers discuss supply chain design in terms of strategic objectives (e.g. how to design supply chains to be lean, agile or sustainable), others focus on supply chain network design (i.e. the number, location, capacity and operation of different supply chain nodes). Yet. some may still that supply chain design involves identifying product design criteria and evaluating their impact on supply chain configuration (Alfalla-Luque at el, 2013) .

This research took all of these perspectives into account during the design of the proposed framework, as the various functions described are mutually complementary. The aim is, therefore, to develop an integrated framework incorporating the various strategies supply chains can use to achieve their goals along with the process configurations and networks they can employ to implement these strategies.

The strategic fit concept is employed to explain the strategic role of the framework and the supply chain network design concept to illustrate how supply chain networks are structured.

4.3.1 Supply Chain Strategy: Achieving Strategic Fit:

Supply chain management requires the strategic management of the various aspects of the coordination process including information, technology, distribution, products, raw materials, finance and, relationships. Successful companies understand that they cannot compete effectively in all dimensions but know where to focus their energies.

The survival of the supply chain depends on the consistency between customer expectations (what customers want) and SC performance (what the chain is able to deliver). The concept of strategic fit is defined as the need for a company to ensure that its supply chain capabilities enable it to meet the needs of its customers. Evidently, the company must have a clear understanding of what these needs and capabilities are (Chopra and Meindl, 2018).Strategic fit requires the competitive and supply chain strategies of the company to aligned their goals. There are three steps to achieve strategic fit (Chopra and Meindl, 2018); which are explain in the next section.

4.3.1.1. Understanding customer needs

Customer demand can vary in a number of ways, for example, lot quantity may vary from small (e.g. customised or emergency orders) to large planned orders, while response time (the amount of time customers are willing to wait for orders) may be longer for customised products. A company may have to hold a wide range of products to appeal to different customer segments, especially if the business environment is unstable. A high level of product availability usually requires high inventory levels and more detailed and frequent information sharing, which will lead to reduce competitive advantage. On the other hand, customers who expect a high level of service, more product variety and short response times tend to be less sensitive to product price. Customer demands for product innovation tend to vary according to product purpose, with less expectations for functional products compared to consumed products. All of these attributes can be combined in one key metric, i.e.: implied demand uncertainty. Unlike demand uncertainty, which reflects the uncertainty of customer demand for a product, implied demand uncertainty describes the uncertainty only for that portion of demand that the supply chain plans to satisfy based on the attributes the customer desires.

4.3.1.2. Understanding the supply chain's capabilities

Creating strategic fit is about finding the supply chain strategy that best meets the demand a company has targeted, given the uncertainty it faces. If it is to find the balance between responsiveness and efficiency that best supports its competitive strategy, the company must have a clear understanding on the logistics and cross functional drivers that affect SC capability, which are:

- Facilities: where the product is stored or fabricated. Decisions regarding the role, location, capacity and flexibility of facilities have a significant impact on the supply chain's performance.
- Inventory: changing inventory policies can dramatically alter the supply chain's efficiency and responsiveness. High inventory levels, for example, can increase a company's responsiveness and raise service levels but may reduce its efficiency.
- Transportation: the SC may employ multiple combinations of modes and routes, each with its own performance characteristics. This has a direct impact on SC efficiency and responsiveness; faster transport modes, for example, may make the chain more responsive, but as they tend to be more expensive they are also less efficient.
- Information: managers must use the available data and analyses concerning facilities, inventory, transportation, costs, prices and customers to make the supply chain more efficient and responsive. For example, using the information to better match supply and demand will improve responsiveness while keeping production and distribution costs down.
- Sourcing: the choice of who will perform a particular supply chain activity such as production, storage or transportation can have an impact on both responsiveness and efficiency. Opting to source some products from a distant supplier because for a lower cost may improve a company's efficiency but it will also compromise its responsiveness. On the other hand, opting supplier with small or urgent orders is likely to increase transportation costs.
- Pricing: pricing affects the behaviour of the buyer of the goods or services, thus affecting supply chain performance. For example, if a haulage company varies its charges based on the lead time demanded by the customer, it is likely that customers who value efficiency will order early and customers who value responsiveness will be willing to wait and order just before they need the product to be transported.

4.3.1.3. Achieving strategic fit

The goal of strategic fit is to target high responsiveness for a supply chain facing high implied uncertainty, at the same time, achieve high efficiency for a supply chain facing low implied uncertainty. An increase in implied uncertainty from customers and supply sources is best addressed by improving the responsiveness of the supply chain as shown in Figure 4.3 below. To achieve a high level of performance, companies should aim to move their competitive strategy and supply chain strategy towards the zone of strategic fit.

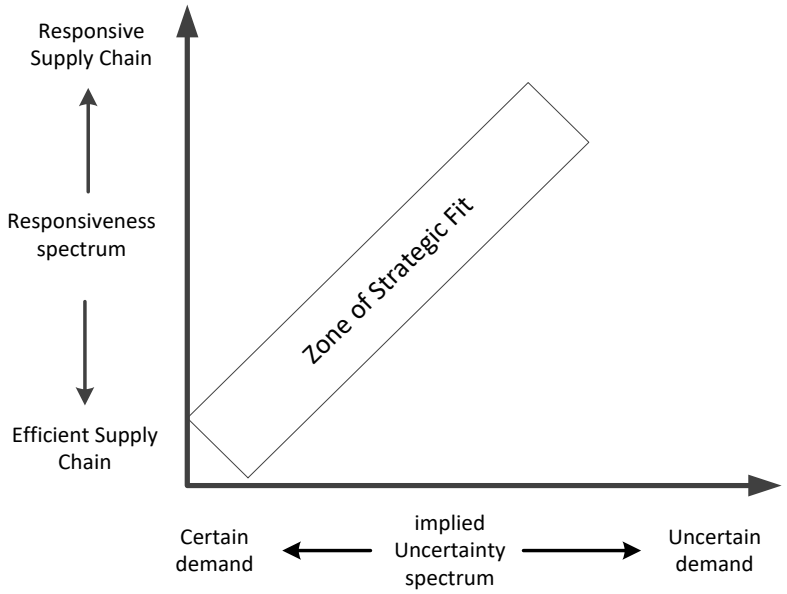

Figure *4.3: Finding the zone of strategic fit*

Source : Chopra & Meindl, 2018

Strategic fit is the optimum combination of efficiency and responsiveness; achieving it requires companies to have a clear understanding of their customers' needs (in terms of demand characteristics and certainty) and the capabilities of the supply chain. Designing the right combination of logistics drivers is vital for achieving responsiveness and efficiency, first in the company and then across the supply chain as a whole. The company must ensure that all its functions are implementing consistent strategies, and that these support the company’s competitive strategy. Figure 4.4 presents the process by which strategic fit is achieved.

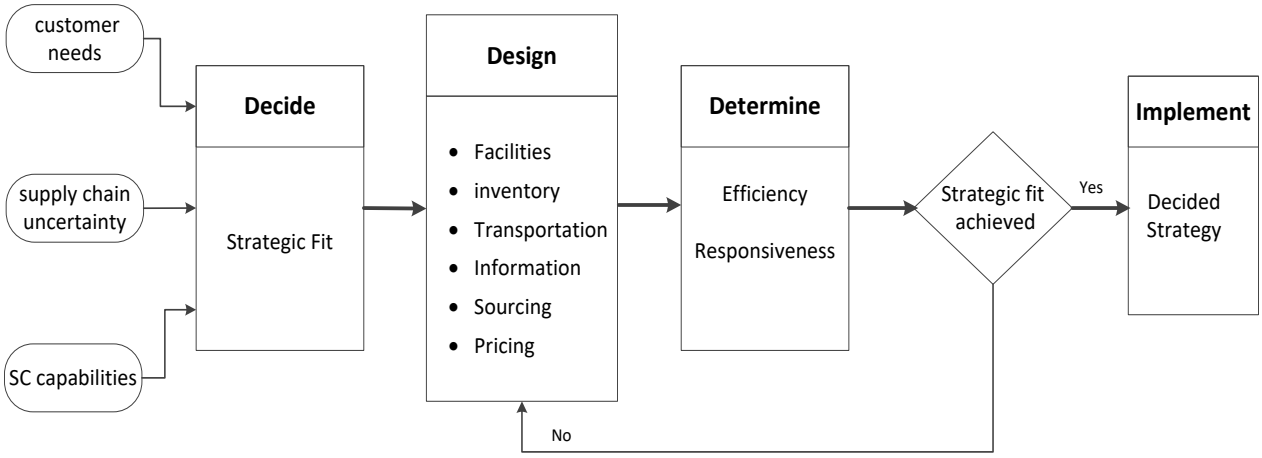

Figure 4.4: Process of Achieving Strategic Fit
Source: Chopra & Meindl, 2018

The strategy of any single supply chain member is closely connected with those of the chain's other upstream and downstream members. A given level of responsiveness can be achieved within the chain by adjusting the respective roles played by each stage. For example, allowing one stage to absorb most of the uncertainty will make it more responsive, at the same time allowing upstream and downstream stages to become more efficient. Table 4.1 represents multi options to design supply chain drivers, different designs can be directed to achieve a specified strategy to eventually reach a desired outcome of the supply chain.

Design of Supply Chain drivers	**Efficient / Responsive Strategy** for supplier, Manufacturer, Distributor, and retailer	**Supply Chain Measurements**	**Supply Chain Aim**
Facilities: • Single / multiple facility location (plant, warehouse, retailer,…) • Flexible / inflexible process. • Product / function focus process. • Low / high investment in facilities. **Inventory:** • Low / high inventory level. • Finished products, parts, or raw materials. **Transportation:** • Slow cheap / fast expensive modes transportation. • Low-cost full track load / higher-cost less than track load quick shipments. • Fixed / flexible numbers and types of tracks. **Information:** • Pull process (rely on information) / Push process. • Low / high level of information sharing. **Sourcing:** • In house / out sourcing. **Pricing:** • Low, steady / High, changeable price.	**Efficient Strategy** • Low costs. • Limited items • Various supply time. • Fixed batch size. **Responsive Strategy** • High costs. • Quick response • Various items • Short & fixed delivery time • Various batch size.	• KPIs of Whole Supply Chain • KPIs of Supply Chain members	Desired outcome

Table 4.1: Types of Supply Chain Strategies & Design

4.4: Strategic Objective Model

The strategic objective model outlines the ways in which different supply chain strategies attempt to meet customer requirements while taking into account demand uncertainty and supply chain capabilities and performance. Several strategic models have been offered in the literature, including those by Ivanov (2010), who proposes a model to support decision making on supply chain strategy, design, tactics and operations; Hwang (2010), focuses on the role of cost leadership, differentiation and focus in shaping overall strategic direction while; Sabet, Yazdani and Leeuw (2017), consider the role of uncertainty and product importance in shaping supply chain strategy. The proposed framework is instead based on Christopher, Peck and Towill's (2006) model, which recommends strategies for different demand characteristics.

4.4.1: Demand characteristics

Since customer demand is the main driver of strategic supply chain decision making, it is essential to understand the features of this demand and how they affect supply chain performance.

Uncertainty

Demand uncertainty focuses on the difficulty of predicting customer demand. Martin Fisher (1997) uses two types of supply chains as examples, namely functional products and innovative products. Functional products are maintenance, repair, and operating (MRO) materials and other commonly purchased items and supplies. These items are characterised by low profit margins, relatively stable demands, and high levels of competition (Lee, 2002). Factory maintenance products, for example, might fall into this category. On the other hand, Innovative products are characterised by short product life cycles, volatile demand, high profit margins, and relatively less competition. Consequently, the sourcing criteria for these products may be more closely aligned with a supplier's quality reputation, delivery speed and flexibility, and communication capabilities. Thus, companies purchasing functional products most likely concentrate on finding a dependable supplier selling at a low price (Lee, 2002). Examples of innovative consumer goods are the Amazon Kindle and GM's Volt. In factory settings, innovative products might be new types of control mechanisms, new software applications, or a new robotics system. Companies have three safety buffers for handling these uncertainties namely, safety inventory, safety capacity and safety time. These buffers are often used to reduce variations in the supply chain and meet customer demand for better service at a lower cost (Hopp and Spearman, 2004).

Lead Time

The order lead time limits the extent to which the supply chain can be order-driven. If a very short order lead time is required, it may be necessary to make-to-stock (MTS) and

provide local warehousing or vendor-managed inventory. In some cases, however, it is not possible to MTS because the product is customised or provided in such wide variety that finished stocks are not economically viable. In this case, the product is made-to-order (MTO) and the manufacturing process may require buffers in terms of excess manufacturing capacity and raw material stocks to support a short order lead time.

Reducing product development lead time means a product can get to market earlier. This has a number of important advantages such as an extended sales life, a higher imposable price, acquiring new customers, and a high market share by building upon the initial lead. Moreover, by reducing overall lead time, product complexity and process set-up times, the production of a particular product can be scheduled more frequently with smaller production batches. This improves the variety of products available to a customer over a given time (Harrison, Van Hoek and Skipworth, 2014).

Variety

Cooper and Griffiths (1994) state that: “Issues of variety and complexity are strongly linked.” An increase in external variety (i.e. in the choice being offered to the end customer) has implications for the level of internal variety that will be required of the SC (Harrison, Van Hoek and Skipworth, 2014). Increasing variety makes logistics operations more complex and so increases both direct and indirect costs, though these may be mitigated to some degree by redesigning systems. Ideally, the variety should be increased only when it adds value.

Variability

Where the demand for a product is stable and significant, SC members may be able to rely on a small supply base to provide a high volume of standard ship-to-stock components and materials (Gill, Lopus and Camelon, 2008).

These high volumes can be leveraged to reduce ordering frequency, allowing a more efficient operation in which inventory turns are high and there is little exposure to excess and obsolete inventory. However, if customer demand is volatile, for example because the product is specialised, a low-volume approach is more sensible. Supply chain members who are forced to rely on a wide range of suppliers, each producing unique components, are particularly exposed to the risk of excess or obsolete inventory.

4.4.2 Suggested Strategies

Birhanu, Lanka and Rao (2014) argue that providing the right degree of responsiveness and efficiency simultaneously is difficult, since increased responsiveness is generally perceived to come at the expense of efficiency, and vice

versa. The strategic objective model presents four SC strategies, allowing managers to choose the option that is best suited to the combination of supply/demand conditions they face.

Lean strategy (plan and execute)

This is the most appropriate strategy where demand is high-volume, low-variety and predictable, and lead times are long. Materials, components and products can be ordered in advance and manufacturing and transportation facilities can be optimised (Christopher and Holweg, 2011).

Lean strategy (continuous replenishment)

In cases where demand is predictable and replacement lead times are short, a lean strategy of continuous replenishment is possible. At its extreme, products are replaced as they are sold or used (Christopher and Holweg, 2011). Christopher, Peck and Towill (2006) suggest that point-of-sale data facilitates this strategy as it allows vendors to manage their own inventory and rapidly replenish individual stores.

Agile strategy (quick response)

Christopher (2000) defines agility as the ability of an organisation to respond rapidly to changes in demand both in terms of volume and variety. Where demand is unpredictable and lead times are short, the SC can adopt a quick-response strategy such as MTO. Agile SCs must be capable of reading and responding to real demand, virtual which is information-based rather than inventory-based. Processes are integrated, with buyers and suppliers working collaboratively and products being developed jointly, and SC members sharing common systems and information. The agile SC is network-based; individual businesses are no longer competing as stand-alone entities but as part of a larger chain (Christopher and Holweg, 2011).

Leagile strategy (postponement)

Leagile strategy is an option when lead times are long and demand is unpredictable, highly variable and out of the organisation's control. A hybrid lean/agile strategy requires the SC to be "decoupled", whereby, strategic inventory is held in some generic or unfinished form, with the final configuration being completed rapidly once the real demand is known. If the final physical configuration cannot be postponed in this way, it may be possible to postpone the distribution of the product instead by holding it in fewer locations and using express transportation to move it to the final market or point of use once the actual demand is known. The goal of the hybrid strategy should be to build an

agile response upon a lean platform by following lean principles up to the decoupling point and agile practices after that point (Christopher and Holweg, 2011).

4.5: Good Distribution Practise (GDP) Model for the Pharmaceutical Industry:

Goods Distribution Practise (GDP) is a set of documented requirements governing various procedures during the processes of distribution. The distribution flow of a typical pharmaceutical supply chain is shown in Figure 4.5 below. Typically, all distribution processes should fulfil all the requirements stated by the GDP guidelines. GDP guidelines consist of 15 different elements that covers the whole distribution processes as shown in Figure 4.6.

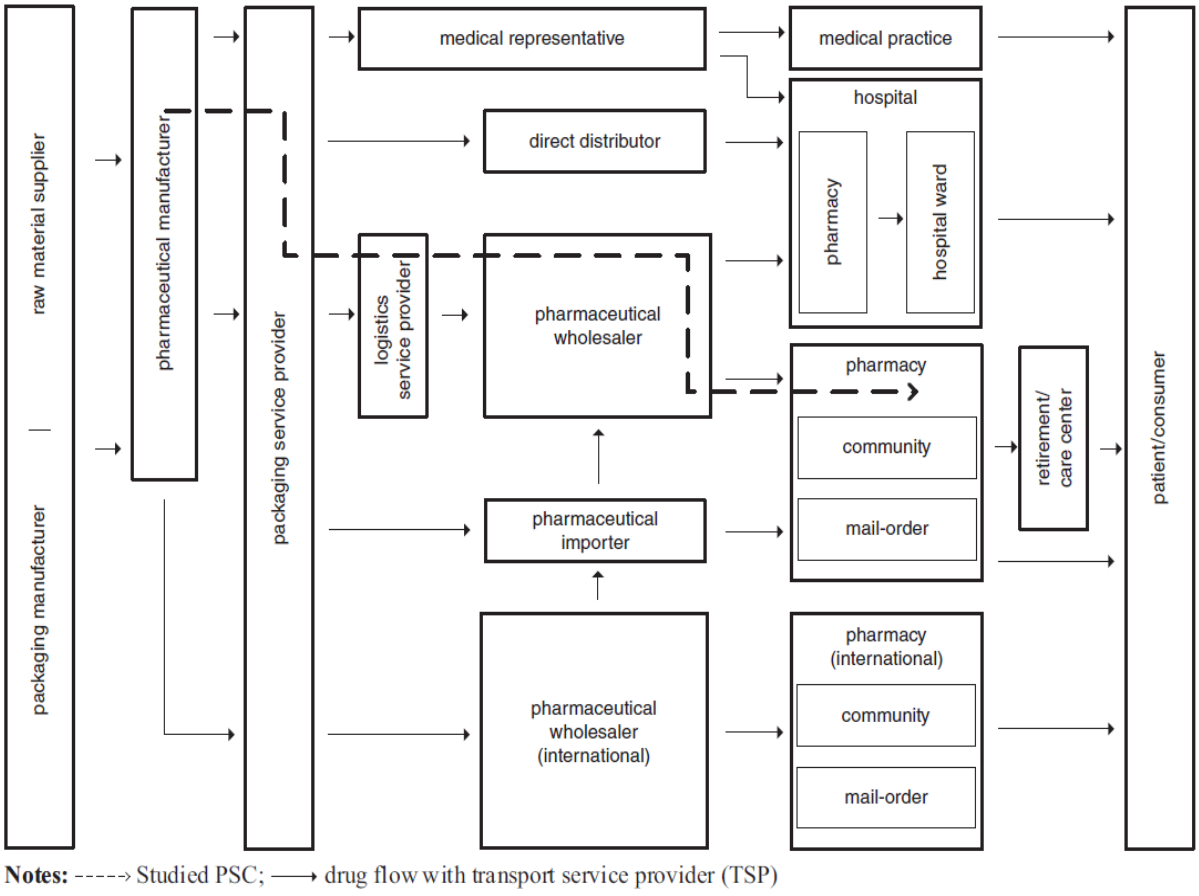

Figure 4.5: Pharmaceutical Supply Chain

Source: Abramovici et al, 2010

Figure 4.6: Elements of Good Distribution Practice

The first element of GDP is quality management. It is stated that there should be a documented quality policy to describe the overall intentions and policies of the distributor with regards to quality, as formally expressed and authorised by the management. Also, quality management should include appropriate organisational structure, procedures, processes and resources, and systematic actions. The quality system should include provisions that the holder of the marketing authorisation labelled entity (if different from manufacturer) the appropriate national and/or international regulatory bodies, as well as other relevant competent authorities. Where electronic commerce (e-commerce) is used, defined written procedures and adequate systems should be in place to ensure traceability and confidence in the quality of materials and/or products received and distributed based on batch numbers. Inspection and certification of compliance with a quality system by external bodies is recommended. If seal control programmes for transit shipment are in place, they should be managed

properly. There should be written procedures for control of incoming materials and/or products.

The second element is personnel. The key personnels who supervise and/or control the store or warehouse functions should possess the necessary competency, knowledge and experience, professional and technical qualifications required for the tasks assigned to them. Also, personnel in responsible positions should have specific duties recorded in written job descriptions and adequate authority to carry out their responsibilities. Their duties may be delegated to designated deputies of a satisfactory qualification level. There should be no gaps or unexplained overlaps in the responsibilities.

Premises and facilities should be defined and reserved areas or other control systems for the following activities:

- Receipt, identification, storage and withholding from the use of materials and/or products pending release
- Sampling of incoming materials, if necessary
- Holding rejected materials and/or products before disposal
- Storage of released materials and/or products; Packaging and labelling operations
- Quarantine storage before release of materials and/or products

Apart from that, dedicated vehicles and equipments should be used, where possible, when handling materials and/or products. Where non-dedicated vehicles and equipments are used, procedures must be in place to ensure that the quality of the materials and/or products will not be compromised. Appropriate cleaning should be performed, checked and recorded. Vehicles, containers and equipments should be kept free from rodents, vermin, birds and other pests. There should also be a written programme for such pest control. Cleaning and fumigation agents should not have an adverse effect on the material and/or product quality. Special attention should be given to the design, use, cleaning and maintenance of all equipments used for the handling of materials and/or products which are not in protective shipping cartons or cases.

Measures should be established to ensure that materials and/or products have a form of documentation that can be used to permit traceability of the materials and/or products throughout the distribution activity. Materials and/or products containing narcotics and other dependence-producing substances should be transported in safe and secure containers and vehicles, and stored in safe and secure areas, and where it is a mandatory requirement transported in safe and secure containers and vehicles. In

addition, applicable international agreements and national legislation should be complied. Third party drivers should be segregated from the warehouse and only allowed in the shipping/receiving area. They should also identify themselves and present paperwork as evident that they are authorised for the load. Subcontracting carriers are not recommended. If subcontracting occurs, they must uphold the same standards as the contracted carrier. Materials and/or products in transit must be accompanied by the appropriate documentation. For each importation, the Certificate of Analysis (CoA) for each batch of product and/or cosmetic must be kept by the importer.

Next, the element product recall is a process taken by the manufacturer, importer and wholesaler to remove or withdraw a particular material and/or product and/or cosmetic from all links of distribution. The removal or withdrawal may be due to critical quality defects discovered or serious adverse drug reactions reported that might cause health risks to users of the materials and/or products. The degree of recall is classified according to the severity of quality defects and adverse reactions to the products:

- Degree I- Materials and/or products with major health risks that might cause serious injuries or death. These materials/products should be under an embargo within 24 hours.
- Degree II- Materials and/or products with minor health risks or are substandard. They should be under an embargo within 72 hours.
- Degree III- Materials and/or products with other reasons for recall. They should be under an embargo within 30 days or as specified.

Self-inspections should be conducted in an independent and detailed way by a designated, competent person, according to an approved written procedure. These should be conducted in order to monitor implementation and compliance with the principles of GDP and to trigger necessary corrective and preventive measures. Apart from that, any counterfeit materials and/or products found in the distribution network should be physically segregated from other materials and/or products to avoid any confusion. They should be clearly labelled. The regulatory authority and the holder of the marketing authorisation of the original materials and/or products should be informed immediately.

Lastly, the critical element of this research is the management of cold chain products/materials. Written procedures should be available and appropriate training should be provided for all staff involved in the handling, receipt, storage, packing and delivery operations for cold chain products/materials to ensure the quality of cold chain products/materials is maintained. Cold chain products should be identified immediately after receipt and stored under the storage conditions that comply with the directions on the product label. Written procedures should be provided to ensure that the activities of

receipt, storage, and distribution are done without compromising on the quality, efficacy and safety products/materials that should be stored under cold conditions. Inspection upon receipt of products / materials should be done to prevent signs of aggression, destruction and non-conformance during the cold chain storage and distribution, as well as physical damage to the packaging materials, labels and quantity of the product compared to the information in the purchase order. These inspections shall be conducted under the recommended storage conditions as written on the product label. Alternative power systems should be established for cold rooms to ensure that the cold room temperatures are maintained and the temperature/humidity detector will continue to function in the event of power failure. Alternative power systems should periodically tested to ensure it is properly function. Alternative plan to provide alternative areas where storage temperature equivalent should be provided if no alternative power systems can be provided. Refrigerated vehicles or containers to transport cold chain products should be mapped and monitored. Delivery route planning for cold chain products should be created to prevent the risk of exposure to the cold chain products to beyond the ambient temperature. Cold chain medicines should be clearly identified from other items in the same distribution activities

4.6: Total Quality Management (TQM) Model:

Total quality management (TQM) is concluded based on a few philosophies. This includes all functions of the organisation, an “end-to-end” process that integrates interrelated functions at all levels and interaction between various elements in the organisations. TQM also focuses in continuous improvements.

The framework of this research was designed using the principle of the most influential quality guru of the last century, W. Edwards Deming. Deming is known best for the 14 points summarising the philosophy of quality management. The summary of points are shown in Table 4.2. Besides, many frameworks are developed based on the points articulated by W. Edwards Deming and the most recent is shown in Figure 4.7.

1	Create constancy of purpose for improving products and services.
2	Adopt the new philosophy.
3	Cease dependence on inspection to achieve quality.
4	End the practice of awarding business on price alone; instead, minimise total cost by working with a single supplier.
5	Improve constantly and forever every process for planning, production and service.

6	Institute training on the job.
7	Adopt and institute leadership.
8	Drive out fear.
9	Break down barriers between staff areas.
10	Eliminate slogans, exhortations and targets for the workforce.
11	Eliminate numerical quotas for the workforce and numerical goals for management.
12	Remove barriers that rob people of pride of workmanship, and eliminate the annual rating or merit system.
13	Institute a vigorous program of education and self-improvement for everyone.
14	Put everybody in the company to work accomplishing the transformation.

Table 4.2: Deming's 14 Points for Total Quality Management

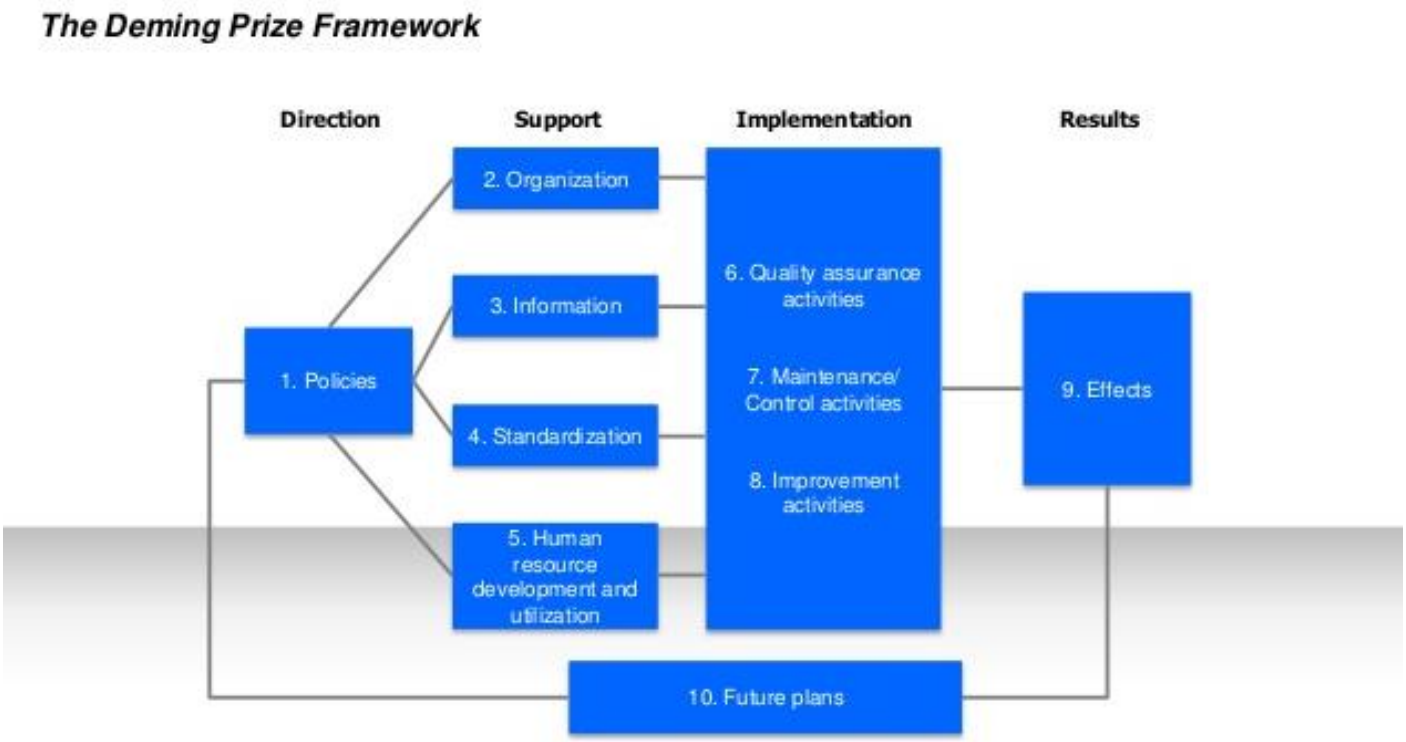

Figure 4.7: The Deming Prize Framework

Source: Porter & Tanner, 2004

The framework of TQM below was formulated on the basis of the theoretical model of TQM implementation constructs and overall business performance. The

combination of the elements of TQM and overall business performance was the framework of TQM, as displayed in Figure 4.8. Thus, the framework of TQM consists of the 11 elements of TQM and the four elements of overall business performance. Of the 11 TQM elements, leadership is perceived as the most important element. Of the four elements of overall business performance, employee satisfaction has effects on product quality and customer satisfaction. It also has an indirect effect on strategic business performance through product quality and customer satisfaction. In turn, product quality has effects on customer satisfaction and strategic business performance. It is also believed that in the long run, customer satisfaction may have positive effects on strategic business performance. In this framework of TQM, the 11 TQM elements are regarded as enablers that can lead to improvements in overall business performance. In other words, overall business performance is the result of TQM implementation. Some of the practises that are related to the elements are presented in Figure 4.9.

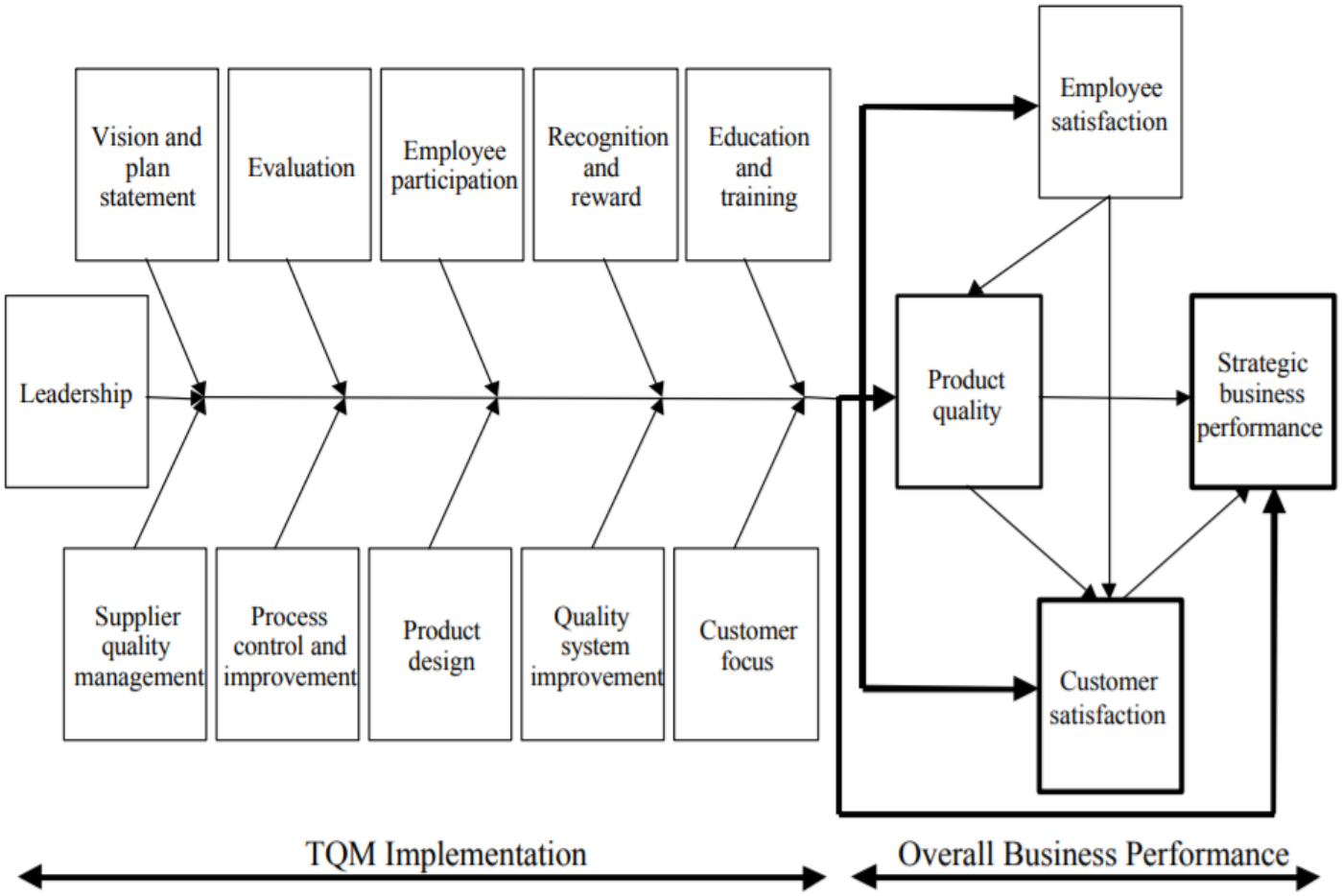

Figure 4.8: Framework of Total Quality Management
Source: Ching, 2012

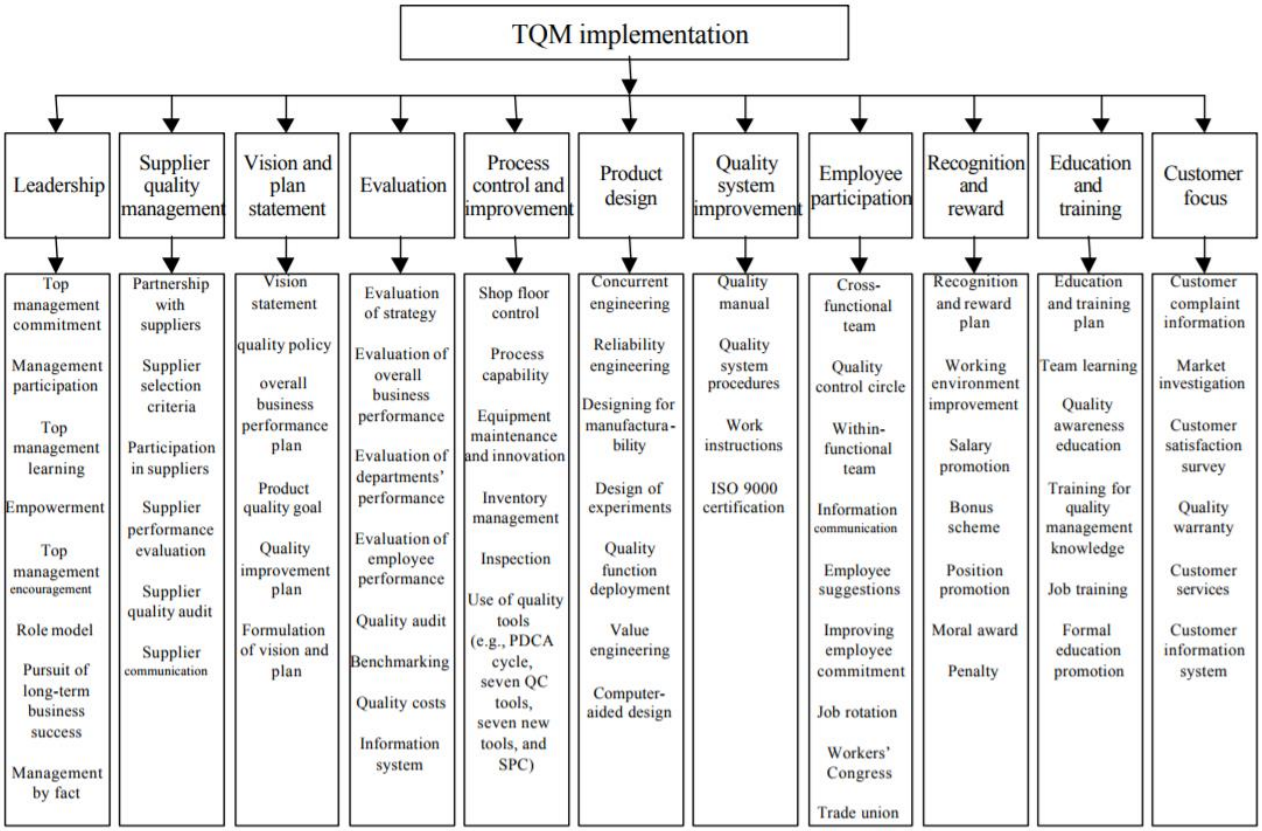

Figure 4.9: Model of TQM Implementation Practices
Source: Ching, 2012

4.7: Quality Risk Management (QRM) Model:

Since 2014, Quality Risk Management (QRM) has become a mandatory regulatory requirement for healthcare organisations. QRM is an overall and continuing process of minimising risks to product quality throughout its life-cycle in order to optimise its benefit and balance the risk. It is a systematic process for the evaluation, control, communication and review of risks to the quality of the medicinal product. An effective QRM approach can further ensure the high quality of the drug product to the patient by identifying and controlling potential quality issues during development and manufacturing. Use of QRM can improve decision making if a quality problem arises. Effective QRM implementation can facilitate better and well versed decisions to provide regulators with greater assurance of a company's ability to deal with possible risks (HHSFDA, 2006).

Quality Risk Management is developed around the four main principles mentioned below (WHO, 2010):

- The assessment of the risk to quality should be based on scientific knowledge and ultimately link to the protection of the patient.
- QRM should be dynamic, iterative and responsive to change.
- The level of effort, formality and documentation of the QRM process should be commensurated with the level of risk
- The capability for continuous development and enhancement should be embedded in the QRM process.

Quality Risk Management is a systematic process for evaluation, control, communication and review of risks to the quality of the drug product across the product lifecycle. Risk can be defined as the combination of the probability of occurrence of harm and the severity of that harm. Figure 4.10 shows the general Quality Risk Management process.

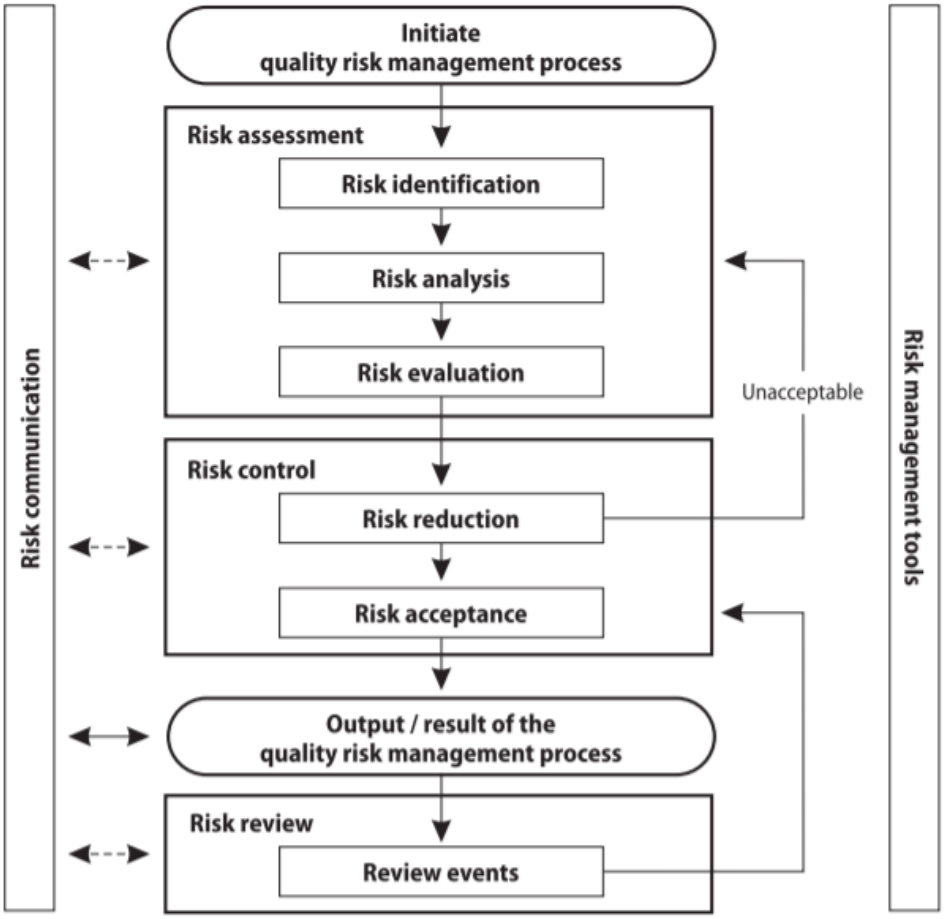

Figure 4.10: Overview of a General Quality Risk Management Process

Source: HHSFDA, 2006

Quality Risk Management should include systematic processes designed to organise, facilitate and improve science-based decision making with respect to risk. Steps used to initiate and plan a quality risk management process might include the following (HHSFDA, 2006):

- Define the problem and/or risk question, including relevant assumptions to identify the potential for risk.
- Assemble background information and/or data on the potential hazard, harm or human health impact applicable to the risk assessment.
- Specify a timeline, and appropriate level of decision making for the risk management process.

4.7.1: Risk Assessment:

Risk assessment consists of the identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards. It includes risk identification, risk analysis and risk evaluation (Williams, 2012).

Risk identification is an organised use of information to identify hazards referring to the risk. Information can include historical data, theoretical analysis, and the concerns of stakeholders. Risk identification addresses the “What might go wrong?” question, including identifying the possible consequences. This provides the basis for further steps in the quality risk management process.

Risk analysis is the estimation of the risk associated with the identified hazards. It is the qualitative or quantitative process of linking the likelihood of occurrence and severity of harms. In some risk management tools, the ability to detect the harm (detectability) also factors into the estimation of risk.

Risk evaluation compares the identified and analysed risk against given risk criteria. Risk evaluations consider the strength of evidence for all three of the fundamental questions.

4.7.2: Risk Control:

Risk control includes decision making to reduce and/or accept risks to an acceptable level. The amount of effort used for risk control should be proportional to the significance of the risk (HHSFDA, 2006).

Risk Reduction focuses on processes for mitigation or avoidance of quality risk when it exceeds a specified level. Risk reduction might include actions taken to mitigate the severity and probability of harm. The implementation of risk reduction measures can introduce new risks into the system or increase the significance of other existing risks. Hence, it might be appropriate to revisit the risk assessment to identify and evaluate any possible change in risk after implementing a risk reduction process.

Risk Acceptance is a decision to accept risk. For certain types of harms, even the best quality risk management practices may not eliminate risk entirely. In these circumstances, it might be agreed that an appropriate quality risk management strategy has been applied and that quality risk is reduced to a specified (acceptable) level. This (specified) acceptable level will depend on many parameters and should be decided on a case-by-case basis.

Risk Review is the output/results of the risk management process that should be reviewed and to take into account new knowledge and experience. Once a quality risk management process has been initiated, that process should continue to be utilised for events that might impact the original quality risk management decision. Risk review might include reconsideration of risk acceptance decisions

Risk Communication is the sharing of information about risk and risk management between the decision makers and others. The output/result of the quality risk management process should be appropriately communicated and documented. The included information might relate to the existence, nature, form, probability, severity, acceptability, control, treatment, detectability or other aspects of risks to quality.

4.8: Supply Chain Network Optimisation Model:

An optimisation is “narrowing your choices to the very best when there are virtually innumerable feasible options and comparing them is difficult” (Institute of Operations Management and Management Science). An important component of supply chain design is determining how to achieve an effective design, given a performance measure or a set of performance measures (Beamon, 1998). Due to an increasing popularity of trends like globalisation and mass customisation, supply chain configurations involving multiple facility locations for different target markets, and multi-product systems to cater to a vastly diverse customer base, are becoming prevalent in multinational companies. As a result, many companies are adopting the global supply chain optimisation model as shown by Figure 4.11.

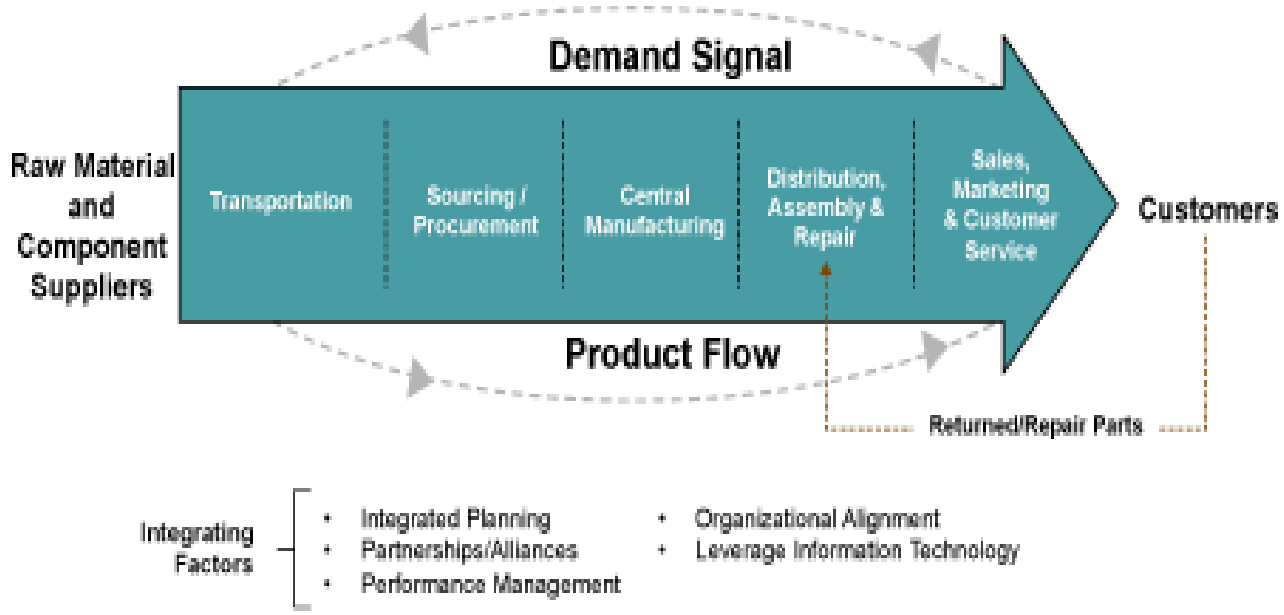

Figure 4.11: Global Supply Chain Optimisation Model

Source: Committee on Supply Chain Integration, National Research Council (2000)

The network optimisation model adopted here is solved using a two-phased approach. Phase one involves the formulation of a mixed integer problem which helps in determining the strategic level location-allocation decisions. Phase two uses the results from the first phase as input and fine-tunes them further to provide a detailed distribution plan that optimises the transportation and inventory costs (Canel and Khumawala, 2001). Ozsen, Coullard and Daskin (2008) has integrated of the following functions into a main model:

- *Capacitated location function:* This function deals with the capacitated location of the manufacturing facilities and the allocation of customer demand to these facilities. Taking into consideration the different constraints such as capacities, demands, and fixed and variable costs at each facility, this function helps in the optimal location of manufacturing facilities to satisfy customer requirements within the constraint framework.

- *Production function:* The capacities of the manufacturing facilities and the customer demands act as some of the inputs of the production function which determines the production quantities of every product at each of the facilities.

- *Distribution function:* The demand for each product from the customers and other parameters such as holding costs, fixed costs and transportation costs determine

the inventory control policies and the average inventory levels. This function receives inputs such as travel times and, transportation costs, to optimise the decisions such as the number of shipments, shipment schedules, and shipment sizes.

This model also considers two approaches for solving the capacitated-location/production/distribution (CLPD) problem (Ozsen, Coullard and Daskin,2008):

- *Mixed integer programming (MIP)* – A MIP model must be developed to represent the integrated problem and solved in the first phase using Spreadsheet Modelling. The output from this model is the optimal location of manufacturing facilities and the customer demand allocation to these facilities.
- *Continuous approximation* – Phase two uses a continuous approximation to model the material flow in the system and to determine the optimal distribution plan based on the different shipping patterns considered. It determines the number of shipments, and the shipment sizes for each shipping pattern thus providing a customised solution for each company-customer relationship.

A combinatorial strategy is thus developed in which the two approaches are combined to first obtain the upper level solutions in the decision hierarchy, followed by lower level optimisation. This phased approach helps in reducing the complexity of the model as well as to achieve the overall system integration.

The first phase uses the given data to optimise the decisions with respect to location, production, and customer allocation. These results are then used in the second phase along with additional data to obtain the number of shipments, shipment sizes, and optimal inventory and transportation costs (Pujari, 2005). Along with data such as inventory holding costs and, customer waiting costs, these additional data include the “inventory distribution patterns” that may be unique not only for each customer but also for each of its products. This two-phased approach allows us to use the initial solution to the Capacitated Location, Production, Distribution (CLPD) problem from the first phase and further improve its quality in the next phase (Pujari, 2005). In other words, it meets the broader objectives by fixing the plant locations, and allocating customer demands of each product from each of these plants, thus setting their production levels while taking into consideration the plant capacities, input and manufacturing costs, and shipping logistics. This solution is then fine-tuned and proceed further to obtain a shipment plan such that inventory and transportation costs are minimised. Separating the two phases is essential because after obtaining the plant-to-customer shipping pairs for each product, this approach allows customisation of shipment plans for each of these pairs

according to the customer's needs specified by their inventory distribution patterns (Zhou and Liu, 2008) . A detailed framework of the two-phase integrated model is shown below in Figure 4.12.

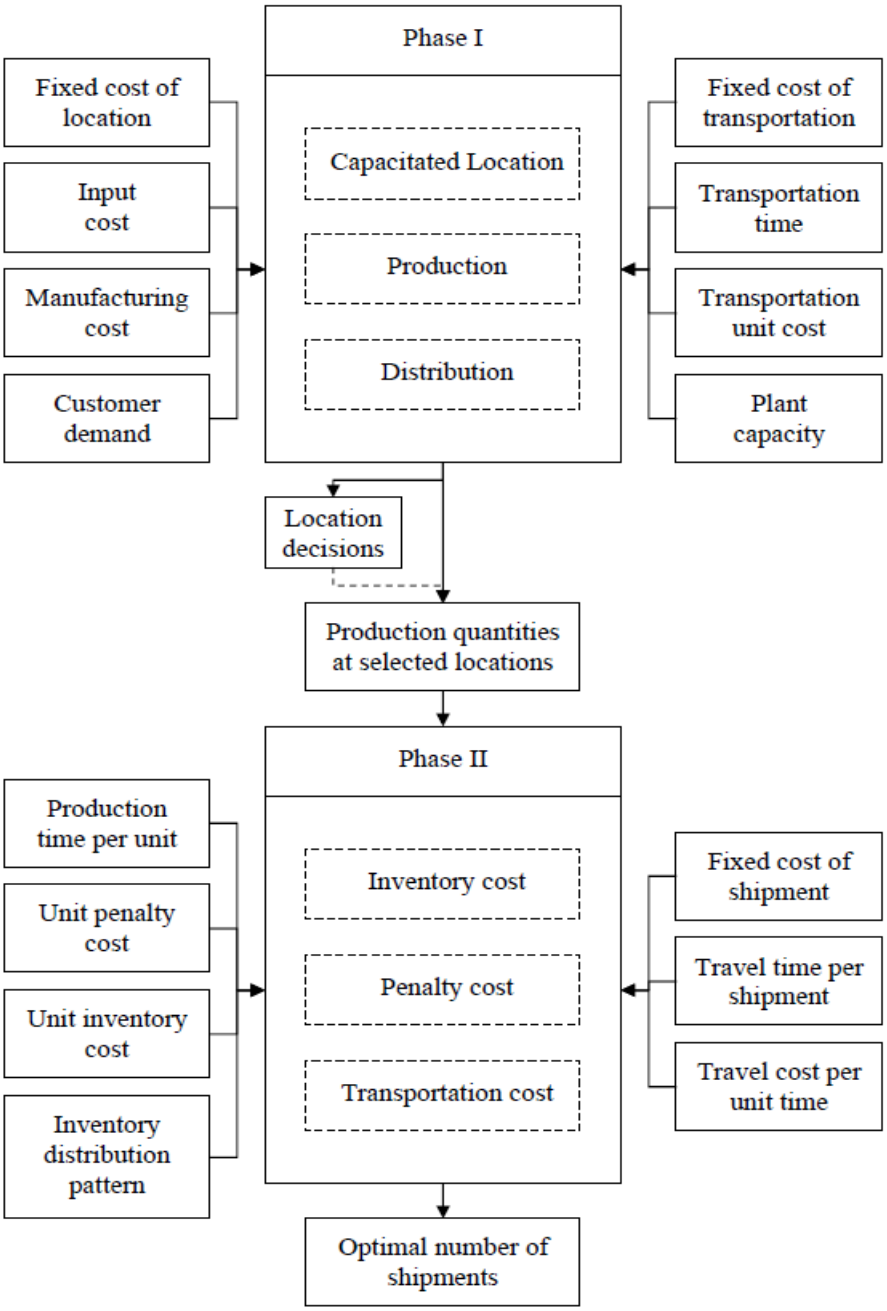

Figure 4.12: Detailed Framework of Supply Chain Optimisation Model

Source: Pujari, 2005

4.9: Key Performance Indicator (KPI) Model

The last model included in the framework is a performance indicators model. This measures supply chain efficiency and effectiveness and determines the extent to which the chain is achieving its objectives.

4.9.1 Efficiency performance indicators

Cost

As a critical performance indicator, the cost is tracked more carefully and comprehensively than any other aspect of competitive performance. Supply chain costs include all costs associated with operating the supply chain, including the costs of planning, sourcing, material landed, production, order management, fulfilment and return.

Asset management

This refers to an organisation's ability to manage its assets so that it is able to satisfy demand. The three indicators that measure supply chain asset management efficiency are cash-to-cash cycle times, inventory days of supply and asset turns. Asset turns are calculated by dividing the revenue by total assets, including both working capital and fixed assets (Bolstorff and Rosenbaum, 2003)

4.9.2 Effectiveness performance indicators

The measure of how well an organisation can move its product or services from the point of origin to the customer. The attributes of an effective supply chain will offer transparency, flexibility and alignment to tailor the system to the strategic benefit of the organisation (Vorst, 2000). An overall calculation of supply chain effectivess would be; the average time taken (days/weeks/months/years) to source, design/make and deliver a product/ service from order to customer receipt. However, there are often parts of the supply chain that need to be measured, for instance the time taken from order to delivery of raw materials to a factory (Committee on Supply Chain Integration, National Research Council (2000).

4.10: Conclusion

To summarise, the proposed framework integrates the four key elements of supply chain, namely strategy, process, network optimisation and performance into a single framework. The strategic objective model propose four supply chain strategies that can be deployed in response to different combinations of supply or demand conditions to achieve set goals and objectives. The process model then demonstrate how these strategies can be implemented through different process configurations. It allows each entity in the supply chain network to be adopted to ensure that all resources are being utilised in accordance with the chosen policies and strategy. Also, the proposed framework addresses the complexities of the pharmaceutical industry by including different aspects of supply chain performance to achieve the optimal levels of efficiency and effectiveness throughout the supply chain.

Chapter 5: Validation & Improvement

5.1: Introduction

This chapter will firstly analyse the feedbacks gather from the interviews from three pharmaceutical companies and two third party logistics provider (3PL) companies that offers distribution and storage for pharmaceutical companies. Figure 5.1 illustrate project map of the relationship and data collected. This indicate that multiple codes are assigned to the same grouping of data as well by going through the same process. Next, the proposed framework will be validated.

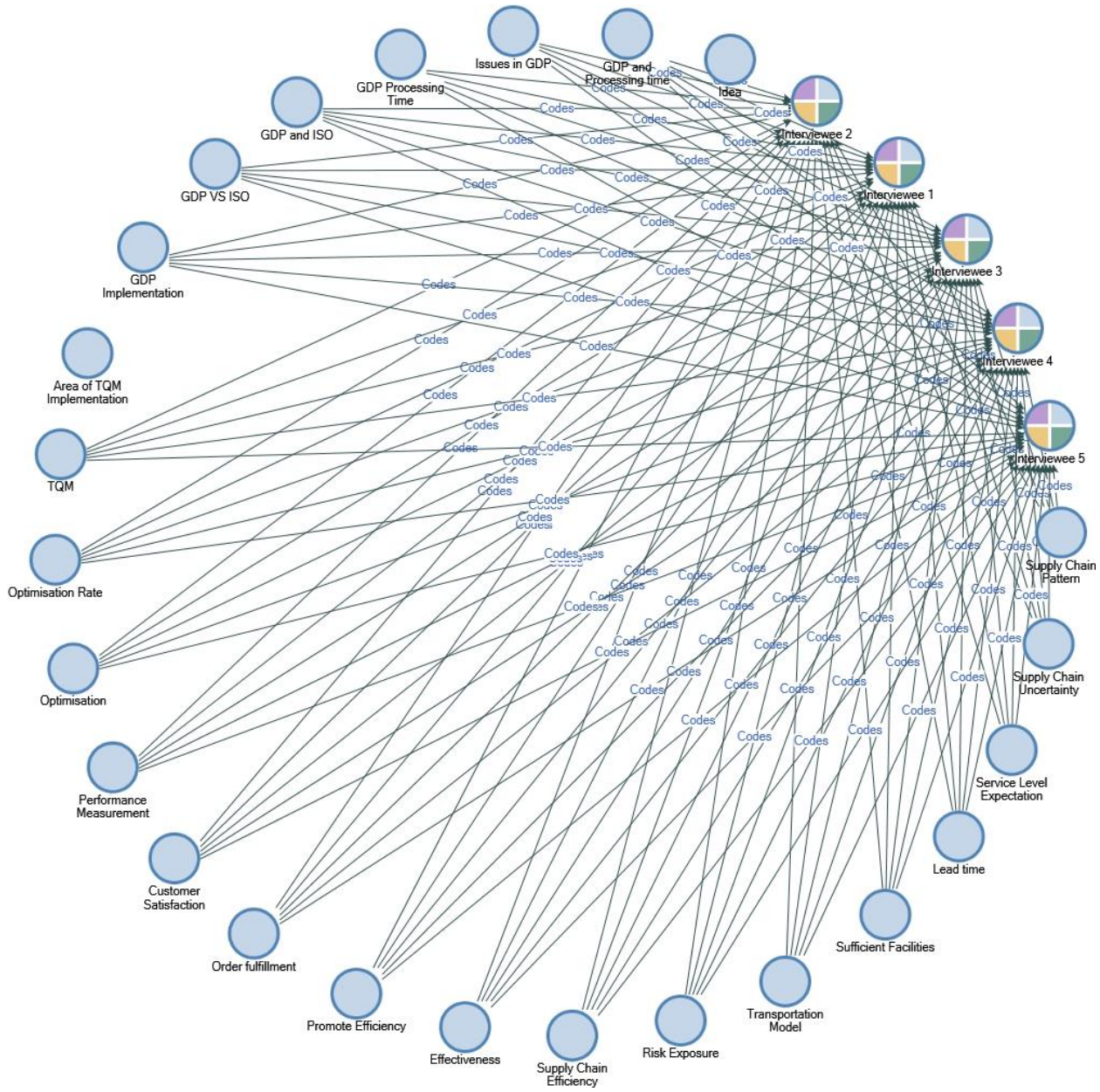

Figure 5.1: Project Map- Overall Output

5.2: Interviews Findings

5.2.1: Interview 1

Interviewee 1 is the senior manager in the operations department in B Healthcare, Malaysia, established for more than 85 years. B Healthcare have pioneered significant medical innovations that changed the healthcare industry. From the first commercially produced intravenous solutions to today's leading acute, nutritional, renal and surgical care innovations, B Healthcare are committed to providing leading healthcare solutions. Besides, B Healthcare is recognised by numerous global, national and local industry associations and publications around the world. Some examples of their recent accomplishments highlight B Healthcare as an employer of choice, its efforts to nurture an inclusive and diverse workplace and as a socially responsible and sustainable business. Figure 5.2 depict the nodes containing all the concept and principles gathered from this feedback. The data obtained are coded and are linked to its relevant nodes.

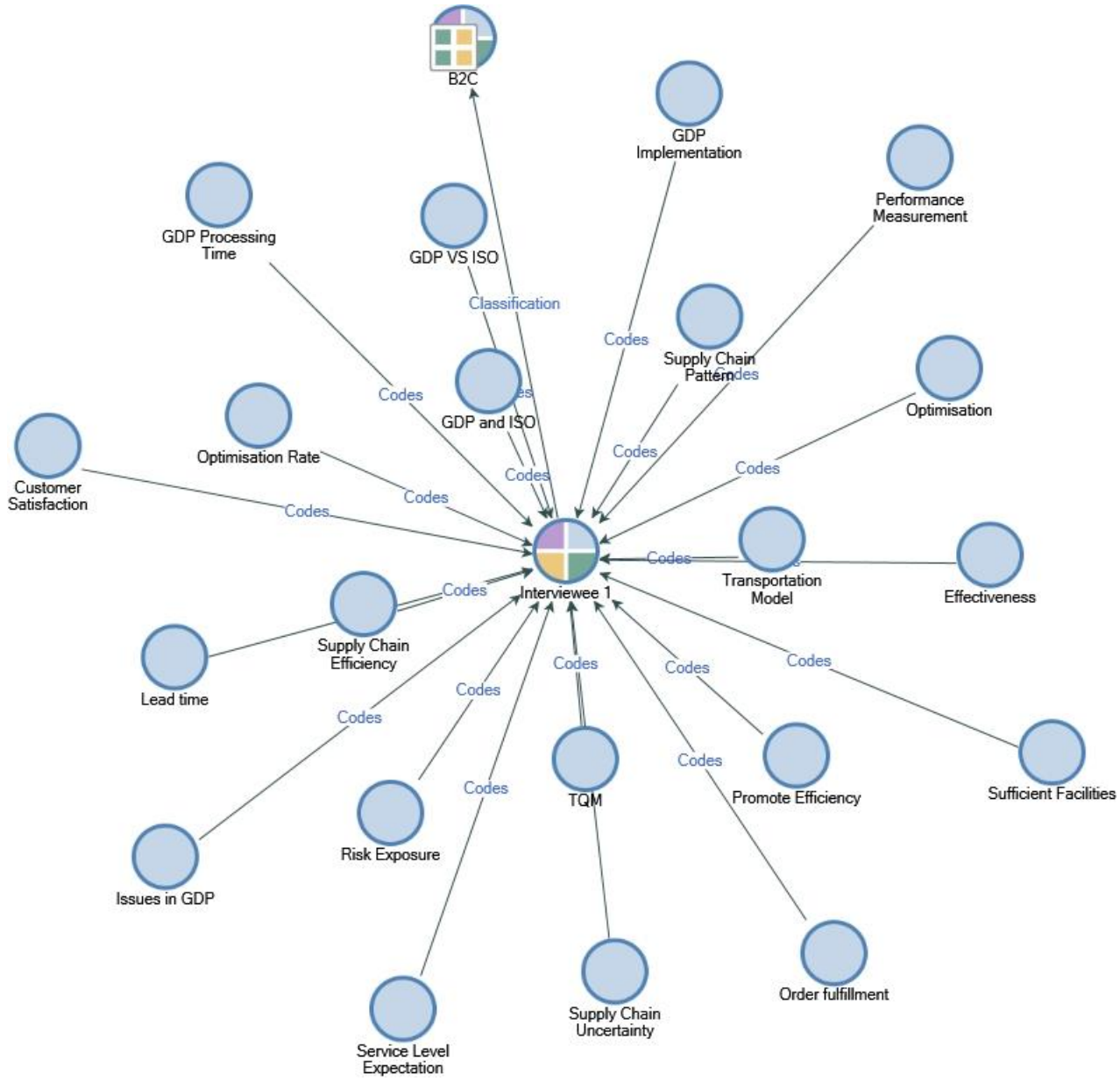

Figure 5.2: Project Map- Interviewee 1

1	What are the supply pattern in your industry/company?	We are supplying straight to customers, which is also called B2C. We will arrange and process all order including packaging. But deliveries are outsourced to 3PL.
2	Are there any supply chain uncertainty in your daily operation? If yes, how	We have list of regular patients with scheduled deliveries every month. We

	often?	will usually deliver a month worth of stock to our patients. But for sure there is uncertainty. For instance recently our dialysis solutions went out of stock and there are backorders to fulfil. With that, we have to arrange for urgent deliveries as our patients need this solutions for their dialysis every day. Apart from that, there are also cases where our customer change their required date (ETA) which causes disruption in the whole planning and delivery schedule. This doesn't happen very frequently, about 2-3 cases in a quarter.
3	What are the service level expected by your customers?	Of course it is 100%. Which means on time delivery. Liked I mentioned, we always supply one month worth of stock to our patients. Therefore, we have a scheduled delivery date to meet. Is it not acceptable for late deliveries because they need to do their dialysis every day. Also, they do not accept early deliveries too, as they complaint they do not have space to store 20 cartons of solutions.
4	What are the lead time/response time required?	There is no specific lead time in our case, it is more like Just-In-Time (JIT). Liked I said, we have a list of regular patients. So our planning will go according to that list. Patients can confirm their order as early as a month in advance, but we will deliver according to their scheduled date. But if you are referring to new patients or urgent outstation deliveries, we will advise our patients to put in order at least 3 days in advanced. This will allow us to have sufficient time to pack and arrange 3PL for delivery.
5	Do you think your company has the right/sufficient facilities to support/compete with your competitors?	Yes, we recently renovated and extended our facility to accommodate more orders. We are also looking into upgrading our system to have a better information flow. So for sure, we are

		better than our competitors.
6	What transportation model do you practice?	We engaged our 3PL to do the delivery. It is order by order basis. So it is less than truck load (LTL). They will deliver using van or truck.
7	What are the risk exposure/measures taken?	I guess for all form of orders, the highest chances of hazard is accident. That is why we have insurance for all products and delivery.
8	How do you define supply chain efficiency?	To me, efficiency is about on time delivery.
9	How is this different from effectiveness?	I guess is the same as efficiency, but effective is more like deliver when it is required by customers.
10	What are the steps taken to ensure or promote efficiency?	We will generate daily report to track and trace our daily operations and output. This report will be able to tell us if there are orders that are not fulfilled or left out. If we missed an order, we will arrange an urgent delivery so that the order is delivered on the same day itself. By the end of the day, this daily report must have 100% fulfilment.
11	What are the % of order fulfillment(i.e. on time , in full)?	At the moment we managed to achieve 89% of on time in full order fulfilment. But our company's target is set at 99%.
12	What is % of customer satisfaction? Is it as per your targeted %? If no, why?	We do not have the percentage now, but I think we managed to achieve the targeted %. There are a lot of reasons for customer dissatisfaction in our cases. It can be as simple as the truck driver arrive in after lunch when customer state they prefer morning delivery. There are also serious cases where our 3PL are not able to deliver on the scheduled date due to truck breakdown or too many orders, not sufficient truck/drivers. For cases like this, we are not able to control and we sometimes only find out orders

		did not arrive when customers call and complain. For such cases, we will make sure to solve and close the case within 3 working days.
13	What are the measure/metrics used to measure your performance?	We measure using On Time In Full (OTIF) and this rate is set by top management. This rate will be reviewed monthly to analyse performance and decide on improvements if required.
14	Does your company implement supply chain optimisation?	Not really. But I know we strive to operate at the lowest possible cost.
15	How would you rate your optimisation level?	For me, as long as we deliver on time then its sufficient.
16	Does your organisation practice TQM?	Not that I am aware, but we do have ISO certification to ensure quality assurance organisation wide. We have ISO standards for all departments such as client service department, warehouse department, HR, Finance. All departments in general.
17	What are the areas of TQM implementation?	If TQM is similar to ISO, then it is organisation wide.
18	What are the areas of GDP implementation?	We have GDP certification and this is related to warehouse department only. Also, the 3PL that we engaged with are also GDP certified.
19	Do you know what are the differences between ISO VS GDP?	ISO is quality assurance organisation wide, which include our product and services. This is required by our customer/clients. As for GDP, it is related to distribution only and it is government's requirement for all pharmaceutical industry.
20	Till what extend do you think GDP & ISO are related?	Both are focuses on quality assurance. Not much different to me.
21	Which are the areas in GDP requires longer processing time?	Processing time is the same, the tedious part is where we need to pay attention

		our segregation and storage because GDP have this requirement where we are not supposed to share same storage area if the product is different.
22	What are the common issues do you face while implementing GDP?	Understanding the requirement is the main issue. For instance, in GDP we are supposed to segregate product based on type. But in our SOP or ISO, we segregate based on temperature requirements. So for us the operations team, we are caught in the middle, which procedure are we supposed to follow?
23	Does implementing GDP reduce the production/delivery/processing time? If yes, why?	In my opinion, it is the same.
24	What are the risk exposure/measures taken?	As you are aware, our industry usually handle products that are highly sensitive in certain way as it is used to save lives. Therefore, to ensure all products are safe for consumption, we have to ensure we have Certificate of Authenticity (COA) when we do our receiving. Apart from that, for products that are temperature sensitive, we need to monitor and update the temperatures of our cold room in our logbook to ensure consistency.

Any other comments or suggestions:

In my opinion, communication is very important because the forecasting of our stocks are prepared by client service. If they do not update us on the stock level or delivery, we are not able to react on time if there is any hiccups in our supply chain. Also, with the new introduction of ISO13843 for medical devices, we find that there are too many standards to follow and most of the standards are similar or redundant. There is no consistency in terms of practise as well, as some QC officers will release the goods based on ISO standard/SOP, and some QC officer will reject the same batch of product reason being did not meet GDP requirements.

5.2.2: Interview 2

Interviewee 2 is the senior officer in the operations department in J Medical, Malaysia was founded in 1886. However, it was not until 1959, 73 years and 2 major acquisitions later that J Medical developed its significant presence in the pharmaceutical industry. The company focuses on three main areas, namely; Consumer, Medical devices and Diagnostics, and Pharmaceuticals. According to Malaysian Competition Commision (MyCC) (2018), J Medical was the top importers in Malaysia in the year 2017 by dominating a total of 10.2% of the market share. One of the principle of J medical is to be responsible to the patients, doctors and nurses, to mothers and fathers and all others who use their products and services. In meeting their needs, everything must be of high quality. J Medical must constantly strive to provide value, reduce its costs and maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Figure 5.3 represent the nodes containing all the concept and principles gathered from this feedback.

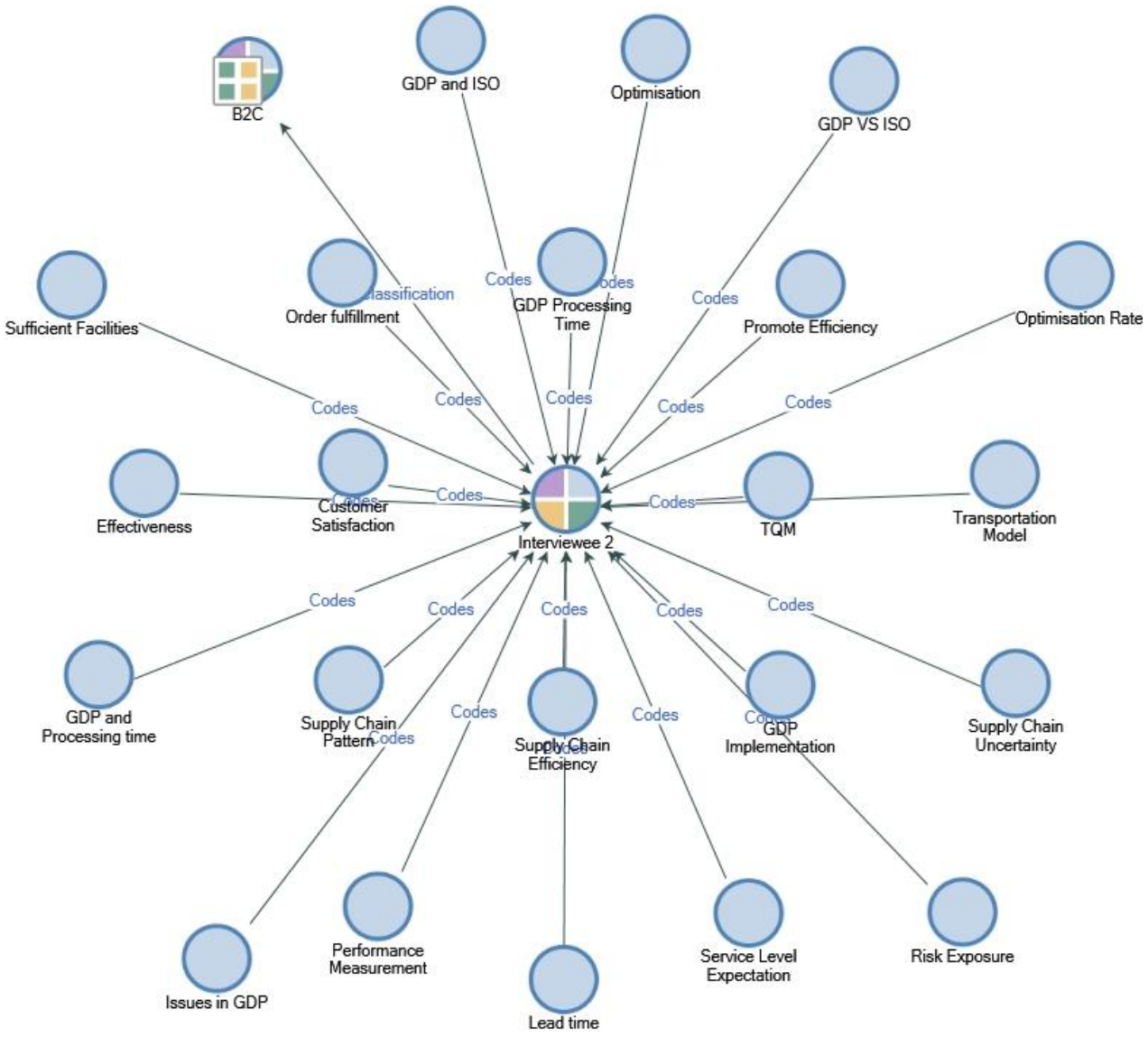

Figure 5.3: Project Map- Interviewee 2

1	What are the supply pattern in your industry/company?	Our supply chain pattern as very fast pace as in on demand orders because our customers are hospitals or clinics. We usually supply them with medical devices or solutions for surgery. But deliveries are outsourced to 3PL (SPT Logistics).

2	Are there any supply chain uncertainty in your daily operation? If yes, how often?	We deal with uncertainty every day. This is because we can't forecast or we do not receive the order few days in advanced. We deal with trauma cases every day, for instance hospital will call to place an order at 11am and they require the surgical kit to be delivered at 1pm for the surgery at 2pm. So the usual problem that we faced every day is locating the surgical kit as we have limited quantity and we do not only service one hospital but we have about 30 hospitals and clinic to service just in Klang Valley.
3	What are the service level expected by your customers?	100% on time delivery. Liked I mentioned, we deal with trauma cases. We deliver surgical kits and solutions to hospitals. If we do not deliver, hospitals may not have the equipments and solutions to perform the surgery.
4	What are the lead time/response time required?	Usually we will inform customer to give us at least 12 hours notice. But it is always case by case basis. Certain cases are urgent, we are required to deliver within 2 hours. But there are also cases where hospitals actually give put in an order 15 hours in advance. So it is all on demand basis.
5	Do you think your company has the right/sufficient facilities to support/compete with your competitors?	Yes for sure, we are better than our competitors. I don't think they are able to provide a service as rapid as us.

6	What transportation model do you practice?	Our deliveries are handled by our 3PL (SPT Logistics) and it is order by order basis.
7	What are the risk exposure/measures taken?	The kit that we supplied has missing components. This happened before and resulted with a huge complain. Also, there are risk of not being able to meet the delivery as we may face problem in locating and retrieving the kit. At times, hospitals are not able to release the kit due to certain requirements or processes. So when this happen, we will speak to the surgeon if they can accept a replacement kit, not specifically for their surgery but probably a "general" kit to perform the surgery. To reduce risk of making mistakes, 2 rounds of checking are required before delivery. This is to ensure all the parts and tools are prepared accordingly.
8	How do you define supply chain efficiency?	Efficiency is able to deliver on time.
9	How is this different from effectiveness?	On time and without any mistakes.
10	What are the steps taken to ensure or promote efficiency?	We recently migrate to SAP-ERP system for real time information. Previously, we will track and trace the kit manually using the spreadsheet that we prepared. Using the system will be more effective but of course there are more steps to be taken such as system tend to be more rigid.

11	What are the % of order fulfillment(i.e. on time , in full)?	I am not very sure on the actual percentage, but we did fulfil all of our orders every day.
12	What is % of customer satisfaction? Is it as per your targeted %? If no, why?	In terms of customer's satisfaction, we are quite bad in this area. We do have a lot of complains from our customers. But most of the complains are usually on late deliveries where we can't control as it is delivered by 3PL. So, this is very difficult to measure as we don't know if it is considered our mistake or not.
13	What are the measure/metrics used to measure your performance?	We measure using On Time Delivery (OTD).
14	Does your company implement supply chain optimisation?	Yes, we also practise assemble to order (ATO).
15	How would you rate your optimisation level?	Not sure on the rate.
16	Does your organisation practice TQM?	Yes, we have TQM, ISO, GDP. Literally all quality practises we have it.
17	What are the areas of TQM implementation?	Organisation wide. From service to products to management.
18	What are the areas of GDP implementation?	We have GDP certification and this is related to warehouse, storage and distribution. Also, the 3PL that we engaged with are also GDP certified.
19	Do you know what are the differences between ISO VS GDP?	ISO is quality assurance organisation wide, which include our product and services. As for GDP, from the name

		itself we know it is related to distribution only.
20	Till what extend do you think GDP & ISO are related?	Both are focuses on quality assurance.
21	Which are the areas in GDP requires longer processing time?	In my opinion, the stock handling and control is very time consuming. This requires very thorough checking. Each kit will roughly take at least 30 minutes on checking for replacement parts.
22	What are the common issues do you face while implementing GDP?	Understanding the requirement is the main issue. As certain standards mentioned are not implementable.
23	Does implementing GDP reduce the production/delivery/processing time? If yes, why?	Yes, I guess id due to the proper documentation process required. With this in place, we are able to track and trace the kit faster, also the checking and restock of parts are identified faster.
24	What are the risk exposure/measures taken?	Speed and time is very crucial to us. So we need to ensure that we deliver on time and need to be very precise in preparing our kit. The possible mistake that can happen is missing parts in the kit. In order to reduce the chances of happening, we have a very proper documentation to record all this. Before returning the kit, hospitals are required to fill in the check sheet on items or parts they use, and we will check and tally the items during receiving.

Any other comments or suggestions:

In my opinion, if our organisation can implement RFID system in all the kits it would be easier for us to track and retrieve the kit faster. Also, I think the authority need to relook

into the GDP requirements as some of the standard are not clearly defined which sometimes results in inconsistency.

5.2.3: Interview 3

Interviewee 3 is the manager in the logistics department of Z Pharma, Malaysia. Z Pharma is one of the largest healthcare services groups in Asia and its purpose is to make healthcare more accessible. Z Pharma provide world-class distribution, digital and commercial services to support the growing healthcare needs in this region. The company started almost a hundred years ago and has grown to become a US$13 billion business covering 13 markets with over 10,000 employees. The company serve over 350,000 medical facilities and work with over 1,000 clients, including the top 20 pharmaceutical companies in the world. According to MyCC (2018), Z Pharma is the second largest pharma wholesalers in Malaysia in the year 2017, controlling 27.3% of the Malaysian market share. Figure 5.4 illustrate the nodes containing all the concept and principles gathered from this feedback.

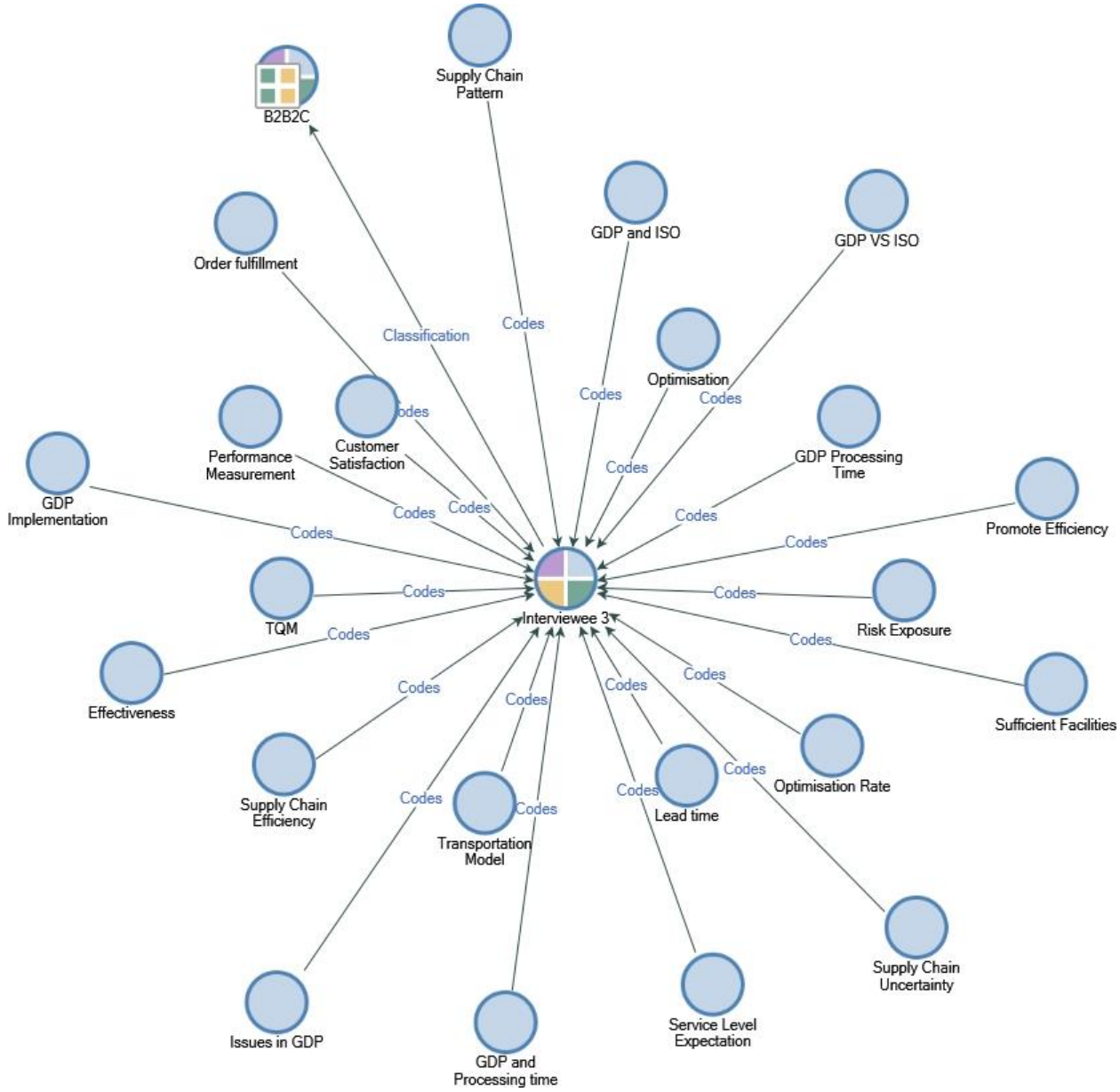

Figure 5.4: Project Map- Interviewee 3

1	What are the supply pattern in your industry/company?	We are actually like a "middle-man". We help our clients to store and manage their products and when our client receive an order, we will provide services like picking, packaging, re-package if required and then arrange for delivery. Our deliveries are handled by 3PL.

2	Are there any supply chain uncertainty in your daily operation? If yes, how often?	Yes. Every day the team will need to squeeze our brain juice to deal with this problem. We faced many times of uncertainty, it could be as simple as the stock quantity is not tally. In our system is stated that have the product and is ready for delivery, but when we check for physical stock, it is not there.
3	What are the service level expected by your customers?	On time delivery, order fulfilled.
4	What are the lead time/response time required?	Once client send us the sales order, we are required to deliver within 36 hours. But there are also urgent deliveries, where we are required to fulfil within 12 hours.
5	Do you think your company has the right/sufficient facilities to support/compete with your competitors?	We are looking into expanding our warehouse and also upgrade our ERP system. So, I think we are compatible.
6	What transportation model do you practice?	We engaged our 3PL to do the delivery. It is order by order basis.
7	What are the risk exposure/measures taken?	We have a standard/SOP to follow for every process. Also, extra measures are also implemented using our ERP system. We are not allowed to update our stock status if our QC department did not approve the incoming stocks. This is to ensure all products that we accept and deliver are in proper condition.

8	How do you define supply chain efficiency?	Getting things done at the shortest time.
9	How is this different from effectiveness?	Effectiveness is achieving the targeted outputs.
10	What are the steps taken to ensure or promote efficiency?	Our management always promote and encourage clear and transparent communication and information sharing. When information or updates are pass down, the process can be seamless.
11	What are the % of order fulfillment(i.e. on time , in full)?	The target set by our management is 98%, but we are only touching about 80%.
12	What is % of customer satisfaction? Is it as per your targeted %? If no, why?	This is usually conducted by our client, but we do get feedback from them saying that we need to re-look into our processes as most of the time we are not able to deliver within the time frame set.
13	What are the measure/metrics used to measure your performance?	We measure using On Time In Full (OTIF). This rate will be reviewed every quater.
14	Does your company implement supply chain optimisation?	If cost saving is considered optimisation, then yes.
15	How would you rate your optimisation level?	We are working within the budget given. In fact, just last month, we managed to achieve cost saving in terms of operations. For example, no over-time claim.

16	Does your organisation practice TQM?	Yes. Not only TQM, but we also have ISO.
17	What are the areas of TQM implementation?	The whole company practises TQM. Every month, we will have a meeting to discuss on potential improvements.
18	What are the areas of GDP implementation?	We have GDP certification, we pay extra attention in receiving, storage, documentations, packing, and delivery. We also engaged with GDP certified 3PL.
19	Do you know what are the differences between ISO VS GDP?	To me, they are similar. Just that GDP provide a clearer standards and requirement of each process. And of course, GDP is required by our Ministry of Health (MOH).
20	Till what extend do you think GDP & ISO are related?	Both are emphasised on quality assurance.
21	Which are the areas in GDP requires longer processing time?	In my opinion, it would be the inspection process because we do not have sufficient QC personnel. We receive about 30 SKUs and at the same time we delivers close to 50 orders a day. A lot of time wasted to wait for QC to approve the product.
22	What are the common issues do you face while implementing GDP?	Understanding the requirement is the main issue. Apart from that, is engaging 3PL who is GDP certified. Not many available.
23	Does implementing GDP reduce the production/delivery/processing time? If yes, why?	Yes, the documentation process makes it easy for us to track and trace when there's problem.
24	What are the risk exposure/measures taken?	Transparent documentation procedures and real time updates on product status.

Any other comments or suggestions:

The need to knock down traditional functional silos to create an internal organisation focused on the overall supply chain. I suggest that traditional functions like transportation, inventory, warehousing, purchasing, and manufacturing needed to be more integrated and pulled closer together by a common mission within a single supply chain group. Within an internal supply chain organisation, metrics and incentives could be aligned to insure everyone was striving to achieve the same goals. Roles and responsibilities could be clearly defined, managers could be empowered to make necessary changes, and accountability for supply chain processes would become much clearer.

5.2.4: Interview 4

Interviewee 4 is the manager in the operations department of D Supply Chain Malaysia, has extended far and wide in Malaysia with over 700 skilled logistics employees working in more than 8 major facilities that spread across an approximate 800,000 sq. feet of ambient and air-condition warehouse space. The company's committed supply chain team has been continuously providing successful integrated supply chain solutions based on global best practices for its customers within the Fashion, Retail & Consumer, Consumer Electrical, High Technology/Aerospace, Pharmaceutical and Healthcare, and Service Parts Logistics sectors. D Supply Chain Malaysia offer its customers a comprehensive product portfolio ranging from inbound transportation to warehousing, co-packaging and value added technical service to domestic distribution deliveries to end users. With the support of a strong quality management system, the company have consistently delivered exceptional results with continuous improvements. Figure 5.5 show the nodes containing all the concept and principles gathered from this feedback.

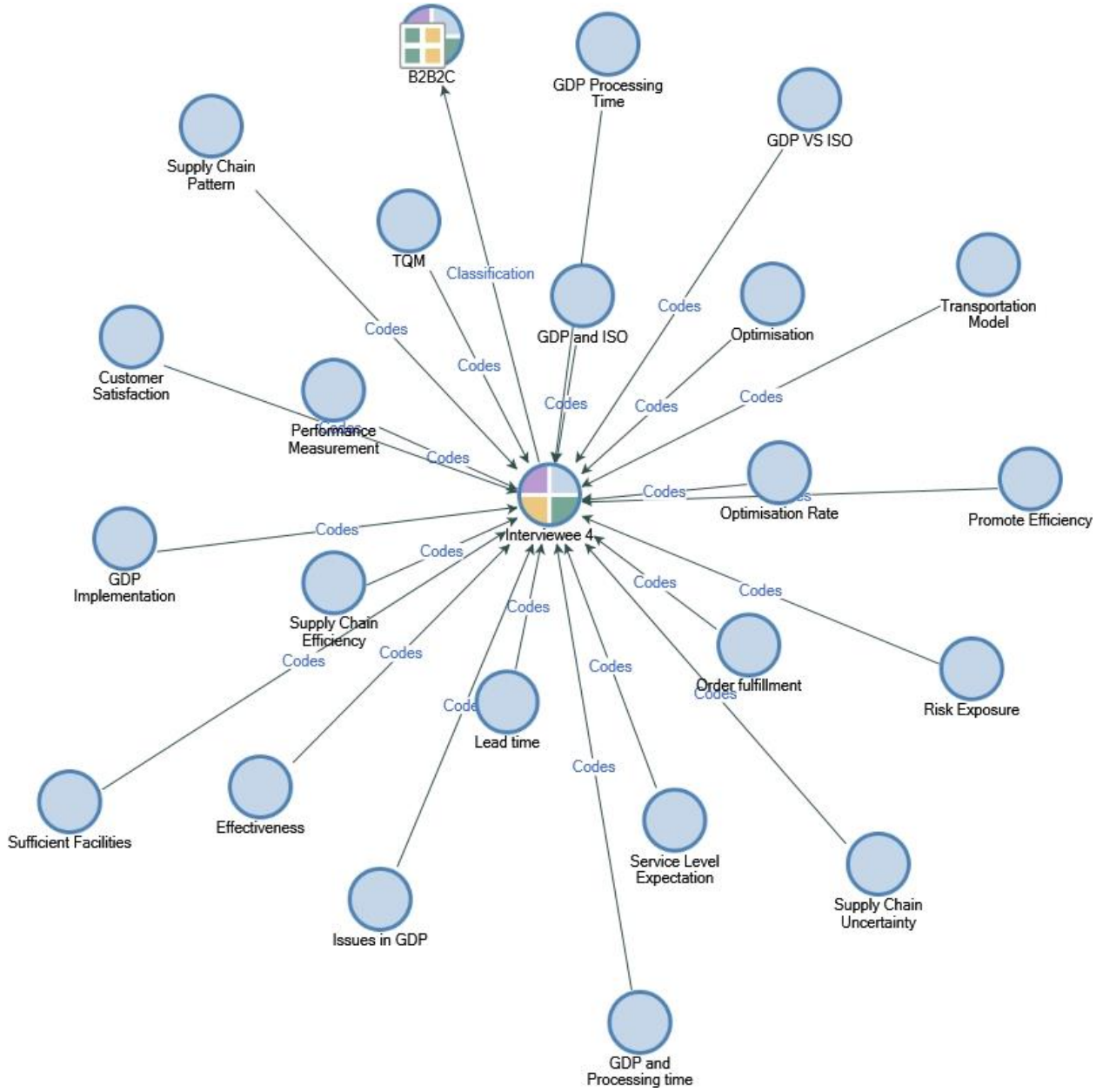

Figure 5.5: Project Map- Interviewee 4

1	What are the supply pattern in your industry/company?	We are a 3PL where we provide mainly delivery services and warehousing to our customers. Our customers ranges from conglomerate, SMEs, and walk-in customers. Most of our customers are contract based but we also deal with one time off business.

2	Are there any supply chain uncertainty in your daily operation? If yes, how often?	We don't really have uncertainty because most of the deliveries are scheduled at least 3 days before the actual day. For surgical products, we have trucks on standby at all time because this are usually urgent deliveries. But we do sometimes faced problems like truck breakdown, driver on leave. This are all minor cases and it doesn't happen all the time. At most is once or twice a month or no cases at all.
3	What are the service level expected by your customers?	On time delivery is very important to us. As you are aware, we deal with pharmaceutical products. Certain products are very sensitive in terms of temperature so we need to deliver them ASAP. We deal with surgical products too, so if we are not able to deliver on time, doctors or surgeon are not able to perform the surgery.
4	What are the lead time/response time required?	For normal deliveries, we require customers to confirm order at least 3 days in advance so we can our deliveries better. For urgent cases, it's on demand basis. We will take into consideration of the urgency.
5	Do you think your company has the right/sufficient facilities to support/compete with your competitors?	Yes, we are expanding and improving our facilities. And I don't think our competitors are able to provide a service as rapid as us.
6	What transportation model do you practice?	This is depends on the orders. We usually consolidate the orders to achieve full truck load (FTL). But for urgent cases, it is order by order basis.
7	What are the risk exposure/measures taken?	The risk that I can think of is not able to deliver on time. To eliminate this, we always encourage real time updates on

		our deliveries. We also have a tracking system that allows us and customers to track and trace their order status/location.
8	How do you define supply chain efficiency?	Achieve maximum output with minimum resources.
9	How is this different from effectiveness?	Achieving the targeted output with minimum resources.
10	What are the steps taken to ensure or promote efficiency?	We rely heavily on our system. From order processing, scheduling, picking, packing, tracking, even documentation. This will ensure all process are done accurately.
11	What are the % of order fulfillment(i.e. on time , in full)?	100%. Whatever deliveries that are scheduled on that day, we are committed to delivery them all.
12	What is % of customer satisfaction? Is it as per your targeted %? If no, why?	We are very proactive in dealing with customers. We are currently at 93% out of 100%.
13	What are the measure/metrics used to measure your performance?	We measure scorecards and dashboards, will be reviewed every month for process and quality improvement.
14	Does your company implement supply chain optimisation?	Yes, in fact we are one of the few who offers supply chain optimisation solutions to our customers.
15	How would you rate your optimisation level?	Optimisation is embedded into our processes. So, if we are able to achieve 100% fulfilment, our optimisation level shall be 100% too.
16	Does your organisation practice TQM?	Yes, we have TQM, ISO 9001, GDP, QRM and we are looking into implementing ISO13845 too.

17	What are the areas of TQM implementation?	All areas in the organisation. In fact, we do have an internal quality team to study all the operations and processes, and suggest improvements.
18	What are the areas of GDP implementation?	From the starting point of receiving to delivery.
19	Do you know what are the differences between ISO VS GDP?	ISO certification is for all industries certifying the quality standards. GDP is only for pharmaceutical related industry.
20	Till what extend do you think GDP & ISO are related?	Both are focuses on quality assurance.
21	Which are the areas in GDP requires longer processing time?	All processes requires similar processing time. GDP or not doesn't really impact the operations.
22	What are the common issues do you face while implementing GDP?	Understanding the requirement is the main issue. As certain standards mentioned are not really practical, especially when you try to achieve optimisation.
23	Does implementing GDP reduce the production/delivery/processing time? If yes, why?	GDP coupled with our tracking system do ease us in track and trace our mistakes when problems arises.
24	What are the risk exposure/measures taken?	By implementing all the possible certification and strategies. We have ISO, GDP, TQM, optimisation, QRM, I can say that we took all the possible risk control measures.

Any other comments or suggestions:

We should always emphasised on integrated, transparent systems that provide real-time information and visibility throughout the supply chain. I firmly believed that the seamless flow of information (for instance, quality standards, documentation

requirements, or updates on order status) is an essential building block of an efficient and effective supply chain.

5.2.5: Interview 5

Interviewee 5 is the assistant manager in the distribution department of F-T Corporation (Corp.), Malaysia, provides customers and businesses worldwide with a broad portfolio of transportation, e-commerce and business services. With annual revenues of $58 billion, the company offers integrated business applications through operating companies competing collectively and managed collaboratively, under the respected F-T Corp. brand. Consistently ranked among the world's most admired and trusted employers, F-T Corp. inspires its more than 400,000 team members to remain "absolutely, positively" focused on safety, the highest ethical and professional standards and the needs of their customers and communities. Figure 5.6 present the nodes containing all the concept and principles gathered from this feedback.

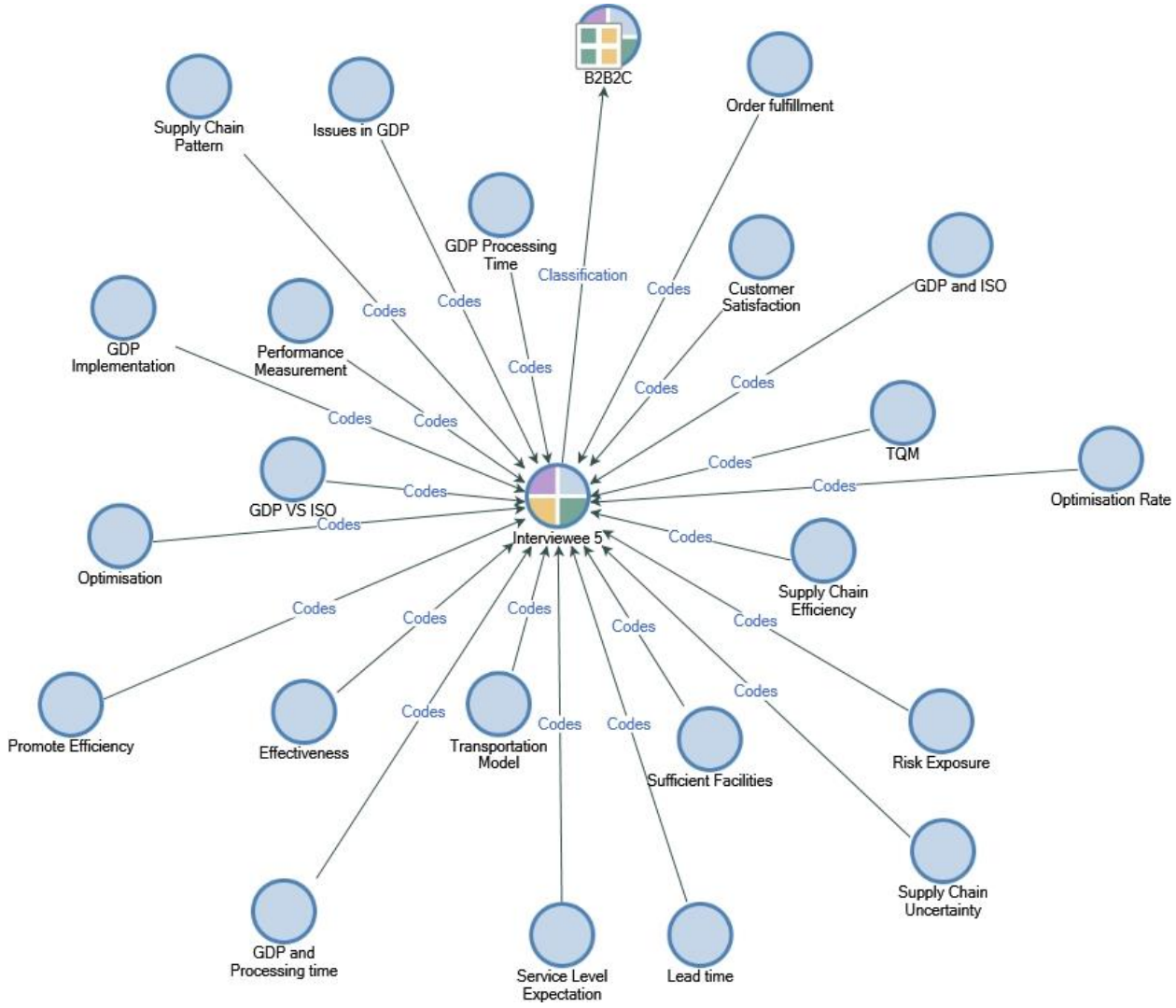

Figure 5.6: Project Map- Interviewee 5

1	What are the supply pattern in your industry/company?	We are a 3PL where we provide delivery services. We handle many types of products namely chemicals, healthcare/ pharmaceutical products, documents, food and beverages, etc. Different products will have different handling process.
2	Are there any supply chain uncertainty in your daily operation? If yes, how	We don't really have uncertainties in terms of order processing and fulfilment. But uncertainties due to manpower or

	often?	trucking is quite common. I would say 1-2 cases a month.
3	What are the service level expected by your customers?	We always strive to achieve the 7 Rights. With that, we are able to achieve high level of customer satisfaction.
4	What are the lead time/response time required?	Similar to our competitors, for normal delivery we require at least 3 days in advance notice. As for urgent cases, it's on demand basis.
5	Do you think your company has the right/sufficient facilities to support/compete with your competitors?	At this moment we may not be as compatible but we are expanding our customer base and improving our facilities.
6	What transportation model do you practice?	For normal deliveries are usually full truck (FTL) and urgent orders are by order basis (i.e. LTL).
7	What are the risk exposure/measures taken?	Similar to all 3PLs, not able to deliver on time. We do have a tracking system to update us on the order status and location. Shipments that were not delivered on time are either classified under Right Day Late (RDL), Wrong Day Late (WDL), or lost shipments. Causes of delays are also specified such as weather, mechanical, and clearance, to name a few.
8	How do you define supply chain efficiency?	To be able to deliver at the shortest possible time.
9	How is this different from effectiveness?	To be able to deliver at the shortest possible time with minimum input(resources).
10	What are the steps taken to ensure or	Clear SOP. Management have a clear set of SOP for us to follow in order to

	promote efficiency?	ensure efficiency.
11	What are the % of order fulfillment(i.e. on time , in full)?	We are currently at about 87% and targeted rate is 99%.
12	What is % of customer satisfaction? Is it as per your targeted %? If no, why?	We are currently at about 90% out of 98%.
13	What are the measure/metrics used to measure your performance?	We implement benchmarking system.
14	Does your company implement supply chain optimisation?	Yes, we do. We practice optimisation in delivery and returns.
15	How would you rate your optimisation level?	This is a very challenging question because its depends on the number of business units. I would say we are at an acceptable level but of course there are areas for improvements.
16	Does your organisation practice TQM?	Yes, we do. Apart from TQM, we also have ISO 9001.
17	What are the areas of TQM implementation?	The whole organisation. We always focus on continuous improvements.
18	What are the areas of GDP implementation?	We offer full service solutions i.e. end to end. From order processing to delivery.
19	Do you know what are the differences between ISO VS GDP?	GDP documents are usually structured, focusing more on quality management systems, procedures and documentation rather than technical details such as equipment and facilities. They address quality systems and risk management, responsibilities, records, training, self-inspections, complaints and corrective measures. On the other hand, ISO focuses on complying to the standards.
20	Till what extend do you think GDP & ISO are related?	Both are focuses on quality assurance.

21	Which are the areas in GDP requires longer processing time?	All processes requires similar processing time.
22	What are the common issues do you face while implementing GDP?	No one fixed standards and focus area. There are about 50 versions of GDP documents worldwide by now. While the focus used to be on cold chain management to reduce temperature excursions, the scope has now expanded to include issues related to security and counterfeiting. Thus, it's not easy to handle and keep changing the focus and processes.
23	Does implementing GDP reduce the production/delivery/processing time? If yes, why?	Our Quality Management System (QMS) are embedded with GDP and GMP which is specially designed for pharmaceutical/ healthcare industry. It provides a very clear details for us to track the shipment's location.
24	What are the risk exposure/measures taken?	We have a very clear and practical set of QMS to ensure all safety measures are considered.

Any other comments or suggestions:

The value of optimising delivery and return of critical parts is essential in our highly competitive 3PL industry. Optimising resources for the business of service is a challenging task. Therefore we need all parties involved, parts and information must be integrated in a unified and effective process. All these factors collaborate to optimise distribution and return costs of critical inventory, improve customer satisfaction, and increase profits.

5.3: Conclusion

It is no doubt that GDP implementation is an important issue for all companies. Several decision making processes require accurate and clear standards in order to choose proper actions relevant to production planning, receiving, storage and inventory,

packing and picking, delivery, and so forth. For this reason, over the years, Ministry of Health (MOH) Malaysia and many independent consultants have devoted particular attention to identify the problems of non-standardised standards, and how GDP implemendation can be improved to increase quality assurance (Ministry of Health Malaysia, 2012). The results of this study offer new insight for all pharmacuetical and healthcare organisation, Table 5.1 below shows the matrix coding query to support this statement. Figure 5.7 depicts the coding reference count of the interviews results.

	A : B2B2C	B : B2C
1 : Area of TQM Implementation	3	2
2 : Transportation Model	6	5
3 : TQM	9	6
4 : Supply Chain Uncertainty	4	2
5 : Supply Chain Pattern	4	4
6 : Supply Chain Efficiency	3	2
7 : Sufficient Facilities	4	2
8 : Service Level Expectation	3	2
9 : Risk Exposure	9	7
10 : Promote Efficiency	5	5
11 : Performance Measurement	5	3
12 : Order fulfilment	6	3
13 : Optimisation Rate	6	2
14 : Optimisation	6	4
15 : Lead time	5	5
16 : Issues in GDP	3	2
17 : GDP VS ISO	7	5
18 : GDP Processing Time	3	3
19 : GDP Implementation	5	6
20 : GDP and ISO	3	2
21 : GDP and Processing time	3	3
22 : Effectiveness	3	3
23 : Customer Satisfaction	4	4

Table 5.1: Matrix Coding Query

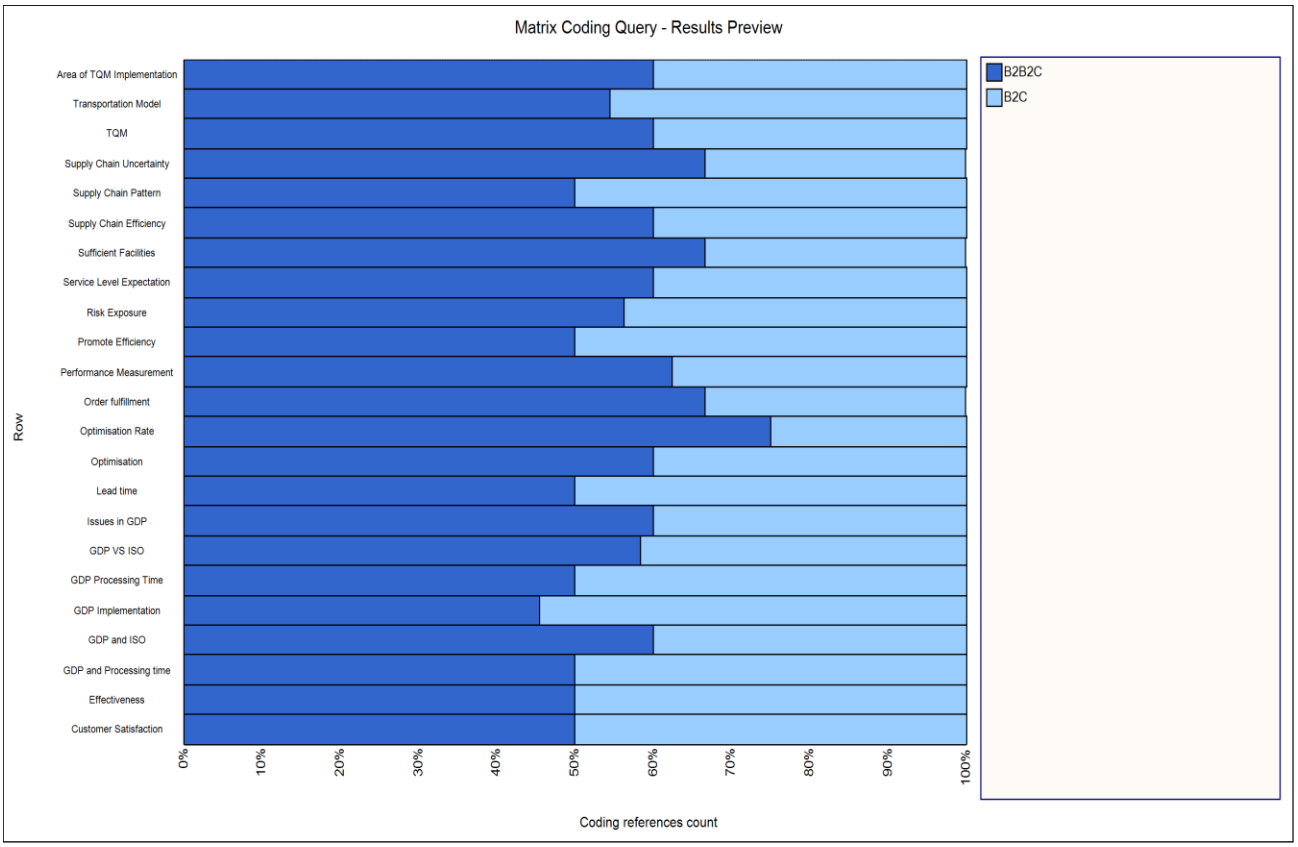

Figure 5.7: Matrix Coding Query- Results

Firstly, the framework suggest that adoption of GDP policy in the process configuration stage is the best approach as effective communication and integration is crucial in this process to enable one standard to be used throughout the business. This can be achieved by discussing the standards and requirements, and adding in business knowledge from all parts of the business that include operations, warehouse and inventory, logistics, and production, so that a consensus is reached and non standardisation will be eliminated. By practising this, efficiency and effectiveness of the whole supply chain will increase tremendously.

Secondly, optimisation level should be implemented by all departments and adjustment can be made to increase the accuracy of the results. For instance, the company can implement a process that uses computer software such as capacitated location, production, distribution model with external factors, and knowledge input from delivery team, customer service, and other personnel to adjust these optimisation results. Apart from that, quality and risk mangement should be prioritised as this models are very cricual in the pharmaceutical/ healthcare industry. By integrating these three models, the company can improve the overall distribution process and achieve on time delivery.

As a conclusion, companies should realise the importance of efficiency and effectiveness in its operations. As they improve their efficiency and effectiveness, they may experience reduction in costs and increase in customer and employee satisfaction. Also, costs decline in inventory levels, raw materials, production, logistics, and transportation. Greater customer satisfaction accrues from more accurately anticipating demand and subsequently, fulfilling the demand more often. Greater employee satisfaction also comes from a more understandable process, easier information access and transfer. But company must recognise that the first step to gain these benefits and advantages is to recognise the importance of efficiency and effecivenss as a management function. With this recognition comes willingness to commit to necessary resources to improving this critical process.

Chapter 6: Conclusion , Recommendation & Contribution

6.1: Introduction

Previous supply chain design research has focused on developing frameworks that aim to improve certain aspects of supply chain performance. This framework takes a more integrated approach to supply chain design by incorporating the strategy, process and resource dimensions, thereby enabling the assessment and improvement of supply chain performance across multiple areas. This chapter summarises the findings of this research followed by a discussion on its contribution to our knowledge and offers suggestions for further study.

6.2: Summary of Research

Chapter 1 expresses the overview of the pharmaceutical industry in Malaysia. This chapter also outline the research aim and objectives.

Chapter 2 consists of sections namely context background and literature review of supply chain, and process and requirements of Good Distribution Practise (GDP). The context background aims to introduce the main terminologies and concepts that the reader needs to know before reading the literature review and other chapters. It starts by introducing the perception of supply chain management, and then it introduces the requirements of GDP. The literature review discusses similar works and different techniques adopted and ends by summarising the limitations.

Chapter 3 discusses the research methodology employed and appraises the potential supply chain frameworks and models available that are widely implemented in the industry.

Chapter 4 describes, in chronological order, the proposed integrated supply chain design framework, which integrates six different models, each of which performs a defined role within the overall supply chain design.

Chapter 5 analyses the interview feedback from companies that was undertaken to implement and verify the proposed framework.

Chapter 6 concludes the outcomes along with the remaining limitations, provides recommendations, and identifies future works.

6.3: Research Aim & Objectives

This research was designed to address an overall aim and supported by a set of specific research objectives, as follows:

6.3.1: Research Aim

To design and develop an integrated framework in which efficiency, effectiveness, optimisation, and Good Distribution Practices (GDP) are concurrently considered in the design of pharmaceutical supply chains in Malaysia.

This research aim is achieved by integrating six model that are widely implemented by the industries. To address the objectives; how this was achieved is discussed in the following paragraphs.

6.3.2: Research Objectives

1. **To perform a comprehensive literature review to establish the current knowledge and practices in the field pharmaceutical industry, in particular, supply chain design, supply chain planning, supply chain operations, and key performance indicators (KPIs)**

   This objective is achieved through a critical review of academic and practitioner literature in Chapter 2 covering various areas of supply chain namely supply chain management, supply chain management framework, supply chain design, supply chain strategy, strategic supply chain management, supply chain performance, supply chain efficiency, supply chain effectiveness, supply chain optimisation, and cold chain. In the aspect of pharmaceutical, elements of Good Distribution Practice is review in detailed. The review of these areas helped in formulating an initial conceptual framework.

   Apart from that, methodology mentioned in Chapter 3 was applied to describes the philosophical approach that is suitable in this study and process of developing a supply chain management framework. It evaluates the potential supply chain frameworks and models that are implementable in the pharmaceutical industry.

2. **To develop the proposed framework used for the management of an efficient and effective cold supply chain**

   This objective is achieved by integrating six models as mentioned in Chapter 4. The framework developed consist of Strategic Fit model to explain the strategic role and objective of the framework, Good Distribution Practise (GDP) model to clarify the supply chain specifications and requirements, Total Quality Management (TQM) and Quality Risk Management to establish all processes that are designed encompass quality assurance and continuous improvements, Supply Chain Network Optimisation model to ensure the optimal distribution pattern has been achieved, and lastly performance indicator model to measure efficiency and effectiveness.

3. **To verify and validate the proposed framework**

   This objective is achieved by gathering feedbacks from interviews from three pharmaceutical companies and two third party logistics provider (3PL) companies that offers distribution and storage for pharmaceutical companies. In analysing the data, the interviews were recorded in audio files, those audio files were transcribed using NViVo. Project map for each interview are created to further verify and validate the framework.

4. **To conclude the overall work**

   This objective is achieved in Chapter 6 that summarises the findings of this research followed by a discussion on its contribution to our knowledge and offers suggestions for further study.

6.4: Summary of Findings

1. No consensus among authors on the definition of supply chain design

Although the concept of supply chain design has been known since 1998, no researcher has yet to produce a widely accepted definition of either the concept or its scope. Various researches have been carried out in this field of study, most of which historically focused on questions such as facility location, and if supply chain design should consider the operational dimensions limited to scheduling and resource allocation, or

whether it should also encompass strategic issues. Nonetheless, the scope of supply chain design research has extended to cover service requirements, supply chain security, risk and sustainability. A number of researchers have discussed supply chain network design from the perspective of process, investments and structure.

2. ***There is no single framework that addresses all three dimensions of efficiency, effectiveness, and optimisation***

Supply chains must reconcile the competing pressures of effectiveness, which usually incurs a higher cost, and cost-efficiency, which is often achieved at the expense of market responsiveness. Efficiency is also likely to be impacted by the growing pressure to meet "green" demands and operate sustainably. Any attempts at optimisation must therefore consider all three dimensions simultaneously. However, to date frameworks have not been developed to improve all the three performance aspects. The closest framework to meet all aspects has been Ambe and Badenhorst-Weiss's framework, which considers efficiency and responsiveness.

3. ***No integrated framework has been developed to tie the important aspects of supply chain design together***

Literature review revealed that no researcher has yet to produced a framework integrating the strategy, process and network aspects of supply chain design. The framework proposed in this study comprises a strategic model, a process model and a network model, each of which performs a defined but complementary role. Collectively, this offers an integrated model of supply chain design.

6.5: Contributions to Knowledge

The proposed supply chain framework integrates strategy, process and resources to investigate efficiency and effectiveness simultaneously during the design process. Being demand-driven, it assumes that supply chains are designed to satisfy certain demand characteristics. The proposed framework comprises a strategic model, process model, network optimisation model and a performance model, each performing a defined role but integrates with each other.

The strategic objective model seeks to identify the most effective way of meeting customer requirements, taking into account supply chain capabilities and uncertainty. Its main strategic offerings are lean, agile and leagile strategies. Where demand is predictable, supply chains are advised to adopt a lean strategy; if lead time is short,

they may implement a continuous replenishment policy of replacing products as they are sold or used, but where lead time is longer, a plan and execute policy may be more appropriate.

In either scenario, the process model suggests that companies following lean strategy should adopt a make-to-stock policy in which processes are configured to reduce costs and make the maximum use of available resources. Supply chain capabilities tend to be pre-planned for long periods of time, unvaried, and fixed with no excess capacity. Since supply chain functions must operate within these capability restrictions, production is massive and standard, inventory is high level and unvaried, and transportation processes utilise low cost modes (e.g. FTL) and seek to reduce transport time as much as possible.

Conversely, the aim in agile strategy is to satisfy unpredictable customer demand with short lead times and perfect fulfilment. In this case, the process model suggests a make-to-order policy in which resources are variable, varied and excess. Production policy is characterised by product variety, low product volume and short process time. Inventory is kept low but varied, postponement or quick response policies are the norms, and transportation modes are fast and flexible. Lastly, in the leagile strategy option, the process model suggests a make/assemble-to-order policy. This is a combination of the make-to-stock and make-to-order policies.

The next component within the framework is the process and network model, namely, total quality management (TQM), quality risk management (QRM), and optimisation. All of these resources and the associated decision making (e.g. regarding locations, capacities and technologies) are directed towards achieving the strategic objectives of the supply chain using the policies suggested by the process model.

The last component in the framework is the performance model, which aims to measure supply chain performance and show the extent to which the supply chain is achieving its objectives of efficiency and effectiveness.

6.6: Industry Implementation Process

Firstly, in defining process configuration stage, companies should familiarise themselves with the elements and requirements of GDP. This stage should be implemented through the preparation and establishment of an approved Quality Manual (QM) that is controlled under the Documentation Management system. Appropriate Key Performance Indicators (KPIs) should be defined in the Quality Manual for critical activities and for performance of the Quality Management System (QMS) itself.

Requirements for monitoring KPIs should also be defined in the Quality Manual and reflected in individual Standard Operating Procedures (SOPs).

Secondly, in the stage of deciding the strategy, companies should involved the stakeholders to reflect on the key strategic issues and obtaining information from market and customers to understand their market position. Once companies have identified its current position in the market and outline its potential strategic objectives as mentioned in section 6.5 and aligned with their mission and vision, companies can determine a timeline and identify the resources needed to achieve the goals, as well as key performance indicators (KPIs) to make its success measurable. It is important to set up regular reviews with individual contributors determine check-in points to ensure objectives and goals are in line. This also gives companies an opportunity to re-evaluate its priorities and course-correct based on past successes or failures.

In stage three, structuring supply chain design, companies should focus on continuous improvement in all area of its business and this is the main objective of Total Quality Management (TQM). Continuous improvement must deal not only with improving results, but more importantly with improving capabilities to produce better results in the future. From the feedback obtained through the interviews, the five major areas of focus for capability improvement are demand generation, supply generation, technology, operations and people capability. It was also mentioned that if an organisation has a track record of effective responsiveness to the environment, and if it has been able to successfully change the way it operates when needed, TQM will be easier to implement. If an organisation has been historically reactive and has no skill at improving its operating systems, there will be both employee scepticism and a lack of skilled change agents. If this condition exist, a comprehensive program of management and leadership development may be introduced. A management audit is a good assessment tool to identify current levels of companies' functioning and areas in need of change.

Apart from that, companies should establish an appropriate and structured supply chain to maximises effectiveness as well as efficiency in order to bring the most benefit in its supply chain. This can be achieved by maintaining healthy relationship with its suppliers and understanding the total cost of ownership/consumption (TCO) of a product or service. This will provide companies with a clearer view of its cost of acquisition and profit margin. As a result, companies will be able to reduce supply chain costs, improving responsiveness to customers' needs, enhancing delivery performance, minimising supply chain complexity, strengthening supply chain sustainability, improving volume flexibility, optimising end-to-end visibility, and mitigating risk.

Lastly, to design a good performance measures or Key Performance Indicators (KPIs), it is best to keep it simple, clear, and easily measured. From the feedbacks obtained, it is suggested to have performance measurement embedded into routine planning, reporting, decision-making and performance improvement processes. Management team should align and link goals and measures throughout the whole organisation. This will ensure consistency, effectiveness and efficiency in all the supply chain management processes.

6.7: Limitations

Although interviews are useful as a mean of gaining in-depth information, there are practical difficulties associated with the attempt to undertake an interview as a precise and effective method of research. Designing and scoping a questionnaire in order to ensure that the research question can be adequately and appropriately answered can be difficult, and data collection for this research method can be time-consuming and tedious. Furthermore, interviews often result in the accumulation of large amounts of data (Yin, 1984).

Besides that, the availability of suitable participants may be restricted, as business and other organisations are not always willing to participate in interviews. The feedback given may not always be accurate and reliable as participants tend to provide bias opinions.

Apart from that, the lack of real-life data on existing supply chain is also a limitation because this prevents the researcher from modelling and running simulations to investigate other aspects of supply chain design.

The lack of a common research approach to supply chain design questions the extent to which this research is consistent with supply chain design practice in the industry. Therefore, future study should investigate is the extent to which this research support real-life practice and the factors that shape this practice.

6.8: Future Work

Literature review informed that simulation researchers who investigate supply chains at the strategic level rarely employ simulations as a method used in their investigations. Thus, more research is needed to determine whether simulation-based research contributes to supply chain practice, especially at this level, where simulation is important. Therefore, future work to expand the aspects where this research are:

- To model and simulate this research to investigate the other potential aspects of supply chain designs
- To apply the concept of strategic fit by examining empirically the optimum strategy each supply chain member should adopt to improve overall supply chain performance
- To investigate and model different process configurations by designing supply chain capabilities to implement specific strategies
- To identify the best supply chain network configurations in terms of centralisation and decentralisation strategy and business location
- To further explore the interactions between the framework models, such as how sustainability assist in achieving supply chain strategy, the impact of different supply chain network configurations and the impact of decoupling point locations on strategy achievement.

6.9: Conclusion

It is no doubt that supply chain efficiency, effectiveness and optimisation along with GDP implementation is an important issue for all pharmaceutical companies. Several decision making processes require accuracy and consistency in order to choose proper actions relevant to production planning, sales budgeting, new product launches, promotion planning, and so forth. The results obtained highlight the importance of achieving consistency between customer expectations, in terms of cost and service level, and supply chain performance in today's competitive business environment. Despite this, however, no integrated supply chain design framework exists to control all the important functions related to supply chain strategy, structure, process and performance.

This research contributes to knowledge by designing and developing a framework that integrates strategy, process and resources, and considered the three dimensions of efficiency, effectiveness and optimisation concurrently during the design process. The proposed framework was applied and validated using the interview method because this allowed supply chain performance to be assessed under a range of scenarios.

As a conclusion, companies should realise the importance of GDP implementation in its operations. As they improve their efficiency, effectiveness and optimisation, they may experience reduction in costs and increase in customer and employee satisfaction. Also, costs decline in inventory levels, raw materials, production,

logistics, and transportation. Greater customer satisfaction accrues from more accurately anticipating demand and subsequently, fulfilling the demand more often. Greater employee satisfaction also comes from a more understandable process, easier information access and transfer. But company must recognise that the first step to gain these benefits and advantages is to recognise the importance of GDP implementation as a management function. With this recognition comes willingness to commit to necessary resources to improving this critical process.

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