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RISK ASSESSMENT OF A SUPPLIER IN THE PHARMACEUTICAL INDUSTRY

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ABSTRACT

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The topic of this Master's Thesis is risk assessment in the supply chain, and the work was done for a company operating in the pharmaceutical industry. The unique features of the industry bring additional challenges to risk management, due to high regulatory, documentation and traceability requirements. The objective of the thesis was to generate a template for assessing the risks in the supply chain of current and potential suppliers of the case company.

Risks pertaining to the case setting were sought mainly from in-house expertise of this specific product and supply chain as well as academic research papers and theory on risk management. A questionnaire was set up to assess the found risks on impact, occurrence and possibility of detection. Through this classification of the severity of the risks, the supplier assessment template was formed.

A questionnaire template, comprised of the top 10 risks affecting the flow of information and materials in this setting, was formulated to serve as a generic tool for assessing risks in the supply chain of a pharmaceutical company. The template was tested on another supplier for usability and accuracy of found risks, and it demonstrated functioning in a differing supply chain and product setting.

TIIVISTELMÄ

Tekijä: Jukka Riuttala

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Diplomityön aiheena on riskien arviointi lääketeollisuudessa toimivan yrityksen toimitusketjussa. Toimialaa ohjaava lainsäädäntö , viranomaisvaatimukset sekä potilas- ja käyttäjäturvallisuuden korostunut merkitys tuovat lisähaasteen lääketeollisuusyritysten riskienhallintaan. Diplomityön tavoitteena oli luoda kyselylomake, jolla yritys pystyisi arvioimaan nykyisten ja potentiaalisten toimittajien operatiivisia riskejä toimitusketjussa.

Liiketoimintaympäristöön liittyviä riskejä pyrittiin tunnistamaan hyödyntämällä yrityksen omaa asiantuntemusta kyseisessä tuote- ja toimitusketjuympäristössä, sekä perehtymällä akateemisiin toimittajariskitutkimuksiin ja riskienhallintamalleihin. Löydettyjen riskien arvioimiseksi laadittiin kyselykaavake, jossa riskit arvioitiin niiden vaikutuksen, todennäköisyyden ja havaitsemisen mahdollisuuden mukaan. Riskien vakavuuden arviointi toimi lähtökohtana luotaessa kyselylomaketta toimittaja-arviointia varten.

Kyselylomake koostui kymmenestä vakavimmasta riskistä, jotka vaikuttavat haitallisesti informaatio- tai materiaalivirtaan toimitusketjussa. Lomake laadittiin toimimaan yleisenä työkaluna riskien tarkastelua varten yrityksen toimitusketjuissa. Kyselyn yleispätevyys vahvistettiin testillä, jossa kysely suoritettiin myös toisella toimittajalla. Näin varmistettiin kyselykaavakkeen toimivuus myös toisenlaisessa tuote- ja toimitusketjuympäristössä.

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Writing the thesis for a multinational pharmaceutical company has been a superb and interesting task. Accommodating oneself to a new country is always challenging, but with the help of new friends and colleagues this was also overcome. I would like to thank my professor, supervisors, and other colleagues for their input and guidance in the thesis writing process.

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1 INTRODUCTION

Globally there is an increasing demand for various pharmaceutical products. With major advancements in the manufacturing and research of effective medicines, a greater population can afford medicine that saves lives. From the business perspective, this positive trend gives further motivation to do more research to stay on the top of the development curve of new therapies.

As economic instability and turbulence has increased in the new millennia, companies in all industrial sectors are becoming more and more cautious about large investments. The pharmaceutical industry is no stranger to large investments into research and production facilities, but in these times those investment risks might not turn in their favor.

The topic of this thesis deals with pharmaceutical company risk management, and more so assessing possible risk areas of a sought or existing partnership. The background, objectives and limitations, the methodology and the structure of the study are covered in the following chapters.

1.1 Background of the study

From an idea to the use of the final consumer or healthcare professional, the road for a drug is long and costly in the pharmaceutical industry. The process from the research to the pharmacy or hospital shelves takes several years, often times more than five years. Furthermore, due to strong patents on the products, the drugs are usually on the market for a significant amount of years without nearly any competition for that specific drug. This is a unique situation when comparing to a traditional manufacturing industry, especially in today's fast changing business environment.

The area of supply chain risk management in all businesses alike is important, but especially in the pharmaceutical industry as product life cycles are usually long, often times more than ten years. Therefore for the functioning of the supply chain system it is most advantageous to have long-term business partnerships. Changing for example suppliers in the growth or maturity stages can be extremely harmful to the supply of the drug to markets, and also for the revenues of the pharmaceutical company. In order to go into negotiations for a long term contract, it is vital for the case company to know as much about the supplier company as possible. This needs to be done in order to mitigate and give insight to possible risks that the specific supplier brings to the partnership.

Therefore, a standard procedure for analyzing and seeking risks in the supplier selection and evaluation should be in use. The procedure should be proactive, not reactive. With such method or template, the buying company can go into partnership negotiations with better knowledge on the current state of operations of the prospective supplier and the specific risks it may bring along. For the start of a long partnership, it is understandable that the buying company wants a supplier that is in good financial health and that takes care of all agreed issues in an orderly manner. Previous track record of operations and experience from the pharmaceutical industry are also key initial criteria.

1.2 Objectives of the study

Most companies have means for assessing current and prospective suppliers in the general level. The template formulated in this thesis is focused more on the critical risk areas that could disturb the smooth flow of information and/or materials in the supply chain. Generally speaking, the objective of the study can be stated as:

The objective of the study is to create a template for evaluating a supplier of a pharmaceutical company in ensuring efficient information and material flows.

The template is generated for the pharmaceutical industry with contract manufacturing schemes in place, but with some changes it could be used in other industries as well. The template raises questions about the supplier operations, supporting the supplier selection process of the company. The usage of the template is not limited to aiding the new supplier selection process. It could also be used for evaluating current suppliers, as an interim report along with the regular audits. The formulation of this risk assessment template is based on an example product and supply chain orientation in the pharmaceutical industry. As a starting point for accomplishing the objective of the study, one has to consider the following research questions:

1. *How can a company assess risks in their supply chain in a proactive manner?*
2. *What are the possible methods for data collection and evaluation in this case setting?*

With only minor modifications, the template could be used to assess a supplier of another product with a different supply chain orientation. In the event of a successor product launch to the example product used in this thesis is to take place, the template could be used directly as guidance for evaluating the potential suppliers. The buying company is a large corporation, and the production volumes of the medicine are also large.

As for limitations and defining the scope of the study, a few points are to be noted. The geographical location for both the example supplier and the buying company is in Europe, and the major markets for the product are in the European and American regions. For data collection of the risk areas, one supplier of the specific medical device has been chosen. The focus of the research is on the upstream of operations, as downstream supply chain operations from the case company to the consumer are handled well, and is thus out of scope of this thesis. Also, risks in the procurement process are ruled out of the scope. The thesis will focus more on the operative side and partly the supplier selection process where the flow of materials and information

are important aspects. The example supplier is one of the major suppliers of the medical devices, in which the buyer company inserts the drug in its own facilities.

1.3 Research methodology

The research methodology for this thesis is comprised of five parts. The majority of the data collected is done via questionnaires to selected respondents in the suppliers' operations. Data collection has also been done by conducting interviews, visiting production facilities, and viewing internal and external documents of the companies in question. The research methodology process used in this thesis is illustrated in figure 1.

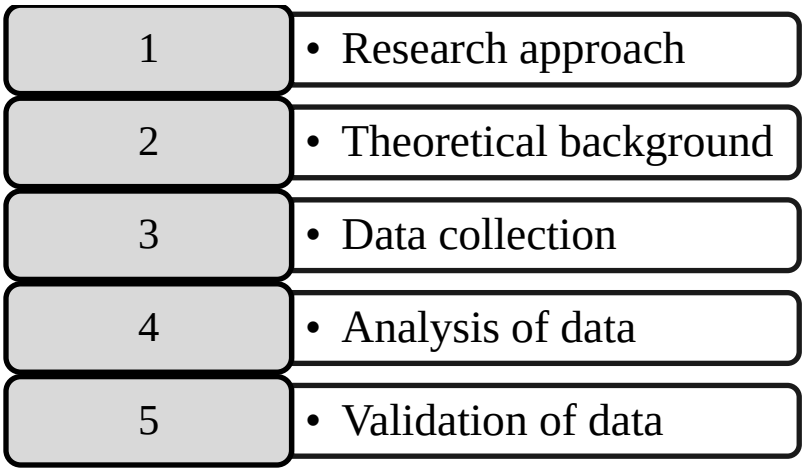

Figure 1. Research methodology process

As seen in figure 1, the first step of the research methodology process is the formulation of the research approach. In this stage, talks were conducted with the case company about the goals and desired outputs of the thesis project. Based on this information, it was possible to acquire knowledge on the subject matter by research of the theoretical background, shown as step 2 in figure 1. This information was mainly sought from academic research journals, but as well as from supply chain management and risk management literature. The third step in the process was the data col-

lection for the empirical part of the thesis. Here the theoretical knowledge on risk management and systematic approach methodologies came into play in formulating the data collection questionnaires. The first questionnaire was formulated to acquire knowledge on the risks in the example supply chain. The second questionnaire was partly an analysis of the found risks, therefore also falling into the fourth step of the research methodology process. In the analysis step, the actual supplier risk assessment template was formulated from the collected data. In the last step, the validation of data, the template was tested on another supplier for ease of use and applicability of the sought risks.

1.4 Structure of the study

This study is structured into roughly four parts following the introduction chapter. The structure is quite similar to the research methodology steps described above. The structure of the thesis is divided into:

- Theoretical background
- Data collection
- Formulation and validation of the template
- Conclusions and discussion

In the theoretical background section, the models, methods and concepts for the empirical part of the thesis are covered. The theory used in this thesis consists of three distinct areas. The first area is the theory of a manufacturing industry supply chain, its orientation and features related to the case of the pharmaceutical industry. The second part consists of the theory on risk in the supply chain. Concepts of defining risk and risk management are elaborated. In the last section of the theory part, approaches to systematic improvement in the risk management field are introduced. Here different methods for assessing risks in the supply chain are presented, namely the FMEA and mathematical modeling methods. Also a decision making/data parsing method used

in the thesis, the Delphi method, is explained. The theory covered is mainly used in the data collection section of the thesis.

In the data collection section, the case setting is firstly explained. Orientation and layout of the supply chain in question is elaborated through a supply chain mapping of the individual nodes. Steps for collecting the data for the formulation of the template are also described. The steps used are in line with the Delphi method.

The formulation and validation of the supplier assessment template is the main output of the thesis. For the formulation of the template, the results of the data collection process were first analyzed and organized. From the classification of the found risks, a selection of ten vital risks was chosen for the template. This supplier assessment template was validated by testing the functionality of it with another supplier of the example product. From the results of this trial, valuable information on the formulation and usability of the template was received. This information was used to improve the template.

In the last part of the thesis, namely the conclusion and discussion, the project as a whole was evaluated. Analysis of the applicability of the theory for the empirical part, methods for data collection and the concrete results of the thesis are discussed. Suggestions for further research and additions to the methods or results of the project are also discussed.

2 THE SUPPLY CHAIN

In this chapter, an insight to the concepts of the supply chain is introduced. In today's supply chain operations, risk avoidance and mitigation are important factors to consider for a sustainable and efficient system. Companies do a lot of research on their supply chain operations, as the supply chain operations are potentially a significant source of cost reductions. Furthermore, a well-functioning supply chain ensures the on time delivery of the goods produced, generating monetary and material flow for the company.

The knowledge of the suppliers and the whole company supply chain are key factors in preparing for unforeseeable events. This is true for both upstream and downstream of the supply chain. A prime example of a company's knowledge on the supplier base and having a risk mitigation strategy is from the turn of the century in the United States. In New Mexico, a natural phenomenon shut down a production plant of an electronics industry chip-maker. One buyer relied solely on this supplier, and waited for weeks for the production to be started again. Another competing buyer had prepared for an adverse event, and had other options for acquiring the chip needed for their products. The end result was that the buyer with a plan in case of such events had very little impact on the final assembly of its products. Therefore the company gained significantly market shares and profits during that fiscal year in comparison to the other company. (The Economist Intelligence Unit, 2009)

2.1 Manufacturing industry supply chain

Before going into detail of the special features of the pharmaceutical industry, an outlook on the basic concept and definition of the manufacturing industry supply chain is explained. In literature, there are many definitions for the term supply chain. A general definition for the term supply chain can be given as:

"*A network of functional organizations that through their activities perform the logistics functions.*" (Goetschalckx, 2011, p. 3)

It should be noted here that the term "chain" can be somewhat misleading, as in today's business there hardly exist chains, but more so networks of suppliers and buyers, with value adding processing in between them. For the scope of this thesis, the terms "chain" and "network" will be used interchangeably.

In the past decades there have been some significant changes in the operations of business that have facilitated a shift towards a network-oriented supply configuration. Firstly, companies themselves have sought new ways to improve their business and logistics chains. By seeking and acquiring a flexible network of suppliers and value adding functions, companies could gain significant competitive advantage. Also, a trend of globalization has further facilitated a shift towards network orientation of the supply chain. In line with globalization, the reductions in barriers to trade and improvements in information availability and sharing give companies in various industries incentives to strengthen and develop their supply network. (Gunasekaran, et al., 2004)

Often times in supply chain literature the basic concepts are explained through traditional, simple manufacturing industry operations. In basic supply chain literature the concept of a supply chain consists of four entities, being the sub-supplier, supplier, buyer and the end customer. The sub-supplier provides the supplier the raw materials and the supplier fabricates them in their desired way. The buyer may still fabricate the product before final consumer packaging and shipping the good to the end consumer. This can be simply visualized in figure 2. It is to be noted that in addition to material flows toward the end customer, there are also information flows up- and downstream in the whole supply chain. The value of the product increases as it shifts towards the end customer, as the fabrication, manufacturing and logistics costs are to be induced on the final price of the good. This addition of value to the final good is depicted by

the grey arrow in the background of the steps in the supply chain. (Scott, et al., 2011, p. 2)

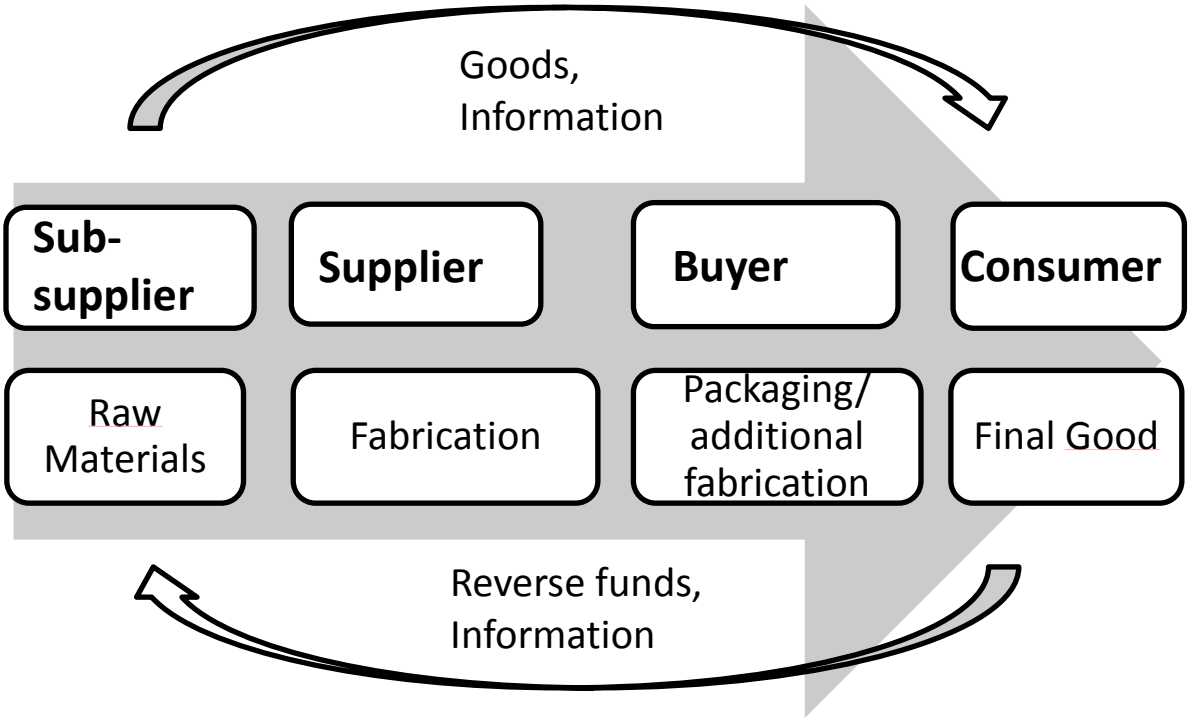

Figure 2. The basic supply chain, adapted from Scott, et al. (2011)

In supply chain literature it has been suggested that there are fundamentally two goals of the supply chain. The goals are to minimize costs and to maximize profits. Ideally, efficient utilization of the supply network possibilities can result in achieving both goals. Accomplishing both goals simultaneously is often very difficult in practice. As an addition to the before mentioned two aims of the supply network, there exists also a goal of time constraint minimization. This means that there would be a minimal amount of slack in the operations, facilitating a smooth flow of information and materials in the network. (Goetschalckx, 2011, p. 498)

As the network is broad with many individual players, the coordination between the entities can be difficult. As the players in the supply chain are at the very least differ-

ent company departments and more often different companies, sub-optimization occurs. Sub-optimization refers to the individual nodes in the network aiming to optimize their own operations with little consideration of the supply chain as a whole. Therefore it is possible that the overall performance of the supply network suffers. (Goetschalckx, 2011, p. 498)

In today's diverse and fast changing business environment, practically no supply chain is as simple as depicted in figure 2. The requirements of customers, suppliers, and buyers have significantly changed the dynamics of how a supply chain operates. This is true especially with the utilization of the internet in day-to-day operations. The chain is often very diverse, requiring flexibility and timely actions from all the entities linked to it. (Beamon & Ware, 1998) Not only the manufacturing industry encompasses the concept of a supply chain, but it also is a key part of operations in the service industry. The breadth of the chain and the stakeholders connected to it vary greatly between industries and also between companies within an industry. As suggested by many literary works, the supply chain is described as a network of connected entities to further facilitate the on-time operations that go into manufacturing a given product or service. (Goetschalckx, 2011, p. 495)

Having a network of players connected to the manufacturing of the end product gives the members of the network a possibility for optimization and decision making for the best possible setup for their specific needs. For example, in a network organization the focal company can disperse its manufacturing locations to better suit the demands of the market. One has to consider whether the company wants the operations to be quick and agile in the regional markets or does it want to seek economies of scale in production by centralizing it. For both alternatives there exists a trade-off of certain factors, such as delivery speed and response times to demand fluctuations. (Goetschalckx, 2011, p. 513)

In order to mitigate operational risks, firms are shifting more so to outsourcing certain activities in the manufacturing and fabrication of the focal product. Outsourcing and contract manufacturing is often a viable option, as the impact of globalization has forced many companies to seek cost efficiencies from various angles. With an increase in the number of activities that are outsourced, an important aspect of quality and process controlling arises. Controlling and investigating the performance of the supply network is an essential part of firms' operations, as the basis of their business relies on the functioning of the supply network. (Gunasekaran, et al., 2004)

A key constituent to a well-operating supply chain in the manufacturing industry is first and foremost good relations to the suppliers, and to the sub-suppliers. Therefore, careful planning and consideration of the possible supplier partners is conducted. Traditionally, suppliers are firstly evaluated on the efficiency, flow of information and materials, and customer satisfaction aspects. This classification is a very general one, and therefore it is helpful to classify the supplier evaluation to three more specific categories: Strategic, tactical and operational. (Gunasekaran, et al., 2004)

In the strategic level, quality and lead time versus the industry norm are evaluated. Further, cost saving initiatives and supplier pricing are considered. In the tactical level, issues regarding the ways of operational planning and the policies guiding them are evaluated. For example, capacity flexibility and cycle times are significant factors. Lastly, in the operational level the day-to-day functions of the supplier are evaluated. Here issues like the ability to stay on the production schedule, number of stoppages and defects in production, and technical competencies on the shop floor level are considered. In literature it can be seen that there are various methods for analyzing and evaluating the performance of the supply network. Many firms are overwhelmed by the array of options for measurement, and spend tremendous amounts of time and money on it. In some cases, the performance metrics tools are unnecessarily complex, and the same evaluation could have been done with basic and more robust methods. (Gunasekaran, et al., 2004)

2.2 Special industries supply chain

In addition to the traditional manufacturing industries, there are a few special industries that have unique circumstances that have to be taken into consideration when formulating and assessing the supply network. As the case company of this thesis operates in the pharmaceutical industry, special features of the supply network in this industry are introduced. Also, as a reference point for relevant abnormalities in other special industries, elaboration on the food and aeronautics industries is briefly described.

Although the three industries are functionally rather different, there are similarities in the operations of the supply network. One of the most crucial similarities as a whole is product quality, and quality management. All three industries have to utilize a form of quality management and surveillance, most often referred to as Total Quality Management, TQM. This concept entails many practical issues on how the company ensures high quality operations throughout the whole supply chain. Utilizing concepts of TQM, the company can ensure that the end product is adhering to the industry specific quality standards. TQM encompasses a diverse spectrum of issues that the company looks to improve and to have in a high-performing state. These issues include at least the following: (Beardsell & Dale, 1999)

- Planning and organization of operations
- Education and training of personnel
- Tools and techniques for production
- Quality management system

For the three special industries discussed here, the most important similarities in the ways of working are product quality and safety. For the operation of the supply chain, on time deliveries and reliability of the supplier are most important similarities between the different special industries. From the end-user/customer viewpoint, the user

experience and consumption of the good are important common factors in the special industries. This leads to companies having a very high reliance on the reputation and trust of the end-users. These special industries are highly influenced by end-user behavior, in which the reputation can be very easily lost in a short amount of time. For every industry here in question, there are numerous examples of how the end-user trust has been lost. Thus the company reputation has been highly negatively impacted in a very short time. In some cases this has also had serious negative effects on the company's financial state, causing substantial losses. Regaining that lost reputation of the end users can be an immensely difficult and long process, as explained in the next examples from the three industries.

An example of such a case in the pharmaceutical industry is the product recall of Rofecoxib in 2004 by the pharmaceutical company Merck. This product recall affected future sales, and within one day the stock price plummeted, taking out more than 25% of the company's market value. The reason for the callback was an article in the Wall Street Journal, emphasizing the elevated heart attack risk when using the product. An allegation that the pharmaceutical company knew about this was the major driver in the loss of consumer trust. It took the company a long time to regain the trust of the consumers and the investors. (Oberholzer-Gee & Inamdar, 2004)

One of the most recognizable adverse events in recent decades in the food industry has been the controversy on the baby formula especially in developing countries, and the aftermath of western consumer behavior. At the peak of the action in the late 1970's, at the focus of the controversy was Nestlé, a market leader in baby formula. Usage of the formula in developing countries was vaguely linked to deaths and illness of infants, due to various factors. This resulted in a widespread boycott of many Nestlé products, even those not linked to baby formulas, staining the company image and resulting in massive loss of sales. (Baker, 1985)

In the case of the aeronautics industry, there has been a recent incident regarding Boeing's new Dreamliner airplane. In January 2013 a battery on the plane caught on fire, which resulted in the FAA putting the planes on a flight ban until the issue was resolved. Deliveries of the planes were ceased for four months, costing the company over 2M€ for reformation of only six planes of the 50 plane fleet already delivered. Therefore a reformation of the delivered planes amounted to nearly 17M€, a sizeable cut on the finances. (AP, Reuters, 2013)

2.2.1 Pharmaceutical industry

The pharmaceutical industry is a unique industry due to several factors that vary from the client base, product qualities, and process specifications. Due to technological advancements in chemical engineering and pharmaceutical production, a wide array of medicines can be produced for nearly any illness or symptom that humans have in today's society.

Generally the pharmaceutical companies can be classified coarsely into three categories based on their size and research activities:

- Large multinational corporations which produce patented, prescription or over-the-counter medicines
- Large corporations that produce generic out of patent medicines
- Small and medium size corporations that produce generic or branded products under license (Abdallah, 2013)

The pharmaceutical industry can be well defined based on its highly regulated characteristics. The drug manufacturing process and the supporting functions have to be validated and qualified by strenuous methods. This is a costly operation, but often times the efforts made pay off with a successful and safe to use drug that saves lives. One of the major unique features of the pharmaceutical industry compared to other

industries is the quality and traceability requirements of all processed goods. Regarding all incoming raw materials and outgoing processed goods, there needs to be a clear overview of who did what and when. More so, as for example drug delivery devices that are to be used with medication and inserted to humans, clean room practices and compliance are important issues. As products need to stay uncontaminated, packaging for transport and loading and unloading practices are also important aspects to take into consideration. (Supplier, 2013)

Generally speaking, the quality and traceability requirements in the pharmaceutical industry can be summed up into a concept of Good Manufacturing Practice, GMP. In this framework there are outlined standard procedures and requirements that companies in the industry have to comply with, in order to operate and sell these products within the EU. The basic principle of the GMP framework is to ensure that the quality and operational practices are consistent within the industry. Issues regarding manufacturing processes, validation, training, facilities, traceability and various others are described in the GMP guidelines booklet published by the European Commission. (European Commission, 2010) In the case that the client sells its final goods to the United States market, it needs to have processes verified by the FDA. This means that also the suppliers' production and operations have to be FDA compatible. The main regulatory authorities for the pharmaceutical industry are the EU legislation, and the American FDA.

Uniqueness of the industry comes also from the rather long life cycles and in the best case very high volumes of the pharmaceutical products. The process of launching a new product out onto the market takes more time than in traditional manufacturing industries. Typically it takes more than five years to bring a new drug onto the markets, mainly due to the regulatory issues and extensive research that ensure that the product is safe for the consumers. All this research and ensuring product safety is very costly, making the pharmaceutical industry itself a rather risk-prone industry,

from the stockholder perspective. Though, when a successful product is out on the market, it has the potential to be very profitable for the company. (Abdallah, 2013)

Because of potentially high-profit products, and the ability to save lives, the pharmaceutical industry faces a great deal of problems from the external markets. There is an array of counterfeit medicines sold on black markets, and in the worst case in legitimate retailers. The main problem with counterfeit products is the functioning of the drug; it may be diluted or comprised of unsafe and unregulated components, causing a serious health hazard to the recipient. Therefore the company image can be adversely affected with end users purchasing counterfeit goods that do not work as the original ones are designed to. (Abdallah, 2013)

The second issue causing problems and increasing costs of operation for the pharmaceutical industry is the patient reactions to the drug. When researching the composition of the drug, not all adverse reactions can be taken into consideration. This is due to the fact that the variance and array of recipients vary greatly, making it virtually impossible to fabricate a drug that suits all patient types. To get a product successfully out on the market, the company has to make decisions on the tradeoffs in research. One area of tradeoffs is the composition of the drug to make it usable for the largest amount of people possible. (Abdallah, 2013)

The last major areas of problems for the pharmaceutical industry are issues caused by the entities of the supply chain operations. For the scope of the thesis, this area is the most interesting. This is because in the case of high-volume pharmaceuticals, logistics and materials management can be a serious pitfall and cost source for the company. Additionally, all direct supply chain stakeholders have to be also validated and ensured of the quality standards, so that they are permitted to operate in the markets. (Abdallah, 2013)

2.2.2 Food industry

Much like the pharmaceutical industry, the food industry is highly regulated, and subject to strenuous checks and validations for product and process quality. The food industry is traditionally being subject to having a wide array of suppliers. Therefore in the past, companies have aimed for economies of scale in production and shipping. The markets and especially consumer behavior have though shifted enormously, and nowadays companies are forced to offer a greater variety of products, making the supply chain and production processes even more complex. (van Donk, 2000)

The defining factor that makes the food industry unique is the nature of the goods. A majority of the goods are easily perishable; some within days, weeks or months. Only a few types of goods have a long shelf life, expanding over a year. Therefore total quality management (TQM) principles are vital to ensure a continuous and fresh flow of goods from the suppliers. (Beardsell & Dale, 1999)

Along with the TQM and Good Manufacturing Principles (GMP) supported in the food industry, the FDA imposes a special approach on ensuring product safety. The process uses the acronym HACCP, which stands for Hazard Analysis and Critical Control Point. In this framework there are set guidelines for ensuring product safety in all nodes of the supply chain, from harvesting to processing, and eventually to the end consumer. (U.S. Department of Health and Human Services, 2006) Other bodies along with the American FDA set standards for safe food processing in the whole supply chain. As an example, a collaboration of the French, Italian and German regulatory practices have fabricated a standard for the food industry, namely the IFS (International Food Standard). The practices are used by many major retailers and therefore the producers also have to be compliant with the standard. Along with such external quality and product safety standards, many companies induce their own internal best practices for quality and risk management in the supply chain. (International Featured Standards, 2013) (Nestlé employee, 2013)

2.2.3 Aerospace industry

The third special industry to be addressed here is the aeronautics industry. Much like in the pharmaceutical industry, there is a high level of competition, high development costs of end products and long lead times for new products to reach the markets. The industry is also high risk in the sense that the end products ensure consumer safety. Much like in the food and pharmaceutical industries, the end users are basically individual people. Therefore the product safety and correct functioning is and has to be ensured by various methods. Thus the industry and the products are under close surveillance from several authorities and have extensive quality systems in place, as the bad reputation of a certain product is difficult to regain. In the aeronautics industry the supply chains are often times even more complex than in the pharmaceutical or food industries, merely due to the sheer amount of individual components that go into one aircraft. The processes and sub-assemblies are highly regulated, and there must be extensive quality checks and validations for ensuring the product safety. (Alfalla-Luque, et al., 2013)

Along with the pharmaceutical industry, the aerospace industry is heavily regulated for safety of the products and sub-assemblies all throughout the supply chain. The U.S. based FAA (Federal Aviation Administration) has set comprehensive guidelines for manufacturers on assessing the risks and vulnerabilities in the safety of the products. The FAA has provided a general handbook on risk management in the industry, but naturally each aeronautics company has further its own set of guidelines and methods for risk evaluation. Some of the methods used are modified versions of the FMEA and fault tree analysis, and a special method for electrical components, namely the Sneak Circuit Analysis. The European Aviation Safety Agency (EASA) works closely with FAA in order for compliance and symmetry of used standards. This is to ensure open operation on the overseas markets, from both perspectives. (Federal Aviation Administration, 2000) (Ecorys, 2009)

In addition to the pharmaceutical industry, other special industries have strenuous methods for risk minimization, as described above. A common factor for risk acknowledgement is firstly user/consumer safety. After this, financial operational risks are considered, although these ultimately link to product safety. Gaining an insight to other industries' risk management tools and techniques is a valuable standpoint for improving ones risk management. Some techniques the other industries use may not be directly applicable, but still give a fresh perspective on a given industry's own risk management strategies.

3 RISK IN THE SUPPLY CHAIN

As mentioned in the previous chapter, special industries can in some cases be considered as high risk industries. A key element in these industries is product safety and end-user compatibility. Factors affecting the end-user experience and product safety are found in various nodes in the company supply network. For example the supplier of the medical device that is used to insert the medicine to the patient has a key role in ensuring the product safety. Therefore it is vital for the company to take the actions of the supply chain operators into close consideration. This is done in order to minimize the probability of adverse events happening, like previously described. (Kleindorfer & Saad, 2005)

3.1 Defining risk

To get an idea of what the term "risk" in the supply chain entails, it is useful to firstly define the concept of risk in the broad sense. Many researchers in supply chain management and general management give the concept of risk various definitions. Harland et al. (2003) have defined risk as a general concept as follows:

"Risk is defined as a chance of danger, damage, loss, injury, or any other undesired consequence." (Harland, et al., 2003)

Many authors, such as Zsidisin (2003) have compiled in their work a comprehensive list of definitions of risk from other researchers. Zsidisin (2003) focuses in his work on the specified definition for supply risk. In his work he bases his definition on supply risk on a research of various case studies, and the works of other researchers on the same topic. His proposed definition for supply risk is as follows:

"Supply risk is defined as the probability of an incident associated with inbound supply from individual supplier failures or the supply market occurring, in which its out-

comes result in the inability of the purchasing firm to meet customer demand or cause threats to customer life and safety." (Zsidisin, 2003)

This definition of supply risk is very comprehensive and a good starting point for gaining a view on various factors affecting the supply for a given product in the manufacturing industry. It was noted before, that scholars have various views on defining the concept of risk in supply networks, and also the term risk in general. Manuj & Mentzer (2008) though propose that although there are several views on how to define risk, nearly all the definitions address the following three components when conceptualizing the definition of risk.

1. *What are the potential losses if the risk is realized?*
2. *How likely are the losses?*
3. *What is the significance of the consequences of the losses?* (Manuj & Mentzer, 2008)

Therefore these three components give a basis for the process of investigating the occurrence and severity of a given risk. This idea is discussed in detail in chapter 4.

3.2 Risk management process

As many processes are described, the general risk management process can be simply visualized by using a diagram. Figure 3 is an adaptation from the research of Tummala and Schoenherr (2011), as they have provided a more in-depth outline for the risk management process in the supply chain. Their model is categorized into three phases. Other researchers have also concluded the risk management process to entail mainly the same phases. Variances occur in the classification of what each phase contains. For example Zsidisin & Ritchie (2009) present in their research a model consisting of four phases. In the research model of Zsidisin & Ritchie (2009), a phase of risk management has been included as its own phase, which in figure 3 would en-

compass the risk mitigation & contingency plans step in the second phase (Zsidisin & Ritchie, 2009). Kleindorfer & Saad (2005) in turn also use a three phase model, which is named the SAM (Specify risk sources, Assess risks, Mitigation). (Kleindorfer & Saad, 2005)

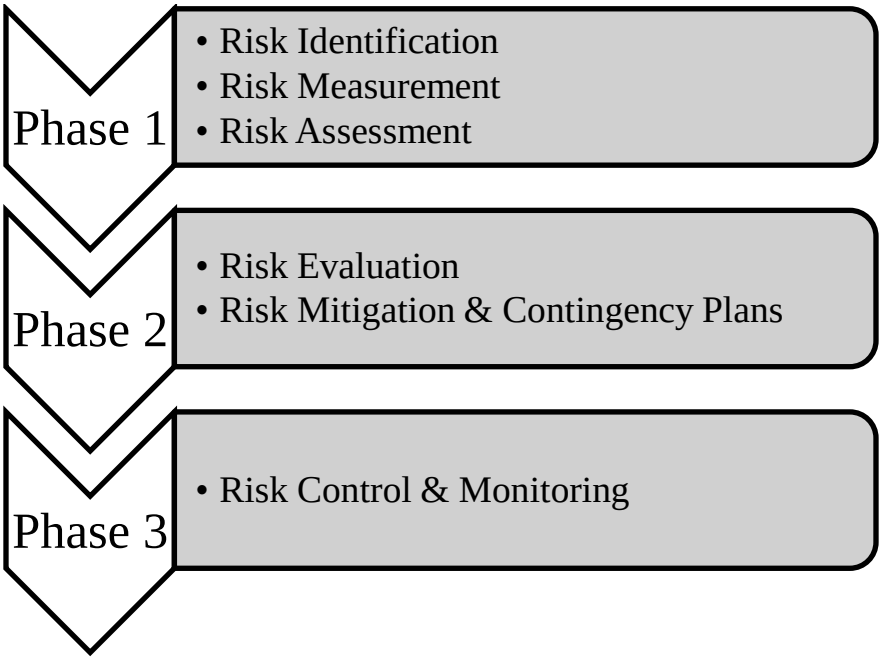

Figure 3. Supply risk management process, adapted from Tummala & Schoenherr (2011)

For the purposes of this thesis, an adaptation of the model presented by Tummala & Schoenherr (2011) is used, which is illustrated in figure 3. In the first phase of the supply risk management process depicted in figure 3, there are the steps of risk identification, measurement and assessment. Risk identification can be done by utilizing various models and methods. Supply chain vulnerability checklists, supply chain mapping, and the FMEA model are three of the most common means of identifying risks in the supply chain. In the risk measurement step, the identified risk is classified by categories of occurrence, severity and predictability. After this, there is the rather difficult task of assessing the risks. For this there are various methods and these include objective expert opinions, probability distributions, or involving a group of re-

spondents to evaluate the risks via decision making tools. One of these tools is the Delphi method. As the thesis concentrates more on the first and second phases of the supply risk management process, concepts of supply chain mapping, FMEA model, and the Delphi method are explained in detail in chapter 4. (Tummala & Schoenherr, 2011)

The second phase of the supply risk management process entails risk evaluation and risk mitigation & contingency plans steps. In the risk evaluation step, the found risks are quantified into categories by a given set of values. The three categories are classified as occurrence, impact, and predictability. The categories have a scale on which the risk is assessed, and therefore they can be organized into three classes of severity: acceptable, tolerable, and unacceptable. The scale used varies between researchers, but the main idea of the categorization is fundamentally the same. In the risk mitigation and contingency plans step, the company makes a detailed outline of the actions needed to take to avoid the found risks from realizing. (Tummala & Schoenherr, 2011)

The last phase which includes the risk control & monitoring is considered to be the final step in the supply risk management process. In this phase the risk mitigation and response plans are supervised and reported. Therefore it can be seen whether there is progress in reducing adverse events in the supply chain operations. (Tummala & Schoenherr, 2011)

3.3 Areas of risk

As suggested by literature, there are mainly four distinct areas of risk in the supply chain. Some research shows that these can be divided into more detailed areas. Manuj & Mentzer (2008) have suggested in their research for the four areas of risk to be; supply, operational, demand, and information risks. (Manuj & Mentzer, 2008)

Supply risk can be conceptualized into the idea that a disturbance from the supplier end of operations is preventing a flow of materials or information. This results in the focal company in a situation where it cannot satisfy the end-customer demand. Operational risk deals with the company's internal actions, resulting in stoppages in the ability to produce products or services. An example of this could be the breakdown of manufacturing machinery, resulting in a drop in production volumes. Demand side risks deal mainly with the variances and for example seasonality of demand from the end-user. Information, or sometimes as referred to as the environment risk area, is considered a risk area that is external to the supply chain, but affects the functionality of the chain. An example of this would be the theft or unwanted disclosure of classified information. The information risk spans from the supply side all the way to the demand side, as there are vital information flows to these nodes. (Manuj & Mentzer, 2008) (Christopher & Peck, 2004)

It needs to be noted here that the classification of the risks into these four categories is not exclusive and exhaustive. This means that a certain risk can belong in two or more of the categories. Furthermore, it is also common that the risks are not independent of each other. This leads to the realization that a certain risk can incur another, a greater risk in some other node of the supply chain. (Harland, et al., 2003)

Christopher & Peck (2004) have classified supply chain risks in their research into five categories. Their suggested areas of supply risk are divided into areas internal and external to the company. The internal areas are process and control risks, whereas the external areas are supply, demand, and environmental risks. In the process area, risks relating to the internally owned assets or infrastructure are considered. Controls are the rules, assumptions and policies that govern the processes and the used capital assets. Supply risks are related to the potential or actual disturbances to the flow of information or materials in the supply chain. The demand side risks are defined similarly as in the work of Manuj & Mentzer (2008), dealing with the variance of demand caused by the end-user. The environmental area deals with the natural phenomena

that may impede the processes from functioning as intended. (Christopher & Peck, 2004)

In the definitions of the areas of supply chain risks, both Manuj & Mentzer (2008) and Christopher & Peck (2004) give thorough explanation and justification for their classifications. In essence there are many similarities in the views on the areas of risks, and an overlap of the areas exists to some extent.

Also the company size and power relationships of the different players in the supply network have to be noted in order to fully assess and understand the areas of risk. In the study by Hallikas, et al. (2002), they found that for example in the electronics industry the second tier supplier can have a more significant role in the supply chain than the first tier supplier. In the example the second tier supplier is much bigger and significant than the first tier supplier, causing a supply risk to the buyer as the first tier supplier has difficulties ensuring a stable supply. This is due to the weak negotiation status of the first tier supplier, thus ultimately affecting the risk portfolio of the buyer. Therefore the buyer might need to reconsider its stance with the first tier supplier, in order to minimize operational risks. (Hallikas, et al., 2002)

3.4 Effects of risk actualization

It is clear that the actualization of a given risk has adverse effects on the company operations. The purpose of the risk management process is to find to what extent the effects carry out. The effects can be roughly classified into operations, financial, and image categories. As noted before, a given risk can have a multitude of effects, and therefore can be classified into several effect categories.

Disruptions in the supply chain can extend beyond the initial financial impacts. Due to the risk actualization there can be erosion in brand equity, loss of consumer confidence, and possibly it can result in legal ramifications. In line with legal ramifica-

tions, an actualized risk can result in a change in legislation or governmental policies. This in turn can have harmful effects in the supply network. (Speier, et al., 2011) An example of this could be the government policy to refrain from using nuclear power after a minor accident at a facility. As a result of a new government policy on sources of energy, direct impacts to labor force of the power plant, supporting service providers and logistics entities would follow.

As noted in chapter 2.2, issues arising in the supply network due to realized risks can have serious effects on the company value and image. This phenomenon is common to all industries, not only to the three special industries discussed in the earlier chapter. Disruption in the supply chain can potentially have severe adverse effects on share value in the long term. Often times this is the case if the disruption is significant enough that it needs to be announced to the public. Thus, it can be generalized that this rule applies to medium and large size companies, with higher output volumes. The cases where a public announcement is made, are for example product recalls, product bans, or long term stoppages in production. Hendricks & Singhal (2005) have done an extensive study on the topic, and have found that the supply chain disruptions have more extensive and longer term consequences than previously thought. In their research Hendricks & Singhal (2005) noted that after a publicly announced disruption in the supply, there is to be expected abnormal returns for roughly three years. In some cases when the disruption has been expected, the abnormal returns begin before the announcement. Abnormal returns means the alteration of the stock price, loss of consumer and investor confidence. (Hendricks & Singhal, 2005)

4 SYSTEMATIC APPROACH TO RISK IDENTIFICATION AND ASSESSMENT

In this chapter the purpose is to investigate the systematic approaches to risk identification and assessment in the supply chain. The manufacturing industry supply chain will be used, as the service sector supply chain has unique features that are not applicable for this thesis. The discussed methods and models for identifying and assessing the risks are supply chain mapping, mathematical modeling, as well as the FMEA model and the Delphi method. What is common for all methods and models is that there needs to be an adequate amount of time and resources for the moderator and the respondents to investigate and go over the required process steps. This is to ensure a comprehensive view of the supply chain risks. In some cases, iteration rounds and relying on external experts is required, as the views in-house may be biased or relying on a certain viewpoint.

As with nearly any business function, there is an incentive for improving and developing the operations further. This is also the case in seeking the supply chain risks. There are three main points for operatives to consider before embarking on the task of identifying and assessing the supply risks. These three questions have been suggested by Beamon & Ware (1998) in order for the practitioners to get into the mindset of improving their operations.

- *What are the goals of the supply chain process?*
- *What are the internal/external customer requirements/expectations from the supply chain process?*
- *What is our competitors' definition of quality?* (Beamon & Ware, 1998)

Supply chain mapping is more of a method for the identification rather than assessing the risks in the supply chain. Mathematical modeling, the FMEA and the Delphi

method are means of evaluating and assessing the risks in an analytical and systematic manner. These are going to be explained in the following chapters.

4.1 Supply chain mapping

Supply chain mapping is a useful tool as a starting point for the process of identifying and assessing risks in the supply network. In the simplest terms, supply chain mapping is a graphical representation of the individual nodes and how they are connected to each other in the supply network. Once the layout of the supply network is clearly visualized, it provides a simple standpoint to start seeking the possible risk areas between the nodes. (Tummala & Schoenherr, 2011)

The mapping of the supply chain has three main distinctions: the orientation, the level of detail, and the purpose. Supply chain mapping is not to be confused with process mapping, which is a more detailed depiction of a certain node within the supply chain. Supply chain mapping is a more general, strategic and moderate in detail. (Gardner & Cooper, 2003)

4.2 Mathematical modeling

In mathematical modeling, the risks found through for example supply chain mapping are analyzed through certain formulas. In order to assess the risks, there is wide agreement in supply chain risk management literature that the following formula 1 can be used to assess the severity and thus the effects of a given risk. In their research, Hallikas et al. (2002) use the following equation for assessing the severity that a given risk has on the operations of the supply chain.

Formula 1. $$Severity\ of\ an\ event = probability\ of\ event * impact$$

This formula is also supported by the methods described in the ISO14971 standard. In the standard, a general method and requirements for risk management of medical device production is presented. As the formula is adapted by the ISO standards, it can be said that it is a very valid and sound method for assessing the impact of a given risk. (European Committee for Standardization, 2000)

Although the formula 1 mentioned above can be considered as the industry norm, variations of the formula exist. The formula 1 can be also adapted to emphasize the impact of the risk, and therefore the formula has the impact raised to the second power, as shown in formula 2. (Pajarinen, 2010, p. 25)

Formula 2. $Severity\ of\ an\ event = probability\ of\ event * (impact)^2$

Upon evaluating the severity of a given risk with either formula, the next step is to classify the risks in a clear and comprehensive manner. One method is to rank the risks from highest severity value to the lowest. Therefore it is simple to see that to which risk areas the focal company should focus resources on to fix the issues. Here is to be noted that for the risk assessments to be comparable with other assessments made in different departments, the scale used should be the same. For the functioning of the method, the scale used is irrelevant. The key point is to have the scale simple and clear for the evaluator and the analyzer of the results to distinguish the difference between one specific increment in the scale. For example, the impact of the event can be classified by a three, five, or ten tier scale, as depicted in table 1 with the three different layouts presented. The values can also be chosen rather freely, again just that it is consistent for the whole process, and that they are also in line with the written explanation.

Table 1. Example scales for assessing the impact of a risk

Layout 1		Layout 2		Layout 3	
Scale	**Explanation**	**Scale**	**Explanation**	**Scale**	**Explanation**
1	No impact	1	No impact	1	No impact
2	Some impact	2	Low impact	2	Very low impact
3	Very high impact	3	Some impact	3	Low impact
		4	High impact	4	Moderate impact
		5	Very high impact	5	Some impact
				6	Harmful impact
				7	High impact
				8	Substantial impact
				9	Very high impact
				10	Catastrophic impact

As we can see from table 1, the scale used for the assessment of the found risks can be freely modified. In some supply chain orientations there are very subtle differences in the severity of events. In the case that subtle differences are to be expected, a more detailed scale should be used, like the ten tier scale. (Mishra & Shekhar, 2011)

4.3 FMEA

Failure mode effect analysis (FMEA) is a useful tool for assessing the found risks in the operations of a company. This tool is another method for assessing the severity of a risk, along with the two mathematical modeling formulas. There exist several specific FMEA models for certain processes, but in this context only the general FMEA is discussed. The FMEA is a systematic way for assessing the potential failure modes in a given process or product. Fundamentally the idea is much like the mathematical modeling described in chapter 4.2, with a difference in the amount of variables considered. Whereas in the mathematical modeling and ISO standard the probability and

impact of a risk are evaluated, in the FMEA model also the probability of detection is evaluated. (Chan, et al., 2012)

In the work of Dani (2009) there is a comprehensive list of the steps involved in the FMEA process. The FMEA process can be thought to be borderlining between the phases 1 and 2 in the risk management process, described in chapter 3.2. The following list of actions to be carried out in the FMEA process is adapted from Dani (2009) and Case Buyer (2011):

1. *Define scope, process steps, design parameters*
2. *Identify potential failure modes, i.e. risks*
3. *Investigate the effects of the failure on other entities*
4. *Assess the severity of the risk*
5. *Seek potential causes*
6. *Evaluate the probability of occurrence*
7. *Current controls for risks*
8. *Detection of risks*
9. *Risk priority number*
10. *Actions recommended for risk mitigation* (Dani, 2009) (Case Buyer, 2011)

There has been some criticism towards the applicability of the risk priority number (RPN) in the ninth step of the FMEA process, as it is only a quantitative figure on the risk. It does not describe the realized effects of the risk. The risk priority number can be calculated by using formula 3, given below.

Formula 3. $$RPN = Impact * Occurence * Detection$$

Furthermore, the standalone risk priority number may not give the best interpretation of the severity of the risk, unless it is expanded and explained. This is due to the dilemma that the same risk priority number can be obtained with various different com-

binations of the three figures. This observation is also true for the two mathematical modeling formulas. As an example, in table 2 is elaborated how to arrive at the same risk priority number of 10 with different scenarios, by using formula 3. It is assumed that the scale in all three criteria of impact, occurrence and detection is from 1 to 10. When analyzing the results of the FMEA process through the risk priority numbers, one has to consider the individual analysis criteria what constituted to the formation of the given RPN.

Table 2. Variations for the formation of the RPN

Impact	Occurrence	Detection	RPN
10	1	1	10
1	10	1	10
1	1	10	10
1	2	5	10

Because arriving at a certain RPN value is possible with a number of different assessments described in table 2, Braaksma et al. (2012) suggest that the risks should more so be categorized into failure scenarios, rather than failure modes. A failure scenario is a more descriptive explanation of the risk actualization, whereas failure mode is a simplified risk statement, such as used in the FMEA model. Further, they suggest that the risks should be categorized in terms of probabilities and costs. (Braaksma, et al., 2012)

Formulating the assessed risks into scenarios is in part further supported by the case company standard operating procedure (SOP), in which the FMEA model is used to assess the risks in a given situation. In the SOP when ranking the risks, the detection criterion is left out of one stage of the analysis. Therefore the result in the SOP is in much relation to the method suggested by Hallikas, et al. (2002) and the European Committee for Standardization (2000).

The assessment of risks is vital for the company, as it can in a relatively simple method help recognize the problem areas. Using for example the FMEA model helps the company to specifically focus on the most critical risks. It needs to be noted that in the process the classification of the risks is subjective, and prone to the evaluators' varying opinions. Therefore the company should broaden the scope of the analysis and have as many experts within the company to do the evaluation of the risks. The models and methods discussed here give therefore only a direction, and are not to be considered as absolute value of the risk. The evaluation of the risks is also not a one-time fix. Business setting and the client base change over time, therefore it is vital for the company to assess the risks at regular intervals, at least when major changes in the supply network take place. (Hallikas, et al., 2002)

4.4 The Delphi method

The Delphi method is a useful and systematic tool for assessing and collecting information on a specific subject. The method can be applied to many scenarios, and for assessing the risks in a supply chain, this method fits well. The Delphi method has four distinct phases, which are listed below.

1. *Exploration of subject*
2. *Discussion on how the group views the issue*
3. *Exploration of differences in views*
4. *Evaluation of gathered data* (Linstone & Turoff, 2002)

In the first phase, a group of experts within the organization is gathered to discuss the implementation of the Delphi method and the purpose of going over the issues at hand. This is to ensure that the respondents are all on the same level of understanding and comprehension of the subject matter.

In the second phase, the group is led to come to a conclusion on their views on the issue at hand. This can be done via open discussion, questionnaires, or presentations. After this, the group members write down their thoughts and views on the subject individually and anonymously. (Linstone & Turoff, 2002)

In the third phase the moderator of the group assesses the results of the second phase, and shares them with the group. The results are shown anonymously, via an average result or other means of sharing the results. Anonymity of the answers is done in order to avoid power differences within the group, and to ensure that all the group members can express their views in an open and honest manner. If there are major differences within the group results, the task of the moderator is to facilitate open discussion of the subject, where all the group members can voice their opinions. Often times, the group is given a possibility to alter their first round of answers, upon seeing and discussing the differences found between the opinions of the other group members. This is once again done individually and anonymously. After this, the three steps of the Delphi method have been concluded, and the moderator can review and assess the results, draw necessary conclusions and decide on further actions depending on the subject investigated. This is represented by the fourth and last step of the Delphi method, namely the evaluation of gathered data. (Linstone & Turoff, 2002)

5 THE CASE SUPPLY CHAIN

In this chapter the case supply chain is described. An introduction to the case company is given, and more emphasis is set to the supplier operations and the upstream supply chain operations. A generic explanation of the drug, and more so, the delivery device is also explained. The information in the following chapters has been obtained from interviews at the case company and the first tier supplier, from questions which were sent via e-mail to the supplier, and from a visit to the production facilities at the supplier end. Therefore references to a specific meeting or interview are in most cases omitted, only specific Q&A sessions are referenced. In the following chapters the terms supplier and contract manufacturer refer to the same company producing the sub-assemblies to the case buyer company. These terms are therefore used interchangeably.

5.1 Company profile

The case company is a large multinational pharmaceutical company. The company can be classified to the first category of pharmaceutical companies, which were discussed in chapter 2.2.1. The case company operates on a global scale, but the specific department for this product type operates in Europe.

As the case company is a large multinational company, it has many different operational departments and drug areas. In the department and drug that this thesis focuses on, the financial status is assumed to be good. Therefore there are sufficient funds and joint interest for improving the supply chain operations. Also, the demand for the product in question is good, ensuring steady production volumes at both supplier and buyer end of the supply chain. In the current state, the financial status of the company as a whole is not considered for the topic of the thesis.

The product in question for this specific supply chain is a patented drug for a common illness in the world. The product has been in the global markets for several years, and has gained a strong footing in the user base. The main market regions are currently the European and American markets. The patient uses a medical device manufactured by the supplier, to inject the medicine into their body. The device consists of plastic and metal parts, which are molded and assembled at the supplier facilities into sub-assemblies. At the case company, the drug cartridge is inserted to the device, and final assembly and packaging take place.

5.2 Supplier operations

As noted earlier, the case company operates in the pharmaceutical industry, and produces a drug for a common illness in the world. Therefore, the supply chain operations can be viewed from the perspective of a manufacturing industry. Although the product is not a traditional manufacturing industry output, much of the same elements are present in the case company supply chain. As depicted in figure 2**,** the basic elements are also present for the case supply chain. The case supply chain is more complex, as there has been included several second tier suppliers to the main contract manufacturer of the sub-assemblies.

In order to get a comprehensive view of the supply chain for this specific product, the method of supply chain mapping was used. This can also be utilized later when seeking the possible risk areas in the supply chain. The information on the supply chain has been obtained via the case company's internal documents, as well as interviews with personnel at the case company and the first tier supplier.

Typically a company uses several suppliers to manufacture the sub-assemblies, but for the simplification of the initial research process in this thesis, only one supplier is taken into consideration. Along with the first tier supplier, the second tier suppliers

are investigated, to get a full view of a single supply chain of the example product. A graphical representation of the supply chain in question is illustrated in appendix 1.

The chain starts from the operations of the second tier suppliers, described as the raw material, component and tray suppliers. As the medical devices are plastic, the raw materials in question are raw plastic granulates. For clarification on the specific drug inserted into the devices, certain parts of the sub-assemblies are varied in color. Also, color variations have a visual appeal, enhancing consumer usability of the end product. Therefore, before the raw plastic granulates are shipped to the contract manufacturer, there is a compounder who adds the desired color dye to the granulates. The component supplier delivers a metal part, and no further fabrication is needed for that. In the mechanics of one of the sub-assemblies there are moving parts, which need a special lubrication. A manufacturer of special grease provides the supplier with it.

At the supplier operations, the individual plastic components are molded from the plastic granulates, printed and assembled into sub-assemblies. This is done in the molding, assembly and print lines, portrayed in the supply chain mapping in appendix 1. All of the operations of the supplier are done at one production site. These finished sub-assemblies are placed on plastic trays, which are provided by the third category of second tier suppliers.

The trays of finished sub-assemblies are packaged and shipped via trucks to the case company facilities in central Europe. In the current state the trays are single-use, and are recycled at the case company operations. The duration of the transport is on average two days. An inspection of the incoming goods is done, and the sub-assemblies are set into the production schedules for the final assembly of the product. The medicine that the case company produces is in a glass cartridge, as is industry norm for liquid medicines. The glass cartridge is combined with the sub-assemblies in the final assembly process. The finished product is placed in its final packaging and shipped to its specific markets. In table 3 below are described the transportation layout of raw

material, trays and components in the supply chain. The grease used in the sub-assembly manufacturing is shipped only a few times a year, as the usage is small and the containers are rather large. Therefore it is omitted from the table 3.

Table 3. Transportation arrangements in case supply chain (Supplier, 2013)

Components to supplier	**Method**	**Frequency**	**Shipping Duration**
Raw material	Truck	Weekly	1 Week
Metal component	Truck	Every 3 weeks	2 Weeks
Plastic tray	Truck	Weekly	1-14 Days
Components to buyer	**Method**	**Frequency**	**Shipping Duration**
Sub-assemblies to case company	Truck	5 Days/week	2 Days

From table 3 it can be seen that the in- and outbound logistics of the supplier play a crucial role in ensuring a seamless flow of the sub-assemblies to the case company. Many components are arriving from different sub-suppliers on a weekly basis. Therefore the warehouse layout and capacity is crucial in keeping operations flowing smoothly.

5.2.1 Contractual issues

As with any business partnership, the contracts between the companies play an important role. The contracts give the foundation and the definition for the scope of the partnership, and it includes the terms and conditions for various scenarios. There are special clauses for various events, such as a shortage situation from the supplier. The case company has to take into consideration the contracts that the first tier supplier makes with the second tier suppliers, as the supply chain is relatively streamlined and vulnerable to extended disruptions in supply. Therefore, the case company has a significant amount of influence on the sub-supplier contracts and negotiations. One reason for this is the size and power differences in the markets for the raw plastic granu-

late, for example. The first tier supplier is not a very significant player in the global markets as a buyer for the material, but with the multinational case company backing the process, there is a possibility to come to an agreement on terms beneficial for the contract manufacturer as well. As for penalty clauses for lost or significantly late shipments, a guideline is in place. Up to now it has not been required to refer to this clause in the operations. In previous cases any supply issues have been dealt with via normal communication between the supplier and the buyer. Thus far this has been the same for the contracts between the first and second tier suppliers.

As the first tier supplier is a subcontractor, there are some special aspects regarding the ownership of the capital employed. The supplier owns the general injection molding machinery, and the general know-how for producing the sub-assemblies. The supplier also provides the maintenance for the assembly and print lines, the trained and skilled labor force, and the up-to-standards facilities for the production of medical devices. The case company in turn owns the assembly and print lines, and the product specific tools and anything else that is strictly involved in the fabrication of the product.

There are some fixed points of focus in the supplier interactions that affect the production at the case company end. A yearly quota for the production of sub-assemblies is set in the second half of the fiscal year. This is based on demand estimates on the markets. Information from the market set certain quotas that affect the production at the case company. Interestingly, the demand fluctuates to some extent in the downstream of operations from the case company perspective, although the product is not used for emergency care. Upstream the orders and production quantities are in contrary mainly inflexible and demand should not fluctuate beyond agreed range. This causes sometimes difficulties for the supply chain management at the case company. The challenge is in filling in all the changing demand in different regions, when there is a fixed quota of incoming sub-assemblies arriving from the suppliers. Safety stocks and other arrangements can help in eliminating shortages to the customer, but in the

long run adjustments have to be made to avoid a stockout. In this supply chain setting, there is limited flexibility of manufacturing capability of the suppliers. Increasing production volumes can be done in the short run within the possible allowance of work time, by increasing labor force and shifts. Increasing production volumes by technical means is a significantly longer process, with testing and validation of new production equipment. Decreasing production volumes is more straightforward in the short run, with adjusting the amount of work shifts and operating machinery. In long run decrease of production volumes, employee layoff regulations have to be upheld to according to each country's own specifications. This can be a time-consuming process, as well as liquidating capital in the form of excess machinery.

Along with the contracts of general terms and quantities to be produced, there has to be efficient forms of communication between the suppliers and the buyers. This holds true for interactions between all tier levels. On a very broad level, there are regular business review meetings. For example the yearly quotas for the supplier are conveyed in these meetings. On a smaller scale, there are monthly meetings on performance and operational issues. In these meetings the capacity planning, logistics and quality issues are discussed. Also, a monthly report card on the planned, and actual production volumes of the supplier are sent electronically to the case company. In the current state there are plans to implement an EDI (Electronic Data Interchange) system between the case company and the supplier in order to facilitate a smoother and faster means of communication. Along with these communication methods, there is also daily communication via emails or phone on any issues that either party deems applicable to inform. (Supplier, 2013)

5.2.2 Production in the supply chain

The case company production description was already briefly given in chapter 5.1. As the thesis focuses on the upstream operations in the supply chain, there is not required any further detail on the manufacturing process of the case company.

As shown in the appendix 1, there are many flows into the supplier system. For all incoming materials, there is a quality control according to the regulatory authority and GMP guidelines. Depending on the material, the extent and scope of the tests varies. For the raw material granulates, the in-house laboratory does certain quality testing. For the trays, there is mainly visual verification. As for every node in the suppliers' internal production process that has a quality control and inspection, the batch has to be released by the quality department before the next phase can use it.

Some of the raw material granulates have to be dried before the injection molding process, and this is done in specific drying cyclones. After the individual components of the sub-assemblies have been molded, sampling and quality control take place. Within the facility, the components are in a temporary storage. In practice this is between production halls, in order to ensure minimum movements of components and to keep production at a first-in first-out basis.

Some of the molded components are printed in the printing lines. After the batch release, all the ready components are fed into the sub-assembly lines. The supplier produces sub-assemblies from the molded components and the bought-in metal component. The finished sub-assemblies are packaged on pallets, and await a sampling and quality control in the outbound storage. Afterwards the batch is released for shipping. The storage is an integrated part of the facilities, and there is a stock of a few days of demand of the sub-assemblies.

The policy for production of the sub-assemblies in the current state is make-to-order, which is typical in the manufacturing industry. For the purchasing of the raw materials and components, there are set order points for replenishment of stocks. As for the bought-in goods, there is roughly a minimum stock level of 2-3 weeks of production needs. This is valid for the raw materials, trays, metal components, and packaging materials.

Currently, the safety stock level of the finished sub-assemblies is rather low at the supplier facilities. This is due to high demand from the buyer and lack of physical space at the supplier facilities. The output of the molding and assembly lines cannot be increased, as they are for the most part already running at full capacity. With this sort of setting, a quality issue may arise. One tends to ask, does the supplier have adequate time to do outgoing quality controlling of their products? Also, if their production stops for some given reason for a longer time, there is constant loss of "sales" as they do not have a larger buffer stock to feed to the buyer meanwhile the line is being fixed. This though does not affect operations at the buyer end that much, as they have their own buffer stock of the sub-assemblies. Furthermore, the example supplier is not the only supplier of the sub-assemblies to the case company.

The performance of the supplier is constantly being monitored by different metrics. On a monthly basis the ordered and actual delivered amount of the sub-assemblies is monitored via certain key performance indicators. On a quarterly basis, larger scale performance reviews take place to ensure the high standards for production that is required in the pharmaceutical industry.

6 COMPILING DATA FOR THE TEMPLATE

In this chapter the purpose is to go through the empirical part of the thesis. For the formulation of the template, the process of the data collection, classification of the found risk areas, and the evaluation of the individual risks are explained. It can be noted here that the scope of the thesis revolves mainly around the first two phases of the risk management process, depicted in chapter two. Therefore the areas of interest are the risk identification, measurement, assessment, and evaluation steps. Risk mitigation & contingency plans as well as risk control and monitoring are left out of the scope, as the thesis does not deal with realized risks.

6.1 Steps for template formulation

The process of formulating the template entails four distinct steps. The steps are illustrated in figure 4 and explained out in detail in the next chapters.

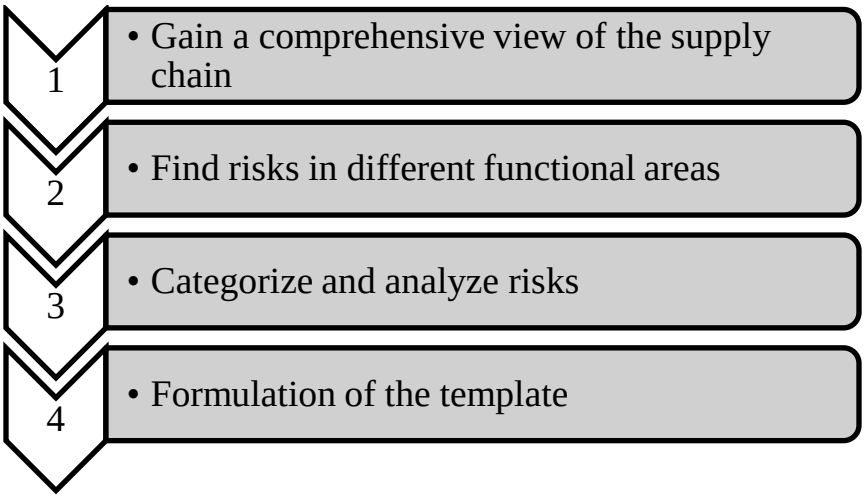

Figure 4. Steps for template formulation

The first step is to gain a comprehensive view of the supply chain as a whole. The basis for comprehending the different actions of the supply chain is in the theory of

the manufacturing industry supply chain. With basic knowledge on the theory of the supply chain in the manufacturing industry, the concept of supply chain mapping was used for a more comprehensive view on the individual nodes of the chain. For this, a limitation has been set that only one first tier supplier of the specified product is used. All second tier suppliers are considered, as they have a direct influence on the production at the supplier facilities, and thus affecting the supply of goods to the case company. The mapping was done via the help of interviews of employees on the buyer and supplier side, and as well via internal documents of supply chain orientation. This step is further explained in chapter 6.2.

The second step after gaining a view of the supply chain operations was for the moderator to consider the possible risk areas on his own, before consulting the experts employed at the first tier supplier. The formulation of the risks has been accomplished by considering the supply chain mapping which has been done in the previous step, and the theory and knowledge on the functioning of the manufacturing industry supply chain. Additional ideas for possible risks have been gathered from research papers discussing risk areas in various industries. The industries of most use were the aeronautics and food industries, as they both possess complex supply chains and strenuous quality controlling schemes in place. Therefore some of the individually thought risks may not be most applicable for the case supply chain. As the initial purpose was to create an exhaustive list, many of the risks were left in the list in order to spark ideas and discussion in the expert answer group. The experts refer to the individual employees of the first tier supplier who have conducted business in their respective departments for a number of years, and potentially on the same product as well. Therefore, the next logical step is to conduct a questionnaire for the key employees in the supply chain operations, in order to gain a more comprehensive list of risks. This process and the questionnaire are further described in detail in chapter 6.2. The usage of a questionnaire to gather information on the subject at hand is also the first step in the Delphi method for acquiring knowledge on a given issue.

The third step is to categorize the risks in a systematic and logical manner. The classification is based on the theory of risks and risk management in the supply chain, according to the basis which has been discussed in chapter 3.3. This will be covered in detail in chapter 6.3.

After having a comprehensive and complied list of risks from both the moderator and expert viewpoints, it is necessary to assess the risks. This is done by the questionnaire 2, which is filled out anonymously by the same experts who answered the first questionnaire. The risks are evaluated on impact, probability of occurrence and the possibility of detection. This is in line with the theory discussed in chapter 4. In order to get a valid and sound base for the results, a round of open discussion and going over the average results of the rated risks take place. This is done after the results of the second questionnaire are analyzed and transferred into easy to interpret graphs and figures. These are a part of the Delphi method for evaluating the risks areas. The explanation of the second questionnaire and the process is expanded in chapter 6.4.

Upon completion of the data collection and the discussion round at the end of the Delphi method, there is a comprehensive list of assessed risks for the moderator to generate the template on. This is the fourth and last step depicted in figure 4. The risk severity assessment gives a direction to the critical risks that affect adversely to the supply of goods or information. Therefore the buyer can see that these areas are critical in assessing the potential suppliers on. The results are presented in detail in chapter 7 along with the formulation of the supplier assessment template.

6.2 Initial data collection

For the initial data collection, knowledge on the functioning of the supply chain as a whole was required. This is the first step in the Delphi method used. As the respondents of the questionnaires were already familiar with the topic, the exploration of the subject was mainly the task of the moderator. In order to accomplish this, interviews,

specified questions via email, and discussions from both supplier and buyer side were conducted. Also, thorough production visits at both buyer and supplier locations were conducted. After these appointments, it was possible to formulate a supply chain map of the operations, shown in appendix 1.

The purpose of the supply chain mapping in appendix 1 is to give a general view of the processes. At first glance the network seems rather simple and straightforward. Upon closer inspection, this is not entirely the case. At the top of the chain are the raw material, component, tray and grease suppliers. It is in accordance to industry GMP to have several suppliers, in order to ensure production in adverse scenarios. In the appendix there is depicted only one second tier supplier per category. A challenge arises logistically for the first tier supplier in this case, as only one of the second tier suppliers operates in the same country as the first tier supplier. As seen in appendix 1 and table 3, all transportation is done via trucks. Therefore the transportation and lead times are rather long as the sub-suppliers are in different countries. This means that the first tier supplier has to have a larger safety stock of the raw materials compared to the situation where the second tier suppliers would operate in the same country and have shorter transportations times. Alternatively, the shipping frequency could be increased, resulting in increased traffic at the supplier end. Already in the current state there is high truck traffic at the supplier end as seen in table 3, therefore increasing the shipping frequency has not been a viable option.

In the supplier section of the mapping, there is depicted the steps for production of the sub-assemblies. The process consists of four main steps, being raw material drying, injection molding of components, printing, and assembly of the components. In addition to the core processes, intermediate storing, sampling and quality control are done alongside.

After the supply chain mapping has been done, the individual listing of risks and the risk areas can be formulated. By looking at the different points in the mapping, it was

possible to list some potential risk factors. This along with the theory on supply chain vulnerability and the ideas obtained from the production tours facilitated the initial formulation of the list of risks. If these risks were to realize, the supply of information or goods to the buyer could be jeopardized. Based on the theory covered on risk management and examples from other case studies, a total of 45 risks were initially formulated. Aside from the moderator's ideas, the main sources for the ideas for the possible risks were in the works of The Economist Intelligence Unit, (2009), Case Buyer (a), (2013) and Tummala & Schoenherr, (2011). This was prior to consulting the experts of the supplier side to weigh in their opinions. The second step in the Delphi method, namely the consensus on how the group views the issues, was conducted in two phases. The first phase consisted of questionnaire 1, in which the risks were sought. The second phase was questionnaire 2, in which the risk areas were assessed.

The opinion and knowledge of an external evaluator of the supply chain risks is not enough to create a comprehensive list of risks. Therefore a questionnaire was formulated to the key personnel working in different departments of the first tier supplier. The respondents represented as wide of a spectrum of departments as possible. In total there were six respondents to the questionnaire 1, representing materials, production, product and general management. Also representatives from the quality and IT department were included.

The questionnaire 1 can be viewed in full in the appendix 3. In the questionnaire the respondents were asked to think of the possible risks that could impede the efficient flow of information or materials in the supply chain operations. From the supplier perspective, the respondents were asked to consider both upstream and downstream of their operations for the possible risk areas. The main points of the questionnaire 1 were the following:

- What are the possible risks within your department that could disrupt/stop the flow of information/materials?

- What are the potential risks that affect a continuous supply of components to the buyer that are outside your department?

The respondents of the questionnaire were asked to consider in their answers the current state of operations. To gain other perspectives, they were also asked to consider a scenario where changes are induced to the supply chain. These changes could mean an introduction of a new product or the change of a supplier of materials. It was also known that the first tier supplier is planning to change their ERP (Enterprise Resource Planning) system in the near future. Therefore the aspect of changing ERP systems was also asked to be considered in the risks. The respondents had for the most part similar risk areas in their answers as the moderator. Some vital risks were also introduced, and therefore the total amount of risks to be included in the second questionnaire was 61. The appendix 2 gives the full list of the risks covered in the research.

6.3 Risk areas

Many researchers have done extensive work on classifying risks into different categories. In the book by Sodhi & Tang (2012) there is a comprehensive list of how different researchers have done this. From the list it can be seen that many scholars have aimed for a simple approach for classifying the risks, limiting the categories to a maximum of five. For the use of this thesis a classification of the risk areas suggested by Christopher and Peck (2004) will be used with a slight modification. Their version of the classification of risks is in line with the one suggested by Manuj & Mentzer (2008). Classification of risks into the demand side factors is left out of consideration since the scope of the thesis concentrates on the upstream risks in the supply chain. Therefore the risks found in the supply chain are categorized into the following four categories, which is a combination of the two publications by Christopher and Peck (2004) and Manuj & Mentzer (2008):

- Process
- Control
- Supply
- Environment

In the process category, the individual risks deal with for example breakdown of machinery, manufacturing capability, or process variations in production. In essence, the process category includes the risks that deal with value adding activities done by the companies in the supply chain. The control category includes the rules, regulations and policies that the processes undergo in the manufacturing. In this category it is specified why something is done the way it is done, and lacks in these policies could entail risks for the function of the supply chain. The supply area is the area of actual and potential disturbances in the flow of information and materials in the chain. It involves product complexities, as well as transportation scheduling and methods. In the environment category the issues that are external to the company but relating to the supply chain, are covered. These include information systems security, natural incidents, and disturbances caused by third parties. The risks in this category can affect individual nodes, links, or the chain as a whole. In this category an interesting addition has been brought to light by Speier, et al. (2011), as they elaborate in their work on the risks caused by intentional factors. These disturbances in the supply chain are for example theft or vandalism of the product, an area that has been neglected by many researchers but could potentially cause significant disturbances.

For the classification of the risks into these four categories a few key points need to be noted. Firstly, some risks can be put into more than one category. For example a risk concerning the maintenance of the assembly lines can be placed under two categories. How the maintenance is done can be placed under the process category, whereas the policy (frequency and depth) for conducting the maintenance can be placed under the control category. Secondly, the risks described in the list are not in most cases independent events. This means that often times the actualization of a giv-

en risk is a consequence of another risk happening. For example, the event of the buyer company ordering too late actualizes the risk of the production schedule to be cramped. In the worst case the actualization of a certain risk gives way for a snowball effect, in which many other adverse events take place.

When considering the individual risks affecting the flow of information or materials, a few special points were considered. Firstly, as the case company operates in the pharmaceutical industry, the quality issues play an extensive role in the list of risks. Industry specific good manufacturing practice, quality control and validation of methods are considered in the questionnaire and listing of risks. Also, a generalization has to be made about the supplier selection process. When seeking new suppliers, the case company seeks for suppliers which already have to a large extent similar and adequate quality controlling means in place and optimally some experience in operating in the pharmaceutical industry.

The second special point worthy of consideration is the possibility of the supplier changing its IT systems. In this case, the first tier supplier was expected to change their ERP provider in the near future. Hence in questionnaire 1 the respondents were asked to consider also the risks from the standpoint of the ERP system changing. As this is a major change in the internal processes, there are many risks that may affect the flow of information or materials to the supplier and also the buyer. Some of the risks suggested by Grabski, et al. (2001) are the risks relating to project leadership, complexity, and the companys internal capabilities for carrying out the change. Furthermore, there may arise a compatibility issue with the ERP systems of the supplier and the buyer, causing unnecessary lags and diffculties in information exchange. The ERP implementation process as such is a very long and complex process especially when there should not be stoppages in production of sub-assemblies. Huang, et al. (2004) suggest in their research the following risk areas to consider in the process: Organization fit, skill mix, project management and control, software system and design, user involvement and training, as well as technology planning.

These risk areas have been included to some extent in the appendix 2 of the list of risks. Too much weight has not been placed on the risks of an ERP project, as the purpose of the thesis and the data collection from this example supply chain is to generate a general template for assisting the supplier selection/evaluation process and not to focus on the ERP system risks. (Grabski, et al., 2001) (Huang, et al., 2004)

6.4 Assessment of risks

The assessment of the found risks based on the questionnaire 1 and moderator opinion was conducted via the questionnaire 2. The same expert group of six respondents which helped compile the list of risks in questionnaire 1 did the assessment. The assessment of the risks by the moderator would not be beneficial, as the knowledge on the functioning of the supply chain is much weaker than the respondents'. The questionnaire 2 is presented in its entirety in the appendix 4. In the questionnaire 2, the individual risks were formulated into statements. Therefore it is then simpler to assess the criteria of the event rather than have the risk in the form of a question. The risks were also categorized according to the four applicable risk areas, as discussed earlier in chapter 6.3. The respondents were asked to evaluate the severity, occurrence, and the detection of the risk. All risks were evaluated in the short run (SR) and as well in the long run (LR). To specify the time scale, the short run was set to be 1 month, and the long run 12 months. The respondents of the questionnaire were asked to think of the risks as individual events. In this way the thought process of a risk actualization snowball effect was minimized.

As discussed earlier in the theory section in chapter 4.2, there are various methods for setting the scale for the assessment of the risks. For this thesis a scale from 1 to 10 was chosen. In the tables 4, 5, and 6 there is an explanation of the scale, and how to evaluate the individual risks. Along with an explanation of the individual numbers on the scale, a word scale for quantifying the value has been included. In the beginning of the questionnaire 2 there is also an example evaluation of a risk, in order for the

respondents to get a general idea of how the questionnaire should be filled. There is also included a comment section, where the respondents can write out their thought process and justification for the way they have evaluated a given risk.

Table 4. Reference for evaluating the impact of the risk

Value	Impact	Explanation SR and LR
1	No impact	No effect on operations
3	Low impact	Minor disturbance, eg. no effect on deliveries
5	Some impact	Disturbances in production, eg. shipment is late
7	High impact	Major disturbances in production, eg. batch is scrapped/ recalled
10	Very high impact	Production stops for more than a month

In table 4, the guideline for the assessment of the impact of the risk is described. The explanations for the short-run and long-run scenarios are the same. The reasoning gives a guideline for the respondents to in some way quantify the impact. The financial impact has been consciously ruled out from the explanation, as evaluating the financial impact of a given risk is extremely difficult.

Table 5. Reference for evaluating the occurrence of the risk

Value	Occurrence	Explanation SR	Explanation LR
1	Highly unlikely	1 in 1M units or either 1 per month	1 in 10M units or either 1 in 12 months
3	Unlikely	1 in 750k units or either 1 in 3 weeks	1 in 7,5M units or either 1 in 9 months
5	Possible	1 in 500k units or either 1 in 2 weeks	1 in 5M units or either 1 in 6 months
7	Very likely	1 in 300k units or either 1 per week	1 in 3M units or either 1 in 3 months
10	Certain	1 in 50k units or either 1 per day	1 in 1M units or either 1 per month

As certain risks can have a varying probability of occurrence depending on the time scale, explanations were given for both the short-run and long-run, seen in table 5. The occurrence criterion is the most difficult one to assess. To minimize confusion to the respondents, numerical values were given to the scale in order to quantify the occurrence of the risks. Some of the risks can be more easily evaluated based on production volumes, and others on the number of events per a given time scale. This issue has been resolved, and there is a guideline in the questionnaire for quantifying the probability of occurrence. This explanation is given in table 5. The figures have been chosen as an estimate of production volumes that are possible in the current state of the example supplier. The figures can naturally be altered to a different supplier, but the purpose of these figures was to give some range for the quantification of the risk. Thus the respondents of the questionnaire have some tangible basis for their evaluation of the risks.

Table 6. Reference for evaluating the detection of the risk

Value	Detection	Explanation SR and LR
1	Certain	In nearly all of the cases the event can be detected with the forecast and control methods
3	Easy to detect	A majority of the events can be detected with the control and forecast methods
5	Possible	Control and forecast methods have a good chance of detecting event, human error possible
7	Difficult to detect	Detection is achieved with random checks/forecasts, human error likely
10	Impossible	Event is not possible to detect, human error certain

In table 6 there are explained the values for assessing the detection of the risks. The explanation is the same in both short-run and long-run, similar to the assessment of the impact criteria. In the explanation there is a reference to forecast and control methods. The forecast method is explained as a footnote in the questionnaire, stating that it is: means of anticipating a given event happening through media, personnel and client/supplier communication. Therefore it is assumed that the supplier company

has some control system for detecting faults in production and also a method for forecasting demand and adverse events.

The scale and the assessment criteria were based on the mathematical modeling and the FMEA method. The scale for the three criteria could have also been chosen differently, for example from 1-5. The used scale of 1-10 was selected for mainly two reasons. Firstly, a broader scale could promote variance in the answers from the experts. Secondly, the scale gives the respondents the ability to express their view on the subject more precisely, rather than the scale being a vague yes/no/maybe that a narrower scale would have presented.

After the second questionnaire was returned, the third step of the Delphi method followed. In this step the group met and discussed openly the differences in their results. Here the aim of getting variance into the answers with a broad scale comes into play. In the discussion phase, going over the responses could promote elaboration on why the respondents deemed a certain risk more adverse than the others. This could further facilitate the realization of further risks to be added to the list. The discussion phase is elaborated more in the next chapters.

7 RESULTS

In this chapter, the results of the data collection and assessment of the found risks via the Delphi method are covered. As noted earlier in chapter 6.2, the used method produced 61 risks. In the discussion phase of the Delphi method, no new risks were formulated. The discussion session was nonetheless very helpful for the respondents to share their views on the risks, and to discuss the different viewpoints.

As the re-evaluation of the risks was conducted openly as a group, it deviated slightly from the Delphi method described in literature, where the re-assessment of the risks would be done anonymously. In the session, the moderator showed the respondents the average results, and also the standard deviation in their answers. Thus the group could see easily where there had been significant differences in the thinking process while assessing the risks. Individual risks with which the standard deviation was over 3, were discussed more in depth to find the reasons that caused the differences in the answers. Other risk criteria were also discussed in detail by the wishes of the respondent group. Therefore the end result was a newly filled questionnaire 2 with the average results on the majority of risks, and a select few special cases where the assessment was changed according to the group decision. From this master sheet of the results, the risks were categorized in severity.

7.1 Severity of the risks

Each of the four risk categories will be explained in the following chapters, and the basis for the classification was the same for all categories. Based on the assessment of the individual risks in questionnaire 2, an average result was formulated. This included the changes made during the discussion session. Using formula 3 from chapter 4.3, the risks were calculated to receive a risk priority number (RPN), which was in accordance with the FMEA method. The RPN was calculated in the short run and also in the long run. The data was color coded, in order to visually clarify the risk severity.

For the three-color coding, a scale was given. A very low RPN (5) had a green color, an intermediate RPN (125) had a yellow, and the critical RPN (225) values had a red color. Although theoretically the maximum for the RPN would be 1000, it was chosen that anything over 225 would receive the critical red status. This was due to a given risk having a RPN of over 300 was deemed very unlikely in this setting. More so, if a given risk would have all three assessment criteria rated as 5, the midpoint value of the (1-10) assessment scale, the RPN value would be only 125.

In the tables and figures following, the risks are sorted by the RPN in the long run criteria. This is because in this case setting, long term partnerships are sought, or alternatively existing long term partnerships are evaluated. Alongside, the short run data is also presented, showing the differences in the time scale. The different risks have been given shortened names in the tables. This is still done in a manner that the expanded explanation of the risk can be easily sought from the master list of risks, found in appendix 2.

As mentioned in the theory section for assessing the risks, the RPN value may not give the best interpretation of the severity of the risk. Therefore, the mathematical modeling techniques were also used to calculate and thus categorize the risks. Formulas 1 and 2 were used, and similarly the risks were sorted from greatest to least severity in the long run time scale. The results are also presented in the chapters below for each category. In these tables, the risks have been sorted always in the long run, in order for the results to be comparable with the different risk area categories and calculation methods.

7.1.1 Process category

In the process category, a total of 12 risks were found. The process category dealt with the risks in the material and information flows in the facility and execution of manufacturing. In table 7 and figure 5 are presented the results. With the used color

coding, it can be clearly seen that in this category two risks stand out from the rest in the long run. The deviation handling process and the specification requirements are risks worthy of careful investigation. Also the maintenance of the mold/print/assembly lines along with the quality management system of the supplier are the noteworthy risk areas.

Table 7. Process category risk priority numbers

Process category	**Risk severity RPN SR range**	**Risk Severity RPN LR range**
Deviation handling	84	200
The specification requirements	148	175
The maintenance of lines	64	117
The quality system of the supplier	15	100
The facility infrastructure is out-dated	37	93
Side projects affecting production	66	93
Manufacturing and molding of tools	41	89
Faults and stoppages in production	28	79
Fault in the line that causes minor stoppages	44	72
Heavy lifting	37	70
Occupational health hazards from operation	36	69
The layout of the supplier	9	45

In figure 5, the data from table 7 has been formulated into a graph in order to ease the visualization of the differences in short run and long run time scales. As expected, the risk priority number is in all cases higher in the long run.

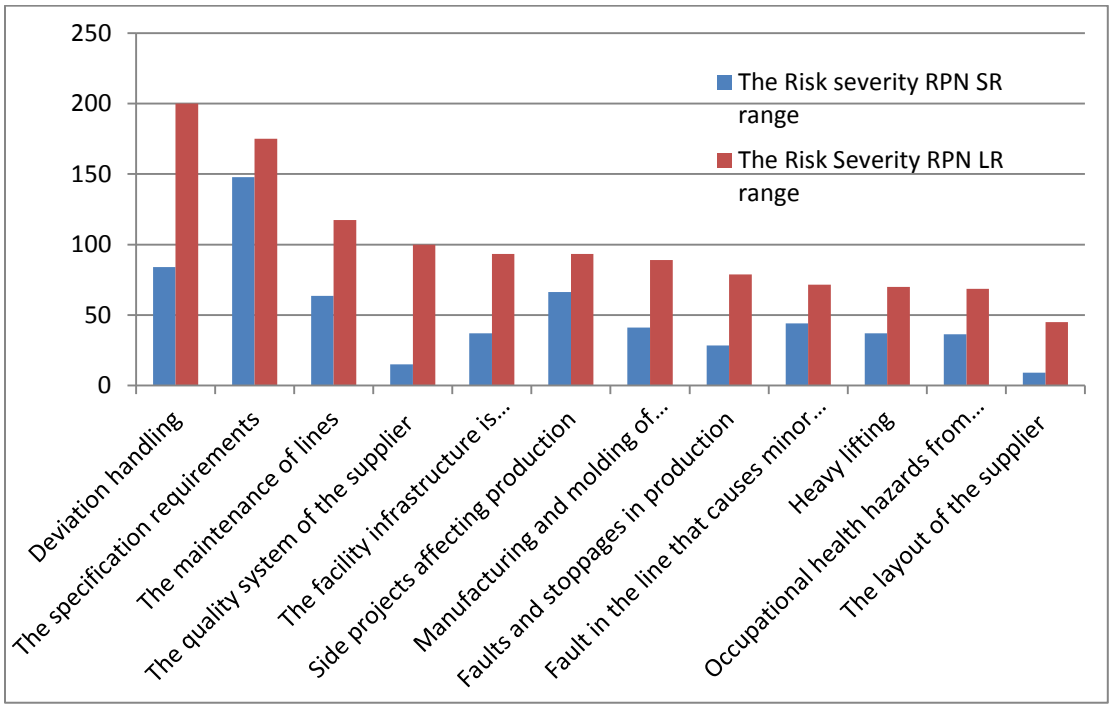

Figure 5. Process category risk graphing

In most cases there is not a large difference in the RPN between the short run and long run time scales. The only risk areas where larger differences are present, are the deviation handling and quality management system of the supplier. This may be due to realizing faults in the quality management system takes a long time, and it could be noted much downstream of operations. In table 8 there are presented the differences in the assessment of the risks by the three calculation methods.

Table 8. Variability of the assessment methods in the process category

RPN Formula 3	**Risk severity Formula 1**	**Impact emphasis Formula 2**
Deviation handling	Deviation handling	Deviation handling
The specification requirements	The specification requirements	The specification requirements
The maintenance of lines	Faults and stoppages in production	The facility infrastructure is outdated
The quality system of the supplier	The maintenance of lines	The maintenance of lines
The facility infrastructure is outdated	The facility infrastructure is outdated	Faults and stoppages in production
Side projects affecting production	Side projects affecting production	Manufacturing and molding of tools
Manufacturing and molding of tools	Heavy lifting	Heavy lifting
Faults and stoppages in production	Manufacturing and molding of tools	The quality system of the supplier
Fault in the line that causes minor stoppages	Fault in the line that causes minor stoppages	Side projects affecting production
Heavy lifting	Occupational health hazards from operation	Occupational health hazards from operation
Occupational health hazards from operation	The quality system of the supplier	Fault in the line that causes minor stoppages
The layout of the supplier	The layout of the supplier	The layout of the supplier

From table 8 one can see that for the most part the different assessment methods produce similar results. In the top 5 most important risks in this category there are four same risks in all three calculation methods. After this, some differences in the classification start developing.

7.1.2 Control category

The control category dealt with the rules, regulations and policies that the processes undergo in the manufacturing. This category was the one with the largest amount of found risks with a total of 21 risks. In table 9 and figure 6 are presented the results. In this category, no critical risks were found, unlike in the process category. Conflicting

information, documentation and traceability, as well as change control issues were assessed to be the most significant risk areas in the long run.

Table 9. Control category risk priority numbers

Control category	Risk severity RPN SR range	Risk Severity RPN LR range
Conflicting information	113	143
Documentation and traceability	95	137
Change control	61	128
Negotiation power	53	101
Personnel fluctuations	72	95
Policy for maintenance	58	90
Policy for manufacturing (SOP)	43	87
The ERP systems compatibility	52	83
Supplier insolvency	17	80
Communication	53	79
Personnel training and competence	68	77
Update or change of ERP	37	77
IPR of the processes	52	71
The estimation accuracy of capacity requirements	71	67
Servers issues	44	63
Investment readiness	48	60
Availability of raw material	22	56
Maintenance contracts	49	51
Shipping contracts	21	41
Excess of safety stocks	93	37
Shipping frequency and planning	22	30

In figure 6 the data from table 9 was formulated into a graph. Unlike in the process category, there are some risks that have a higher RPN in the short run than in the long run. The estimation accuracy of capacity requirements and the excess of safety stocks are more severe risks in the short run than the long run. As for the other risks, the trend is as expected with risks having a higher RPN in the long run.

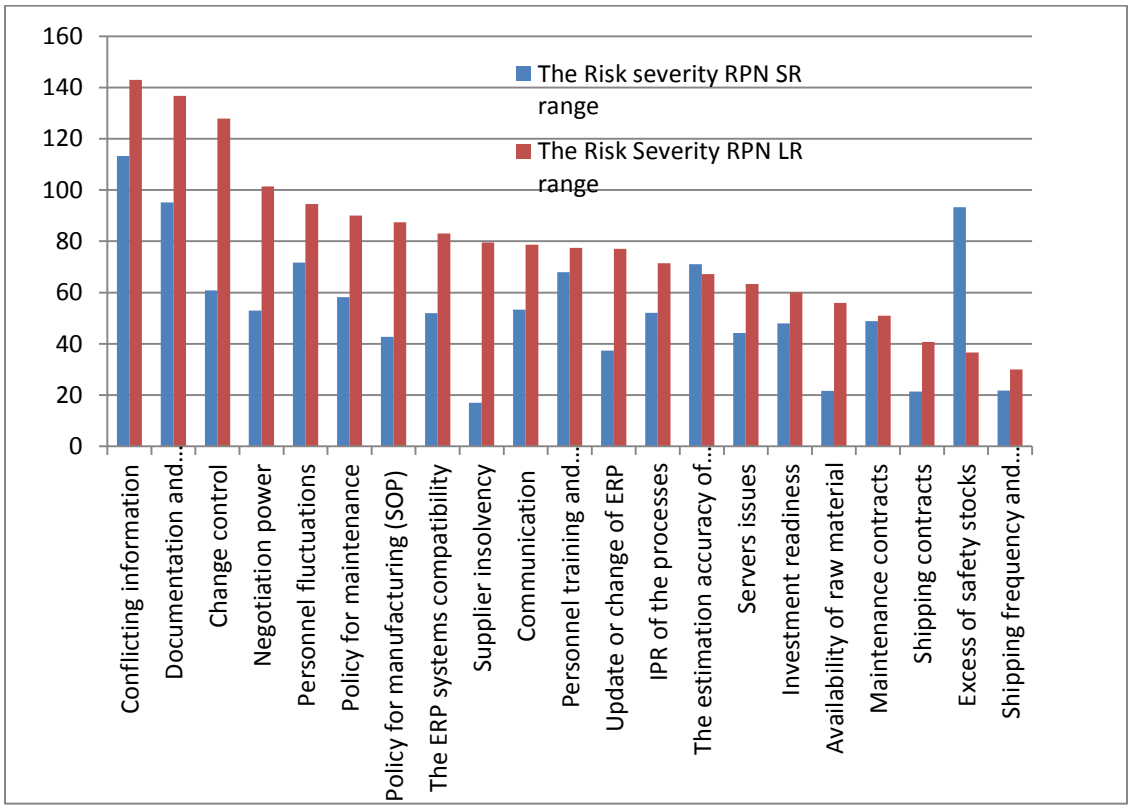

Figure 6. Control category risk graphing

In the case of supplier insolvency, the short run RPN is significantly lower than in the long run. This may be due to the fact that the risk is not noticed until it has already happened, when financial statements are examined at the end of reporting periods or fiscal year. Also, the effects of poorly executed change control may become apparent only much later. Therefore in this risk the difference between the short and long run RPN is larger than in other risks in this category. In table 10 below there are presented the differences in the assessment of the risks by the three calculation methods.

Table 10. Variability of the assessment methods in the control category

RPN Formula 3	**Risk severity Formula 1**	**Impact emphasis Formula 2**
Conflicting information	Excess of safety stocks	Excess of safety stocks
Documentation and traceability	Documentation and traceability	Documentation and traceability
Change control	Change control	Update or change of ERP
Negotiation power	Conflicting information	Conflicting information
Personnel fluctuations	Update or change of ERP	Change control
Policy for maintenance	Negotiation power	Supplier insolvency
Policy for manufacturing (SOP)	Personnel fluctuations	Investment readiness
The ERP systems compatibility	Servers issues	Policy for manufacturing (SOP)
Supplier insolvency	Policy for manufacturing (SOP)	Availability of raw material
Communication	Communication	Servers issues
Personnel training and competence	Supplier insolvency	Personnel fluctuations
Update or change of ERP	Investment readiness	Communication
IPR of the processes	Personnel training and competence	Personnel training and competence
The estimation accuracy of capacity requirements	Availability of raw material	Negotiation power
Servers issues	Policy for maintenance	Policy for maintenance
Investment readiness	The ERP systems compatibility	The ERP systems compatibility
Availability of raw material	The estimation accuracy of capacity requirements	Maintenance contracts
Maintenance contracts	IPR of the processes	The estimation accuracy of capacity requirements
Shipping contracts	Maintenance contracts	IPR of the processes
Excess of safety stocks	Shipping frequency and planning	Shipping frequency and planning
Shipping frequency and planning	Shipping contracts	Shipping contracts

In the control category, there is more variance with the results from the three calculation methods. From the top 5 risks in the RPN calculation, only three are common to the other calculation methods in the top ranked risks. There is one critical outlier in the set, the risk “excess of safety stocks”. In the RPN method this risk is assessed

very low in the list, whereas in the two other calculation methods the risk is the most critical risk. This can be explained by the functioning of the formulas. In the RPN formula the detection value is 1 (certain detection), causing the RPN value to be low in the classification. In the other methods the detection criteria is not considered, making this risk more critical for the functioning of the supply chain in the long run.

7.1.3 Supply category

The supply category was for the most part about the concrete materials management and ensuring the supply of raw materials and components to the production. In the supply category, a total of 12 risks were found. In table 11 and figure 7 are presented the results. Although there are no critical risk areas in this category like in the process category, there are some significant risks worth considering. Nearly half of the risks in this category are in the proximity of the halfway mark of 125 of the color coding scale. The most important risks in this category were the behavior of the sub-supplier, and the sufficient backup of machinery for production.

Table 11. Supply category risk priority numbers

Supply category	Risk severity RPN SR range	Risk Severity RPN LR range
The behavior of the sub-supplier	92	135
Sufficient backup of machinery	53	129
Order point setup	47	119
Availability of spare parts	73	113
Material stock balance	45	112
The sub-supplier actions	63	92
Wrong or missing spare part	29	86
Demand forecasts accuracy	56	63
The orders of the buyer are not on time	49	61
The behavior of the supplier	39	58
Customer support	46	54
Currency risk	18	35

The data from table 11 was graphed, and is shown in figure 7. Similarly to the majority of risks in the two previous risk categories, the long run RPN was here in all the cases higher than in the short run.

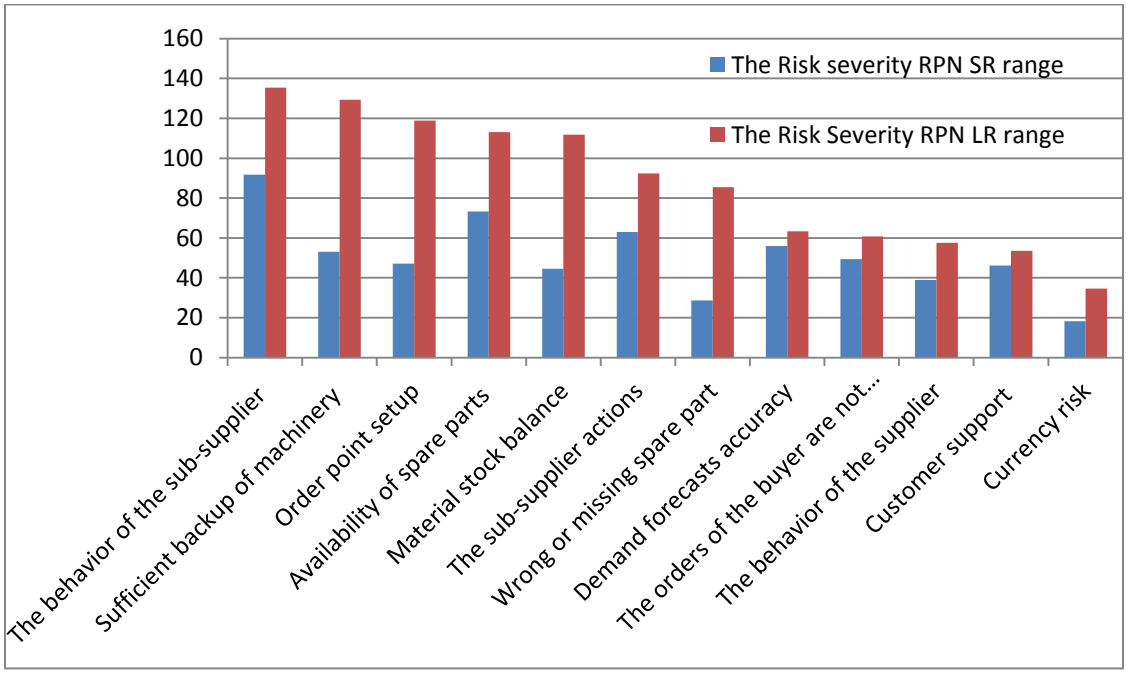

Figure 7. Supply category risk graphing

Similarly to the previous, only a few risks had a large difference in the RPN between short run and long run. For example in the risk “sufficient backup of machinery”, it is thought that in the short run the supplier can utilize safety stocks of goods to make up for the downtime of the machine. In the long run such a system is not sustainable, therefore resulting in a significantly higher RPN. The different calculation methods are summarized in table 12 below.

Table 12. Variability of the assessment methods in the supply category

RPN Formula 3	**Risk severity Formula 1**	**Impact emphasis Formula 2**
The behavior of the sub-supplier	Sufficient backup of machinery	Sufficient backup of machinery
Sufficient backup of machinery	Order point setup	Order point setup
Order point setup	Availability of spare parts	The behavior of the sub-supplier
Availability of spare parts	The behavior of the sub-supplier	Material stock balance
Material stock balance	Material stock balance	Availability of spare parts
The sub-supplier actions	Wrong or missing spare part	Wrong or missing spare part
Wrong or missing spare part	The orders of the buyer are not on time	The orders of the buyer are not on time
Demand forecasts accuracy	Demand forecasts accuracy	The sub-supplier actions
The orders of the buyer are not on time	Customer support	Demand forecasts accuracy
The behavior of the supplier	The sub-supplier actions	Customer support
Customer support	The behavior of the supplier	The behavior of the supplier
Currency risk	Currency risk	Currency risk

From the results of the different calculation methods seen in table 12, it is clear that in this risk category the results did not have much variance. Of the top 5 critical risks in the RPN category, each risk is included in the other two calculation methods. The order of the risks may vary by one position, but nonetheless the same risks are present. Similarly to the process category, risks in the top 5 of this category should be considered for the template.

7.1.4 Environmental category

The environmental category was the second largest, with 16 risks. External factors affecting the functioning of the supply chain were listed in this category. In table 13

and figure 8 are presented the results. The environmental category differed from the other ones in many ways. Firstly, the risks found were external to the firm, but when actualized they affect the whole supply chain. Secondly, based on the assessment it was found that there were no critical risk areas in this setting. All of the assessed risks were at or below a RPN value of 90, belonging well in the lower half of the color coding scale.

Table 13. Environmental category risk priority numbers

Environmental category	**Risk severity RPN SR range**	**Risk Severity RPN LR range**
Contamination in production	78	90
Production and transport temperatures	44	75
Contamination in transport	76	74
Information leakage	41	73
Pest control methods	33	57
Transportation problems	31	44
HSE policy	11	40
Power outages	16	35
Rise in energy prices	10	22
Strike at the supplier	14	17
Governmental policies	9	17
Flood	10	14
Hurricane, tornado, earthquake	10	10
Close proximity to hazardous industry	10	10
Forest fires	12	10
Theft or vandalism	8	10

Nonetheless, the highest rated risks in this category are still worthy of consideration for the template. Contamination of the materials or sub-assemblies in either production or transport was assessed as of high importance. Also the production and transportation temperatures were thought as of high importance. In figure 8 the data from table 13 was graphed, like with the other risk categories.

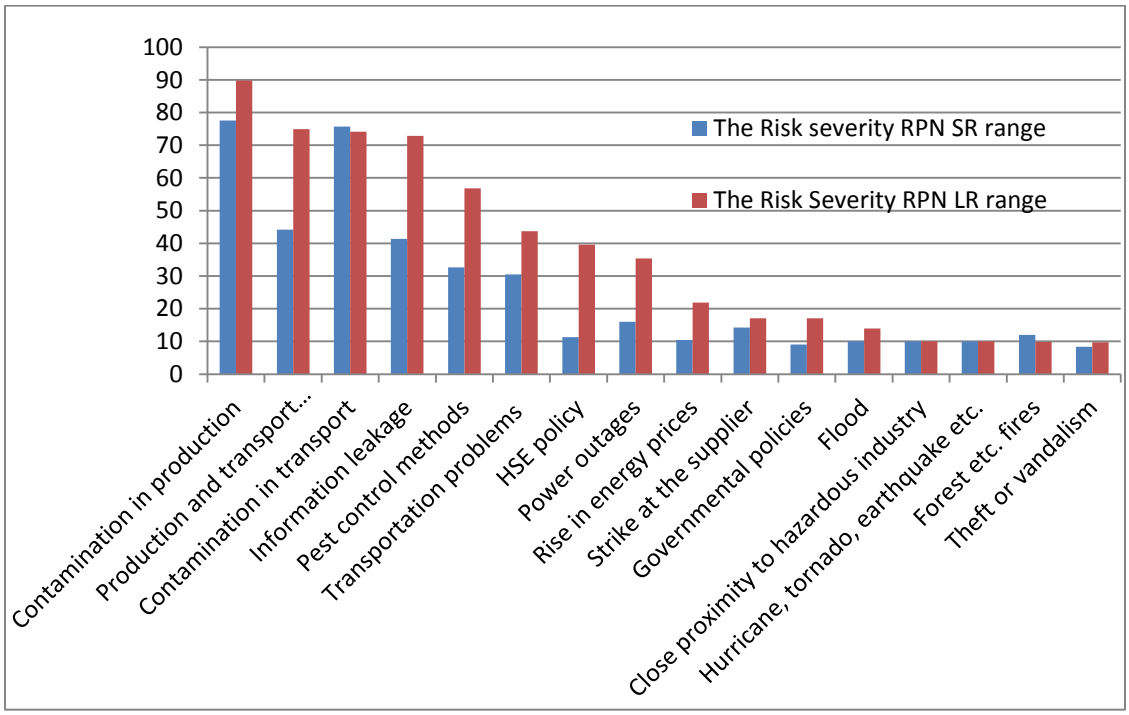

Figure 8. Environmental category risk graphing

Contrary to the other risk categories, the environmental category had several instances where the short run and long run RPN was nearly the same, or the short run was higher. This can be explained firstly by natural phenomena being random incidents. People deem to rate an adverse natural phenomena as very unlikely, and easy to detect due to for example weather forecasts. Secondly, the RPN values are very low, roughly 10, thus causing the risks to be insignificant in either short run or long run. Contamination in transport on the other hand is slightly more significant in the short run, as it potentially causes batch recalls and extra quality assurance work immediately upon notice. Similarly to the other groups, the different calculation methods are summarized in table 14 below.

Table 14. Variability of the assessment methods in the environmental category

RPN Formula 3	**Risk severity Formula 1**	**Impact emphasis Formula 2**
Contamination in production	Power outages	Power outages
Production and transport temperatures	Contamination in production	Contamination in production
Contamination in transport	Production and transport temperatures	Flood
Information leakage	Transportation problems	Production and transport temperatures
Pest control methods	Contamination in transport	Information leakage
Transportation problems	Information leakage	Pest control methods
HSE policy	Rise in energy prices	Hurricane, tornado, earthquake
Power outages	Pest control methods	Close proximity to hazardous industry
Rise in energy prices	Flood	Contamination in transport
Strike at the supplier	HSE policy	Transportation problems
Governmental policies	Strike at the supplier	Strike at the supplier
Flood	Governmental policies	Governmental policies
Hurricane, tornado, earthquake	Hurricane, tornado, earthquake	HSE policy
Close proximity to hazardous industry	Close proximity to hazardous industry	Rise in energy prices
Forest fires	Forest fires	Forest fires
Theft or vandalism	Theft or vandalism	Theft or vandalism

Of the four risk area categories, the environmental category was prone for the most variance in the results of the different calculation methods. From the top 5 risks in the RPN category, only two are present in the top 5 of both the other calculation methods. In comparison to the other risk categories, the environmental category was not considered as severe, as the highest ranking risk “contamination in production” was still well below the halfway mark (125) of the color code scale of severity. This does not though mean that environmental risk factors should not be included in the tem-

plate. In the following chapter the justification for the chosen risks and the functioning of the template is explained.

7.2 The template

The purpose of the supplier risk assessment template is not to be another evaluation of the risks of a supplier via the Delphi method. Instead, the found risks in the example supply chain are formulated into questions that the supplier candidate or current supplier can elaborate on. The template is thus a single questionnaire that is to be used alongside the more general supplier selection/audit process. There is no specification that who is to fill out the template questionnaire at the supplier end. A member of general management or a team of respondents can elaborate on the issues in question.

The assessment of the risks in the case supply chain gives the buying company insight on what might be the critical risk areas in ensuring a flow of information and materials in a similar supply chain and product. With this knowledge, the conductor of the questionnaire from the buyer end therefore knows which areas to stress and require detailed information on. This is because the risks have been seen to be critical in the example supply chain for ensuring the flow of information or materials within the network.

From the 61 risks found in the risk assessment process, only 10 are included in the template. There are two main reasons for limiting the number of questions to so few. Firstly, as the questions deal with the critical risk factor areas, the buyer is expecting to have very detailed and in-depth answers from the respondent. This level of detail and comprehensiveness can be attained with also a large number of questions, but this would take a long time and is very strenuous for both the conductor and respondent of the questionnaire. Secondly, a large number of the assessed risks in the example supply chain were not ranked as critical. As seen in the tables in chapters 7.1.1-7.1.4,

only a small proportion of the found risks are in the yellow or red categories of severity in the color scale. The classifications of the risks with the mathematical modeling formulas 1 and 2 give similar results, giving further justification for choosing only 10 risks to consider in the template.

The chosen risks for the template were firstly based on a high risk priority number acquired with the formula 3. Secondly, the chosen risks were to be also in the top 5 risks in the classification by the mathematical modeling methods. Therefore the choice of the risks has more validity, as not only one method for assessing the severity is used. All three assessment methods did yield rather similar results although some outliers were present, as explained in the previous chapter.

The template as a whole is presented in appendix 5. The appendix presents already the changes made to the template based on feedback from another supplier in the validation of the template, explained in the chapter 7.3. Below are presented the individual questions for the respondent to elaborate on. For the risk categories process, control and supply, the three most important risks were chosen for the template. The tenth risk was chosen from the environmental risk category. The questions in the process category are the following:

Process category

1. How are deviations in production and general operations handled?
    a. What are the means to ensure that the deviation handling process is clear to all employees who handle the deviations? (SOP, training)
    b. How do you minimize occurrence of deviations in production and general operations?
2. How do your clients quantify the production specifications?
    a. What technical and regulatory means do you have to ensure that the specifications are not too tight and that they are clear to employees?
3. How is the maintenance of the production lines handled?

a. Policy and planning for cost/time efficiency.
b. Concrete execution: what/how/when is this done?

In the process category deviation handling, product specifications and maintenance issues were the most important risks. The questions were elaborated with guiding questions, in order for the respondent to gain a better understanding of the issues. Deviations meant events which differed from the standard operating methods. It was known that deviations occur on a systematic basis, but the methods for handling and controlling them needed elaboration. The questions in the control category are the following:

Control category

4. In which ways do you share information with your clients and suppliers?
    a. How do you avoid having conflicting/inaccurate information internally and externally?
5. What is the documentation and traceability method you use?
6. How do you manage change?
    a. Changes in production, manufacturing capabilities, labor force
    b. Do you make quick, efficient and justified decisions? What steps are you taking to improve this aspect?

As for the control category, the sharing of information between clients and suppliers, documentation traceability methods and change control were the most important risks. Here it was not expected to gain very detailed information on the concrete information the supplier shares with its own supplier, but more so the methods and frequencies. Conflicting information was deemed a severe issue in the supply chain operations and as the network is complex with large amounts of shared information. Regulatory policies determine documentation and traceability durations, but the concrete execution can vary. Assurance that the documentation is secured and easily ac-

cessible was the purpose of including this section in the questionnaire. The questions in the supply category are the following:

Supply category

7. What is your relationship with your suppliers?
    a. Do they have a tendency for opportunistic behavior, i.e. not seeking terms beneficial for both entities?
    b. What is the power balance with you and the suppliers?
    c. What is the overall satisfaction of your suppliers with your operations?
8. What is the level of backup machinery in the case of a breakdown?
    a. How fast can production resume at agreed pace?
9. How do you manage an optimal stock level of raw materials and bought-in components?
    a. Order points?
    b. Material consumption estimates?
    c. Experiences with Lean principles?

In the supply category, the first risk area allowed for a more descriptive explanation of the relationship between the supplier and the sub-suppliers. It was known that in some cases the sub-supplier, for example the raw material supplier, is a significantly larger corporation. Therefore the partnership with the supplier may not be of much importance to the sub-supplier. With this question the purpose was to find possible problem areas which could also reflect to the buyer operations. The other risks regarding backup machinery and stock levels handling were informative in getting an insight to the operations and materials management. The question in the environmental category is the following:

Environmental category

10. How do you ensure the products are not contaminated in production or transport?

The last of the ten most critical risks is found in the environmental risk area. From the quality control and continuous supply perspective, preventing the contamination of the products is very important. This question was nonetheless the most straightforward to answer, as there are often clear and concrete steps for contamination control.

7.3 Validation of the template

As presented in chapter 7.2, the supplier assessment template consisted of ten questions on the supplier operations. In order to see whether this template formulated from an example supply chain could be used in other supply chain orientations, a validation was conducted. The purpose of the validation was to test the usability of this template in a differing supply chain setting. Based on the functioning of the template and the feedback received, possible changes to the template were made. The chosen supplier for the validation was also producing similar sub-assemblies to the case company. Therefore, the supply chain setting was rather similar to the one used in the example. Naturally some differences arose in setup of assembly lines, geographical location and other various details, which was only more beneficial for the validation of the template. In this way it was tested whether the template would work in another supply chain and product orientation, making it a more generic supplier assessment template.

The template was first sent out to another supplier, along with an explanation on how to fill it and what the purpose of it was. Upon receiving the results, a meeting was organized to go over the answers and to discuss on the feasibility and functioning of the template. Feedback and comments were received on the layout, understandability and simplicity of the template. In the discussion, no new relevant risks were introduced by the validating supplier. Therefore it can be deduced that the formulation of the top ten risks from the example supply chain was relevant and accurate.

Based on the discussion held, a few changes to the supplier assessment template were made. Firstly, it was apparent from the case company perspective that the level of detail in the answers was not adequate. Therefore, more emphasis on the explanation of the questionnaire in the template and the expectations of the answers from the respondents was noted for further assessments. Secondly, a few minor changes to the layout of the template were included. The slight change was the addition of an open comment slot for risks that the respondents wanted to add to the list and elaborate on.

The third and most significant change to the template was the addition of an assessment of the ten risks via the FMEA ranking method. This was the same method that was used in the risk assessment section described in chapter 6.4. The ten risks in the supplier assessment template were formulated into statements, and assessed only in the long run. This was due to the case company seeking long term partnerships, or the evaluation of the current partnerships which have been in place for a long time and have no changes in sight in the short run. To ease the numerical assessment of the risks, some of the guiding questions were placed as their own risk to be evaluated. Therefore in the reformatted supplier assessment template in the appendix 5 there are more than ten individual risks to be assessed via the FMEA model. The same assessment criteria and scale (1-10) was used like in the assessment of the risks in the example supply chain, namely the impact, occurrence and detection. This addition to the questionnaire in the template was deemed to give a more comprehensive view of the supplier risks. Along with the written out answers there would be a quantitative representation of the severity of the risks in the template. An open slot for assessment of any new risks added by the respondents was also included in the reformatted supplier assessment template.

8 DISCUSSION AND CONCLUSIONS

The purpose of this thesis was to generate a generic template for assessing the suppliers of a large pharmaceutical company. The template would give insight for the case company on how their current or prospective suppliers deal with risks that may impede the smooth flow of information or materials to the case company. The pharmaceutical industry has special features, which makes it a unique setting for manufacturing operations. High regulatory practices and emphasis on end-user safety along with long life cycles of products set special parameters for a business partnership. As changing suppliers or contract manufacturers in the growth and maturity stages is difficult, time consuming and costly, companies seek long term partnerships in the supply chain. Therefore, a thorough understanding of the suppliers' operations and possible risk areas is vital in making a partnership decision. Therefore the need for generating a supplier assessment template for the case company was realized. To arrive at such a supplier assessment template, the following research questions were considered.

1. *How can a company assess risks in their supply chain in a proactive manner?*
2. *What are the possible methods for data collection and evaluation in this case setting?*

To gain an insight to the research questions, various theories and models were investigated. The theory on manufacturing industry supply chain, risk management, and means for systematic improvement proved to be very beneficial for the empirical part of the thesis. Without a solid understanding on the concepts of manufacturing industry supply chain and especially risk management, the quality and mainly the quantity of found risks would have been much less. Models and methods for assessing the risks were used extensively in the evaluation of the found risks. Some of these models and methods included the FMEA assessment model, and the Delphi method for systematic analysis and collection of data. The usage of several methods for assessing

the severity of a given risk gave the results more validity, as it was not relying on one specific calculation formula. Through these means the objective of the thesis presented below, was fulfilled.

The objective of the study is to create a template for evaluating a supplier of a pharmaceutical company in ensuring efficient information and material flows.

The objective of the thesis was attained in several steps, by initially examining an example supply chain, research articles and literature on supplier risk management. A key part of formulating a list of relevant risks for the given supply chain setting, was the consultation of an expert group in the example supply chain. Based on their views and experience, a total of 61 risks were found in the example supply chain operations. From this master list of risks, the supplier assessment template was formed, based on the evaluation of the risks. The risks were evaluated with three models and three criteria (impact, occurrence and detection), resulting in similar rankings of the severity of the risks. For the template, the top ten severe risks from the 61 evaluated risks were chosen to assess a given supplier on. The risks were formed into questions, to which the suppliers' respondents were to elaborate their answers to. The usability of the template was verified with another supplier, which possessed a slightly different supply chain orientation, but a similar product. Thus validity for the purpose of the template to be a generic one was tested. In the validation stage, only minor changes were made to the template. These changes made the template more descriptive and less prone for individual interpretation of the issues, therefore improving the template's qualities of being a generic one in the pharmaceutical industry. A few issues arise when considering the data collection and assessment process in the thesis, which are covered in the following.

Firstly, the template aims of being a generic one to be used in the assessment of suppliers in the pharmaceutical industry. This template was made to be versatile, as it can be used to assess current and prospective new suppliers. It has been formulated based

on a certain product and supply chain orientation. Therefore, the template may not be the best for a product or supply chain orientation that differs significantly from the example supply chain described in this thesis. For a significantly different supply chain/product orientation, the method for formulating the template is useful to generate a sufficient template for that specific supply chain orientation. In this thesis there are presented the concrete steps how the template was formed through supply chain mapping, data collection and assessing the found risks through the mathematical and FMEA models. In this setting, the Delphi method used for the data collection and assessment with a group of subject experts worked well.

Secondly, a few points on the basis for the formulation of the template need to be noted. The found risks were based on the opinion of the moderator and the expert group. More so, the assessment of the risks is just the interpretation of a select few respondents of one supplier. Therefore the severity (RPN values) of a given risk should not be considered at face value, but more so just a direction of how severe that risk has been in this setting. It can be as such that in another setting or with another respondent group a certain risk deemed high in severity is not a significant one. Therefore this is the reason why respondents from various departments of the supplier were included in the questionnaires to gain differing views.

Thirdly, the functioning of the Delphi method for data collection and decision making in a group raises some questions. As mentioned earlier in this chapter, the method worked well in this setting. One of the main reasons why the method worked well was the small group of respondents, and that it was a closely knit group which had been working together for a long time. It was known prior to the data collection process that the Delphi method has some flaws and is usually strenuous from both the moderator and group perspective. The Delphi method was used with some minor modifications, further facilitating the success of its implementation for this research. One of the major modifications was that after the discussion phase, the alteration of the individual answers was not done anonymously. It was conducted as an open

group discussion, as the respondent group deemed this better for the validity and clarity of the assessment.

Lastly, a few words on the research process and the output are elaborated. Having attended regular business meetings with the example supplier, having visited production at both ends of the supply chain, and having the opportunity to conduct interviews and open discussion on the topics have helped me greatly in understanding the details and peculiarities of the pharmaceutical industry. Research articles and literature on the covered theory parts goes only so far in understanding the case and the concrete supply chain orientation. The most helpful knowledge was obtained from the personal connection to the employees. This was also the most difficult aspect to arrange, as in this case setting finding open slots for discussions and visits proved to be more difficult than initially anticipated. In the end the schedules aligned, and whether it was about data collection, going over the assessment meeting or validating the template with another supplier, all worked out fine for formulating the supplier assessment template. I enjoyed working on such a template, as I knew that the output would be something concrete and to be used by the case company. Sometimes similar projects end up being good ideas, but only to be archived for a later usage or forgotten. From the start I was purpose driven that in my work this will not be the case, giving a further incentive for formulating the template to be user friendly and beneficial for the case company.

As in any business discipline, there is always room for improvement. This is also the case for this template, and further research and modification issues have been acknowledged. As the functioning of the template is sensitive to the supply chain orientation, an update to the risks covered in the template should be done at regular intervals. This is due to changing business environments, legislation, personnel and many other variables. An update to the template should definitely be done when a significant change in the supplier base, product, or information systems happens. This

way the template can reflect the current state of operations, whether the case company is seeking new suppliers or assessing current ones.

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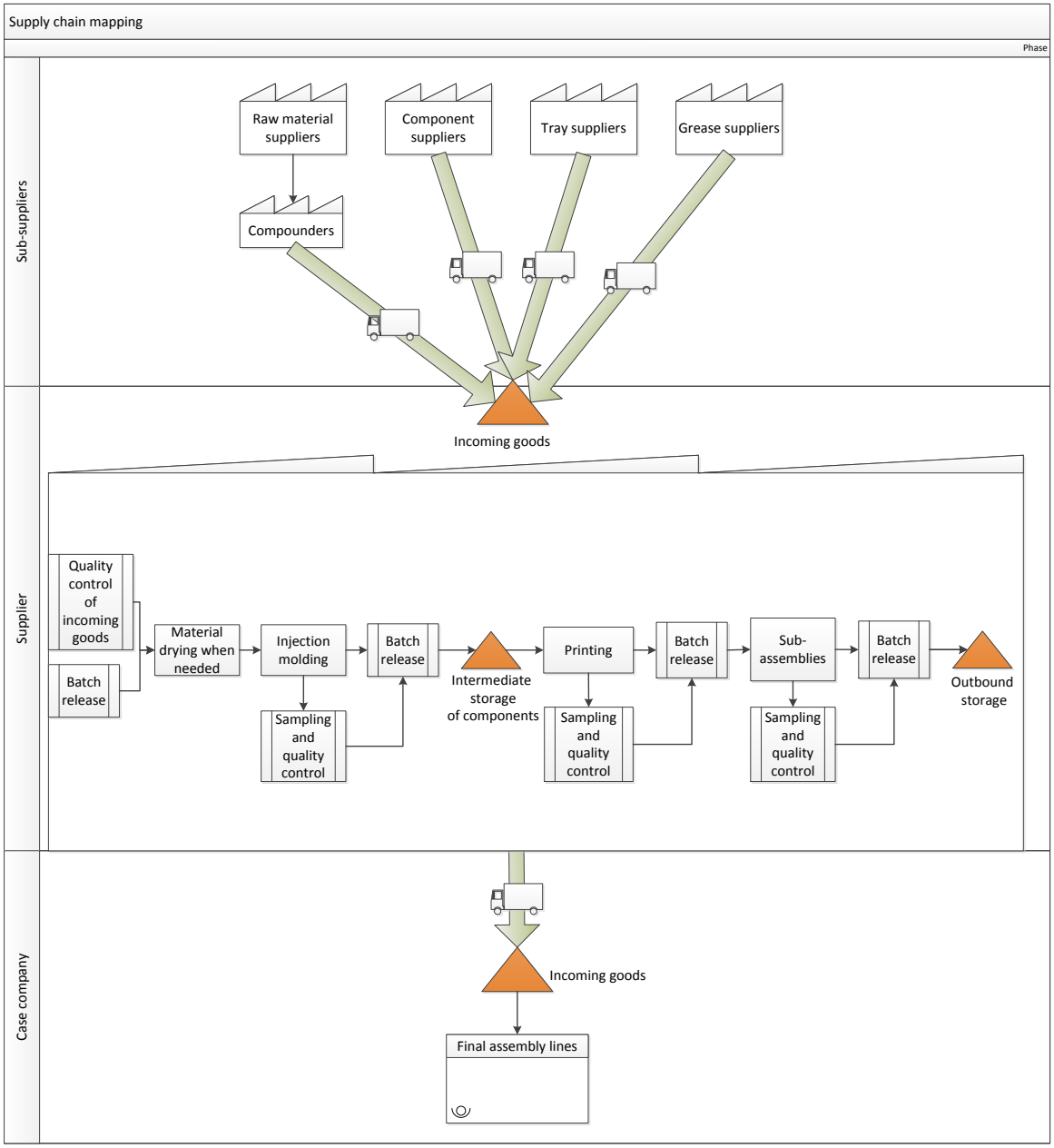
APPENDIX 1. Supply Chain Map



APPENDIX 2. Risk Areas

Process category:

1. There are faults and stoppages in molding/print/assembly that prevent a shipment from leaving on time
2. There is known to be a fault in the molding/print/assembly that causes minor stoppages, but it is too costly to stop the line to fix it more permanently due to dropping output
3. Manufacturing and molding of tools is delayed or is not within specifications
4. The layout of the suppliers' production is not optimized: The flow and warehousing of materials/components within the facility
5. The quality management system of the supplier is not adequate for medical device production
6. The maintenance of molds, assembly- and print lines are not done on time and well
7. The production of the sub-assemblies is prone to cause occupational safety hazards
8. The facility infrastructure is outdated: age, requires renovation, air problems
9. Different side projects disturb actual production; test runs, prototyping
10. The specification requirements are unclear or too tight
11. Deviation handling process is unclear or inefficient
12. In the processes heavy lifting is done, which could be executed by machinery

Control category:

1. The estimation accuracy of capacity requirements and production planning is not adequate, resulting in overtime, late shipments
2. There is poor availability of raw material/bought-in components
3. The shipping frequency and planning is not optimal and inefficiencies can be found in logistics
4. There is an excess of safety stocks increasing the inventory value in the supply chain

APPENDIX 2. Risk Areas

5. The shipping contracts are not mutually beneficial (incoterms)
6. Personnel lacks in training and competence
7. There are personnel fluctuations resulting in the loss of key knowledge and know-how (due to retirement, family leave)
8. There is a lack of communication or the quality of communication is poor within the supply chain organizations (customer + provider)
9. There is conflicting or not shared information
10. The policy and planning for the maintenance of molds, print/assembly lines are not cost/time/value efficient
11. Maintenance contracts are not in place
12. The policies for manufacturing (SOP) are missing or lacking depth and detail or need an update
13. The ERP (Enterprise Resource Planning) systems of the supplier and buyer have compatibility issues or are not up to date
14. Updates or changes to the ERP system cause it to crash
15. Printing servers have problems or crash
16. The supplier is not financially prepared for large investments for mass production
17. The supplier and sub-suppliers carries an insolvency risk or lack of creditworthiness
18. There are not adequate means of managing the intellectual property rights
19. The documentation and traceability is not correct or it is missing
20. Change control methods are inefficient; decision making not quick enough
21. The suppliers' negotiation power is low

APPENDIX 2. Risk Areas

Supply category:

1. The sub-supplier actions add disturbances to the supply chain
2. There is a currency risk with the supplier
3. The behavior of the supplier is opportunistic and not in mutual benefit
4. The behavior of the sub-supplier is opportunistic and not in mutual benefit
5. Raw material or purchased parts ordering point has been set up incorrectly
6. The supplier does not have sufficient backup of machinery in the case of a machine breakdown
7. There is not an adequate number/availability of spare parts for the mold/print/assembly lines
8. The demand forecasts of the buyer are not accurate
9. The orders of the buyer are not on time
10. Material stock balance is incorrect, or material consumption is set up incorrectly resulting in wrong purchase orders
11. The required spare part is wrong or missing
12. Customer support is far away or closed

Environment category:

1. There are transportation problems on the way, causing delays e.g. accident, stuck in bad weather, traffic, strikes
2. There is a strike at the supplier labor force
3. Flood
4. Forest fires
5. Power outages due to cut lines by snow/trees/wind
6. Hurricane, tornado, earthquake
7. The plant is in close proximity to hazardous industry: nuclear, chemical processing
8. There is a contamination of the products in production
9. There is a contamination of the products in transport

APPENDIX 2. Risk Areas

10. There is theft or vandalism of the product during transport
11. There are adverse governmental policies disrupting partnership formation (trade restrictions/quotas to a certain country)
12. There is a rise in energy prices, affecting production costs
13. The IT infrastructure is vulnerable for confidential information leakage
14. HSE (health, safety, environment) policy of supplier is not in line with standards that the buyer possesses
15. The pest control methods are inefficient
16. Production and transportation temperatures are not within specification

APPENDIX 3. Questionnaire 1

Questionnaire 1 on risk areas

Please answer all questions individually, and with as much depth as possible. Even the most obsolete risks can be placed here, as the purpose is to generate an exhaustive list. In this questionnaire criticism toward the buyer can be imposed, if the issue is a genuine risk to the supply. Consider in your answers the current state, and also the event where a supplier of raw material changes or a new product is introduced.

1. What are the possible risks within your department that could disrupt/stop flow of information/materials?
2. What events in the past have caused disturbances/stoppages in the flow?
    a. What steps have been done in the past to reduce or eliminate these risks?
3. What have been the key learning points of previous audits at the company?
4. What are the potential risks that affect a continuous supply of components to the buyer that are outside your department?
5. What kinds of risks are apparent in the change of your ERP system to the flow of:
    a. Information/materials to your company?
    b. Information/sub-assemblies to the buyer?

APPENDIX 4. Questionnaire 2

Questionnaire 2 on risk areas

Below is a list of possible risks that could adversely affect the flow of information/materials/sub-assemblies. Please evaluate for each risk in your own expert opinion the following: impact, probability of occurrence, and the possibility of detection. Base your answers on historical data or your best estimate. These risks are to be evaluated in two time spans:

- short-run (SR) (1 month)
- long-run (LR) (12 months)

For the occurrence criterion, some risks are more applicable to be evaluated on occurrence in terms of production volumes, others in terms of occurrences in a time span. Below is an example how a certain risk could be evaluated. In the parenthesis there is the personal justification/thought process for the evaluation. In some cases it may be beneficial to write it down in the comments section, for example to clarify whether the occurrence is thought by production volumes or time span.

Example risk: There is poor availability of raw material

Impact:
3 in SR (due to safety stocks)
10 in LR (stoppages in production, price of raw material increases)

Occurrence:
3 in SR (markets for granulates are stable)
5 in LR (the material is very generic, there is a large supply)

Detection
1 in SR (information from supplier comes well in advance)
3 in LR (markets for granulates are stable)

APPENDIX 4. Questionnaire 2

Value	Impact	Explanation SR and LR
1	No impact	No effect on operations
3	Low impact	Minor disturbance, eg. no effect on deliveries
5	Some impact	Disturbances in production, eg. shipment is late
7	High impact	Major disturbances in production, eg. batch is scrapped/recalled
10	Very high impact	Production stops for more than a month

Value	Occurrence	Explanation SR	Explanation LR
1	Highly unlikely	1 in 1M units or either 1 per month	1 in 10M units or either 1 in 12 months
3	Unlikely	1 in 750k units or either 1 in 3 weeks	1 in 7,5M units or either 1 in 9 months
5	Possible	1 in 500k units or either 1 in 2 weeks	1 in 5M units or either 1 in 6 months
7	Very likely	1 in 300k units or either 1 per week	1 in 3M units or either 1 in 3 months
10	Certain	1 in 50k units or either 1 per day	1 in 1M units or either 1 per month

Value	Detection	Explanation SR and LR
1	Certain	In nearly all of the cases the event can be detected with the forecast and control methods
3	Easy to detect	A majority of the events can be detected with the control and forecast methods
5	Possible	Control and forecast methods have a good chance of detecting event, human error possible
7	Difficult to detect	Detection is achieved with random checks/forecasts, human error likely
10	Impossible	Event is not possible to detect, human error certain

APPENDIX 4. Questionnaire 2

Process category

Risk	Impact SR	Impact LR	Occurrence SR	Occurrence LR	Detection SR	Detection LR	Comments
There are faults and stoppages in molding/print/assembly that prevent a shipment from leaving on time							
There is known to be a fault in the molding/print/assembly that causes minor stoppages, but it is too costly to stop the line to fix it more permanently due to dropping output							
Manufacturing and molding of tools is delayed or is not within specifications							
The layout of the suppliers' production is not optimized: The flow and warehousing of materials/components within the facility							
The quality management system of the supplier is not adequate for medical device production							
The maintenance of molds, assembly- and print lines are not done on time and well							
The production of the subassemblies is prone to cause occupational safety hazards							
The facility infrastructure is outdat-							

APPENDIX 4. Questionnaire 2

ed: age, requires renovation, air problems							
Different side projects disturb actual production; test runs, prototyping							
The specification requirements are unclear or too tight							
Deviation handling process is unclear or inefficient							
In the processes heavy lifting is done, which could be executed by machinery							

Control category

Risk	Impact SR	Impact LR	Occurrence SR	Occurrence LR	Detection SR	Detection LR	Comments
The estimation accuracy of capacity requirements and production planning is not adequate, resulting in overtime, late shipments							
There is poor availability of raw material/bought-in components							
The shipping frequency and planning							

APPENDIX 4. Questionnaire 2

is not optimal and inefficiencies can be found in logistics							
There is an excess of safety stocks increasing the inventory value in the supply chain							
The shipping contracts are not mutually beneficial (incoterms)							
Personnel lacks in training and competence							
There are personnel fluctuations resulting in the loss of key knowledge and know-how (due to retirement, family leave)							
There is a lack of communication or the quality of communication is poor within the supply chain organizations (customer + provider)							
There is conflicting or not shared information							
The policy and planning for the maintenance of molds, print/assembly lines are not cost/time/value efficient							
Maintenance contracts are not in place							
The policies for manufacturing (SOP) are missing or lacking depth and detail or need an update							
The ERP (Enterprise Resource Plan-							

APPENDIX 4. Questionnaire 2

ning) systems of the supplier and buyer have compatibility issues or are not up to date							
Updates or changes to the ERP system cause it to crash							
Printing servers have problems or crash							
The supplier is not financially prepared for large investments for mass production							
The supplier and sub-suppliers carries an insolvency risk or lack of creditworthiness							
There are not adequate means of managing the intellectual property rights							
The documentation and traceability is not correct or it is missing							
Change control methods are inefficient; decision making not quick enough							
The suppliers' negotiation power is low							

APPENDIX 4. Questionnaire 2

Supply category

Risk	Impact SR	Impact LR	Occurrence SR	Occurrence LR	Detection SR	Detection LR	Comments
The sub-supplier actions add disturbances to the supply chain							
There is a currency risk with the supplier							
The behavior of the supplier is opportunistic and not in mutual benefit							
The behavior of the sub-supplier is opportunistic and not in mutual benefit							
Raw material or purchased parts ordering point has been set up incorrectly							
The supplier does not have sufficient backup of machinery in the case of a machine breakdown							
There is not an adequate number/availability of spare parts for the mold/print/assembly lines							
The demand forecasts of the buyer are not accurate							
The orders of the buyer are not on time							
Material stock balance is incorrect, or material consumption is set up incorrectly resulting in wrong purchase orders							

APPENDIX 4. Questionnaire 2

The required spare part is wrong or missing							
Customer support is far away or closed							

Environmental category

Risk	Impact SR	Impact LR	Occurrence SR	Occurrence LR	Detection SR	Detection LR	Comments
There are transportation problems on the way, causing delays e.g. accident, stuck in bad weather, traffic, strikes							
There is a strike at the supplier labor force							
The plant is in a location prone for natural phenomena that could disrupt supply:							
Flood							
Forest fires							
Power outages due to cut lines by snow/trees/wind							
Hurricane, tornado, earthquake							
The plant is in close proximity to hazardous industry: nuclear, chemi-							

APPENDIX 4. Questionnaire 2

cal processing							
There is a contamination of the products in production							
There is a contamination of the products in transport							
There is theft or vandalism of the product during transport							
There are adverse governmental policies disrupting partnership formation (trade restrictions/quotas to a certain country)							
There is a rise in energy prices, affecting production costs							
The IT infrastructure is vulnerable for confidential information leakage							
HSE (health, safety, environment) policy of supplier is not in line with standards that the buyer possesses							
The pest control methods are inefficient							
Production and transportation temperatures are not within specification							

APPENDIX 5. Supplier Risk Assessment Template

Supplier assessment questionnaire

Dear respondent,

You received this supplier assessment questionnaire from us to gain a more comprehensive view of your competencies and risk management methods. There are four categories of evaluation:

Process category: Material and information flows in the facility and execution of manufacturing.

Control category: The rules, regulations and policies that the processes undergo in the manufacturing.

Supply category: Materials management.

Environmental category: Natural phenomena affecting the supply chain.

In total there are 10 questions for you to elaborate on, with guiding sub-questions. We would like for you to answer all the questions in as much depth and detail as possible. When applicable, please provide examples and references to back your statements by explanation or attached documentation. After a written explanation, there is an assessment of the given risks.

Thank you for your input.

APPENDIX 5. Supplier Risk Assessment Template

Process category

1. How are deviations in production and general operations handled?
    a. What are the means to ensure that the deviation handling process is clear to all employees who handle the deviations? (SOP, training)
    b. How do you minimize occurrence of deviations in production and general operations?

2. How do your clients quantify the production specifications?
    a. What technical and regulatory means do you have to ensure that the specifications are not too tight and that they are clear to employees?

3. How is the maintenance of the production lines handled?
    a. Policy and planning for cost/time efficiency.
    b. Concrete execution: what/how/when is this done?

Control category

4. In which ways do you share information with your clients and suppliers?
    a. How do you avoid having conflicting/inaccurate information internally and externally?

5. What is the documentation and traceability method you use?

6. How do you manage change?
    a. Changes in production, manufacturing capabilities, labor force
    b. Do you make quick, efficient and justified decisions? What steps are you taking to improve this aspect?

APPENDIX 5. Supplier Risk Assessment Template

Supply category

7. What is your relationship with your suppliers?
    a. Do they have a tendency for opportunistic behavior, i.e. not seeking terms beneficial for both entities?
    b. What is the power balance with you and the suppliers?
    c. What is the overall satisfaction of your suppliers with your operations?

8. What is the level of backup machinery in the case of a breakdown?
    a. How fast can production resume at agreed pace?

9. How do you manage an optimal stock level of raw materials and bought-in components?
    a. Order points?
    b. Material consumption estimates?
    c. Experiences with Lean principles?

Environmental category

10. How do you ensure the products are not contaminated in production or transport?

Other risks

11.
12.
13.

APPENDIX 5. Supplier Risk Assessment Template

Assessment of risks

Below is the list of possible risks that could adversely affect the flow of information/materials/sub-assemblies. Please evaluate for each risk in your own expert opinion the following: impact, probability of occurrence, and the possibility of detection. Base your answers on historical data or your best estimate. These risks are to be evaluated in the long run (LR) (12 months).

For the occurrence criterion, some risks are more applicable to be evaluated on occurrence in terms of production volumes, others in terms of occurrences in a time span. Below is an example how a certain risk could be evaluated. In the parenthesis there is the personal justification/thought process for the evaluation. In some cases it may be beneficial to write it down in the comments section, for example to clarify whether the occurrence is thought by production volumes or time span.

Example risk: There is poor availability of raw material

Impact:
10 in LR (stoppages in production, price of raw material increases)

Occurrence:
5 in LR (the material is very generic, there is a large supply)

Detection
3 in LR (markets for granulates are stable)

APPENDIX 5. Supplier Risk Assessment Template

Value	Impact	Explanation LR
1	No impact	No effect on operations
3	Low impact	Minor disturbance, eg. no effect on deliveries
5	Some impact	Disturbances in production, eg. shipment is late
7	High impact	Major disturbances in production, eg. batch is scrapped/recalled
10	Very high impact	Production stops for more than a month

Value	Occurrence	Explanation LR
1	Highly unlikely	1 in 10M units or either 1 in 12 months
3	Unlikely	1 in 7,5M units or either 1 in 9 months
5	Possible	1 in 5M units or either 1 in 6 months
7	Very likely	1 in 2,5M units or either 1 in 3 months
10	Certain	1 in 1M units or either 1 per month

Value	Detection	Explanation LR
1	Certain	In nearly all of the cases the event can be detected with the forecast and control methods
3	Easy to detect	A majority of the events can be detected with the control and forecast methods
5	Possible	Control and forecast methods have a good chance of detecting event, human error possible
7	Difficult to detect	Detection is achieved with random checks/forecasts, human error likely
10	Impossible	Event is not possible to detect, human error certain

*Forecast method: means of anticipating a given event happening through media, personnel and client/supplier communication.

APPENDIX 5. Supplier Risk Assessment Template

Process category

Risk	Impact LR	Occurrence LR	Detection LR	Comments
Deviation handling process is unclear or inefficient				
The specification requirements are unclear or too tight				
The maintenance of molds, assembly- and print lines are not done on time and well				

Control category

Risk	Impact LR	Occurrence LR	Detection LR	Comments
There is a lack of communication or the quality of communication is poor within the supply chain organizations (customer + provider)				
There is conflicting or not shared information				
The documentation and traceability is not correct or it is missing				
Change control methods are inefficient; decision making not quick enough				

APPENDIX 5. Supplier Risk Assessment Template

Supply category

Risk	Impact LR	Occurrence LR	Detection LR	Comments
The behavior of the sub-supplier is opportunistic and not in mutual benefit				
The supplier does not have sufficient backup of machinery in the case of a machine breakdown				
Material stock balance is incorrect, or material consumption is set up incorrectly resulting in wrong purchase orders				
Raw material or purchased parts ordering point has been set up incorrectly				

Environment category

Risk	Impact LR	Occurrence LR	Detection LR	Comments
There is a contamination of the products in production or transport				

Other

Risk	Impact LR	Occurrence LR	Detection LR	Comments