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Keeping the Initiative Through Disruptions

Developing a Business Continuity Model for Gambro Global Operations

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Lund, 18th of June 2013

Axel Hyllienmark & Emil Nilsson

Abstract

Title: Keeping the Initiative through disruptions – Developing a Business Continuity Model for Gambro

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Background: Historically, the risk management activities in Gambro have been focused to ensure safety for patients and users of the company's products where Regulatory and legal demands have driven the development. Lately, the need for a similar approach to assess and manage business risks has risen. When an earthquake hit the company's facilities in northern Italy in 2012, the company did not have a predetermined plan for how to solve the crisis. Through good management and a dedicated workforce, production was quickly recovered and no patient harm occurred. After the experience the company realised the potential benefits of proactive assessment and management of risks for business interruptions.

Purpose: The purpose of this thesis is to develop a model for assessment of risks that affects Gambro's ability to deliver their products, i.e. operational disruption risks. The model should capture different types and levels of risks and be applicable and easy to use throughout the company. The harmonised model should enable Gambro to identify and mitigate risks in a structured and analytical manner.

Method: A constructive research approach is used where a practical solution to the proposed problem is suggested. Academic literature, benchmarking, and Gambro's current organisation is the basis for the development of a framework and governance for business risk management.

Conclusions: A model for assessing disruption risks was developed. The model is divided into two general areas: the organisation and the procedure. An organisation with three different levels with different responsibilities of the process was developed. The three step procedure consists of the methodologies and tools required for identification of critical activities and resources, analyse and quantification of risks in terms of likelihood and business interruption value, and evaluate possible the risk responses.

Keywords: Risk Management, Business Continuity Planning, Business Continuity Management, Risk, Disruptions, Interruption Value, Gambro

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Definitions

In this report, a number of important words and expressions are used. To support the reader a list of definitions is presented below. The reader is encouraged to go back to this list when necessary in order to fully understand the context.

Buffer Time The time from the incident until Gambro's business starts to be affected. The time could be dependent of safety stock, backup systems etc.

Business Recovery Time The time from the end of the buffer time to the end of the downtime. During this time the business process will be interrupted and no output delivered.

Business Interruption Value (BIV) The gross margin of the process' final output multiplied by the Business Recovery Time plus extra costs such as idle capacity labour and equipment, inventory carrying, repair costs etc. The value should also include loss of goodwill if possible.

Business Continuity Capability of the organization to continue delivery of products or services at acceptable predefined levels following disruptive incident.

Business Continuity Management The development of strategies, plans and actions which provide protection for those activities or business processes which, if they were to be interrupted, might otherwise bring about a serious damage to the enterprise.

Business Continuity Plan Documented procedures that guide organizations to respond, recover, resume, and restore to a pre-defined level of operation following disruption.

Business Continuity Strategy Business Continuity Strategy is about using the findings in BIA and Risk Assessment to determine appropriate actions to resume activities within agreed timeframes.

Business Impact Analysis Process of analyzing activities and the effect that a disruption might have upon the company.

Business Recovery Time The time during which no output can be expected from the process in question. This time consists of two components, the total down time minus the buffer time.

Continuity Project Team The Continuity Project Team is determined by the Process Continuity Management Team in order to suit the particular project. The team may include internal and/or external subject matter experts.

Deductive Risk Identification An undesired scenario is imagined and possible causes are found and investigated ("what can cause this undesired scenario")

Detectability An estimate of the ability to identify a cause of failure before the harm actually occurs.

Impact The expected magnitude of a risk's impact. In the proposed model, Business Interruption Value is used as a measurement.

Inductive Risk Identification All sub-steps of e.g. a process is gone through and possible failure modes in each one are found and investigated ("what can be the effect of this event occurring")

Likelihood A term for measuring how expected an event is. Used interchangeably with probability and occurrence

Occurrence A term for measuring how expected an event is. Used interchangeably with probability and likelihood

Probability A term for measuring how expected an event is. Used interchangeably with occurrence and likelihood

Process Continuity Management Team The Process Continuity Management Team includes, but is not limited to, Global Process Continuity Manager, Local Operations Site, Local Supply, Site IT, Site Facility. The team may include internal and/or external subject matter experts

Recovery Time Objective The Recovery Time Objective is the time that is estimated can pass before Gambro's ability to deliver to nearest customer will be affected, and consequently negative business impact will occur.

Risk Management The making of decisions regarding risks and their subsequent implementation, and flows from risk estimation and risk evaluation (Society, 1992, p. 3)

Risk Mitigation The pro-active activities to deal with risks that are meant.

Risk Priority Number The Risk Priority Number is used in order to prioritize between risks. It is found by calculating the geometrical representation of the risks position in the risk matrix. This is done with the formula $\sqrt{(L^2 + S^2)}$.

Severity The expected magnitude of a risk's impact. In the proposed model, Business Interruption Value is used as a measurement.

QA/RA Quality Assurance and Regulatory Affairs.

Chapter 1

Introduction

1.1 Context of the Project

Businesses have been managing risks ever since the market economy started to take shape hundreds of years ago. Balancing risk taking with preventive actions is a large part of what it means to drive a business. However, as the business environment grows more complex and supply chains are spanning over more companies and longer geographical distances, the need for proper risk management is as important as ever. This report proposes a model for evaluating and managing this complex environment in which companies must succeed in order to sustain a long term viable business.

Gambro, a leading medical device company, is one company for which risks is a daily part of the business and requires constant monitoring. As a producer of medical equipment, lives are dependent on Gambro being fully functional in both the delivery capability and in the quality of the products. Historically, the focus of the risk management has lain in securing patient safety by assessing and examining the products and its quality. Chemical production processes and strict requirements for precision in the products' operability have made this an important task for Gambro. Legal requirements and supervision from authorities has also driven the development. Lately, there has also been an increased awareness of the risk of delivery capability and other business risks. As is often the case, a specific event raised the question and challenged the view of the current practices. In Gambro's case, an earthquake in northern Italy in 2012 left one major plant unusable and put strain on the company's global organisation to deliver the necessary products to ensure patient safety. While all treatments could be pursued through and after the crisis the event had a financial impact on the company and highlighted the need for

comprehensive and harmonised procedures for identifying and assessing the risk for such disruptions. (Karlsson, 2013a)

1.2 Risk Terminology

The term risk is used in many circumstances and most people do not reflect upon the formal definition, but generally the word means that future events proceed in an unexpected way and cause disturbance to what is the intended target. In daily life, the word can have a number of different meanings (Mattson, 2000, p. 33)

- A threat or danger ("There is a risk of flooding").
- A probability ("Driving without seatbelt increases the risk of injury").
- A combination of consequences' likelihood and severity.
- A measurement of variability ("Insurance decreases the risk").

More formalised, the triplet of *risk scenario* (what can happen), likelihood of occurrence (how often will it happen) and *severity* of *consequence* (what are the impacts) will always be present and constitutes the word risk in its full sense.

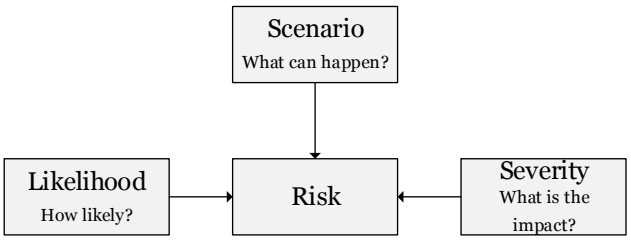

Figure 1.1: Components of the term risk

Other definitions of the word has also been proposed by numerous scholars, for instance Harland, Brenchley, and Walker (Harland et al., 2003) proposes the definition "[risk is] a chance of danger, damage, loss injury or any other undesired consequences", The Royal Society (Society, 1992) goes one step further and define risk as "...the chance, in quantitative terms, of a defined

Corporate function	Scope of risk management
Senior management	Competitors, political risks, legal risks
Procurement	Suppliers' financial situation, quality
Health and Safety	Occupational hazards, dangerous materials
Operations	Machine operability, quality of products
Research and Development	Product safety, quality of products
Logistics	Transportation issues, perishable stocks

Table 1.1: Examples of risks in different corporate functions

hazard occurring. It therefore combines a probabilistic measure of the occurrence of the primary event(s) with a measure of the consequences of that/those event(s)".

In this report, risk is looked upon as the interplay between the likelihood of an event and the severity of its impact. Both categories are accompanied with quantitative measures, as in the definition given by The Royal Society. The risk scenarios are those that can affect Gambro's ability to deliver and thus poses a business risk to the company.

As mentioned, risk management is present in many parts of a company at different levels. The work can be ongoing or done in project form. Examples of functions and their scope of analysis are given in table 1.1

Scope of analysis and delimiters

Supply chain risk has received increasing attention the last decade. The view on the supply chain as an integrated organisation with a common goal together with increased requirements on logistical performance with Just-In-Time deliveries and other Lean principles have driven this development (Waters, 2011, p. 10)

Manuj & Mentzer defines eight sub categories of supply chain risks in their paper "Global Supply Chain Risk Management". Several of the categories are overlapping and risks sometimes fall into more than one category. (Manuj and Mentzer, 2008)

No	Type of risk	Examples
1	Supply Risks	Disruption of supply, inventory, schedules, and technology access; price escalation; quality issues; technology uncertainty; product complexity; frequency of material design changes
2	Operational Risks	Breakdown of operations; inadequate manufacturing or processing capability; high levels of process variations; changes in technology; changes in operating exposure
3	Demand Risks	New product introductions; variations in demand (fads, seasonality, and new product introductions by competitors); chaos in the system (the Bullwhip Effect on demand distortion and amplification)
4	Security Risks	Information systems security; infrastructure security; freight breaches from terrorism, vandalism, crime, and sabotage
5	Macro Risks	Economic shifts in wage rates, interest rates, exchange rates, and prices
6	Policy Risks	Actions of national governments like quota restrictions or sanctions
7	Competitive Risks	Lack of history about competitor activities and moves
8	Resource Risks	Unanticipated resource requirements

Table 1.2: Risk categorisation, adapted from Manuj and Mentzer (2008)

As the risk for Gambro's delivery capability is the main target of this report, not all risk categories apply. Risk category 2, 4, 6 and 8 (operational, security, policy and resource risks) are possible to cover to their full extent by the proposed model. Risk category 1 (supply risks) is being analysed quite roughly on a supplier/component level. Managing the risk of suppliers is already one of the tasks for Gambro's purchasing function, and the major identified risks should be included in the same model as other risks for the sake of managerial overview. However, different suppliers' internal processes are not looked into limiting the analysis upstream to the entry of components at Gambro's facilities. Downstream, the analysis is limited to the exit of finished products from Gambro's manufacturing unit's stock. Further transportation towards the customer is not considered in this report. Risk category 3, 5 and 7 (demand, macro and competitive risks) are not considered in this report as they do not directly affect Gambro's ability to deliver finished products.

Goal

The goal of the thesis is to develop a risk analysis model that Gambro can use for the assessment and analysis of risks for Gambro of not being able to deliver their products. The model should be based on existing theoretical literature as well as the existing practices within the company today. The model should be easy to understand for the stakeholders, but also theoretically correct and relevant. In addition the model should be quality assured by the authors together with the intended future users and by fellow students not active in the project. The goals are thus twofold:

1. Develop a theoretically correct model for risk analysis with Gambro's operations. The model should be relevant to the industry and structured to use for all intended stakeholders.

2. The model should be tested by performing a complete risk analysis on one or several of Gambro's manufacturing units. Strong and weak points should be evaluated in order to prepare for implementation of the model throughout Gambro.

Outcome

The analysis will result in a model for assessing risks within Gambro Global Operations. Theoretical and practical background will lay the foundation for the model and will be motivated in an academic style report. The model will be presented in the form of a manual or working document which can be used unassisted by appropriate stakeholders. In addition the manual will be tested on one or more of the production sites and an evaluation of the results will be made.

Disposition

The report is divided as described in figure 1.2. Chapter 2 gives a background to the thesis, introducing Gambro and explaining the events that highlighted the need for risk management and initiated this thesis. Chapter 3 explains the methodology used in this project. Chapter 4 summarises relevant academic literature, which can be seen as a basis for the model proposed. Chapter 5 shows how risk management is used in practice, both within Gambro and in other companies. In chapter 6 the developed model is proposed, using chapter 2, 4 and 5 as a basis. An test implementation of the model in Medolla, Italy

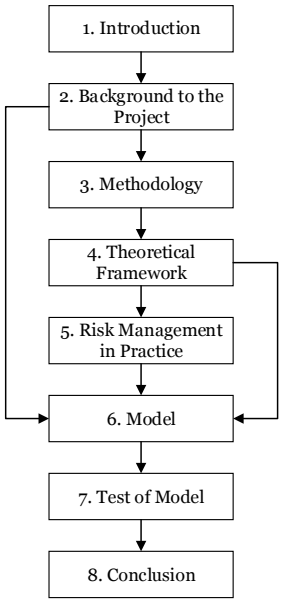

Figure 1.2: The chapters of this report

is described in chapter 7 and the report is summarised in chapter 8 with discussions of the end result,

Chapter 2

Background to the Project

In this chapter, the case company Gambro is introduced. In particular, their business area is described together with a historical background to this project, the earthquake in northern Italy in 2012.

2.1 Gambro

History

Gambro was founded in 1964 on the basis of the invention of one of the world's first artificial kidneys, which had been developed by Professor Nils Alwall since the mid 1940's. At a social event he met industrialist Holger Crafoord who was then active in the packaging industry, but felt compelled to develop and market the new and potentially life saving technology. In 1967 the company's first product was launched and since then Gambro has been one of the world leading companies in its sector. (Gårdlund, 1989, p. 207)

Business areas

Gambro is a global leader in kidney and liver dialysis, Myeloma Kidney Therapy and other extracorporeal therapies for chronic and acute patients. The product range includes different types of complete systems for hemodialysis, complete systems for multiple blood purification therapies and systems for water purification in hospital environments. A large part of the sales is made up of disposable products and consumable chemical substances for one time use. (Gambro, 2013)

The company has approximately 7500 employees and 13 manufacturing sites in 9 countries. The manufacturing units operate in 4 different areas.

The *Monitor* products are monitor equipment for dialysis and other machines such as water purification systems. The *Dialyzer* business area produces the disposable filter used for blood and fluid purification. The *Solution* business area makes the chemical substances used in the different purification processes and their packaging. The *Bloodline* business area produces catheters, cassettes and other products for vascular access. The machines are standardised in their basic setup but can be modified with different types of filters, catheters and needles to suit the exact need of individual customers. An excerpt of Gambro's products is displayed in figure 2.1 (Gambro, 2013)

Figure 2.1: An excerpt of Gambro's products, from left to right: Artis (Monitor), Polyflux (Dialyser) and Artiset (Bloodlines)

Global organisation

The corporate headquarters is located in Lund, Sweden in connection to manufacturing units in the business areas Machines and Solutions. The main production sites and their locations are:

- Monitors
  - Lund, Sweden
  - Crevalcore, Italy
- Solutions
  - Lund, Sweden
  - Sondalo, Italy
  - Daytona, USA

  - Yongin, South Korea

- Dialyzers
  - Hechingen, Germany
  - Opelika, USA
  - Meyzieu, France
- Bloodlines
  - Poggio Rusco, Italy
  - Prerov, Czech Republic
  - Tijuana, Mexico
  - Shanghai, China

Besides those main factories there is also a small unit for liver therapies in Rostock, Germany. The plants in Crevalcore and Poggio Rusco are temporary arrangements after the earthquakes in Medolla, May 2012. A reinstated facility in Medolla is under development and will take over their function. Research and development is performed in the Lund HQ as well as at the different sites. Altogether, Gambro's products are offered in more than 100 countries. (Karlsson, 2013b)

Dialysis – Gambro's main business

In the case of kidney failure, there are three main types of treatment possible, namely:

- Kidney transplantation
- Paritoneal dialysis
- Hemodialysis

A kidney transplantation means that a new kidney from an organ donator is placed into the patient. Paritoneal dialysis is a treatment form where the lining of the belly is used to filter the blood inside the patient's body. The only treatment that Gambro is currently involved in is Hemodialysis, where a machine is used to filter and clean the blood outside of the patients body.(National Kidney and Urologic Deseases Information Clearinghouse, 2010)

In hemodialysis, blood is first pumped out of the body through a catheter and into the dialyser which is connected to the machine. The arterial blood

pressure and the inflow pressure is monitored at all times. In the dialyser, the blood is filtered through semi-permeable materials and purified with chemical substances. The clean blood can then be pumped back into the body in a controlled manner. The entire process is schematically illustrated in figure 2.2.

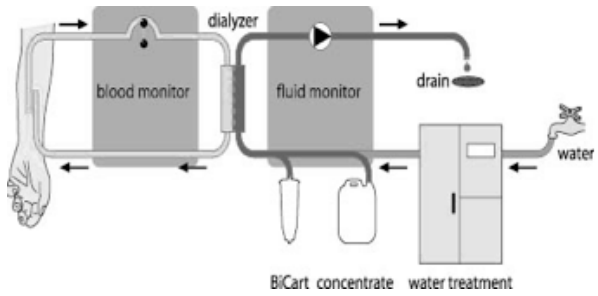

Figure 2.2: Dialysis process

Gambro's solutions are packaged in highly sterile bags or cylinder shaped containers. The demands on the products and packaging require production processes in very sterile environment and exact specifications on all ingoing materials.

2.2 Medolla Earthquake

In May 2012 an event occurred that changed Gambro's view on risks. In Medolla, north of Italy there were two consecutive earthquakes with respective aftershocks. In Medolla, Gambro had a large monitor and bloodlines production site. The earthquakes were measuring up to 5.8 on the Richter scale, and left personal injuries, with 27 people dead and over 14,000 people without homes, as well as substantial monetary and physical damages (Povoledo, 2013a). Furthermore, the earthquake had major impacts on the Italian economy affecting an area that contributes to over 1 percent of Italy's gross margin product, among them the Gambro plant. (Povoledo, 2013b)

For Gambro, the earthquake resulted in two destroyed production lines, disrupting all deliveries and prohibiting access to finished goods. Clearly, the event also had a large impact on all employees and their personal lives. The top priority for Gambro was the continuity of patient care and ensuring that the customers had everything they needed to treat their patients. As a response, a steering committee with senior management members and experts

from all functional areas was formed to manage the recovery. The following measures were taken immediately: (Gambro, 2013)

- Production of spare parts started in a new plant in Crevalcore, Italy and the Artis and Phoenix monitor production was resumed within 3 months.
- A new automated warehouse in Varese, Italy was instated.
- A new temporary plant in Poggio Rusco, Italy was started to restore the bloodlines production.
- New offices were opened in Modena, Italy, where R&D and other support functions were reinstated.
- Gambro was looking into various options to assure that the customers had access to the products they needed to treat their patients, in cooporation the regulatory authorities.
- There were thorough investigations of the status of the customers' stocks, inventory and weekly consumption in order to prioritise deliveries.
- Employees and extra resources were working double shifts in order to ensure deliveries according to plan.

These cautions together with a global effort, e.g. increased production of Artis cassettes in Tijuana, Mexico, made sure that appropriate deliveries were completed and consequently that the patients safety were ensured. (Karlsson, 2013a)

The catastrophe highlighted the importance of appropriate evaluation of risks and preparation of adequate responses. On beforehand, the risk of an earthquake was seen as very low and the area struck was not even listed as a vulnerable region by the Italian Geophysics Institute. (Povoledo, 2013a)

Chapter 3

Methodology

In this chapter, the research approach is described and motivated and the projects main steps are outlined. A description of the literature studies conducted in the beginning of the project is also included.

3.1 Approach

In order to describe and validate the choices a researcher makes, it is important to have a clear and well defined methodology to support the research process. The approach should fit both the intended question of the research, as well as the different stakeholders of the project.

The aim of the project, as described in the chapter 1, is to, with a practical mindset harmonize and develop the assessment procedures for disruption risks within the organisation. The background material will be made up by academic literature on the subject, as well as qualitative, empirical data from interviews and existing documentation both from within and outside of the company. The research can also be considered to be normative, thus giving a result and conclusion based on gathered information.

One method that could be used for projects of this practical nature is the constructive research approach, as proposed by Kasanen and Lukka (1993)

The approach is built around a procedure for producing new and innovative constructs to real-world problems, and by that make a contribution to the theoretical field in which it is applied. In addition, the solution should have a clear connection to existing theory in the field and, of course have a practical functionality. The construct can take shape in many forms, such as diagrams, models, organisational structures, plans and commercial products.

According to Kasanen and Lukka (1993), the constructive approach should fulfil six requirements based on its core features:

- Focus on real world problems felt relevant to be solved in practice.
- Produce an innovative construction meant to solve the initial real-world problem.
- Include an attempt for implementing the developed construction and thereby a test for its practical applicability.
- Imply a very close involvement and co-operation between the researcher and practitioners in a team-like manner, in which experimental learning in expected to take place.
- Explicitly link to prior theoretical knowledge.
- Pay particular attention to reflecting the empirical findings back to theory.

The approach is based in the belief that thorough analysis of what works (and what does not) can make significant contribution to theory. The model has many resemblances to common practice of consultancy projects. However it has a stronger foundation in theory prior to the solution making phase and also includes a reflection of the theoretical contributions in the end phase of the project.

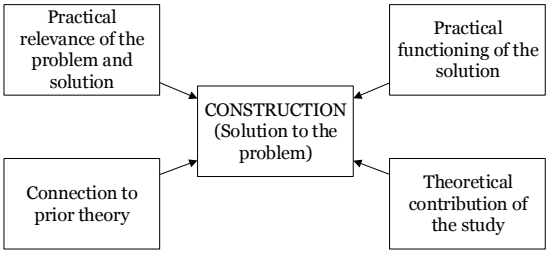

Figure 3.1: The constructive approach suggested by Kasanen and Lukka (1993)

3.2 Procedure

The approach is divided into seven distinct steps, each presented below with additional comments on the theoretical background and the execution in this specific project. The following steps are adapted from Kasanen and Lukka (1993):

Step 1. Find a practically relevant problem, which also has potential for theoretical contribution

Comment: The first step is clearly one of the most important in any research project, as it will define a large part of the following work. The topic should ideally both be of practical relevance and not sufficiently analysed in existing academic literature.

Execution: This step has mainly been addressed by the target firm and the academic institution prior to the start of the project by defining the problem scope (Gambro) and accepting it as applicable as a master thesis subject (LTH). The special legal requirements present in the pharmaceutical and medical device sector is another aspect that makes the research novel and the solution unique to the certain case.

Step 2. Examine the potential for long-term research co-operation with the target organisation

Comment: As the problem is of practical nature it is of importance that co-operation between the external researchers and the target firm is functional and does not inhibit the project process.

Execution: By working from office spaces at the company in direct proximity to relevant personnel, support and aid from the top management as well as having access to the organisation's intranet, the level of commitment is considered to be well sufficient. Direct contact at least weekly with Lina Karlsson, the project supervisor, also plays a major role in keeping the connection tight between the project activities and the ultimate research objective. She is also likely to undertake a managerial role of the continued use of the proposed model and will thus act as a future practitioner.

Step 3. Obtain deep understanding of the topic area both practically and theoretically

Comment: This step contains of applying the common methods of information search such as analysis of existing literature, analysis of company internal

documents, interviews and observations. Deeper knowledge of the subject from a theoretical point of view should be obtained, primarily by studying existing literature. The researchers should also in this step get a thorough understanding of the circumstances of the particular case setting.

Execution: A literature search is done by scanning article databases for relevant scientific articles. Books and book chapters are also consulted in the theoretical search. This process is further discussed under the Literature review section. In order to understand the case at the company all plant managers are asked to provide any documents previously prepared within the area of risk management and contingency planning. Interviews are also conducted with key personnel at various departments in Lund in order to understand how the processes are currently set up and which concerns that have to be addressed. A benchmarking through interviews with two case companies and the author of one case article is also conducted. The interview objects are chosen due to their expertise and knowledge, together with the project supervisor.

Step 4. Innovate a solution idea and develop a problem solving construction, which also has potential for theoretical contribution

Comment: This phase is, for obvious reasons, critical to the ultimate success of the project. Because of the innovative nature of the step, there is little theoretical advice given in the literature but an iterative process with input from both the researchers and the practitioners intended to use the model is usually needed.

Execution: A standard model for risk management, suitable for all intended company units is developed based on the previous steps. The model both includes a background of how and why it is designed in a certain way, and instructional documentation for use in the risk assessment processes.

Step 5. Implement the solution and test how it works

Comment: This phase makes the constructive approach differ from many other analytical approaches in that the theoretical design is actually implemented and tested in real life to confirm its applicability. A true belief in the model, both by the researchers and the company practitioners, is a prerequisite for a successful implementation and valid results.

Execution: The model is after the initial development tested and validated in the reconstruction project of the monitor and bloodlines production facility in Medolla, Italy. The test is conducted with the project manager of the

reconstruction as a highly active participant together with managers from the different business areas.

Step 6. Ponder the scope of applicability of the solution

Comment: Once implemented, the researcher should take a step back from the empirical work and evaluate the outcome of the project together with the case organisation. The applicability and critical success factors should be discussed if the outcome is regarded as a success and the possible contributing factors could be analysed if the project has failed in any way.

Execution: As the project goal is to develop a procedure which could be used throughout the company it is very important to document the steps necessary to take for a successful implementation. The test of the model is also used as a base for finding improvement points and success factors before a wider roll-out is started.

Step 7. Identify and analyse the theoretical contribution

Comment: As in the previous step, in the very end of the project, the researchers should distance themselves from the previous work and analyse it from an objective point of view. Typically, two main types of potential contributions can be found in projects conducted with a constructive approach. The first potential contribution is the novel construction itself as theory is applied to an unknown area. The second possible contribution is the processes and structures that have emerged in the case. Positive relationships between those features and the outcome should be considered and documented if contribution to theory.

Execution: The primary objective of the project is to address the issues raised by the company and to develop a model that works in that particular setting. However, the theoretical knowledge that may be obtained during the different phases is documented, both for the benefit of the organisation and possibly of other project report readers as well.

3.3 Literature Review

When conducting the literature review within the frame of this report a number of different academic areas have been investigated. LibHub, Lund University's search engine has primarily been used to find articles from academic journals. Risk analysis, risk management, supply chain risk management and

hazard identification are examples of the key words that have been used. Often times, the reference list of one article has led to findings of other sources. Printed material such as books and article collections have been found using the search engine at the internet based bookstore Amazon.com. Also used, but to a lesser extent, have been the commercial internet search engine Google, primarily to find white papers prepared by consultancy firms such as Accenture, BCG and IBM.

Chapter 4

Theoretical Framework

In this chapter, relevant academic literature is summarised. This is one of three types of input which has been used in this report, the others being practical use of risk analysis and Gambro's organisational structure.

The theory is furthermore composed by three different levels, resulting in equally many sections in this chapter.

The chapter first discusses risk management in a supply chain perspective, under the name Supply Chain Risk Management. The main focus lies in flexibility, visibility and redundancy, whose importance are highlighted and clarified through case descriptions. In the following section, managerial aspects are discussed, focusing on the two well established managerial processes within the area: Risk Management and Business Continuity Management. Their similarities and differences are studied as well as what their main application areas are. In the last section of the chapter four commonly used methods for Risk Identification and Evaluation are presented. The models can be used in both the Risk Management and Business Continuity Management frameworks.

4.1 Supply Chain Risk Management

Risk management in the supply chain has relatively recently emerged as a recognised field of research in the academic world. The purpose of the research has been to develop methods for understanding and managing risk that appears in an organisation's entire supply chain. (Khan and Zsidisin, 2012, p. 9)

As company's supply chains have become more and more global at the same time as Lean strategies have pushed down inventory levels, the risk level

in supply of raw material and components have in general become higher. There is also evidence that imply that the social, political and economic developments over the last decade have increased the likelihood of disruptions in complex supply chains. (Khan and Zsidisin, 2012, p. 9)

The development in purchasing strategies is another aspect that has put supply chain risk management higher on the agenda. Especially single sourcing of strategic components and materials is an obvious source of risk which can have severe impact on the buying company's result if a disruption occurs.

Most of the literature in this field is based upon cases of successful or failed attempts of managing supply chain risk of different kinds. Some relevant examples of those cases are briefly presented in order to provide a background to readers and also inspire Gambro to critically analyse its supply chain.

Ericsson's disrupted supply of radio frequency chips

On March 18th 2000, thunderstorms over New Mexico caused electrical power fluctuations throughout the state. At a small Philips production facility, the disturbances caused some cooling fans to stop and a small fire broke out in one of the facility's clean rooms. The fire was put out even before the fire department arrived 10 minutes later. Philips notified its two customers, Nokia and Ericsson, about the fire and warned that the incident might cause problems in the deliveries of radio-frequency chips for which the production process in the clean room was vital. Promises were also made that the production would soon be re-established and that there was no need for worry. Nevertheless, after 6 months the production was still at only 50 % and new equipment would take even more time to produce and install. For Ericsson, the impact was huge. The Philips plant was the only supplier of the chip needed for one of its most important consumer products. Consequently they would not be able to answer to the strong demand during the short market window which characterises the mobile phone industry. Later, the business interruption costs calculated to approximately $ 200M were covered by insurance companies. The insurance payment was one of the biggest in 2001, exceeded only by the 9/11 attacks. (Norrman and Jansson, 2004)

Even though the chip was equally important to Nokia, they avoided the financial impact to a much larger extent due to superior management of the incident. The difference was in the response to the information given by Philips on the day of the fire. Nokia immediately started searching for alternative suppliers and secured availability of the vital component. Ericsson, on the other hand, waited for additional information from Philips without contacting other companies. Once the magnitude of the problem was realised, Nokia

had already tied up the global supply of chips and Ericsson was very limited in its possible strategies. (Norrman and Jansson, 2004)

The case illustrates how much impact a seemingly small incident at an upstream supplier can have when the downstream customer becomes too heavily reliant. It also exemplifies the need for adequate action on information once it is available. No one can foresee and avoid all events, but it is of strategic importance to have plans ready for execution when a potentially harmful event occurs.

Visibility

On way of reducing certain risk levels is to increase the so called supply chain visibility. Typically, this means that information sharing is increased and partners let one another in on their flow of data and information. Typical types of information can be stock levels, demands, seasonality, new product launches, unexpected events, lost sales etc. Traditionally, correct delivery size, time and quality have been enough and little information was needed to be passed on. However, having a functioning information flow between partners can be vital when disturbances occur. If information about risks is not passed on, the downstream partners will not be able to act adequately to respond and the supply chain performance is susceptible to risk that otherwise could have been avoided.

In the case of Ericsson and Nokia, Philips did share information about the fire as soon as it happened. Even though the information was not accurate in terms of when operations would be back to normal, there is no evidence that Philips was untruthful in their estimations. The problem was rather that Ericsson did not have the correct structures in place for acting on the information. This turns us onto the next strategy for avoiding supply chain risk. (Sheffi, 2003, p. 10)

Flexibility

Flexibility is one of many buzz words in supply chain management which can be difficult to grasp and translate into concrete actions. When speaking of sourcing, the term can relate to a number of different techniques and strategies in the supplier management. In general it can be describes as an aligned strategy in how many suppliers a company has for a specific component and how the relationship with the supplier(s) is managed. (Sheffi, 2003, p. 215)

For single sourcing strategies a deeper relationship is clearly necessary than if many suppliers are used for the same component or material. For strategic

and engineered components deeper relationship is also of importance to shape prosperous and long term commitments. Simply put, the interface between number of suppliers and the relationship strategy can be explained with figure 4.1 (Sheffi, 2003, p. 215)

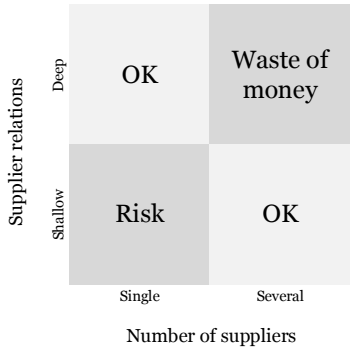

Figure 4.1: Procurement alignment (Sheffi, 2003, p. 215)

The theory and strategies behind those ideas can be described into much more detail than what is possible in the scope of this project; instead one illustrative business case is presented to clarify the concepts and benefits of flexibility.

On the morning of February 1, 1997, Toyota's sole source of P-valves (a small component used in the break system) Aisin Seiki Co. saw their factory go up in flames following some sparks from a broken drill. The P-valves cost around $ 8-14 per piece but all of Toyotas models were dependent upon them. Toyota was at the time expecting a surge in demand on the Japanease market and was already running 115 % of normal production rate. Being a just-in-time manufacturer, Toyota only had a few days stock of the P-valves in stock and on the road towards their factory. On February 4th, 20 out of 30 production lines had to be shut down due to the lack of P-valves, and it would still be months until Aisin would be back to normal production levels. (Sheffi, 2003, p. 211)

But the response was already in action. The afternoon of the 1st, Toyota and Aisin had gathered potential P-valve manufacturers in a conference room where engineers divided blue prints and valve making assignments. The suppliers were found among Toyota's and Aisin's regular supplier base as well as some independent companies found in the companies' extended manufacturing network. A total of 65 suppliers replied to the request and started making

replacements, among them the huge automotive parts manufacturer Denso. Since the P-valves required high precision tapered holes and surfaces, Aisin continued to act as quality controllants, in the supply chain of the P-valves. (Sheffi, 2003, p. 211)

The initial effort did not include financial or legal negotiations; the suppliers trusted Toyota and simply went to work as quickly as possible. The car giant's market position and long history probably acted as clear motivators for the suppliers to perform on their top.

On February 7th, all Toyota plants had started with a single shift and on the 10th, 9 days after the fire, the production volume was at 13-14 000 out of the planned 15 500 cars per day. (Sheffi, 2003, p. 215)

The case illustrates what can be achieved in terms of flexibility when a there is a deep relationship between the supplier and the customer as well as other companies close in geography and business. Nokia demonstrated the same type of capabilities as Toyota when finding alternate suppliers of the radio frequency chips, but in their case the need for supplier collaboration was not as strong, as the component had less need for specific engineering skills than Toyota's P-valves.

Redundancy

At the same time as lean strategies, just-in-time deliveries and continuous improvement programs often times aims at lowering stock levels and removing unused resources, there has also been a tendency towards building redundancy where it is needed. Most of the time, this redundancy is unused and only acts as a cost driver, companies see it as a necessary evil because the potential cost of a disruption is so high.

The parcel carrier FedEx delivers millions of packages in the US. Many of those packages are transported by plane, especially when the value is high and the transportation time needs to be minimised. The cost for a customer of an undelivered package can potentially be very high. If FedEx has to ground planes and the packages cannot be moved to another carrier, the company is very vulnerable of loosing business due to dissatisfied customers. To reduce the risk of this happening, FedEx each night dispatches two planes, one from each coast of the US, completely empty. The planes fly to Memphis and then returns, again empty. The logic behind this is that if a plane with very important goods is grounded, one of the empty ones can be rerouted and take care of the delivery. Several other planes are also sent half-empty every day for the same reason. (Sheffi, 2003, p. 176)

Other companies use different methods for building resilience. Boston Scientific manufactures advanced medical devices and drug coated stents used from keeping arteries open on heart surgery patients. The regulation around the devices is comprehensive and apart from FDA approval, each batch of product must be completely traceable and accompanied with a 40 page document to ensure the quality. After assessing their risk environment, the company realised that in the case of a disruption for whatever reason the time to get new lines in place and approved would be extensive. Such an event could potentially endanger the future of the entire company. To mitigate the risk, the company has built redundant production lines for some of their products, got them FDA approves and trained personnel in operating them. While this extra capacity is not inexpensive, the company decided it to be worth protecting itself the risk. (Sheffi, 2003, p. 175)

Other companies has spare IT capacity ready to take over important information systems in case of accidents. Such a solution came in use for Deutsche Bank when the September 11 attack in New York lay much of its facilities in ruin. Data flows were moved to servers in Ireland and the company could continue it operations. (Sheffi, 2003, p. 177)

The point of those cases is that when a disaster hits, redundant capacity might be the only way to deal effectively with the consequences. If the redundant capacity is controlled, well managed and not used as a measure against weak processes, it can be strategically correct to take the extra cost as a sort of insurance instead of accepting the risk. Companies have to assess where their greatest vulnerabilities lies and invest accordingly. Extra IT capacity is for instance generally not extremely expensive and may provide a necessary alternative if the normal routes of information are disrupted.

4.2 Organisational Culture

The previous section discussed the requirements for an effective supply chain risk management policy and some of its complexities. In the same way as TQM (Total Quality Management) needs to be implemented in the organisation in order to work, risk awareness needs to be a part of the company culture (Christopher and Peck, 2004, p. 50). As earlier mentioned, there are a lot of motivators for moving up risk management on the agenda, concerning everyone and not only a risk management team. But as with every case of culture change, there are some critical success factors that divide the successful ones from the less successful. Three of the most essential follow below:

Support from top management

One key success factor for effective risk management practices is sufficient support from the top management. Similar to TQM, risk management has required the top management to set the context within the company and pass their views down to the rest of the organisation. With that in mind together with the development of risk management, the assessments of risks are getting increasingly important for companies, and take up more and more of the top management's time. (Waters, 2011, p. 80) (Christopher and Peck, 2004, p. 50)

Waters states that risk management is of such holistic nature, that it needs to be initiated and followed up by the top management. It is not only suggested that it is the best solution, but also that it is a requirement in order to be successful. Furthermore he summarises a list of requirements that the board of directors should at the very least do: (Waters, 2011, p. 80)

- Define the organisation's attitude towards risk, its philosophy and the strategic direction of risk management
- Create an appropriate environment for risk management, with necessary systems and resources
- Publish risk management policies defining attitudes, approaches and responsibilities
- Know about significant risks that the organisation faces
- Understand the potential consequences of these risks for stakeholders
- Ensure that appropriate processes are in place for identifying, analysing and dealing with risks, and that these work effectively
- Communicate with stakeholders to ensure that everyone is aware of their responsibilities for risk management
- Know how the organisation will manage a crisis
- Assess the performance of risk management

Furthermore, the annual Global Risk Management Study 2011 done by the consultancy firm Accenture, suggests establishing a dedicated corporate-level risk executive with complete oversight and visibility across the business as a critical success factor that distinguish top risk performers from lower. (Accenture, 2011)

Phase	Activities
Plan (Establish)	Establishing policies for the further risk work. Objectives, targets, processes and procedures are examples of things that need to be determined and aligned to the organisation's objectives.
Do (Implement and operate)	Implementing the planned activities from the previous phase.
Check (Monitor and review)	Monitoring and reviewing the performance of the risk precautions. Reporting results to the management for feedback. Determining and authorising further adjustments and improvements to be done.
Act (Maintain and improve)	Correcting the proposed improvements in the previous step. Re-evaluating the scope of the system's policy and objectives.

Table 4.1: Plan Do Check Act cycle in a risk management perspective (International Standard Organisation, 2012)

Cross-Functional Governance

Another point that most literature agrees on is the importance of cross-functional risk management teams. Waters (2011) and Christopher and Peck (2004) all argue that a cross-functional team needs to be implemented in order to get a complete overview and monitor the functions of the company in a good manner. The Accenture study (Accenture, 2011) goes beyond that and states that organisational silos are actually preventing organisations to mitigate risks in an effective manner.

Continuous Process

Literature of Risk Management and Business Continuity Management suggests that the risk management process needs to be continuous and changed to fit the prevailing conditions in order to be effective and efficient. It can in other words never be seen as finished. (Waters, 2011, p. 97) (International Standard Organisation, 2009, 2013)

This is ensured by clear responsibilities and a cyclical process. ISO standards as well as Waters suggest implementing a well recognised cyclical approach called the PDCA-cycle (Plan Do Check Act). The cycle, described in 4.1, is adapted from ISO 22301:

4.3 Managerial Risk Processes

In research, there are two well-recognised high-level processes that stand out within the area of risk, namely Risk Management and Business Continuity Management. The different processes' activities are quite similar and overlap to a high degree. Their respective definitions are widely debated. Some practitioners argue that BCM is a part of RM while others argue the opposite. A third group even argue that they are completely distinct processes.(Chadist, 2012, p. 23). However, the consensus seem to be that Risk Management is focusing on the risks that are known and can be mitigated in some proactive way, whereas BCM is primarily focusing on reducing the risk consequences, regardless of the cause (that might be unknown beforehand). (Waters, 2011, p. 233)

Risk Management has been addressed by the International Standards Organisation (ISO) in their extensive document ISO 31000, first published in 2009. Business Continuity Management has even more recently gotten similar attention with the guiding document ISO 22301 published in 2012 and the more detailed version on the same subject ISO 22313 published in 2013. Below follows a description of the ISO's two approaches, also supported by other academic sources.

Risk Management

The Royal Society defines Risk Management as *"the making of decisions regarding risks and their subsequent implementation, and flows from risk estimation and risk evaluation"* (Society, 1992, p. 3). The Risk Management process is about understanding risks within an organisation, and minimising their impact by either reducing their likelihood or severity.

ISO 31000 includes the following steps in Risk Management (International Standard Organisation, 2009):

- Establishing the context
- Risk Assessment
  - Risk Identification
  - Risk Analysis
  - Risk Evaluation
- Risk Treatment
- Monitoring and Review

Step 1 - Establishing the context

The initial step of a Risk Management process is about determining how the rest of the steps are to be done. Furthermore it involves defining goals, responsibilities, methodologies, measurements and limitations of the process. One important activity is defining risk criterions, e.g. severity and likelihood ratings, which must reflect the organisation's values, objectives and resources.

Step 2 - Risk Assessment

Risk assessment are the activities that systematically identify, analyse and evaluatee the risk consequences and causes for disrupting the organisation's prioritised activities or resources. Simpler put, it is about finding risk causes, evaluate them in terms of likelihood and severity, and propose a suggestion of how to possibly face them.

Step 2a - Risk Identification

There is an abundance of risk identification methods, usually developed with different industries and production processes in mind. As risks can appear in an endless variety and no deterministic information of the likelihood and severity exists beforehand, there is no perfect identification method that fits all situations. Working in a structured manner will support and stimulate the identification, and reduce the chance of missing critical risks to the organisation (Waters, 2011, p. 122). In contrast, if the identification is left to informal arrangements, there is a high chance that they are found on a too high or low level, either trying to find the most trivial risks, or missing important risks that could have severe consequences. It is not always clear what level of detail that should be, literature naturally suggests that it differs from organisation to organisation, and the level should be adapted to the complexity and potential consequences of the organisation and its activities. In the end it comes down to management judgement (Waters, 2011, p. 105) .

One way to stimulate the identification phase is to sort risks into different categories and then assess the different categories with some type of tool. One example of such a categorisation, done by Manuj and Mentzer, was described in the introduction of this report (Manuj and Mentzer, 2008). Some typical risk identification and evaluation tools are Failure Mode and Effect Analysis (FMEA), Fault Tree Analysis and Hazard and Operability Studies, which will be further elaborated on later in this chapter. The tools are furthermore typically divided into two main categories; deductive and inductive approaches. With deductive thinking an undesired scenario is imagined and possible causes

are found and investigated ("what can cause this undesired scenario"). With inductive thinking, all sub-steps of a process is gone through and possible failure modes in each one are found and investigated ("what can be the effect of this event occurring").

When trying to identify risks of larger magnitude, an unstructured brainstorming approach may be more effective than specific frameworks. However, using tools such as a map of the site, process maps and component lists can help the brainstorming. (Kelly, 2013)

Step 2b - Risk Analysis

In order to prioritise the risk responses, if they are to be reduced in some way or deemed acceptable, an evaluation needs to be done. As mentioned before, the term risk consists of likelihood and severity, apart from a description of what is happening. As a consequence, this step consists of assigning risks from the risk identification with quantitative measurements in terms of likelihood and severity.

Step 2c - Risk Evaluation

This step is a quite natural consecutive step where the risk analysis' outcomes are evaluated. The evaluation is primarily focusing whether the risks are accepted or any action should be implemented, depending on the level of acceptability that was set in the first process step (establishing the context).

In addition the evaluation involves setting priorities of the risks, determining what risks are more important to treat than others.

Step 3 - Risk Mitigation or Risk Treatment

By the term risk mitigation it is the pro-active activities to deal with risks that are meant. There are of course many approaches for dealing with risks, if not endlessly many. However some basic principles can be generally be seen and elements from accept, share, transfer, reduce and avoid risks will most certainty be included. (Norrman and Jansson, 2004)

- Risk acceptance could for instance mean neglecting risks consequences that are very small.
- Risk sharing could be contracts that are shaped to let more than one stakeholder bear the consequences if the risk was to happen.

- Risk transferring is letting another organisation take over the whole risk. Insurance is an example of this strategy.
- Risk reductions are the strategies that reduce risks, either in terms of occurrence or severity. An example of an occurrence reduction would be using a fireproof material decreasing the likelihood of a fire. An example of reduction of severity is implementing sprinklers to decrease the fire's impact.
- Risk avoidance are the strategies that eliminate the risk source completely. For instance if there is some process connected to a risk which could be eliminated or changed to an alternative one, the risk would be avoided.

There is no systematic way to determine what response to prefer since the environment differs greatly between organisations and from situation to situation. However it quite naturally involves balancing benefits with drawbacks, where factors to consider are financial costs, time of implementation and the result of mitigation strategy in terms of organisational goals. Risk sharing and transfer may in fact not be mitigating the risk from a supply chain perspective. The focal company may nevertheless decrease their potential risk impact by those strategies. It can therefore be an effective incentive to make supply chain partners implement actual risk treatments themselves.

Norrman and Jansson (2004) exemplify this decision in their article about Ericsson's pro-active work, as seen in figure 4.2. Ericsson quite simply compare cost of a preventive action to the business value that also is measured in financial terms.

Step 4 - Monitoring and review

As discussed, the Risk Management Process needs a feedback loop in order to be relevant for an organisation. The aim is to ensure that the procedures and strategies are maintained continually. This can involve periodic and ad hoc reviews, with different benefits. Although the reviews should be done continually, they are particular important when introducing new products, processes, equipment, facilities, sites, suppliers, trading partners or any other significant change. (Waters, 2011, p. 229)

Business Continuity Management

All significant risks are not known, even if identifying them is the aim of a Risk Management system. Many times, organisations are hit by risks which

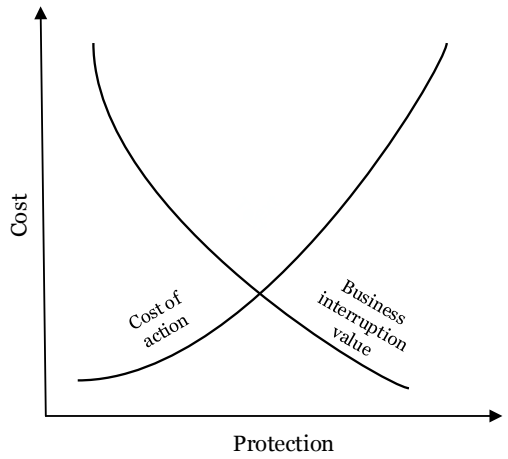

Figure 4.2: Cost of preventive actions versus the business interruption value (Norrman and Jansson, 2004)

were inherently unknown prior to the event. This problem is the main idea behind Business Continuity Management, which is not based on an analysis of identified risks. Instead BCM looks for ways of dealing with disruptions regardless of how they occur. For instance an organisation might consider the failure of an IT-server and what to do to get operations going, regardless of how the server failed. The term Business Continuity Management is defined, by the distinguished researchers Hiles and Barnes, as:

"The development of strategies, plans and actions which provide protection or alternative modes of operation for those activities or business processes which, if they were to be interrupted, might otherwise bring about a seriously damaging or potentially fatal loss to the enterprise" (Hiles, 2010)

Business Continuity Management involves the following activities (International Standard Organisation, 2012):

- Business Impact Analysis
  - Identify Critical Activities and Resources
  - Determine the Recovery Time Objective for resuming the activities

- Risk Assessment
  - Identify risk of disruption.
  - Systematically analyse risk
  - Identify what risks that require treatments and what kind of treatment
- Business Continuity Strategy
  - Establish Business Continuity Plans for stabilising, continuing, resuming and recovering the prioritised activities
  - Mitigating and responding to and managing impacts
- Protection and Mitigation
  - Reduce likelihood of disruptions
  - Reduce the severity of disruptions
- Exercise and Monitoring
  - Review & Update
  - Incident handling
  - Training

The different activities in a Business Continuity Management system will be elaborated on below. Some of the activities are almost identical to those in the Risk Management process, and will not be discussed in detail.

Step 1 - Business Impact Analysis

As one of the main ideas with BCM is focusing on the critical activities and resources opposed to all, the Business Impact Analysis (BIA) should be seen as the foundation on which a comprehensive BCM is based on. By focused efforts, the further assessments are considering the activities and resources the business really depends on and is disregarding the others. This will let the organisation focus on what is important and will give a better end result (Khan and Zsidisin, 2012, p. 192). The critical activities and resources are defined as those that cannot be re-established or recovered in an easy manner. Each activity or resource is also assigned a related recovery time objective (RTO), meaning how long the organisation can accept the activity or resource to be unavailable without suffering significant loss.

A pre-requisite for finding the critical activities and resources is deep knowledge of the organisation and its business model. By understanding what actually creates value within the organisation, critical points, resources and activities can be found. The identification step is preferably done in a systematic manner by using for instance process maps, but can also be made in more unguided ways. Resource maps, including human, capital and IT resources are also valuable assets for indicating vulnerabilities and central points of failure for an organisation. (Basu et al., 2008)

The *Recovery Time Objective* is determined by appropriate individuals and describes a target time in which a function must be operational following a disruption, to avoid suffering financial impact (Blos et al., 2010). When determining RTO it is of course very tempting to set it very low; that the timeframe of recovering or re-establishing activities and resources is in a very short time. But as the measurements should aid the further assessments it should be set reasonable and be reachable by some strategy or plan.

To summarise, a Business Impact Analysis should provide the following according to ISO 22313 regarding Business Continuity Management systems:

- Obtain an understanding of the organization's key products and services and the activities that deliver them
- Identify the key resources likely to be required for continuity and recovery
- Identify dependencies (both internal and external)
- Determine priorities and recovery time objectives

Step 2 - Risk Assessment - Risk Identification, Analysis and Evaluation

The Risk Assessment in BCM is very similar to the assessment done in the Risk Management process. The main difference is that the BCM focuses on the risks that are specified in the Business Impact Analysis without going to detail of specific causes. Therefore the classifications in terms of likelihood and severity are not given the same weight in Business Continuity Management as in Risk Management.

Step 3 - Risk Mitigation

ISO 22313 suggests that even if Business Continuity Management primarily focuses on the risks consequences, it is usually appropriate to investigate the

cause and if the risk can be reduced pro-actively in some way. This step is very similar, if not identical, to the Risk Mitigation step in Risk Management.

Step 4 - Business Continuity Strategy

Business Continuity Strategy is about using the findings in BIA and Risk Assessment to determine appropriate actions to resume activities within agreed timeframes.

ISO 22313 suggests that the following may be alternatives for such strategies (International Standard Organisation, 2013):

- Activity relocation – Is it possible to transfer activities internally or externally?
- Resource relocation or reallocation – Transfer resources to another location, internally or externally.
- Alternate processes and spare capacity – Establish alternate processes or create redundancy capacity in processes and/or inventory.
- Resource and skills replacement – Enhancing people capabilities or create access to additional people capability through outsourcing.
- Temporary workaround – Adopt a different way of working which provides acceptable results for a limited time.

The chosen strategies need also to take into account any risk mitigation or treatment that is already in place within the organisation.

Step 5 - Establish and implement business continuity plans

This step is about arranging for appropriate responses to a disruption, resulting in a Business Continuity Plan. Furthermore it includes establishing appropriate internal and external communication protocols, e.g. alarming the stakeholders as well as determining responsible individuals and teams.

The Business Continuity Plan should at the least include the following information (International Standard Organisation, 2013):

- Purpose and scope
- Objectives and measures of success in terms of prioritised activities
- Activation criteria and procedures

- Implementation procedures
- Roles, responsibilities, and authorities
- Communication requirements and procedures
- Internal and external interdependencies and interactions
- Resource requirements
- Information flow and documentation processes

The telecom company Ericsson has divided the continuity planning into three phases (Norrman and Jansson, 2004):

1. Response plan: the required reaction to an incident or emergency to assess the level of containment and to control activity.
2. Recovery plan: the recovery phase actions shall include the actions that are needed to resume critical or essential business operations, functions or processes.
3. Restoration plan: the process of planning for and implementing full-scale business operations again and to allow the organization to return to normal service level.

Step 6 - Exercising and Testing

The business continuity procedures of an organisation must in addition to establishing Business Continuity Plans, actually try them out in order to be reliable. For that reason proper exercise routines must be implemented and regularly maintained. They should also be monitored and reviewed with the same arguments that were discussed in the Risk Management section.

Challenges with Risk Assessment

The risk assessment phase, which is included in both RM and BCM, naturally involves some challenges due to the subjectivity of finding and measuring risks. The challenges of identifying, measuring and classifying the risks are discussed in the following section.

Problems with Risk Identification

When discussing risk identification, it immediately becomes clear that it is a very hard task. For instance, a small disruption at one location can have a large effect for an organisation at another location, similar to the famous butterfly effect where it is said that a butterfly's wings could cause a ripple effect resulting in a storm.

Donald Waters proposes the following four main categories of difficulties with risk identification and its dynamic nature: (Waters, 2011, p. 124)

- Inherently unknowable risks
- Time-dependent risks
- Progress-dependent risks
- Response-dependent or secondary risks

Inherently unknowable risks are the risks that are simply not known to exist, completely hidden and then emerge completely unexpected. As there is no evidence of such risks, there is no real possibility to reduce them. The best chances of dealing with such risks is to have an implemented Business Continuity Management system. (Waters, 2011, p. 123)

Time-dependent risks are the risks that only emerge with the passing of time and are not yet visible. Government policies are for instance first visible and presented when they are formalised and adjusted, and cannot be known beforehand. (Waters, 2011, p. 124)

Progress-dependent risks are those that only appear when some progress at the organisation has occurred. For instance, if the organisation decided to reduce redundancy and therefore cut inventory costs, e.g. lower the inventory levels, the risk of stockouts may increase and consequently the ability to deliver will be reduced. (Waters, 2011, p. 124)

Response-dependent or secondary risks are the consequences that occur after an action is taken in response to an identified risk. Another warehouse example is if a risk of stockout occurs, and increasing the inventory levels mitigates the problem. With that change the risk of having too high stock levels is introduced instead, and as a response to an existing identified risk. (Waters, 2011, p. 124)

Measuring risks

A risk analysis can be done in a quantitative manner by simply evaluating the risks in terms of likelihood/probability and severity and multiplying them.

This would give an expected value of a risk event. For instance, if the likelihood is said to be 10 % chance on a yearly basis and the severity is 30 000 €if that risk is to occur, the expected value of a risk event would be 0.1 x 30 000 = 3000 €. However, it is clear that 90 % of the years no risk event will occur (cost of 0 €), 10 % of the years something will happen (cost of 30 000 €), but never will the cost be 3000 €.

This example is pointing out one large difficulty with risk assessment; that risks only can have a severe effect when and if they actually happen. This together with the often quite subjective estimations of severity and likelihood consequently mean that an expected value is something imaginary that should rather be used to prioritise risks than an estimation of costs. To aid the prioritisation, it is possible to put them in different spectrums that suggests different attention, either they are so small that they can be safely neglected or large that it really needs to be reduced or prepared for.

Risk classifications

A measurement of risks requires some classifications of risk levels to be determined. Company size and risk acceptance level can determine the severity classification whereas the types of risks to be analysed normally influences the likelihood classification. It is often a good idea to choose a measurement that clarifies how often an event actually happens, e.g. years between every occurrence. For more frequent events, with reliable historical data, more exact probability factors can be used instead.

For severity ratings, it is essential to choose a measurement that is aligned with the purpose of the risk analysis. For example, Gambro extensively use product risk and quality analysis in order to ensure patient safety. In that case it is natural to use patient harm as severity, e.g. factors such as *result in death* and results in *temporary injury* (Gambro AB, 2011). For a risk method with the purpose of analysing operational or disruptive risks, i.e. an event that may disrupt deliveries, a value-related measurement can be used. In that way, decisions are more apparent and most parts of the organisation will be able to relate to that specific risk. (Norrman and Jansson, 2004)

4.4 Methods for Risk Identification and Analysis

Neither Risk Management nor Business Continuity state explicitly how the Risk Assessment, e.g. Risk Identification, Risk Analysis and Risk Evaluation, should be done. In practice, there are several techniques and approaches with their respective advantages and disadvantages. This chapter will describe four

System	Component	Failure mode	Local effect	System effect	Suggested actions
Bicycle	Left pedal	Break off at pedal arm	Impossible to use with foot	Only right pedal can be used to power bicycle	Shorten service intervals

Table 4.2: Example of FMEA table

of the most typical approaches for an operative risk assessment, namely Failure Mode and Effect Analysis, Fault Tree Analysis, Hazard and Operability Study and Hazard Analysis and Critical Control Points.

The methods are comprehensive and involve a number of predetermined steps. They can be put in contrast to more intuitive methods, such as brainstorming and what-if analysis.

Failure Mode and Effect Analysis

One of the most classical and commonly used frameworks for working with and assessing risks is the so called FMEA, short for Failure Mode and Effect Analysis. The method was originally developed by the US airline and space industry in the 1950's and has been in regularly use since the 1980's by Swedish manufacturing firms.

There are two main application areas of FMEA, product and process. Both use the same type of methodology and give a similar output. However, one focuses on how certain product functions can decrease the total product functionality. The other focuses on how parts of the production process can cause the product's total functionality to decrease. (Bergman and Klefsjö, 1995, p. 135)

Methodology

The theory of FMEA is simple, the system is analysed component by component and possible failure modes are found. For each failure mode, there is a corresponding effect on a local and global system level. The analysis can also include recommended changes to the system in order to improve the system with regard to each identified failure mode.

In the example presented in table 4.2, a bicycle is assessed using a FMEA framework. A failure mode is found at the left pedal, leading to a local and system effect. A suggested action is proposed to mitigate the risk proactively. Realistically, more failure modes are probably found, the example is strictly illustrative.

Quantification of certain parameters is often done in an extended version of FMEA, called FMECA, Failure Modes, Effects and Criticality Analysis. Each failure mode's Occurrence (probability of incidence), Severity (harmfulness of effect). These parameters are rated on a predefined scale, 5 or 10 steps are sometimes found in the literature. Each rating (e.g. Frequent) should be characterised of well-defined prerequisites, for instance an interval of probabilities. (Bergman and Klefsjö, 1995, p. 138)

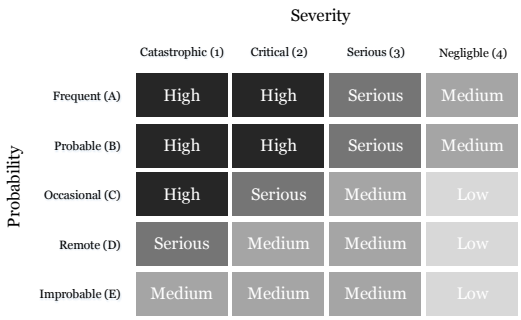

Figure 4.3: A risk assessment matrix, adapted from Department of Defense - Standard Practice (2012, p. 12)

It is also possible to add the third dimension Detection (probability of detection before effect occurs) to the analysis making it three instead of two-dimensional. In this case, the three ratings are usually combined into a Risk Priority Number, RPN. This is most commonly calculated by multiplying all three ratings.(Bergman and Klefsjö, 1995, p. 138)

The work flow in a typical product FMEA/FMECA could include the following steps (Bergman and Klefsjö, 1995, p. 138):

1. Definition and limitation of the system
2. Choice of level of detail
3. Review of the system's functions
4. Review of the components functions
5. Identification of possible failure modes and their consequences
6. Assessment of failure likelihood

7. Possibilities of failure detection and localisation
8. Assessment of failure severities
9. Analysis of failure dependencies
10. Presentation

Benefits and drawbacks of FMEA

The main benefits of FMEA include: (Gould et al., 2000)

- It gives an understanding of the construction, by following the consequences of failure modes up to system level.
- The summary should give a decision base for alternative construction solutions.
- It points out components which are critical to system functionality.
- Testing and error search is simplified with a FMEA background.

Major drawbacks are: (Gould et al., 2000)

- No concern is taken to the dependencies of individual failure modes for the system effect.
- A complete FMEA can be time consuming and may require many experts to perform.

FMEA is one of the methods extensively used at Gambro for patient risk on a product and process level.

Fault Tree Analysis

Another widely used method is the fault tree analysis, or FTA. The first implementation was done 1962 by Bell Telephone Laboratories to analyse the risks when developing rocket launch pads. The model was then further developed by the American space industry and its first commercial use was in 1966 by Boeing. The model is still used extensively as an analysis tool within the field of reliability. (Bergman and Klefsjö, 1995, p. 139) (Bergman and Klefsjö, 1996, p. 431)

The main difference between FTA and FMEA is that the later is an inductive method wheras the former is a deductive method (Bertsche, 2008).

This ultimately means that FMEA examines the effects of a failure whereas FTA traces the reasons of an undesired scenario, from the top event down to its causes. The main benefit with this is the increased understanding of the system as a whole and how the failures are connected. Shortly, the main objectives of a fault tree analysis can be described as: (Bertsche, 2008)

- A systematic identification of failures and how they are related
- Illustration of critical event combinations
- To gain objective evaluation criteria of system concepts
- Provide a clear documentation of the failure mechanisms and their functional relations

Representations

The fault tree itself is a graphic model of the combinations of faults that will result in the predefined undesired event. Logical gates are used in the construction of a fault tree. The gates are represented by standardised symbols, as defined in figure 4.4.

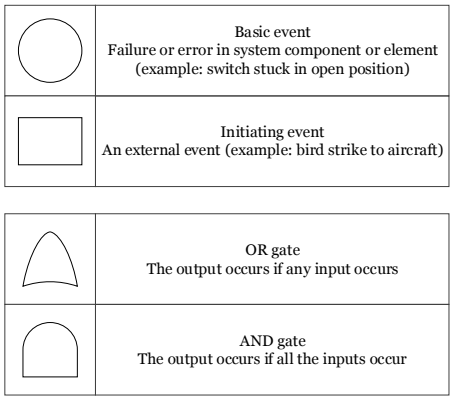

Figure 4.4: The standardised symbols of fault tree analysis

Methodology

The construction of a fault tree is initiated by specifying the undesired top event, e.g. a specific machine breaks down. During the next step the reasons

for that undesired event are identified, breaking it down to a lower and lower level with logical gates, either OR- or AND gates. (Bergman and Klefsjö, 1995, p. 140)

In order to illustrate a FTA, consider another example with a bicycle. The top event is loss of breaking power. The bicycle is equipped with two independent break systems, one hand break on the front wheel and one hub break on the rear wheel engaged by pedalling backwards.

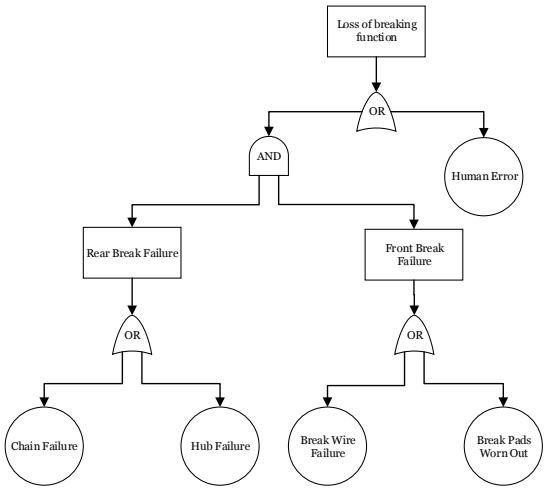

Figure 4.5: A bicycle example of fault tree analysis

In order for the bicycle to lose its breaking ability, the two breaks have to be compromised independently. The front break can fail in two different ways, each one enough to make it stop working. The case is similar for the rear break with both possible failure modes enough to make it stop work.

Qualitative and quantitative use of a Fault Tree Analysis

A fault tree analysis is by definition a qualitative assessment, as experts opinions are used to connect causes to potential effects (Stamatelatos et al., 2002). However, a quantification of the model can be made by evaluating the probability of each sub event from bottom up and an aggregated probability of the event can be determined.

This practice should only be considered when sufficient amount of historical data is present and given the often subjective nature of probability

assessments, the result should be looked upon as a guidance and basis for prioritisation rather than a certain forecast of the future.

Benefits and drawbacks of FTA

The main benefits of FTA include: (Gould et al., 2000)

- Increased understanding of the system's structure and design.
- Possibility to find weak spots and critical failure modes also without component data.

The main drawbacks are: (Gould et al., 2000)

- As the procedure should be done in small steps in order to find appropriate level of detail, the work can be time consuming.
- Complex systems can lead to large trees which are difficult to comprehend.

Hazard and Operability Study

The HAZOP method, short for Hazard and Operability Study, is another qualitative technique developed by engineers working for Imperial Chemical Industries during the 1970's. The purpose of the method is to identify hazards in processes by a systematic team effort. It was developed as a response to the qualitative traditional methods that mostly investigated more obvious hazards, not being able to see the unexpected and sometimes more severe hazards.

HAZOP is an inductive method and an underlying assumption of the method is that a problem can only arise when a deviation occurs. Therefore unexpected events in the production process, and their cause, are to be investigated. The focus of the analysis is normally to find expected or foreseeable deviations to the process' intended operations, for instance higher pressure in a certain pipe than what it is designed for. Another important aspect of the model is the team-based approach, where a distinct leader performs the study together with a chosen team, using flow charts of the plant. (Rossing et al., 2010)

Methodology

HAZOP is performed as a brainstorming activity, going through a production process or plant part by part. A cross-functional team with engineers from different departments is normally gathered for the task.

In the brainstorming, guidewords are introduced. Typically examples of such guidewords are no/not/none, more, less, part of, reverse, other than, as well as. These are used to stimulate imaginative thinking in the brainstorming process and are combined with parameters, such as temperature or pressure. This combination, e.g. more pressure, is investigated by answering the following questions: (Rossing et al., 2010)

- What could be a cause of increased pressure?
- What is the consequence?
- What can be done as a safeguard?
- What is our recommendation to mitigate the risk of increased pressure?

The answers are well documented in a template. It is a thorough systematic approach that has shown to be very intuitive in some industries.

Benefits and drawbacks of HAZOP

The main benefits of HAZOP include: (Gould et al., 2000)

- Systematic and comprehensive technique that takes a holistic view of the plant.
- Examines the consequences, as opposed to only the causes, of a failure.

The main drawbacks are: (Gould et al., 2000)

- Is originally designed for use in chemical or process industries, the applicability of guidewords can therefore be low in other areas.
- Time consuming and complicated.
- Requires experienced practitioners.

HACCP

Hazard Analysis and Critical Control Points origins from the food and beverage industry and was developed by a supplier of space food for the US space program in the early 1970s. The method was implemented to provide the lowest risk possible for letting contaminated food reach the consumer. The method is based around the core concept of finding critical control points for examination of a product for deviations in predetermined risk categories. (Hulebak and Schlosser, 2002)

Mehodology

A HACCP is started by considering all possible hazards which may be applied to the specific product. For instance, the food and chemical industries always include the hazard of foreign pathogens in their analysis. The second step is to identify where such hazards can appear in the production process and also find points in which measurements can be done and deviations found. This step is often done with the help of process maps and flow charts. Thereafter acceptance levels for all measurements and procedures for the control should be established.

The methodology is best suited for continuous process flows and mainly addresses risks which are quite easily thought of and may cause the end product to not be fully functional in some sense. (Hulebak and Schlosser, 2002)

Benefits and drawbacks of HACCP

The benefits of HACCP include:

- Very suitable for food and chemical product risks.
- Focuses on risk prevention.
- Increases process awareness.

Some drawbacks are:

- Only considers foreseeable risks.
- Limited applicability to industries with non-continuous flows.

Chapter 5

Risk management in practice

This chapter discusses how risk management can be used in real situations. The chapter is started with cases of three different companies' risk management approaches, Tetra Pak, Alfa Laval and Ericsson. The cases are used as inspiration and is coloured by the individuals that were interviewed and is consequently not a complete overview of the companies' risk management approaches. The chapter continues to describe Gambro's approach to product risks, which can be used as learning and inspiration for the model proposed in this thesis. The chapter is finished by a summary of Gambro's approaches to disruption risks from the different sites.

5.1 Cases

Tetra Pak

Tetra Pak is a global company specialised in processing and packaging for the food and beverage industry. The company is based in Lund and has around 20 000 employees operating in more than 150 countries. (Tetra Pak, 2013)

Tetra Pak's and Gambro's history coincide through Gambro's founder Holger Crafoord who, earlier in his career was one of the most important individuals in the build up of Åkerlund & Rausing and the subsequent foundation of Tetra Pak. (Gårdlund, 1989, p. 207)

The company has business in several different areas. Packaging Solutions delivers different kinds of processed packaging material, ranging from ready made packages to large rolls of material which need further processing at the customer. Processing Solutions delivers systems and machinery for filling of food and beverages at the customer's premises. (Tetra Pak, 2013)

Tetra Pak's operations span over a wide range of domains with many different types of operations, suppliers and customers. This makes their risk environment heterogeneous and also dependent on legal issues, given the need for food safety. (Grönwall, 2013)

An interview was held with Tetra Pak's vice president of Supplier Management, Jan Grönvall. The interview primarily concerned risk management of the supplier base, but also Tetra Pak's overall risk management practices were discussed.

Tetra Pak has three overall methods for identifying and assessing risks. The first, bottom-up approach is conventional but systematic. Every manager is asked once a year, where they can identify risks in their respective area of work. The risks are collected and assessed in terms of probability and impact by a group of more senior management. Impact is assessed on a scale of 0-1000 including sales, costs, reputation, people and compliance. Probability is assessed in the groups A-F where A is expected to happen every 100 years and F happens all the time. The risks are also classified into one of 13 families, for instance, market, fire and legal risks. The quantitative risk assessment is done by the company's full time risk officer who has knowledge about earthquake vulnerability, fire hazards and similar areas where historical data can be used to determine the risk level. (Grönwall, 2013)

The risks and their families are then mapped into a matrix for improved visualisation. The appropriate decisions makers can then take the risks into account and decide whether the risk should be accepted or lowered via the probability or the impact side. (Grönwall, 2013)

On the supply side, every account manager makes a risk assessment of his/her supplier. Normally, this is only done on tier one suppliers, but in the case of strategically important partners it is sometimes done also further up in the chain. A concrete example of activity is to send fire experts to make an evaluation of the protection at the supplier. When a new supplier is about to be accepted, there is an assessment based on 11 standard risks. Examples of those are IP-risks, CSR-risks, political risks and export regulations. (Grönwall, 2013)

Tetra Pak does not demand that the suppliers notify about incidents and near misses. According to Jan Grönvall this might make the suppliers less open and prone to holding on to information instead of the intended target.

The third type of risk assessment is an evaluation of the insolvency risk of the suppliers done 6 times per year. All key account managers answer 13 "common sense" questions aimed at finding suppliers who might be in financial trouble. Some examples of the questions are:

- Have there been any negative newspaper articles about the supplier?
- Has the supplier discarded employees lately?
- Are other companies in the same sector facing problems?
- Have there been late deliveries?
- Has the supplier asked for early payment?
- Has the supplier been more difficult to negotiate with?

The questions are answered by the responsible purchasing manager and issues are discussed in the bimonthly meeting where also representatives from the legal, financial and supply chain department are present. The routine started after the 2008 financial crisis when Tetra Pak faced problems due to supplier bankruptcies and has continued since then. (Grönwall, 2013)

Alfa Laval

Alfa Laval is a global manufacturer in the areas of heat transfer, separation and fluid handling based in Lund. The company delivers to over 100 countries and has approximately 16 000 employees worldwide. (Alfa Laval, 2012)

The first products manufactured by Alfa Laval were produced in the late 1800s. The manufacturing site in Lund is mainly focused on plate heat exchangers and employs approximately 2000 persons.

An interview was held with Håkan Nilsson, General Manager of the Component Unit at the Lund production site. Håkan is deeply involved in the use of Business Continuity Planning of the production processes in Lund but also worldwide. The focus of the interview was therefore in this area.

Alfa Laval's focus in risk management lies in their so called Business Continuity Planning. The rationale behind the focus is to ensure the continuity of profitable activities, as opposed to viewing the work as a cost cutting activity. (Nilsson, 2013)

The work is initialised when a decision is made to investigate a certain area of the operations. Critical processes are identified by going through templates of questions with machine costs, what they are producing and whether the processes can be re-established someplace else. This identification process is performed by a steering group made up of representatives from the IT, production and facility department. (Nilsson, 2013)

Once the critical processes have been identified an area specific team is formed. This team is constituted by competent employees such as the line

manager and other experts. Those will identify the weakest links in the process. IT-support or certain machine parts are examples of what can be identified. FMEA is the primary methodology used in this process. Once the weakest links are identified, it is possible to make plans over what should be done in the case of a breakdown or an emergency. (Nilsson, 2013)

The re-use of already performed Business Continuity Plans is extensive. When an assessment of a similar area to what has already been made, the old one can be used as a blueprint and only necessary adjustments have to be made. The BCPs are re-evaluated and updated every six months. (Nilsson, 2013)

The processes are valued in their contribution to monetary profit for Alfa Laval, this makes them simple to prioritise and also gives the project weight when presented to top-level management. (Nilsson, 2013)

Ericsson

Following the disruptive fire described in chapter 4, Ericsson took a new approach as to how supply chain risks were to be viewed and worked with in the company. A description of the company and its model for managing supply chain risk is used as a benchmark in the preparation of the model. No interview has been done with employees at Ericsson, but a thorough description of the process is provided by Norrman and Jansson in their article "Ericsson's proactive supply chain risk management approach after a serious sub-supplier accident". An interview with the academic co-author of the article, professor Andreas Norrman was also held. (Norrman, 2013)

Ericsson is a global provider of equipment for telecommunications and services to operators of fixed and mobile networks. In 2012 the company had approximately 110 000 employees worldwide and sales of over 33 billion USD. (Ericsson AB, 2012)

Organisation

The supply chain risk management is organised into two main levels. It is led by the corporate function Risk Management who is responsible for all risk management activities in the Ericsson group, including contact with insurance companies and setting directives. Within the supply function, a risk manager is responsible for developing and coordinating all the work. A matrix organisation with the Supply Chain Risk Manager, members from different business areas (products) and corporate functions (production, logistics, etc) is responsible for tasks such as:

- Maintaining an optimal level of risk exposure and costs versus protection activities (Supply Chain Risk Manager)
- Securing the reliability of supply chains to deliver (Supply Chain Managers)
- Supporting SCM with risk issues (production)

The SCRM is working closely with both the corporate risk management and with the matrix organisation's "line people". (Norrman and Jansson, 2004)

Step 1 - Identification of critical components and suppliers

The first step of Ericsson's risk management approach is the identification of critical components and suppliers. Components are analysed one by one and classified. The component is put into one of four classes with the specifications:

1. The component is currently sourced from more than one approved supplier (different manufacturers or different sites of the same manufacturer).
2. The component is currently sourced from one approved supplier, but others are ready and available.
3. The component is currently sourced from one approved supplier, others are available but not approved.
4. The component is currently sourced from one supplier, others are not available.

The second step of the analysis of each component is to try and assess the business recovery time, meaning how long time an accident would affect deliveries. The components are put into one of four classes:

1. It takes less than three months to get deliveries from an alternate source.
2. Three to eight months to get approval and deliveries from an alternative source.
3. 9 to 12 months, re-design the only alternative.
4. 12 months, re-design of a unit/product of high complexity.

Step 2 - Risk Assessment process

Once the classification is done, the suppliers and sub-suppliers of critical components are assessed using the own developed Ericsson Risk Management Evaluation Tool (ERMET). Risks in different categories are identified and possible sources are found and analysed by cross functional groups in a manner similar to Fault Tree Analysis. Some categories of risks are:

- Business Control
  - Management systems
  - RM organisation
  - Audits & Inspections
  - Financial structure
- Natural hazards in the surrounding
  - Earthquakes
  - Blizzards
  - Landslides
  - Hurricanes
- Man-made hazards in the surrounding
  - Dams
  - Pollution
  - Sever building collapses, fires
  - Transportation incidents
- Hazards at the site
  - Materials
  - Property protection
  - Production processes
  - Key persons
  - IT-systems
- Business interruption handling
  - Crisis organisation

- Mitigation measures
- Contingency plans

Ericsson thereafter tries to evaluate the risks in terms of severity and probability in a risk matrix, however, they have found that the probability measure is often difficult to find and focuses more on the financial impact when prioritising between risks. The financial impact is assessed by multiplying the gross margin of the product and the business recovery time and adding extra cost such as idle capacity, inventory carrying and loss of goodwill. The combined value is called Business Interruption Value. The risks are classified into one of four classes in terms of BIV:

1. Severe: $>$ \$100 million
2. Major: \$50-\$100 million
3. Minor: \$10-\$50 million
4. Negligible $<$ \$10 million

These severity classifications span from around 0.05% to 0.5% of the company's turnover in 2004. (Ericsson AB, 2012)

The third part of the risk management process is to find and decide upon risk mitigation strategies. This is responsibility of supply chain managers for risks concerning suppliers and the production managers for internal risks. The process is supported with templates where risk description, causes, strategies and their costs are presented. The ratio between the costs of preventive actions and the BIV is regarded as very important in this stage.

Ericsson has also added a step of risk monitoring, meaning continues follow-ups of unmitigated or very high risks. Suppliers and other supply chain partners are monitored as to how they fulfill their commitments.

Step 3 - Business Continuity Plans

The last part of a risk management process is the incident handling and business continuity plans. The information flow in the case of an incident at an external or internal supplier is formalised and emergency response teams are available in the case of an accident. For the cases where the impacts cannot be minimised on beforehand, continuity plans are developed in accordance to a predetermined format. The plan is divided into a response (immediate), recovery (medium term) and restoration (long term) phase with instructions of what should be done and who is responsible for the result.

Benchmark summary

In order to use the benchmarking in the best possible way, the similarities and differences between the companies' practices are distinguished and presented below:

- A cross functional approach to business risk management is common for all benchmarked companies. Different departments are active when identifying and analysing the risks.
- All companies update and re-assess their risks periodically to keep the information up to date.
- Financial value is used as a measurement of severity at Ericsson and Alfa Laval. The companies have found it an effective measurement for communication and prioritisation.
- Risk mitigation is put on high impact risks at Ericsson and Alfa Laval, as likelihood is considered difficult to assess effectively.
- Tetra Pak and Ericsson divide their risks into classification of likelihood and severity to simplify the communication.
- Ericsson differs in the sense that the approach takes a wider look on the supply chain, by to a larger extent considering both suppliers and sub-suppliers in their model.

5.2 Product risks

Given Gambro's business of medical devices, the company is used to strict demands on the evaluation of risks concerning the safety of patients. Due to the importance, there are several regulatory requirements from instances as the US Food and Drug Authorities (FDA) and European Union (EU). Until the mid 1980's, the requirements for medical devices were not as high as they are today, but after a couple of disreputable incidents, the importance of regulatory requirements was highlighted and the demands were increased. (Barkman, 2013)

In order to comply with these regulatory demands, Gambro has introduced a corporate function responsible for the risk management through the entire product life cycle. The function, called Product Risk, coordinates and performs assessments and mitigations of the risks that may affect patient safety.

The working procedures for Product Risk are described in Gambro's quality management system through standards operating procedures and working instructions, made in accordance to the existing requirements concerning medical technology, e.g. ISO 14971 (Application of risk management to medical devices). All risk assessments, regardless of product stage, are done by cross functional teams, combining for instance individuals from the departments product risk, medical, R&D and sometimes systems analysts and HFE (Human Factor Engineering).

The product life cycle can in Gambro be divided into four major phases the, R&D, design, production and post-production phases. The Product Risk department's focus lies in the three last phases.

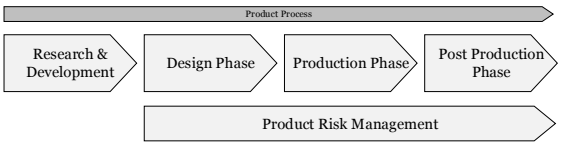

Figure 5.1: The product risk work in the different product life cycle phases

First, the product development is initiated by a R&D process where the rough guidelines of a new product are drawn up. In this quite fuzzy and unguided phase no structured risk management is conducted.

During the product's design phase around 80 % of the Product Risk department's activities are conducted. Investigations are made of what potential harms could occur from a specific design, and how they could be prevented. This is typically done deductively by an approach not much different from a Fault Tree Analysis. The approach is effective as the exact design and list of components is not yet decided upon making an inductive methodology difficult. The process is supported by design phase documentation from similar products and the work is done in collaboration with the different components. In the design phase, there is a considerable weigh towards qualitative approaches, not measuring severity and probability to a high degree.

During the production phase inductive approaches, such as FMEA are used. Hazard and Operabilty studies (HAZOP) and Hazard Analysis and Critical Control Point studies (HACCP) are other methodologies sometimes applied. This phase is generally done more quantitatively than the design phase, and sometimes include a third measurement of risk detectability in addition to probability and severity. (Barkman, 2013)

For the Product Risk department, probability is defined as the qualitative

and/or quantitative estimate of the probability that the patient will suffer harm, per treatment. The probability classification is done according to a 5 step scale (ranging from frequent to improbable), each with specific percentile ranges (Gambro AB, 2013). Regulatory demands require that a report is filed every time a patient is harmed by the treatment, which makes that data more available to use as probability instead of equipment failure. (Barkman, 2013)

Severity is measured as the impact of a potential hazard and the five classifications are ranging from catastrophic (resulting in death) to negligible (inconvenience, no injury) (Gambro AB, 2013). The classification is determined by the medical expertise included in the cross functional team.

The third measurement of detectability is an estimate of the ability to identify a cause of failure before the product or customer is affected. The scale is ranging from none/very low (There are no detection methods in place. Impossible or extremely difficult to detect or the methods are unproven or very unreliable) to certain (Detection methods are extremely effective, reliable, and validated with statistical significance). (Gambro AB, 2013)

After the phase of classifying the risks they are evaluated and divided into one of three classes. They are deemed as either acceptable, unacceptable or ALARP (as low as reasonable practicable). (Gambro AB, 2011)

- If the risk is seen as unacceptable it must be mitigated to either acceptable or ALARP.
- If the risk is seen as ALARP, the risk is considered as acceptable only if no further mitigations are technically or economically practical and that the medical benefits of the intended use outweigh the residual risks.
- If the risk is considered acceptable, no further justification of risk control measures is required.

Given the strict requirements on carrying out risk management activities, thorough documentation is done to ensure visibility to authorities and other stakeholders. This is also considered valuable in order to transfer knowledge from one risk assessment to another. (Barkman, 2013)

5.3 Gambro's Approach to Business Risks

Prior to the initialisation of this project, there has not been a coherent and harmonised process for the identification and assessment of disruptive business risks in Gambro. Despite this, individual plants and business units have certainly addressed the issues and carried out activities closely related to what

is the intention of this project. The level of detail and scope of analysis differ between the different plants, but provide a good basis of where the greatest issues lie and how the analysis may be performed. Material from a number of Gambro's site was acquired at an early stage of the project by requesting information from all sites within Gambro. The purpose of the request was to get an overview of the analysis's that have been done in the last years. Three distinct types of risk analysis's can be identified from the acquired material. It is important to note that the acquired material may not represent all activities the sites have performed in relation to analysis of disruption risks.

- The comprehensive type identifies high-level risks and assesses them in terms of probability and severity.
- The detailed level analysis assesses production processes on a detailed level and identifies failure modes and their consequences.
- Emergency plans focus on the outcome of different types of potentially catastrophic scenarios and establishes action plans about how they should be dealt with.

Comprehensive risk analysis

Dialysers - Hechingen

The plant in Hechingen has made the most comprehensive work with business risks. Risks are identified through a free brainstorming session with the plant's EHS (environment, health and safety) manager and the concerned area manager (e.g. HR manager).

The risks are identified, given name and ID number and sorted into one of four categories (Management & Organisation, Strategic & Market, Operational and Legal).

Possible causes of the risks are identified and evaluated in terms of probability of occurrence and impact on scales of four steps. The evaluation of the risks, meaning the underlying assumptions and calculations in terms of probability and occurrence, are kept rather short and are therefore easy to overview. There is also room for suggestions of possible strategies of how the risks should be implemented and other appropriate information.

The work process is done with support of specialised software which has been used for around 10 years. The implementation of the process was done together with consultants from the developer of the software that also helped with defining categories and suitable scales for the occurrence and severity

rating. The software also includes functions for presentation of the risks with matrices and overview spreadsheets.

As of March 2013, Hechingen has 28 active risks (3 organisational, 4 strategic and market, 1 financial, 19 operational, 1 legal).

Dialysers - Meyzieu

The manufacturing unit for dialysers in Meyzieu, France, uses 11 risk categories (raw material, product quality, production process, production equipment, tools, supply, building/infrastructure, environment, market & customer, people & organisation and other financial risk).

Within each of those categories, different risks have been identified and given ratings in terms of severity and occurrence. Both scales have five defined steps measured in financial impact (severity) and probability of yearly occurrence. Each risk can also be accompanied by some remarks, but there are no explanations of how the evaluations have been done. As an overview, the risk categories are presented in a conventional risk matrix.

The documentation is done with a quite simple but for the task sufficient Excel spreadsheet.

Meyzieu has currently identified 49 different risks with between twelve and one risks in each of the 11 categories. Most risks are found in the production processes and the supply of raw material.

Bloodlines - Prerov

The bloodlines manufacturing unit in Prerov, Czech Republic, has had two risk analysis performed by their insurance companies where in the second instance from 2010 an assessment of 10 risk categories has been done.

The areas (management, human element, security, construction, compartmentation, active protection, machinery breakdown, utilities, natural hazards and industry risk standard) were assessed on a scale of four steps by the insurance company's representative.

The analysis is accompanied by a short description but no complete identification procedure has been followed and the risks in each category seem to be aggregated into a mean value. The rest of the risk analysis is mainly focused on fire risks and protection against them.

While this is certainly interesting and necessary, it does not by any means give a complete oversight of all of the plant's risks.

Solutions – All sites

All plants in the *Solutions* business area (Daytona, Yongin, Drycart Lund and Sondalo) have done a risk brainstorming following the same model.

The plants use eight different categories in the brainstorming (building, equipment, personnel flow, material flow, regulatory/good manufacturing practice, captive products, unique production processes and single source suppliers).

The risks are analysed on a one-dimensional scale of five steps, ranging from low to high without giving individual scores to the likelihood and severity of each risk.

At least in the case of Yongin, the risk identification has been done using an overview process map and a list of raw materials and important equipments used in the manufacturing.

Detailed level risk analysis

Solutions - Daytona

Apart form the high level comprehensive risk analysis done in Daytona, there has also been made thorough studies of production processes using a FMEA framework. The processes are assessed both on a high level evaluating large production elements and common events and also on a more detailed level where there has been quality events or complaint issues. (RM1-H, TSS Process overview, Prisma Products; RM1-25-F, Kiefel bag manufacturing process, prisma Products)

The risk analysis is primarily concerning product risks and patient safety but for some identified risks there are also process impacts described in some cases. An example of an identified process harm is the delay in bag manufacturing due to power interruptions.

In the FMEA the risks and their causes are analysed in severity, occurrence and detectability and then multiplied resulting in a risk priority number, all according to Gambro's working instructions for Product Risk Management. However, the ratings are with few exceptions only based on the product risks identified, finding business risks has not been a primary objective of the analysis and there is no evaluation of the financial impacts that a disruption may cause.

Bloodlines - Italy

The bloodline manufacturing, now located in Poggio Rusco, has presented detailed level HACCP analysis considering issues that could affect the patient safety. The entire production flow has been analysed using an overview process map for the production. Risks have been identified and critical control points are found for all risks.

The risks are assessed in the same way as in the Daytona example (severity, occurrence and detectability) and classified according to GWIN 12-01. As for Daytona, the primary objective is not to find risks of financial burden to Gambro.

The manufacturing unit has also presented an analysis for production issues which has been resolved using root cause analysis with 5-why and cause-and-effect diagrams. Quality issues which could potentially lead to disruption of Gambro's ability to deliver to have thus effectively been resolved.

Apart from those activities, Poggio Rusco has also been conducted an assessment of disruption risks together with the site in Crevalcore in preparation for the factory rebuild in Medolla. This work is further described in chapter 7.

Emergency Plans

Bloodlines - Shanghai

The documentation obtained regarding risk management at the bloodline manufacturing in Shanghai is limited to regulations and procedures in the case of emergencies, especially fires. While this documentation is necessary, it does not take a holistic approach as how to identify and evaluate all risks. It should be noted however, that the documentation is written in Chinese and the translation from Google Translate may not have captured the text's full context.

Solutions – Sondalo

The production facility in Sondalo has done an assessment of potential disruptive scenarios. The analysis covers disruptions in the supply of water and other utilities, the production process, the supply of raw materials and problems regarding the facility. While the analysis is presented in short terms in PowerPoint format, it covers the essential parts of the plant. The risks are not analysed in terms of severity or likelihood, which may make it difficult to

prioritise and evaluate the proposed mitigation strategies. A more structured form of presentation could address this issue.

Summary of Gambro's approaches

From the information gathered it is clear that Gambro are used to working with risk management on their different production facilities. The information also imply that the current risk assessments are quite diverse throughout Gambro, both between and within the stated categories. As an effect of the regulatory requirements, the assessments are mainly considering product risks and the risks of harming patients. Hechingen in Germany, Meyzieu in France and all the *Solutions* factories have identified and analysed business risks, but there is certainly room for harmonisation and improvement.

As the company, regardless of site, have established procedures for product risks and wide experience of such risk assessments, they should be able to expand the risk focus and consider business risks without too much struggle. Using approaches similar to the methodologies currently used, such as FMEA, will ease the transition for the sites affected.

Chapter 6

Model

This chapter proposes a risk management model for Gambro. It furthermore motivates the model and its three major parts, the Business Impact Analysis, Risk Assessment and Risk Mitigation & Business Continuity Strategy and proposes appropriate governance strategies and routines. The first stage, the Business Impact Analysis, is where the direction and level of detail of the analysis is set. Subsequently the Risk Assessment stage includes identifying, analysing and evaluating risks, followed by the Risk Mitigation & Business Continuity Strategy where appropriate pro-active and re-active action activities are proposed.

6.1 Sources of Model

The model is influenced by three major sources, namely the Gambro environment, relevant literature and case benchmarks, all in accordance with the constructive approach methodology chosen. This is shown in figure 6.1.

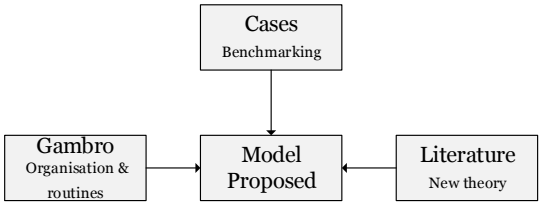

Figure 6.1: The sources of the proposed model

Gambro

As many authors, such as Waters (2011) and Christopher and Peck (2004) actually suggest that the organisation is the most important aspect to consider when developing a risk agenda, Gambro's current methods and organisation was considered when developing the model. This includes the structure of the organisation, i.e. responsible roles, geographic locations of the facilities and the currently used risk management practices. This includes both the current business interruption practices as well as the more extensive product risk management.

Academic literature

Academic literature has laid the basis of the development of the model, determining what aspects that are critical to the success and what activities that are required. The model is furthermore deeply supported by the ISO-standards of Risk Management and Business Continuity Management, ISO 31000 and ISO 22313 respectively. The purpose of this combination is to consider both unknown and known risk scenarios to have appropriate pro-active and re-active preparations ready.

Cases

The cases of Alfa Laval, Ericsson and Tetra Pak are used as both an inspiration as well as a benchmark for the developed model.

6.2 Organisation

When developing an environment for risk management, it is first essential to structure the organisation around it (Waters, 2011, p. 197). The current organisation, the need for a global overview but also adequate expertise, are the main incentives for the proposed level of governance.

- Global Process Continuity Manager (GPCM) – is responsible for the risk management on a global level.
- Process Continuity Management Team (PCMT) – at each site a management team is responsible for all risk management activities. Representatives for the production, information technology, facility and supply make up the team. The GPCM supports the teams at all sites in their tasks.

- Continuity Project Team (CPT) – cross functional teams formed to perform detailed level risk evaluations. The PCMT is responsible for identifying and guiding the appropriate specialist for each evaluation.

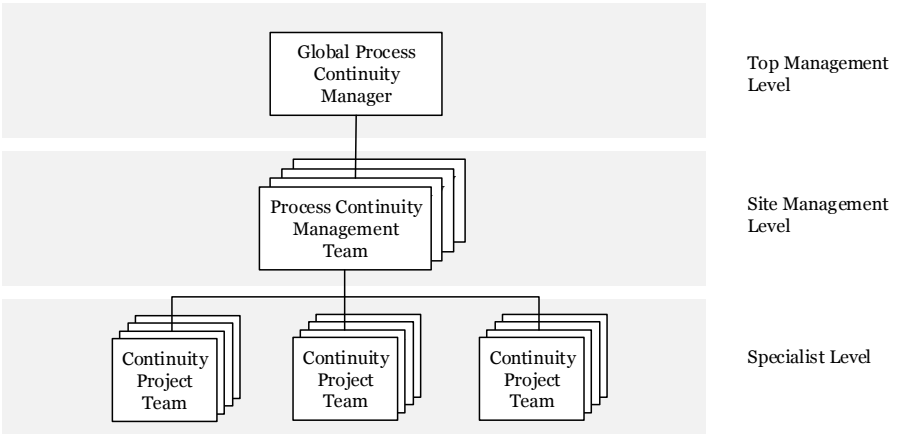

Figure 6.2: Proposed governance model for Gambro

Global Process Continuity Manager

Leading Gambro's risk management work is a Global Process Continuity Manager, GPCM. This person has the overall view of all risk management projects going on throughout the company and is also leading the training of staff in risk management techniques.

Responsibilities:

- Monitoring which risks has been considered and what the sites are ready to deal with.
- Communicate with top level management.
- Spread knowledge of methods and solutions between different sites.
- Responsible that risks are monitored.
- Develop the methods of risk management.
- Responsible that business continuity plans are harmonised and ready.

- Determining appropriate redundancy levels.

The main objective for this role is making sure that the risk agenda is aligned in a global perspective. As the theory chapter also suggest, this person also has regular contact with top level management, making sure that the risk management has necessary support, and setting appropriate redundancy levels for the different risks.

Process Continuity Management Team

The GPCM together with representatives from the line organisation comprise the Process Continuity Management Team at each site. Representatives from the following functions are regarded as necessary to get a complete view of the sites' risk environment:

- The production is the core process which this part of Gambro's risk management revolves around, the involvement of this function is therefore obvious.
- IT support is vital in many of the production processes and a complete oversight of risks to those systems is therefore necessary.
- The buildings and utilities such as electricity, water etc are also vital to most operations and have also a large exposure to different types of threats, the involvement of persons with insight in those matters is also necessary at this level. (Överstyrelsen för civil beredskap, 1999, p. 52)
- The supply of components and raw materials is of course vital for the output of products. This function should thus be represented in the management team.

In matters where necessary, persons with different expertises e.g. regulatory affairs, legal questions or EHS (Environment, Health and Safety) should be consulted by the PCMT.

As the PCMT responsibilities include identifying critical activities and resources, the members should be experienced individuals with a complete overview of their respective functions and how they relate to the extended organisation (this task is further described later in this chapter). They should furthermore be on a site management level as they need access to relevant information as well as have the authority to priority the site's activities (Waters, 2011, p. 80). The involvement of the GPCM in the team also keeps the process harmonised throughout Gambro.

Responsibilities of the Process Continuity Management Team:

- Identify critical processes which require further assessment.
- Evaluate the business value of the critical processes in terms of potential lost sales.
- Collect and develop ideas of how to mitigate risks.
- Taking into account the overall effect on Gambro of their respective process risks.

Continuity Project Teams

Appointed by the PCMT are Continuity Project Teams who are temporary cross-functional teams with necessary expertise for the detailed work in each process assessment. The composition of the groups varies from time to time. It is however clear that most Continuity Project Teams include several different functions. Their responsibilities can be summarised as:

- Identifying risk scenarios to specific critical resources or activities.
- Identifying risk root causes at specific critical resources or activities.
- Evaluating the risk in terms of likelihood and severity.
- Propose possible mitigation strategies.

In the event that the PCMT decides that the need for specific experts' input is not necessary to make the complete risk analysis, the CPT is simply not formed and the PCMT takes over its responsibilities.

6.3 Procedure

Managing a large set of risks to an organisation may seem as a daunting task difficult to succeed with. However, by breaking down the each problem into smaller pieces and brainstorming around them it is easier to identify where the critical points are located and how threats to them should be looked upon. This approach is consistent throughout the suggested procedure.

The work stream is divided into three major steps discussed below, namely Business Impact Analysis, Risk Assessment and Business Continuity Strategy & Risk Mitigation. Note that all steps are performed on site level, meaning that the GPCM only acts in a managing role. He or she does not have any specific work tasks in the suggested model, other than those mentioned above.

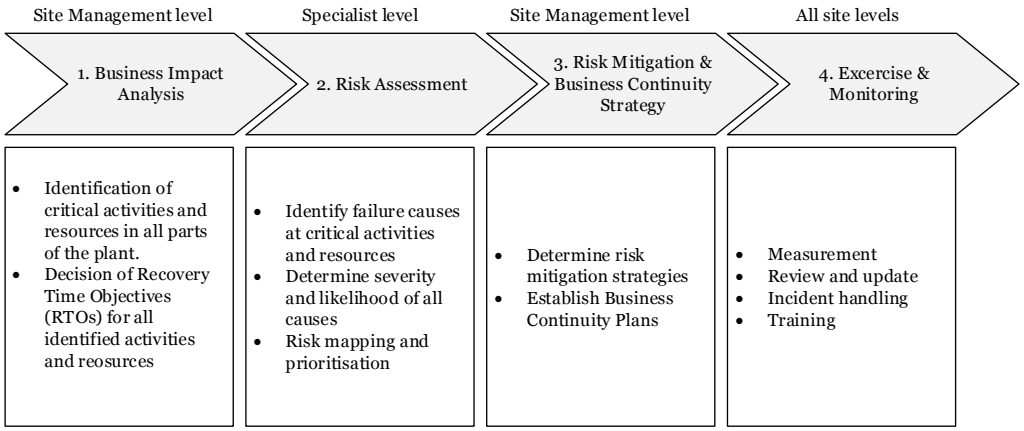

Figure 6.3: Overview of the model proposed

The steps are furthermore inspired by the ISO-standards Risk Management and Business Continuity Planning. (International Standard Organisation, 2009, 2013, 2012)

Some characteristics of the procedure are described below:

- Focusing on the critical activities and resources, in contrast of focusing on all.
- Using both inductive and deductive approaches in the Business Impact Analysis, identifying critical activities and resources as well as risk scenarios that should be further investigated.
- Using both inductive and deductive approaches in the Risk Assessment, to support the process and maximise the risk coverage.
- An approach similar to FMEA is used, as the method suits well and is known from Gambro's current risk toolbox.
- Recurrent risks are listed to support the identification process.
- Using the business recovery time and business interruption value as a financial estimation of the severity of a risk consequence.
- Both mitigating risk pro-actively, as well as planning activities to minimise the consequences of risks.

Business Impact Analysis

The Business Impact Analysis (BIA) is about pinpointing activities and resources where the risk management work should be focused, i.e. activities and resources that are directly linked to Gambro's ability to deliver and therefore critical to Gambro's capability to manage disruptive events. Subsequently the BIA involves setting timeframes of when the activities need to be resumed, setting the levels of requirements of the assessments. Furthermore the BIA also involves identification of overall risks that cannot be attributed a specific cause.

Scope of identification

When identifying risks, the PCMT have to decide the level of their analysis. Preferably, both risks to the entire plant and to smaller parts should be captured. To succeed with this task, a top-down perspective should be taken, by starting with overview risks and continuing with more detailed ones.

The idea can be presented by a set of maps, all with different scales. First, a map of the plant's country can be pictured, seeing the plant as a critical resource in itself. Next, a map of the plant, showing its individual sections could be pictured to identify the most important parts. Finally, using a detailed level map showing all equipment in each section completes the analysis.

The thought pattern allows for both high, medium and detailed level risks to be identified and makes the identification process easier to structure.

Inductive and deductive thinking

The risk identification may be done both deductively and inductively. If a deductive approach is used, an undesired scenario is pictured and (if possible) its causes are assessed (e.g. how may all communication lines within the plant break). An inductive approach means that individual parts of the plants are assessed and the consequences of a disruption in that part are assessed. Preferably, both methods are used in parallel during the business impact analysis.

Focus on critical activities and resources

Critical activities and resources are those that cannot be re-established or recovered in an easy manner and consequently imply a higher recovery cost. For instance, certain simple assembly processes can be re-established on another

location quite easily whereas complex manufacturing processes with high requirements of equipment and facilities are more difficult to start up if compromised. The idea of covering only critical activities and resources as opposed to all activities and resources is an important aspect. This enables the risk organisation to focus and prioritise what is important, and postpone or neglect what is not as important. Clear prioritisations are seen as essential, and will have a direct implication on how the organisation deals with process continuity. (Khan and Zsidisin, 2012, p. 192)

Some tools for identification of critical resources and activities are shown in table 6.1.

The next step is to assign the scenario a Recovery Time Objective (RTO) where RTO is the time the PCMT estimates can pass before Gambro's ability to deliver is affected, and consequently negative business impact will occur. This is a managerial decision which is affected by for instance the risk acceptance level, safety stocks and the impact the disrupted product mix has on Gambro's business performance.

Checklist of risk categories

Some of the typical categories of disruption are shown in table 6.2. These can be used in BIA as a support for identifying critical activities, resources or scenarios, or in the following step, Risk Assessment, for identifying risks.

Risk Area	**Type of material that may be used**
Production	By using a detailed process map a complete overview of the production is obtained. All operations can and should probably not be extensively worked on in a risk perspective; therefore the goal of the first step is to identify those that are critical to the operations of the plant.
Facility	Maps of the facilities, electrical and water system, etc as well as insurance reports can be used to localise the critical resources.
IT	IT may use process maps and hierarchical maps, e.g. Server – OP – Database – Application.
Supply	Supply may use lists of key supplier and materials.

Table 6.1: Appropriate material for identification of critical activities and resources

Production	**IT**	**Facility**	**Supply**
-Tool breakdown -Machine breakdown -Loss of know-how -Severe employee absence -Strike -Chemicals -Legal obligations -Human errors -Loss of information input	-Loss of internal data network -Loss of external data network -Loss of telephone -Hardware failure -Software failure -Cooling failure -IT-sabotage -Servers failure -Operating systems failure -Databases failure -Applications failure	-Fire -Flooding -Other natural disasters -Electricity supply failure -Water supply failure -Waste handling -Sabotage -Theft -Building maintenance failure -Failure of maintenance of lifts, doors etc -Road access failure -Leakages -Heating/Cooling Failure	-No delivery because of supplier -No delivery because of Gambro -Severe sudden quality problems -(Financial problems at supplier) -(Operational problems at supplier) -(Logistical problems from supplier)

Table 6.2: Typical categories of disruption

Forming of Continuity Project Teams

For each process or resource identified in the Business Impact Analysis, in which the PCMT does not have adequate expertise, the responsible member forms a cross functional team and calls the initial meeting. This team analyse the resource or process (Risk Assessment)and should be constituted by individuals with as much detailed level knowledge of the process as possible. In production, the production manager responsible for the workstation or machine is most certainly a group member. Other possible contributors are:

- The purchasing agent responsible for the material that is used in the work station.
- A maintenance specialist with knowledge about the machine used in the operations.
- An IT-specialist with knowledge about which information flow is involved in the process.

These are just examples and it should not be predetermined who is included in this group. The risk management team should be knowledgeable enough to be able to assess this from time to time.

Outcome

The outcome of the Business Impact Analysis is a list of identified scenarios, activities and resources that are deemed critical and should be further considered. They should be documented and refer or include the following information:

- Short description of resource.
- What departments that are concerned.
- The recovery time objective, i.e. the time in which Gambro aims to recover the resource or process.
- Responsible for the subsequent risk assessment, defined as the Continuity Project Team.

The completion is supported by a template, shown in figure 6.4.

Site part **Production**

ID	Type	Risk name	RTO	Expected downtime	BIV rating	Likelihood rating	Documents
1001	Production	Insert molding breakdown	4 days				
1002	Production	Automatic packaging breakdown (product X)	2 days				
1003	IT	Test computer software failure	4 days				
1004	Facility	Lift breakdown production room 4	3 days				

Site part **General**

ID	Type	Risk name	RTO	Expected downtime	BIV rating	Likelihood rating	Documents
3001	Facility	Loss of road access at goods arrival	5 days				
3002	Facility	Loss of access to high bay in warehouse	1 day				
3003	IT	Loss of server hall A	1 day				
3004	IT	Loss of telephone connections	3 days				

Figure 6.4: Completed business impact analysis

Risk Assessment

The second step of the analysis typically executed by the Continuity Project Team, which has the ability to analyse each activity and resource regarded critical. Risk Assessment is as mentioned in the theory chapter, typically built by three different steps: risk identification, risk analysis and risk evaluation. The Continuity Project Team performs the two first steps and normally leave the last step to the PCMT.

Task 1 – Identify potential risks and their causes

There are as mentioned two major approaches for Risk Identification, the deductive and the inductive. They are preferably used in parallel, as it minimises the risk of overlooking relevant information. The input to the work is the list prepared by the PCMT as shown in figure 6.4.

First an inductive approach is used, by employing a framework similar to FMEA. It involves going through subcomponents and brainstorm potential failures implicated by that component. It is important that this is done in a structured way, component by component, in order not to overlook any failure modes. All potential causes of a failure mode should be considered and documented. Preferably, causes are given descriptive names in order to avoid falling into patterns of using the same causes for all risks.

Second, the group should also consider overall failure modes in the process which cannot be attributed to any specific sub-process, but rather hits the process as a whole. For instance, a sensitive machine could be made unavailable by a minor flooding, caused by internal or external factors. Regardless of the cause, the result and corresponding actions are the same. Those scenarios can be difficult to capture when going through components of a given system but should nonetheless be considered by this group. If necessary, the group can use fault tree analysis to complement a more unstructured brainstorming approach.

For each failure mode, the group should consider an expected business recovery time (BRT). It is defined as the time during which no output can be expected from the process in question.

This time consists of two components, the total down time and the buffer time illustrated in figure 6.5.

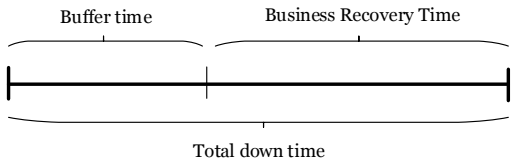

Figure 6.5: The components of the business recovery time and their relation

Finding the business recovery time can thus for instance be done by evaluating each of the two times and then find the difference. When no buffer time is expected, the BRT and the total down time are simply equal.

Task 2 – Evaluate likelihood

The second task of the group is to determine the likelihood of the event to occur, which is connected to the specific risk source of the event. As the kind of events that the model aims at capturing occurs very seldom this step relies heavily on experts' opinions and subjective matters. In order to standardise and improve the quality of the subjective assessment as far as possible, a checklist of questions has to be gone through and answered to the best possible degree.

The classifications of the likelihood ratings, described in table 6.3 are adapted from the currently used likelihood ratings in Hechingen and Meyzieu with the difference that it is defined as years between occurrences instead

Description	Likelihood
Improbable	More than 20 years
Remote	Every 5-20 years
Occasional	Every 1-5 years
Probable	Every 0-1 year

Table 6.3: Proposed likelihood ratings (years between occurrences)

of likelihood per year. Using the expected number of years between occurrences is, in the authors view, more intuitive than assigning percentages of the likelihood of yearly occurrence.

Task 3 – Evaluate Business Interruption Value

A third task is to determine the business value of the process. A failure of a critical process whose downtime extends the buffer time leads to a loss of sales. It is therefore possible to calculate how much profit is lost while the process is not working properly. The advantage with this multi-stage procedure is being able to break down the severity, making it easier to estimate.

The business value can thus be determined by the intuitive multiplication of the products' net margin and the expected number of produced units during the Business Recovery Time. This gives the lost profit because of the failure. In addition to this, other cost associated to the lack of delivery should be considered, such as governmental fines and loss of goodwill.

$$\begin{cases} BRT = \text{Total downtime} - \text{Buffer time} \\ BIV = (BRT \cdot \text{Net margin}) + \text{additional costs} \end{cases}$$

In the cases where a process' output is needed for a subsequent or parallel process, also that value should be considered. A difficulty with assessing the BIV is the chain reaction caused by a disruption. As a disruption could potentially hinder a semi-finalised product to get delivered to another site, it is essential to take those effects into account. For that, representatives from the global supply organisation should be consulted during this step.

To reflect the correct value of a process for Gambro, it is the financial transaction from which the process origins from that should be considered. If a disruption occurs in the first of several sub processes, illustrated to the left in figure 6.6, it is the value of the finished product affected that should be considered, not the value of a semi-finished product or a sub component.

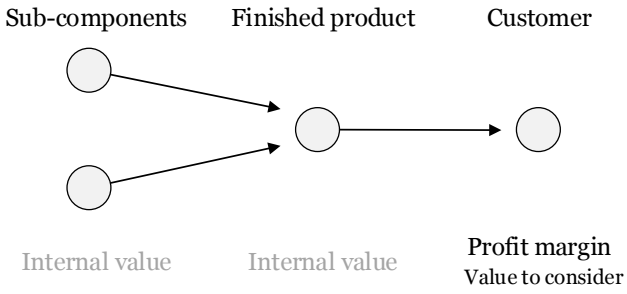

Figure 6.6: Business interruption value in a supply chain perspective

As for non-production processes, it could be less straightforward to determine the direct value of a critical process. For instance, an IT process might serve different parts of the production and could strike at different levels at the same time. Even though it might be difficult, the PCMT should evaluate which products that can not be delivered because of the failure and determine a value in a similar fashion as otherwise.

To support the calculation of the Business Interruption Value, some questions and guidelines are presented in appendix A. The result should be presented in a FMEA based framework as shown in figure 6.8 and 6.7. The project group can also in this stage provide some additional information which may be of value in the continued risk assessment, and that the Continuity Project Team may have additional knowledge of. Some examples of this can include:

- Possible mitigation strategies to decrease the expected likelihood
- Expected improvements in likelihood or BRT with implemented mitigation strategies.
- The possibility to run the process on reduced speed during parts or all of the down time.

The Business Interruption Values are then divided into one of four categories, as shown in table 6.4. The classifications of BIV are also adapted from the sites in Hechingen and Meyzieu, but should be scaled to fit the site that is investigated. The scaling can for instance be done based on the site's turnover. One could argue that the same classifications should be used

Description	Value (MEUR)
Minor	0-0.1
Serious	0.1-1
Critical	1-15
Catastrophic	>15

Table 6.4: Proposed severity ratings (in million euro)

throughout Gambro and that loss of sales means as much for Gambro wherever its cause occurs. However, with the same classification used globally, the resolution of the analysis at the smaller sized plants is decreased, making the prioritisation more difficult.

A global classification for all sites is therefore proposed when the sites are compared on a global level, whereas a local classification should be preferred when risks are compared within a site. The BIV classification should also be accompanied by a motivation expressed in monetary terms making the conversion straight forward.

Presentation of Risk Analysis

The output of the second step is a list of possible (process and sub process) failure modes together with their expected business interruption value, expected occurrence rate and some additional information, all completed in a template. Each cause is assigned a Risk Priority Number (RPN) defined as the risk's distance from origo in a quadratic matrix with side's of length four.

$$\text{RPN} = \sqrt{(\text{likelihood rating})^2 + (\text{BIV rating})^2}$$

Risk Priority Number

In order to make the risk analysis more presentable to management the template from the Business Impact Analysis can be used again. The expected downtime, severity and likelihood rating from the risk cause which gives the highest RPN is transferred to the template. This is done to get an overview of which part of the site is most vulnerable to risks and to have a more effective presentation tool to management.

All risks are also shown in matrices, one for each part of the plant. This gives management an intuitive tool to assess and prioritise which risk to mitigate.

Risk ID	Risk name	Cause name	Risk type	Expected downtime	RTO	BIV description	BIV rating	Likelihood rating	RPN
1001	Insert molding breakdown	Earthquake	Production	6 weeks	4 days	New facility set up in 6 weeks.Production of 26 days lost sales, daily output 5000 units at 0.9 € profit. 26*5000*0.9 = 117000 €	Serious (2)	Unimaginable (1)	2.24
		Fire	Production	6 weeks	4 days	New facility set up in 6 weeks. Production of 26 days lost sales, daily output 5000 units at 0.9 € profit. 26*5000*0.9 = 117000 €	Serious (2)	Unlikely (2)	2.83
		Breakdown of component X	Production	2 weeks	4 days	New component delivered in 2 weeks. Production of 6 days lost sales, daily output 5000 units at 0.9 € profit. 6*5000*0.9 = 27000 €	Minor (1)	Possible (3)	3.16

Figure 6.7: Completed risk analysis template part 1

Risk ID	Risk name	Cause name	Risk control measures (implemented)	Possible actions (proposals)	Cost of action	Residual BIV	Residual Likelihood
1001	Insert molding breakdown	Earthquake	Machine located close to exit 1	Keep spare molding tool at another site	70,000 €	Minor (1)	Unimaginable (1)
		Fire	Sprinker system				
		Breakdown of component X		Keep spare of component X in warehouse	5,000 €	Minor (1)	Possible (3)

Figure 6.8: Completed risk analysis template part 2

Site part **Production**

ID	Type	Risk name	RTO	Expected downtime	BIV rating	Likelihood rating	Documents
1001	Production	Insert molding breakdown	4 days	6 weeks	Minor (1)	Possible (3)	riskID_1001.doc
1002	Production	Automatic packaging breakdown (product X)	2 days	6 weeks	Serious (2)	Possible (3)	riskID_1002.doc
1003	IT	Test computer software failure	4 days	2 weeks	Critical (3)	Unlikely (2)	riskID_1003.doc
1004	Facility	Lift breakdown production room 4	3 days	8 days	Serious (2)	Possible (3)	riskID_1004.doc

Site part **General**

ID	Type	Risk name	RTO	Expected downtime	BIV rating	Likelihood rating	Documents
3001	Facility	Loss of road access at goods arrival	5 days	3 weeks	Serious (2)	Unlikely (2)	riskID_3001.doc
3002	Facility	Loss of access to high bay in warehouse	1 day	4 weeks	Catastrophic (4)	Unimaginable (1)	riskID_3002.doc
3003	IT	Loss of server hall A	1 day	8 days	Critical (3)	Unlikely (2)	riskID_3003.doc
3004	IT	Loss of telephone connections	3 days	6 days	Minor (1)	Unlikely (2)	riskID_3004.doc

Figure 6.9: Completed risk assessment template

Risk Mitigation & Business Continuity Strategy

The third step is normally done by the Process Continuity Management Team, and involves developing ways to mitigate the identified risks as well as coming up with continuity plans for the more unknown scenarios.

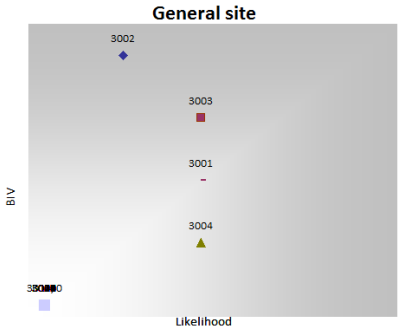

Figure 6.10: Matrix that provides an overview of the highest risks

Risk Mitigation

The Risk Mitigation step is about mitigating or treating the identified risks. The risks can be mitigated in terms of likelihood and/or severity. As mentioned in the theory chapter the mitigation strategies typically fall into any of the following categories; accept, share, transfer, reduce and avoid. The case descriptions in chapter 4 can be used for inspirational purposes. The mitigation strategy should be filled in the templates provided.

For instance Ericsson and Alfa Laval reason that likelihood is difficult to assess and focuses their mitigation measures on lowering the potential impact of a risk. Given the definition of Business Interruption Value, there are several ways to go about with this strategy. Recall the definition as:

$$\begin{cases} BRT = \text{Total downtime} - \text{Buffer time} \\ BIV = (BRT \cdot \text{Net margin}) + \text{additional costs} \end{cases}$$

The total downtime may be lowered by for instance:

- Improving the process knowledge.
- Investing in spare parts.
- Implementing continuous control systems, for instance according to HACCP

The buffer time can be raised by for instance:

- Raising stock levels of finishes goods, by consulting Global Supply.
- Investing in emergency capacity (for instance power generators).

The additional costs can be lowered by for instance:

- Improving customer relations to avoid lost sales in the case of backlogging.
- Flexible and multi-competent work force.
- Enable repair/extraction of expensive equipment/goods.

Business Continuity Strategy

By considering the key resources or activities whose complete scenarios are unknown instead of known, a Business Continuity Plan should be developed. The Business Continuity Plan includes the appropriate actions to resume activities within agreed timeframes, by combining information from BIA and RA. Furthermore it is divided into three different parts:

1. Response plan: the required reaction to an incident or emergency to assess the level of containment and to control the activity.
2. Recovery plan: the actions that are needed to resume critical or essential business operations, functions or processes.
3. Restoration plan: the planning for and implementing full-scale business operations again and to allow the organization to return to normal service level.

Outcome

Both the outcome of the Risk Mitigation as well as the Business Continuity Strategy should be documented in their respective template together with responsible individuals and risk identification numbers. Examples are attached in appendix 2.

Chapter 7

Test of Model

In order to evaluate and improve the model proposed in last chapter and to get valuable inputs, a test of the model has been conducted at one site. With the experiences from the earthquake and the upcoming reconstruction, the planned site in Medolla was chosen for the pilot study.

After the earthquake events, the different units of the Medolla facility were either moved to interim sites or outsourced. The monitor and bloodline manufacturing were moved to closely situated Crevalcore and Poggio Rusco whereas the distribution centre was outsourced to Varese in the north of Italy. Administration and sales departments moved to Bologna. The interim sites were, as the name suggest, just temporary and a new site in Medolla is currently (spring 2013) under construction. Production is planned to be re-started during 2014.

In Medolla, some brainstorming sessions had been done prior to the start of this thesis project, with the aim of planning the new site's layout with a risk perspective in mind. Another reason was to acquire a complete view of the risks before restarting the production in the new facilities. Therefore, the test of the model developed in this thesis is based on those assessments.

7.1 Business Impact Analysis

A team involving individuals from the Production, IT, Building/Facility, QA/RA, Communication and HR departments were gathered to perform vulnerability workshops on the site in general, monitor and bloodline manufacturing and distribution centre. Based on the earthquake experiences, the team brainstormed vulnerable resources and activities by answering the following questions.

- What would be the effect if some specific event happens (external/internal)?
- What could cause this undesired event to happen?
- What was difficult to recover after the earthquake (tools, machines etc)?

That is to say deductive and inductive approaches for risk identification were used together. Layout drawings of both the planned and the old site were used during the brainstorming. The respective workshops' outcome in terms of business impact analysis are summarised in the attached tables (Appendix 3) and as an example the risks of the bloodline factory are shown in figure 7.1

Production

ID	Type	Unit	Risk Name	RTO	Expected downtime	BIV rating	Likelihood	Documents
2001	Production	Bloodlines	[illegible]	[illegible]				
2002	Production	Bloodlines	[illegible]	[illegible]				
2003	Production	Bloodlines	[illegible]	[illegible]				
2004	Production	Bloodlines	[illegible]	[illegible]				
2005	Production	Bloodlines	[illegible]	[illegible]				

Figure 7.1: The business impact analysis from the test of the bloodlines production in Medolla, Italy

The risk identified concerns resources, which are both critical to the business and hard to replace or recover.

By consulting Global Supply, an approximation of the stock levels of the product-mix affected by the risks can be done. In this analysis, the Recovery Time Objective is set equal to the time this stock level will cover. This procedure is not in complete accordance with the model, preferably the RTO is seen as a management decision based on the product mix importance and stock levels is used as a possible mitigation strategy instead. However, the difference does not have any significant impact on the results.

7.2 Risk Assessment

Causes

For every specific risk, potential disruption causes were identified. Earthquakes, fires, flooding and extreme weather were considered as causes of all risks as they had all occurred before. The earthquake in 2012 was the first in 600 years, but the experience had made the risk considerably more apparent. Fire has always been seen as a considerable risk and as heavy rain is frequent in the area also flooding and other damages from extreme weather conditions

were also relevant causes. In addition to those, social and political aspects were present in the discussions regarding certain risks.

In the reconstruction of the plant, the main goal of the risk assessment is to avoid making mistakes in the design and layout of the plant. If risks can be avoided by clever architectural solutions, the cost of risk minimisation will be kept as low as possible. Therefore the causes are limited to larger disruptive events rather than going in-depth on production processes. That type of analysis is better suited to a plant with well-established processes where greater level of detail can be used when deciding mitigation strategies.

Expected downtime and Recovery Time Objective

For each of the risk causes, the expected downtime was set in relation to how difficult it would be to recover or resume the specific activity or resource. For instance, the bloodlines production in Poggio Rusco is highly automated. Consequently, this was making the downtime easier to estimate as it often involves getting a new machine or tool from the market. Another possible scenario to resume the activity is to repair or outsource the disrupted resource.

As mentioned, the Recovery Time Objective is set to equal the buffer time for risks affecting a specific product mix in this analysis. An approximation of the number of weeks of stock can be used, a figure which is obtained from the Global Supply department, who has updated information of all stock levels. For risks where the product mix affected is too large to make a valid approximation, the RTO is approximated as the product with the lowest weeks of stocks available.

Business Interruption Value

The BIV-ratings was one of the most difficult things to calculate during the risk assessments, but was generally built of three components:

1. The BRT, i.e. the expected downtime minus the possible buffer time.
2. The product mix affected by the disruption.
3. The profit margin of each affected product.

Of the three, the first is the most difficult to estimate. Machine suppliers, facility maintenance companies and repair experts were consulted to obtain estimates of repair and procurement lead times. The product mix affected is rather straightforward and is easy to obtain.

The profit margin of the affected products is obtained by subtracting the Total Manufacturing Cost (TMC) from the Average Sales Price (ASP) for each product. Examples of the calculations with made-up numbers are shown in table 7.1 and 7.2.

In table 7.1, the calculation of the weekly profit margin for the monitor manufacturing is performed by simply taking the profit margin of each unit and multiplying it with the weekly demand. If the process affects both Artiset Evosystem and Phoenix, the Business Interruption Value of the process is 5.8 + 14.4 = 20.2 per week.

Table 7.2 shows how the weekly profit is calculated for the bloodlines manufacturing. The total number of units produced (both Artiset and Artiset Ultra) each week was given. As no information of each product's specific quantity was given, they were assigned a ratio of the total production volume (16.7 and 8.3 in the tables).

Process profit/week= $w_1(ASP_1 - TMC_1) + w_2(ASP_2 - TMC_2) + \ldots + w_i(ASP_i - TMC_i)$

Where w_i is product i's share of the total production rate (25 in the example of table 7.2), ASP is the average sales price and TMC is the total manufacturing costs.

Preferably the calculation should be done in a similar way regardless of what products that are investigated. But as two different approaches needed to be used on the same site, it shows that the calculations may differ and need to be adjusted to fit the situation. It is however essential that the calculation reflects the real profit that would be lost due to a disruption.

	Artis Evosystem	**Phoenix**
Units/year	10	15
TMC/unit	50	50
ASP/unit	80	100
Profit/unit	30	50
Process Profit/week	5.8	14.4

Table 7.1: An example of the Business Interruption Value calculation for the Monitor production

	Artiset	Artiset Ultra
Unit share	66.7%	33.3%
Units/week	16.7	8.3
TMC/unit	1	2
ASP/unit	5	5
Profit/unit	4	3
Process Profit/week	66.7	25.0

Table 7.2: An example of the Business Interruption Value calculation for the Bloodline production. In the calculation a total production per week for the process is estimated as 25 units

Likelihood

In the test, the risk causes are mainly external threats such as earthquakes, extreme weather conditions and fires. The likelihood rating for these types of events is naturally difficult to assess quantitatively and is done to the best judgement of the stakeholders with some aid from historical data.

Proposals of measures for improvement

As the aim of the project was to plan the new layout there were numerous proposals and mitigation strategies how the layout could be improved. The proposals were deeply affected by the experiences of the earthquake as well as the difficulties with the recovery. The proposals were furthermore all inspired of five principles developed during the workshops:

- Accessibility to assets (equipment, tools etc)
- Visibility (physical)
- Robustness (physical)
- Separation (assets)
- Mobility (make unique, critical assets possible to move)

For instance, a proposed measurement was having extra electric transformers to reduce the likelihood of having no power supply. Another example was moving critical tools close to exits in order to get them out as quickly as possible, reducing the impact of a possible fire or earthquake. The completed template is attached (Appendix 3) for further review.

7.3 Business Continuity Strategy and Mitigation

The relevant proposals from the previous step were inserted into the templates together with their costs and benefits in terms of risk reduction. Business continuity plans were also completed for the most serious risks as the model proposes.

7.4 Difficulties During the Test

The model includes assumptions and there are as a consequence difficulties in the procedures. The main difficulties that were experienced are listed below:

Causes to the risks.

- Hard to know how many and what causes that should be investigated further.

Downtime estimation.

- Not always easy to estimate how to recover the activities and resources, and how long time that would take.

Recovery Time Objective

- Recovery Time Objective is a management decision of when a disruption's effects are too large and consequently a subjective matter.

Business Interruption Value.

- May not always affect a value easy to connect to, e.g. paper archives.
- Is not easy to see exactly how a resource affects the whole supply chain.
- The profit margin is considered sensitive material and can therefore be hard to acquire.

Likelihood rating

- The likelihood of natural disasters is difficult to assess but external providers can provide access to databases of the most common hazards. Examples of companies that offer this service are Eqecat, MunichRe and Perils. For internal facility risks, the site's insurance company may be a useful resource. For equipment specific risk causes, the supplier can be consulted. For earthquakes, data from the national seismological institutes can be used as support.

Chapter 8

Conclusion

The first part of this chapter summarises the model briefly and the strong and weak points of the model are discussed. It can be read independently for a quick review of the model. Thereafter, an evaluation of the test of the model is presented together with recommendations of how Gambro could precede to implement the model throughout the company. Lastly, a discussion on the future in this field is presented. The current trends and additional interesting topics of research are touched upon.

8.1 Model Summary

The first goal of this project is to develop a model for managing disruptive risks to Gambro's operations. The proposed model is based on two main features:

- Breaking down of problems in smaller and smaller pieces in order to find root causes of risks.
- An iterative working method where similar approaches are used to assess risks as thoroughly and systematic as possible.

The governance of the model is based on Gambro's current organisation where different manufacturing sites work rather independently. Knowledge transfer should take place to keep process harmonised and avoid unnecessary double work.

One Global **Process Continuity Manager** is responsible for overseeing the activities on all sites from a corporate level's point of view. Transferring

knowledge between sites, harmonised processes and communication to top level management are examples of the position's responsibilities.

At each site, a **Process Continuity Management Team** is responsible for the activities to be performed. The team performs the **Business Impact Analysis**, a task that identifies critical resources and activities and establishes Recovery Time Objectives for the resources and activities found. The identification is made for each part of a site (e.g. production facility, warehouse and the site in general) considering the functions Production, IT, Facility and Supply.

For each of the risks that require experts' knowledge, a **Continuity project Team** is formed. This team is put together cross-functionally with necessary individuals from different departments. The team's responsibility is to perform a complete **Risk Assessment**, meaning to identify potential causes for an identified risk to occur and then evaluate its likelihood and business interruption value. The team should also propose possible mitigation strategies and views of what a business continuity plan could consist of.

Once the Risk Assessments have been completed, the risks are mapped and the PCMT should evaluate which risks should be prioritised to mitigate and which risks that can be accepted. The first task is to establish **mitigation strategies**, meaning activities to perform proactively to decrease the likelihood or severity of the risk. The second task is to establish **business continuity plans**, meaning action plans of what should be done if a specific risk occurs.

Strengths and Challenges

Strengths

- The model allows Gambro to have a comprehensive and harmonised procedure for identifying and managing risks to their operations. By using standardised templates, knowledge transfer is enabled and different sites can learn from one another.

- Overview maps, process maps, drawings, component lists, etc are used to identify critical resources and activities as well as risk causes. Those tools give a systematic approach to avoid overlooking risks.

- The model also makes a point of distinguishing between the cause and impact of a risk. This is important, as it allows management to assess the risks clear sighted and aim the mitigation strategies correctly. To

have many causes for each risk will in addition allow different likelihood and severity evaluations for each cause, giving a better level of detail.

- By introducing the measurement Business Interruption Value, the financial impact of the risks can be assessed and potential investments be weighed against the risk of lost profit. Financial measurements are effective communication tools which will aid the prioritisation process.

Challenges

- The first major drawback of the model is that there is no systematic approach to address string consequences. If one major event causes other seemingly unrelated problems to arise that may have been overlooked in the business impact analysis. While mechanisms may cause grave problems, they are very difficult to capture and the attention could be drawn away attention from the issues which are easier to develop strategies for.

- The proposed governance model uses the geographical divisions of worldwide Gambro's units. All tasks are done on the site level and address the risks which appear there, while the global perspective is not as highlighted. This limit may hide opportunities for different sites to take over responsibilities, and help one another, or worse hide how a disruptive event at one site can affect others. As the model does not completely cover this issue, a large responsibility lies on the GPCM who will have to co-ordinate all activities with a global perspective in mind.

- The model also lacks in depth upstream in the supply chain, as implied by the limitation of the thesis. While risk in the supply of components and raw material should be addressed, there are no specific methods of how to find information and evaluate suppliers further away than the first tier. This is a complex and important topic, touched upon in the theory chapter. While a first step is taken by this model, further investigation in co-operation with strategic and operational purchasers is necessary to fully address the problem.

- Another limitation of the thesis, and a weakness of the model, is the lack of support for reviewing and monitoring the assessed risks. The risk management process should never be seen as finished and there must be established routines for updating the assessments periodically.

- As with all risk management procedures, the model relies heavily on experts' approximations and subjective opinions. While this is certainly a problem, it is one difficult to avoid when making any kind of forecast. The problem has been addressed as far as possible by breaking down problems into smaller pieces and using tools such as maps and checklists.

Contribution to theory

While risk analysis and supply chain risk has been widely addressed in academic literature during the last decade, this thesis contributes to theory by offering a more practical take on the issues at hand. In academic literature, we have identified a gap between the detailed level risk analysis tools and the high level success factors for keeping organisations risk aware.

The methodology bridges this gap to some extent by including governance, working methods and documentation templates. It is tailor made for Gambro, but should be suitable to other organisations as well, with minor adjustments. With the case studies contributing strongly to the model design it is well aligned with practice.

8.2 Discussion of the Model Test

In the last chapter the testing of the model was the described in detail. Even if the test was done to aid a plant's layout planning and not at a site with established processes, the model showed to be very useful and gave a lot of insights about the risk environment at the site. The purpose of the test was twofold:

- Getting inputs for adjustments to the model and assuring the applicability.
- Acquiring an overview of the risk environment in order to plan the new site with those aspects in mind.

Involvement of People

One thing that became apparent as soon as the testing began in Medolla was the need for many departments' involvement. Apart from knowledgeable persons from production, IT and facility, Global Supply was needed to acquire the buffer times for the different products and the Finance department was needed to get the profit margins. The assessments proved to be

quite time consuming and require the business unit's full support. With quite clear interfaces, it made sense to divide the assessments between the units, e.g. bloodlines, monitors, DC and general site in order to be efficient when performing the workshops. This was done differently than what was first proposed when designing the process, but we are confident that this division make the assessments easier to perform from an organizational view.

Difference in challenges between units

When performing the risk assessment, the analysis of the highly automated bloodlines production showed to be the most intuitive. To calculate the business interruption value, the downtime estimate is a major part of the analysis. The streamlined process with automated processes step-by-step can be seen as a quite binary process which is either 100 % or 0 % functioning. For processes which are more flexible than the automated bloodlines production, the downtime is more difficult to estimate, especially when the risk causes are large external events. One example is the monitor production where more manual labour is involved and production often can be maintained at reduced speed even if a problem arises.

Another difference between the bloodlines and monitor production is the customers' expectation of delivery precision. This difference became apparent when estimating the buffer time with Global Supply. The monitors are normally substituted when their life time is over but the customers, typically hospitals, can wait with the delivery a couple of weeks without and consequences in most cases. The bloodline products are consumable goods which are required to perform dialysis, delivery precision is therefore of much higher importance for those products and the deliveries can not be delayed.

Captive products

With the same logic, the importance of considering captivity of products became more apparent during the testing. If the delivery capability of a captive product is lost, the loss of goodwill may be significantly larger than otherwise. For instance, if a governmental healthcare institution has to change treatment methods because of Gambro failing to deliver, the risk of losing the entire market is considerable. In the case of Medolla all critical resources and activities affect captive products, eliminating the need for different approaches to captive and non-captive products. However, at sites where this is not the case the difference should be taken into account when determining the recov-

ery time objective, business interruption value and prioritisation of mitigation investments.

Test summary

Even if a couple of issues and difficulties with the implementation were highlighted during the testing, it is important to remember that the test was successful. The first purpose was to evaluate the model and second to give valuable inputs for the site reconstruction, both targets were considered to be fulfilled. The model was thoroughly tested and a considerably better overview of the prevailing risks was acquired. Many of the already performed risk analysis at the different sites (described in chapter 5.3) shared many elements to what the proposed model suggests and the transition should not be too difficult. The model's templates and ideas on business interruption value is however considerably more structured. Seen in a bigger picture, the purpose of the thesis is to harmonise and structure the sites' risk management procedures; only one test may not be enough to ensure complete applicability and improvements should be added continuously throughout the implementation and use.

8.3 Next Step

The risk management activities can never be seen as finished as the environment constantly changes. With the same argument the model can never be seen as definitive and need further development as time goes.

The future activities can be divided into two major categories. The first regards what Gambro should do to implement the proposed model within the company, and the second regards what can be done to develop the model even further.

Apart from the concrete model and other suggestions proposed in this report, the project has hopefully contributed to Gambro by raising the awareness of proper risk management at different levels. We hope that through the interviews and conversations we have had throughout the last months, the issues have come to mind, making the organisation more accepting to future changes.

Implementation of the Model

During the time when this thesis was written, the model was tested on one site out of 13, meaning that there is still work to be done in terms of carrying out

the procedures as well as establishing the governance and routines throughout Gambro. If the risk management are to be harmonised and coordinated for all sites, which is the aim of the model, it is proposed that Gambro should establish clear responsibilities as a first step.

Ideally, the risk management procedures would be integrated along the whole supply chain. Of course that is a quite theoretical target, which is generally not achieved in any supply chain. But as a first step, Gambro should implement appropriate measures within, before moving the focus outside the organisation's borders.

Establish responsibilities

One idea is the proposed governance model that was discussed in chapter 6, with a global coordinator (the Global Process Continuity Manager), different site responsible (Process Continuity Management Team) and project groups (Continuity Project Teams). The sites with comprehensive risk management procedures (see chapter 5) also have procedures that can be used for inspiration. One part of this step is making the model, its templates and records available for the stakeholders within Gambro. This can be achieved with a so-called e-room, which makes documentation, i.e. templates, instructions and reports, available on the virtual network throughout Gambro. The e-room solution also makes sharing similar solutions between sites easier.

Establish routines

Another decision to take is when and how often the procedures are to be updated. The risk environment should be monitored and reviewed, both on a site and a global level. Preferably, this should be done on a biannual or annual basis by the GPCM together with the top-management and the PCMT within the sites, but is particularly important when introducing new products, processes, sites, suppliers etc. One solution would be to include risks in the continuous reviews which are in place, and introduce KPIs for risk management to stimulate the work. KPIs are however something that needs to be implemented carefully and are not discussed in this thesis.

In addition, practice procedures of the established business continuity plans needs to be introduced. If proper rehearsals are done regularly, the initiation of the continuity plans is ensured if an undesired event would happen, just as fire drills are done as preparation for fire. These tests furthermore highlight any weaknesses and problems with the plans, raise the awareness of

the importance of a BCM and give Gambro confidence that crises can be recovered.

Develop the model further

First when Gambro has established clear responsibilities and routines within the company, the model can be further developed. The most natural way to do it is expanding the risk management's borders. As all members in a supply chain are linked together, a risk for one supplier is deeply affecting other members of the supply chain. The mechanism goes both up- and downstream, a customer may face serious problems if a supplier suddenly quit its deliveries and a supplier can get in equally deep trouble if a customer stops its orders. Given this interdependency, an aligned risk management process is of interest to both parties.

A possible action is to introduce a harmonised management system of supplier risk throughout Gambro. The model proposed in this thesis can be used as a basis for it, but in the future an expanded model is probably going to be necessary. Introducing data driven models for risk identification and assessment, allowing Gambro to make decisions based on facts rather than opinions would stabilise the process. Access to information is the key component, and one first step would be to invite critical suppliers to use a similar risk analysis model as the one proposed and to share their results with Gambro.

Information systems for widening the supply chain visibility

The technological advancements in search engines and internet technology have opened new possibilities to perform risk analysis upstream of the supply chain and it is now possible to extract data from a larger amount of sources than in the past.

One such example is a new technology called Supplier InfoNet, developed by SAP. The service scans through data and information from thousands of sources including financial databases and newspaper articles. Information about suppliers in different tiers of a company's supply chain is thus made available and possible sources of problems are identified. The service can for instance help foreseeing delivery time problems if a supplier further up the supply chain is experiencing problems. The interface share many features with social networks and information about suppliers is only granted to those in direct relationship with the concerned company. While this service is not yet

available in all countries and business sectors, it is an interesting development to keep an eye on for the future. (SAP, 2013)

Adapt model to other segments

If appropriate adaptations are taken, it is also possible to use the proposed model on other area, such as market, legal, transportation and occupational risks. The adaptations that are required are first and foremost in the risk analysis, by changing the severity ratings to fit the intentions.

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Appendix A

Guidelines for Risk Analysis

A.1 Checklist for evaluation of cause likelihood

Production

- Has the risk cause occurred before?
- If yes, has anything been done about the cause?
- Are there any parallel systems which could take over the running of the process in case of the failure?
- What (and how many) external systems is the resource or process depending on? E.g. electricity, water, information system,
- Are all employees involved in the process properly trained?
- Is the resource/process of-the-shelf or customised to Gambro?
- What is the complexity level of the resource?
- What is the age of the resource?
- Has it been serviced properly?
- If spare parts are used, are they of the right quality?

IT

- Has the risk cause occurred before?
- If yes, has anything been done about the cause?

- Are there any parallel systems which could take over the running of the process in case of the failure?
- Are there warnings system built in to the process? E.g. Server overheating warning
- Can human mishandling make the risk occur?
- Can the risk occur as a result of changes in other processes? E.g updates of databases affects the operating system
- Is the process/resource properly maintained?
- Is the maintenance very dependent on one person's competence?

Facility

- Has the risk cause occurred before?
- If yes, has anything been done about the cause?
- Are there any parallel systems which could take over the running of the process in case of the failure?
- Is the risk depending on external suppliers?
- Is the resource properly maintained?
- Is the cause depending on other root causes? E.g. Smoke in one part of a facility accts a sensitive clean room through ventilation system
- Is the maintenance very dependent on one person's competence?
- Is there compartmentation for fire protection?
- Are there any active fire protection measures implemented?

Supply

- Has the risk cause occurred before?
- If yes, has anything been done about the cause?
- Are there any parallel systems which could take over the running of the process in case of the failure?

- Is the material procured from one or several suppliers?
- Has the supplier undergone any organisational changes recently?
- What is the distance to the supplier?
- What is the minimum stock level of the component/material?
- Are other Gambro sites using the same component?
- Is the supplier close to maximum capacity?

*Those questions can be complemented with the supplier audit questionnaire

A.2 Checklist for evaluation of business interruption value

1. Which is the product mix affected by the risk?
2. What is the Business Recovery Time? I.e. the time that Gambro will not be able to deliver the affected product mix (weeks).
3. What is the weekly gross margin that is lost due to the disrupted resource or process?
4. Is there any idle capacity labour or equipment due to the disruption?
5. s there an increase of inventory costs due to the disruption?
6. What are the costs of fixing the problem? (Repairs, alternate sourcing, etc.)
7. Is goodwill loss an effect of the disruption?

The Business Interruption Value can be calculated by the intuitive multiplication:

$$BIV = \text{Business Recovery Time}^{(2)} \cdot \text{Weekly Gross Margin Lost}^{(3)} + \text{Additional costs}^{(4)(5)(6)(7)}$$

Appendix B

Risk Documentation

GAMBRO

Template for Mitigation and Business Continuity Strategy
Revision: 1.0
Effective Date: 2013-05-23

Risk 2001

Mitigation and Business Continuity Strategy

Release and Approval

Release and Approval by Continuity Project Team		
Department/Function	**Name**	**Date and Signature**
Risk Analysis project (Master thesis)	Emil Nilsson & Axel Hyllienmark	2013-05-06
Global Process Continuity Manager	-----	-----
Process Continuity Team Member	-----	-----
Process Continuity Team Member	-----	-----
Process Continuity Team Member	-----	-----
Process Continuity Team Member	-----	-----

Executive Summary
Mitigation plan for Risk 2001 in Medolla cassette manufacturing "Loss of dehumidification process". *The process is sensitive to fire and water damage and should be therefore be located in a segregated area.*

2001	**Loss of dehumidification process**	Date: 2013-05-06 (creation) Date: (update)
BIV rating		
Likelihood rating		

Description	The dehumidification process is necessary for the manufacturing of article HD DN, SNDP, HDF and AFBK and is located in the bloodline manufacturing
Responsible	Alessandro Pecorari
Department	

Mitigation of causes

Earthquake		
BIV rating		
Likelihood rating		
Strategy	Reduce	
Methods	Segregated area *…..	Responsible: Name Responsible: Name
Total expense		
New BIV rating		
New likelihood rating		

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Fire		
BIV rating		
Likelihood rating		
Strategy	Reduce	
Methods	Locate the process in a fire proof area *…..	Responsible: Name Responsible: Name
Total expense		
New BIV rating		
New likelihood rating		

Business Continuity plan		
Responsible		Name
Department		Name
Created:		2013-05-06
Last updated:		2013-05-06
Continuity Plan	Reponse Phase	Order new machine from market ASAP Notify Global Supply of potential shortages of product C
	Recovery Phase	Relocate production to site X. Outsource process to company X
	Restoration Phase	E.g. Machine reparation, new machine purchase etc.