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Adapting a global quality management system to a local site

A study in a Swedish organization

Master's thesis in Service Management and Logistics

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Adapting a global quality management system to a local site: A study in a Swedish organization

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ABSTRACT

In order to be competitive in today's market which is characterized by rapid changes, increased competition, and stringent regulations, companies need to align their business processes with customer needs and requirements. Implementing a quality management system (QMS) can enable companies to not only identify their key business processes, but also to manage them in a structured way towards creating a higher customer satisfaction.

This thesis focuses on a Swedish company operating within the medical technology industry. It has implemented a global QMS and held several ISO certifications. Their global processes seem to be under control, however, as to utilize the system to its full potential, the local sites' needs and requirements must also be addressed. This puts pressure on the company to implement more adapted QMS for local market sites. The purpose of this thesis is to assist one local site in becoming compliant to the company's internal quality requirements and to bring the site closer to an ISO certification. Critical success factors, QMS implementations, organizational readiness and drivers have been investigated to provide recommendations for the implementation. Several qualitative research methods have been used, including an action research approach due to that employee involvement was a necessity. Triangulation has been applied to increase validity and reliability.

By identifying compliance gaps to the company's internal requirement and then prioritizing them in a structured way, an implementation strategy could be formed. This served as a basis for the QMS. One of the most important critical success factors, as pointed out in the literature, is employee motivation. This was therefore researched at the case company in order to provide appropriate recommendations. Due to fact that the case company values quality, motivation for the QMS was expressed from the start. With this in mind, the case company was recommended to involve the employees in the implementation phase right away to make sure that they felt included.

As a result of this thesis and the emphasis on quality at the case company, a 10% resource was hired at the site that would only focus on the implementation of the suggested QMS.

Keywords: Quality management system, medtech, quality practices, motivation, adaptation of quality management system.

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Abbreviations

Abbreviation	Explanation
ISO	International Standards Organizations
MHC	Mölnlycke Health Care
QMS	Quality Management System
RQA	Regulatory and Quality affairs
GM	General Manager
Medtech	Medical technology
Local site	A sub-organization that is connected to the global organization e.g. a local market site
Region North	A site representing the local market in region North (northern region of Europe). In this report, it is referred to as Region North, the local market site or the local site
Motives/drivers/motivations	Used in this report to describe the reasons for wanting a QMS

1. INTRODUCTION

Quality can be defined as a product's or service's ability to satisfy or preferably exceed customer needs and expectations (Bergman and Klefsjö, 2010). Focusing on quality has been a success factor for companies for many years, resulting in better products, services, cost savings and satisfied customers. In today's global economy with increased competition, rapidly changing markets and stringent regulations this focus has become more important than ever. The use of management systems has become a crucial factor for success, but only when used to its full potential (Boiral, 2003, Bergman and Klefsjö, 2011 and Turusbekova et al. 2007). This is the starting point for this research. In the following sub sections the specific area of research will be presented more in depth by describing the problem background and definition, objectives, research questions and delimitations. To understand the structure it also includes the report outline.

1.1 Problem background

A way to manage quality, increase customer satisfaction and manage improvements is to implement a quality management system (QMS). A QMS is defined by the International Organization for Standardization (2005) as "A management system to direct and control an organization with regards to quality", and consists of processes, policies and guidelines that help the organization meet requirements (Bergman and Klefsjö, 2010). To ensure compliance the QMS is often based on quality standards, internal requirements and external regulations. By understanding what is relevant to include and consider when designing a QMS it has the chance to become more effective for the organization after it is implemented (Boiral, 2003, Bergman and Klefsjö, 2011 and Turusbekova et al. 2007).

Commonly used quality standards are the ISO 9000 series, which is provided by the International Organization for Standardization (ISO). The series is applicable in many areas of quality management and provides guidance and tools for ensuring that a company's products and services meet requirements and that continuous improvement are in focus (ISO, 2015). Having a quality management system with an ISO 9000 certificate is in many industries vital, and has also become a stamp of approval proving that quality is in focus.

Drivers for implementing a QMS can vary depending on the organizational needs and view on quality (Sampaio et al. 2009). If a company's main driver for implementing a QMS is to get a quality certification it is seen as an external driver, while if a QMS is implemented to get a more efficient and effective organization it is an internal driver. This can also impact the success rate of the implementation and is therefore important to understand in order to get the wanted effects out of the QMS.

1.2 The Case Company

The medtech industry, with its great focus on safety and quality, is an industry where ISO certifications and QMS' are required. The studied company in this report, Mölnlycke Health Care (MHC), is a world-leading producer of single use products for wound care and surgery. (Mölnlycke Health Care, 2014). Their situation is described as follows:

”Governments and operators continue to put more and more pressure on health care professionals, both in terms of efficiency in the services they administer and the safety of patients they treat. We have aligned ourselves to this trend and are constantly increasing our own focus on ensuring consistent levels of quality and safety in our products and throughout our supply chain”
(Mölnlycke Health Care, 2014)

This great focus on quality and safety has resulted in competitive products and is a key success factor for the company (Mölnlycke Health Care, 2014). To ensure customer satisfaction and compliance to rules and regulations the company has several ISO certifications. To manage the organization in regards to ISO standards and additional requirements MHC has developed a global management system for quality, called Succeed. It contains global processes and guidelines that should be followed by the whole organization, and adapted to fit local needs.

With more than 7000 employees worldwide MHC has local sites in many countries. They used to rely on the global organization for quality management and ISO certifications, but due to increased competition and stringent regulations there is an increasing demand also for local certifications. As a response to that the department of Regulatory and Quality affairs at MHC initiated the development and implementation of local variants of the global QMS. As of today, local market sites in Canada, Australia, Spain and France have implemented local quality management systems and acquired their own local ISO certifications. The local market site in the northern region of Europe is about to do the same, and needs help.

1.3 Purpose

The purpose of this research is to assist a local site in becoming compliant to the company's internal quality requirements and to bring the site closer to an ISO certification. This will be done by assisting in the development of an adapted QMS fitting the local site and by presenting recommendations for how to implement it. Furthermore this research aims to investigate the area of Quality Managements Systems including critical success factors for such implementations, organizational readiness and drivers. The research will also contribute to the field of QMS.

1.4 Problem definition

As previously stated, quality and safety are very important factors to consider when working with healthcare products (Mölnlycke Health Care, 2014). Furthermore, the healthcare industry is facing tougher regulations and increased competition, which means that there is a constant need for quality improvements to stay compliant and competitive. In addition to this Poksinska et al. (2002) and Brown et al. (1998) imply that many companies experience increased pressure from customers to acquire certifications.

For a company in such an environment it is important that the whole organization aims to be compliant to standards. Lack of guidelines and procedures can lead to variations, lack of control and communication difficulties resulting in inefficiencies and non-compliances to customer

needs and regulatory requirements. A QMS is not only a system to assure quality but also a communication tool that can enable an organization to work more efficiently, ease induction of new employees, validate the company's excellence and increase customer trust (Poksinska et al., 2002).

The local site in focus during this report is missing a local QMS today and has expressed a desire to improve their way of working, define processes and identify areas that are important in terms of compliance to standards. By developing and implementing a local QMS, the general manager hopes to get a more lean and structured organization, which in turn will boost business.

1.5 Research questions

To guide the research there are two research questions formulated:
RQ 1: What is required to adapt a global quality management system to a local site?
RQ 2: To what extent is the case company ready for a quality management system implementation?

The first questions aims to investigate what is required when developing an adapted QMS for a local site, when the company already has a QMS for the global organization. It aims to investigate what steps an organization needs to take in order to get a QMS in place and how these can be evaluated and prioritized. The subject of QMS is well researched; however adaptations of QMS' for sub-organizations have not been researched to a greater extent and therefore pose an interesting subject for further investigation. The idea is that research in this area can be applicable for other global organizations with local market sites and sub-organizations, as well as for QMS adaptations at different departments within a company.

The purpose of the second question it to answer to what extent the case company is ready for a QMS implementation. To do that an understanding of the nature of QMS implementations, as well as identification of driver, characteristics and critical success factors must be made. It also aims to study if the awareness of those factors can impact the success rate of QMS implementations.

By using these research questions, this report contributes with a practical example and a structured path of action, which can bring insight and knowledge useful for companies in similar situations. In addition to that, knowledge about QMS and critical success factors will be highlighted.

1.6 Delimitations

In order to develop the local QMS, only areas of the global quality management system (Succeed) that are relevant to the local site will be identified. Furthermore additional local processes that are important to include in the local QMS will be defined. MHC has developed an internal QMS policy that all local market sites should follow. As a starting point the main focus will therefore be to make the local QMS compliant to that policy. Due to the fact that the company already holds ISO certifications (9001, 14001, 13485) and the local market site might

want an ISO certification in the future the requirements from the ISO 9001:2008 standard will be used as a reference as well.

Because of the limited time frame this research will not take part in the actual implementation phase, but rather present recommendations for how to do it. Furthermore, the study is limited to only study the local market on an aggregated level.

During the finalization of this report ISO 9001:2015 was released. Since the prominent part of this research took place when ISO 9001:2008 was the active standard this is the version that will be referred to.

1.7 Outline

The report is divided into seven chapters; introduction, methodology, literature review, company information, empirical data, analysis and discussion, conclusion and recommendations. The methodology chapter (Chapter 2) describes how the research was executed and which methods and tools that were used to answer the research questions and conduct the research. The literature review chapter (Chapter 3) presents findings from previous research relevant for the problem, such as quality management system, implementations and organizational change. The chapter regarding company information (Chapter 4) aims to provide the reader with an understanding of the context where the research is taking place. The empirical findings (Chapter 5) consist both of qualitative and quantitative data, collected during the research period. In analysis and discussion (Chapter 6) findings from the literature review as well as from the empirical research will be compared and discussed, leading up to the final quality management system. This result then leads to conclusions and recommendations (Chapter 7).

2. METHOD

This chapter presents how this research was executed and which methods were used. As a starting point the research strategy and design will be described, leading on to the data collection methods and a discussion of research quality.

2.1 Research strategy and design

Before starting this research there were decisions needed to be made in order for the project to be as successful as possible. The research decisions can be visualized in different layers, from research philosophy in the outer layer to tools and procedures in the middle, see Figure 2.1 (Saunders et al. 2009). Research philosophy relates to the mindset of the researcher and has to do with his or her point of view. For this research a pragmatic research philosophy is adopted, where the focus lies on adapting the findings to what was realistic and useful to the specific situation presented at the company (Saunders et al. 2009).

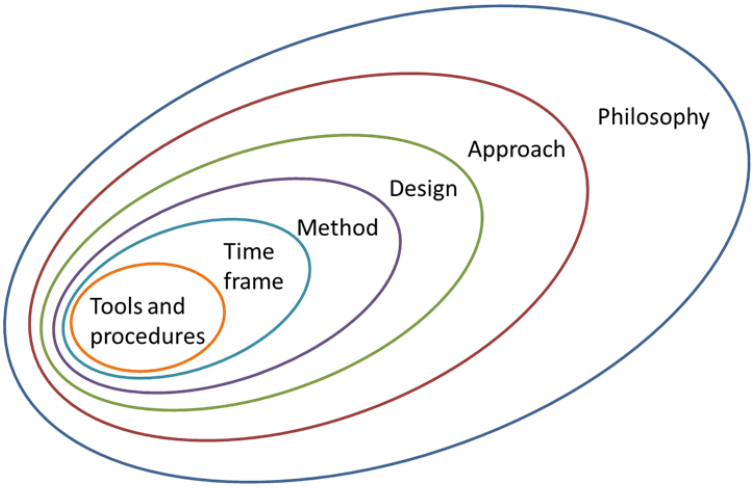

Figure 2.1: The different layers of research decisions by Saunders et al 2009

Dubois and Gadde (2002) present what they call systematic combining, which is an abductive approach to research, also corresponding to approach layer, see Figure 2.1. Systematic combining describes "the continuous movement between an empirical world and a model world" and is when the theoretical framework, empirical fieldwork, and case analysis are developed and ongoing at the same time. In practice it means that the researcher goes back and forth between theory and empirical data and makes conclusions when enough data is collected.

Theoretical study ← → Empirical findings

For this research it was important to understand the perspectives, experiences and needs of the employees to be able to develop a suitable QMS. Systematic combination was therefore considered a good fit. To go back and forth between literature and empirical data collection increased the understanding, eased the analysis and addressed new information as it arose.

The next layer concerned research design, which is the plan for how to answer the research questions (Saunders et al. 2009). It also provides a framework for how to collect and analyze the gathered data (Saunders et al. 2009 and Bryman and Bell, 2011). For this research employee involvement was vital, due to that the system needed to be developed to fit their needs and expectations. The research design that was chosen was action research, due to that it is iterative and focuses on interaction between the researchers and the research subject. Bradbury-Huang (2010. p 93) defines action research as "an orientation to knowledge creation that arises in a context of practice and requires researchers to work with practitioners", which differs compared to conventional social science that often has the purpose to understand different social arrangements. To change the current situation as well as generating knowledge is the aim of action research (Bradbury-Huang, 2010). A researcher is actively involved in changes in the organization, while conducting research simultaneously. The iterative nature of action research is also well in line with the pragmatic research philosophy and abductive approach (Saunders et al. 2009).

The next layer determined which type of methods would be used; qualitative or quantitative (Saunders et al. 2009). To answer the stated research questions qualitative research methods were used. Due to the nature of this research, with a focus on soft values from a limited number of people, quantification of findings was not a priority while it can result in a misleading view, hence could jeopardize the validity of the research. The study has been cross-sectional in its time frame, thus completing the last layer of the research strategy and design, except for specifying tools and procedures that are presented later in this chapter.

2.2 Research process

The overall process that was used to carry out this research is illustrated in Figure 2.2. As a start the problem was formulated and the decision of what was to be delivered defined. To ensure a manageable scope for the project and to make sure that expectations were aligned it was done in co-operation with one of the global quality managers and the local market site manager. In order to get a better understanding of the area a literature review was initiated in parallel. This literature review then continued during the whole research to build knowledge and create a theoretical framework

After defining the scope and problem, research questions were created together with clear delimitations. Once this was done, an empirical data collection began with company research, interviews and observations. The data collection focused on understanding the current state of the site regarding; quality awareness, motivation, processes, as well as to identify gaps that needed to be closed in order to reach the desired state. This phase required high employee involvement and an iterative process began where information was collected and evaluated to better understand the situation.

After the completion of the data collection the analysis of the problem began. Frameworks and findings from literature were used to analyze findings from the empirical data. The gaps found during the data analysis were evaluated in an impact – effort matrix. This then lead to actions for closing the gaps. This work involved the employees to make sure that the authors interpretations

would be in line with the company's and that the results would reflect the company's true desires. The last phase for the research comprised deriving conclusions from the analyzed data and last, giving recommendations to the company.

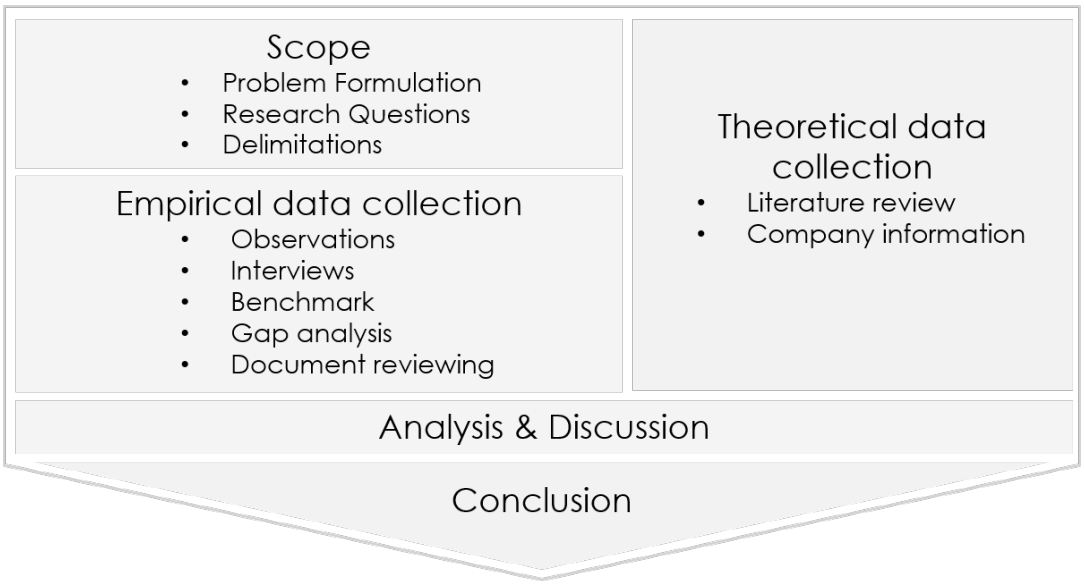

Figure 2.2: The overall research process used in this master thesis.

2.3 Data collection

The data collection was divided into two parts, a theoretical and an empirical. The theoretical data collection consisted of a literature review and also collection of information related to the subject provided by the company. The empirical data collection comprised of observations, interviews, benchmarking and also a collection of company information and reviewing of company documents.

2.3.1 Literature review

When conducting any project it is important to recognize that the project is not done in a vacuum and that the knowledge found in a project will build on previous knowledge and ideas (Jankowicz, 2005 p. 161). Sharp et al. (2002) presents two major reasons for conducting a literature review. The first reason is that reviewing will help in defining the research area and guide the research idea. The second is called critically reviewing the literature, where the current state of the problem is examined, thus relating to Jankowicz's previously mentioned statement. A literature review was therefore decided upon as a necessity for the research conducted at MHC.

The literature review started with the research questions, which were the main guidance for identifying literature to examine. The research questions helped define important parameters for the project and also to generate keywords to search for. But to understand the literature relevant to the research area general information about quality management and standards were a priority to read. Once the basic knowledge about quality management systems and related subject had

been read the literature relevant for the research subject was collected. A funnel method for searching was used by the authors, in starting with literature with a broad view of the subject to narrow down and become more specific as the project moved along. Words used for searching were *quality management system, motivation, implementation, ISO 9000, barriers, marketing, service management, change management, benefits with QMS* and these one's in different combinations.

The search tools used were *Chalmers library search function, Google Scholar* and literature databases connected to Chalmers; *Web of Science* and *ScienceDirect.* The supervisor at Chalmers also provided the researchers with relevant literature.

The literature consisted of; articles in journals, documents from the company and books. The result of the review can be found in Chapter 3. There are many benefits to conducting a literature review. Saunders et al (2009) suggest that it; demonstrates that the knowledge is up to date, provides acknowledgement to other research, and also provides validity to the own work.

2.3.2 Empirical data collection

To raise credibility for the findings triangulation of different methods were used (Bryman and Bell, 2011). This ensures that the data collected can be verified by other methods. As stated above; direct observations, interviews, benchmarking, and collection and reviewing of company documents and records were performed.

2.3.2.1 Observation

There are two different types of observations that can be used when conducting a research project; participant and structured (Saunders et al. 2009). Structured observations take place in a more controlled environment with the goal to investigate frequency of an event. It is characterized by predetermined structure and quantitative analysis. Participant observations come from social anthropology studies (Saunders et al. 2009) and are described by Brannick and Coghlan (2007) as the observer being an insider researcher. They define it as those undertaking research in and on their own organizations, while a complete member, which in this context means both having insider pre-understanding and access and wanting the choice to remain a member on a desired career path when the research is completed. The main objective of the observations was to understand the organization's mindset towards quality and QMS; hence the secondary approach was used. The observations were performed ad hoc, and only when the authors were physically present.

Using observations as a data collection method creates some threats to the study's reliability and validity. Firstly, it is almost impossible to recreate events observed, which decreases validity, and observers' bias is unavoidable, thus reducing the study's reliability (Saunders et al. 2009, Bryman and Bell, 2011, and Cooper and Schindler, 2013). It is also hard to properly present the activities and inferences occurring due to cognitive processes of the researcher. Direct observations also pose the issue of the researchers' limited minds, during observations too much information can arise, and some can easily be missed (Cooper and Schindler, 2013).

Observations provides high ecological validity, due to the setting in where it is performed is the natural one (Saunders et al. 2009). Other benefits of the method include; the securement of environmental context information and reduced obtrusiveness (Cooper and Schindler, 2013).

2.3.2.2 Interviews

During the project interviews were used as a data collection method at many stages. Interviews can be defined as a "purposeful discussion between two or more people" (Saunders et al. 2009, p. 318). There are different types of interviews; structured, semi-structured and unstructured (Bryman and Bell, 2011). For this research semi-structured interviews have been used, since they allow flexibility, provide rich answers and will give a deeper understanding of the context (Saunder et al. 2009).

The interviewees were recommended by the general manager at the site, based on their knowledge about different processes at the site, hence using convenience sampling. During the interviews the interviewees also suggested other employees that had knowledge about different areas under investigation, thus snowball sampling became the second method for choosing interview subjects (Saunder et al, 2009).

The interviewees were from different levels of the site, ranging from top management to assistants, see Figure 2.2. From the beginning there were no set number of interviews that needed to be met and the interviews were performed during a month and the total number of interviews was 13. The interviews were around 1 hour, ranging from 45 minutes to 1 hour and 30 minutes. Since the semi-structured interviews were used an interview guide was followed, seen in appendix A. This helped during the interviews since it created a path to follow and also made sure that no areas of interest were missed (Bryman and Bell, 2011).

The interviews were held in the employee's native language Swedish. Anonymity for the employees was promised to ensure honesty and also to make them feel secure in answering. The interviews were recorded and then transcribed for easier analysis.

Role	Number of interviewees	Interview topic
Manager	2	General management processes, Sales processes

Middle manager	5	Sales processes, Recall processes, Sample handling, Complaints handling, IT processes, Logistics
Non manager	4	Sales processes, Recall processes, Sample handling, Complaints handling
Assistant	1	Sales processes
Sales personnel	1	Sales processes

Figure 2.2: List of interviewees that were interviewed during the research

2.3.2.3 Gap Analysis

A gap analysis is where the current state is evaluated against the desired future state or best practice (Franklin, 2006). Aside from the business operational results employee performance and perceptions are assessed as well, thus providing information about their current needs and expectations.

At MHC the gap analysis method is often used. It aims to identify improvement areas and provide insight to what needs to be done. The gap analysis performed at the site had the goal to identify gaps, between the sites actual performance and what is said in the “Local market Quality management system assignment policy” as well as relevant ISO requirements. The analysis was carried out by the Global QA Commercial Manager, with the assistance from the authors. Data was gathered through meetings with appointed representatives from different functions at the site and also from one of the regional offices.

The interviews focused on the employee's respective area and the interviews took 30 minutes each. The result was compiled and a report was sent out and approved by the interviewees.

2.3.2.4 Benchmark

A benchmark is when a set of standards is used as a reference of evaluation of performance (Business dictionary, 2015). By using benchmark previous knowledge can be obtained and mistakes avoided.

A benchmarking with already certified sales and marketing sites and other departments that faced similar challenges within MHC, was performed to get guidance to how successful implementations have worked on a global level within the company. The chosen offices were recommendations from the company supervisor. The person responsible for the QMS at each local site is the appointed quality manager and also the person contacted for this benchmark.

Semi structured interviews were used for this as well, both face-to-face and by telephone. For the countries where a meeting was impossible to set up the interview guide was sent by mail. To get a deeper understanding company documents and records from the different sites were reviewed and analyzed.

The following countries QMS' were investigated:

- France (Direct interview)
- Canada (Telephone interview)
- Iberia (Mail questionnaire)

The data was transcribed and relevant areas and findings are described in chapter 5.

2.3.2.5 Document and record collection and reviewing

Reviewing documents provide projects with valuable information. During this research organizational documents were the main form of document that was investigated. To ensure the study's credibility and representativeness all documents was objectively considered to avoid bias (Bryman and Bell, 2011). This should however not pose to big a challenge since most of the documents investigated were internal and descriptive. The documents reviewed were customer surveys, audit reports, document regarding the global QMS and also documents regarding local QMS' provided from other local market sites. Interesting findings from these documents have been documented and will be presented throughout the report. The documents regarding QMS' from other local market site were also used for guidance during the development the QMS for the site.

2.4 Data analysis

The analysis is divided into two parts, one regarding the gap analysis and one concerning motives employees have for implementing a QMS. For the gap analysis to be finished actions needed to be concluded. These were found by combining findings from the literature review, ISO 9001:2008 and discussions with the quality department of MHC. To cluster the gaps and analyze the actions an impact-effort matrix was used, with inspiration from a benefit-effort matrix developed by Rosam and Peddle (2010). Three of the employees of the quality department at MHC performed the matrix, this ensured that the company's interest was considered and the prioritization was in line with their intentions. The first step was to find variables to be analyzed in the matrix. Once that was done the matrix helped to objectively compare the gaps and actions in order create an implementation strategy.

The next part of the analysis focused on the motives for implementing a QMS. This part of the analysis was done using the method described by Miles and Huberman (1994). The method consists of three parts; data reduction, data display and conclusion creation and verification. To understand the data collected during the interviews it needed to be reduced and concretized. It was then displayed in a clear and structured way to ease the process of finding conclusions. To find conclusions the interview data combined with the finding from the literature review was used. This helped identify motives for the implementation of the QMS and by that providing the management with valuable information about how to carry out the rest of the implementation.

2.5 Research quality

To ensure the quality of the research an assessment is necessary. According to Bryman and Bell (2011) the same criteria is applicable for both quantitative and qualitative research practices, which in the case in this study was mixed. Two important factors to use for assessment is reliability and validity, both can be divided into internal and external (Bryman and Bell, 2011). Description of the criteria can be found in Figure 2.3.

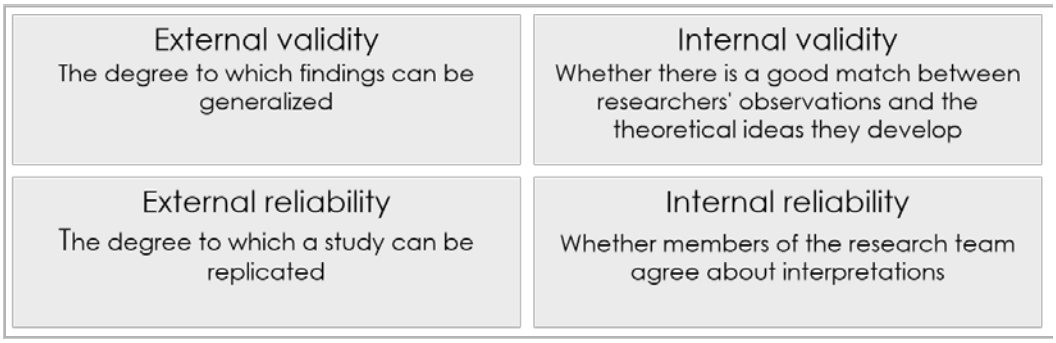

Figure 2.3: Description of the different research criteria found in Bryman and Bell, 2011.

Validity relates to the quality of the conclusions made during the research. To increase internal validity and ensure a better match between observations and conclusions, both authors were present during all interviews and activities at the company as well as during all phases in the research. To mitigate the risk of bias triangulation between methods was also applied.
When it comes to external validity, meaning to what degree the findings can be generalized (Bryman and Bell, 2011); it is always the question whether enough data has been collected to draw a general conclusion. In this study personnel from different levels of the organization was interviewed, and the answers from the performed interviews were considered saturated. However, due to a limited scope and in order to generalize some aspects might have been missed. To ensure that findings from this report could be transferred to others, descriptions about the environment and the company itself have been provided in Chapter 4.

External reliability looks at if the study can be replicated. In this case it can prove to be a challenge due to the study being conducted at specific company. However, if a company in a similar situation would conduct a similar study it is reasonable to believe that the study could be replicated and similar conclusions drawn.

When it comes to internal reliability and to what degree researchers agree about the interpretations, it is considerably high in this study. The research was done by a group of two, where both participated and worked on all parts of the research together, hence agreed on findings and conclusion.

3. THEORETICAL FRAMEWORK

This chapter aims to; further describe what a QMS is, to give an overview of the research that has been done in the field of QMS, and to identify motives and critical success factors for such

implementations. The literature review also aims to identify and highlight models and methods that can assist and guide in the adaptation and implementation of a QMS

3.1 Quality management system

Ever since Deming and Juran initiated research on quality and its practical application in industry in the 1950s, the topic and its necessity have been studied frequently. Areas that have been well covered are quality management, motives, quality standards, ISO 9000, benefits, strategic results, implementation process, TQM and quality thinking. Quality management systems are still heavily studied by researchers and are considered by many as a strategic and effective tool for making companies more competitive (Papassavas et al., 2015).

Quality management systems based on standards set by the International Organization for Standardization (ISO) have since the 1980's been implemented in many service- and manufacturing companies and is of today the most used management systems in the world (Chairini, 2011). In 2010 there were more than one million companies that held such a certification (Priede, 2012).

ISO 9000 is a series of internationally accepted guidelines for how companies should set up quality management systems (Evangelos et al. 2009). The system is designed to assist the organization in achieving and sustaining business success, with the help of a quality approach (ISO 9004:2009). This is done by ensuring that the organization meets the needs and expectations of stakeholder as well as fulfil requirements set by authorities and other parties (Poksinska et al., 2002).

A QMS based on ISO 9001:2008 follows eight quality management principles. The first principle is that the organization needs to have a *customer focus.* It is important for the organization's survival to understand current and future needs of its customers. The second principle is *leadership*; to have committed leadership is crucial for achieving organizational goals and to maintain an environment where employees are committed and engaged, which also connect to the third principle, *involvement of people*. The next principle is called *process approach*; which means that organizations should organize their activities as processes in order to achieve the most efficiency (Bergman and Klefsjö, 2011). *System approach to management* refers to that management should see their organization as a system in order to ensure effectiveness in reaching set objectives. The next principle is *continual improvement*, which should be a permanent objective for an organization. Sedevich Fons (2011) also highlights the importance of actions resulting in continuous improvement, as well as to have resource availability and controlled performance.

The seventh principle is *Factual approach to decision making*, where ISO emphasize that organizations need to collect and analyze data in order to make informed decisions and in turn improve quality. The last principle is called *mutually beneficial supplier relationships* and refers to that organization should strive for deals and relationships with its suppliers that contribute to the ability to create value for both (Bergman and Klefsjö, 2011).

ISO standards are constantly being updated and the version from 2008 is being replaced by another one in 2015. Even though the standards are similar there will be some changes that need to be taken in consideration when going for a certification. One known difference is that there are higher demands regarding management's' responsibilities and commitment for the QMS.

3.2 Motives for implementing a QMS

Quality improvements often result in better products, services and processes (Priede, 2002). A QMS can also result in increased transparency of processes, which in turn can improve internal control and reveal wasteful activities (Brown et al. 1998). Using quality standards, such as ISO 9000, can also improve the corporate image (Poksinska et al., 2002) and assist the company in becoming more competitive in the field, and thus open opportunities in new markets where a certification is required (Priede 2012). A QMS can be seen as a "starting point for embarking on continuous improvement of the firm's' operations" (Prajogo, 2011, pp.94) and is a way for companies to ensure that products and services fulfil customer needs (Turusbekova et al. 2007).

3.2.1 Drivers impact success rate of QMS

The level of success in a QMS implementation is often related to the underlying drivers for wanting it (Psomas et al., 2010). Common drivers for getting an ISO 9000 certification are demands and expectations from customers, pressure from competitors, legal requirement, and new regulations (Psomas et al. 2010). Depending on the organization, different drivers have more or less impact on the success. For instance, companies gain more benefits from a QMS if the employees see it as a means for making the organization more efficient and take part in the implementation processes. If the certification only acts a response to external pressures for example regulations and customer specifications, the improvements are usually not as significant (Brown et al. 1998). According to Boiral (2012) motives with a more internal nature will respond to customer requirements in a better way, highlight quality on a management level and to improve performance due to continuous improvements

3.2.2 Internal and external drivers for implementing a QMS

Sampaio et al. (2009) also divide the drivers into two categories; internal and external. External ones have to do with the pressure companies face from the outside world such as new regulations, customer demands or increased competition. Internal motivation is related to when companies see the certification as a way to achieve organizational improvements.

The motives a company has for implementing an ISO 9000 management system have proven to be one of the most important factors affecting the outcome (Prajogo, 2011). External motives often drive the implementation process but they seldom, by themselves, lead to better operational performance. It will in other words motivate the organization to implement the QMS but it does not ensure increased quality performance. These organizations often see the certification as the ultimate goal and believe that it is the certification itself that the customers desire (Prajogo, 2011). Internal motives on the other hand usually enhance the effect and lead to improved operational performance.

3.2.3 ISO certifications as organizational degrees

Companies that go for ISO certifications can be compared to individuals acquiring university degrees (Boiral, 2012). When it comes to motivation, drivers and behavior many similarities can be found. The research carried out by Boiral (2012) looked at what is called the degree-purchasing syndrome (DPS) theory from education, which explains the detachment between the learning process and the acquired degree. Companies that mainly have external pressure as a driver for implementing ISO standards tend to acquire certifications like an "organizational degree" and mainly put focus on the management system prior to audits to obtain a certification, in the same way as students preparing for an exam. By having such a superficial adoption the ISO standard is not used as an improvement tool but the certifications rather act as a facade, hiding existing uncertainties regarding actual capabilities and ways of working (Boiral, 2012).

3.2.4 Basic and consequential benefits of QMS

According to Alič and Rusjan (2010b) implementing a QMS does not automatically increase the economic performance, but they identified various benefits that companies can gain if they implement a QMS in the organization in an appropriate way. By using the balanced scorecard approach developed by Kaplan and Norton (1996) Alič and Rusjan divide the benefits in four different groups; benefits related to the customer perspective, the internal processes perspective, the learning and development perspective and the achievement of economic goals and improved financial performance. Each group consists of both basic and consequential benefits and can be seen in Figure 3.1.

Area	Basic	Consequential
Customer perspective	Improvement of product and service quality	Greater customer satisfaction
	Decrease cost caused by non-conformity of received goods and incoming control	Improved image of the company
	Improved communication and relationship with suppliers	Retention of existing customer
		Increased volume of sales
Internal processes perspective	Procedures are determined and more visible	Better effectiveness of processes
	Decrease in rework and scrap	
	Decrease in external auditing	
	Higher productivity	
Learning and development perspective	Increased qualification of employees for the implementation of work tasks	Improved employee satisfaction
	Increased transfer and dissemination of knowledge among employees	Innovation, building of a competitive advantage.

	Improved communication and relationship between employees	
	Better work morale and motivation of employees	
	Continuous improvement of product and service quality	
Achievement of economic goals and improved financial performance	Increased income, based on improved products and services	Improved profitability
	Decreased cost, based on process improvements, improved process effectiveness and product	Satisfaction of owners

Figure 3.1: Basic and consequential benefits from using a QMS divided into four groups; Customer, process, learning and financial performance (Alič and Rusjan, 2010b)

3.3 Development of a QMS

When developing and implementing a QMS companies often need to include new processes or change the existing (Boiral, 2003). It is important to remember to include parts that are relevant for the organization that will use the QMS (Bergman and Klefsjö, 2011). It is also suggested to integrate the standard in daily operations as much as possible (Turusbekova et al. 2007).

An important factor to consider is individual accountability, because even if a company gets clear guidelines and procedures in place, the challenge is to get employees to follow them. Once again motivation and attitude among personnel are highlighted as the main critical success factors. Turusbekova et al. (2007) studied the effectiveness of the QMS and the accountability among individuals and found that system support, social support and personalized responsibility are important factors that impact the accountability as well as the attitude towards the QMS. The correlation proves to be both negative and positive, e.g. the lack of them will result in a negative outcome and the other way around (Turusbekova et al. 2007).

Well-performing firms that have sufficient resources to implement, as well as large companies that already have existing management systems often also find it less difficult to adapt to ISO 9000 as compared to companies having to start from zero (Prajogo, 2011, and Briscoe et al. 2005). If the process already exists when developing the QMS the necessary action is mainly to map it and let the responsible employee review it. If the organization however needs to develop a new process it includes more steps, such as raising awareness, document the procedure, follow it up, control records and perform audits to sustain it (Hernandez, 2010).

Since the QMS is a “controlled document” holding important information and documents it is important to make sure unintended alterations are prevented. Consequently there need to be restrictions regarding who have the authority to change and maintain the QMS, without

hindering all employees to have access to the system (Hernandez, 2010). To appoint a QMS responsible will hence ease this and ensure that the system is correct.

3.4 Implement a QMS

Ong et al. (2015) presents a model first developed by Briscoe et al (2005) that divides the process of adapting to ISO standards into three phases; pre-implementation, implementation and post-implementation, which can be seen in Figure 3.2. In the initial phase it is important to prepare the organization and its employees for the implementation of the QMS, by focusing on the quality mindset, hence creating a culture that can embrace the change instead of resist it. In the implementation phase the actual quality practices and changes take place in the organization as to make it compliant to the standard. This phase ends when a certification is acquired and the focus shift on maintaining the certification. The post-implementation phase has a lot to do with how the organization sustain and utilize the implemented QMS.

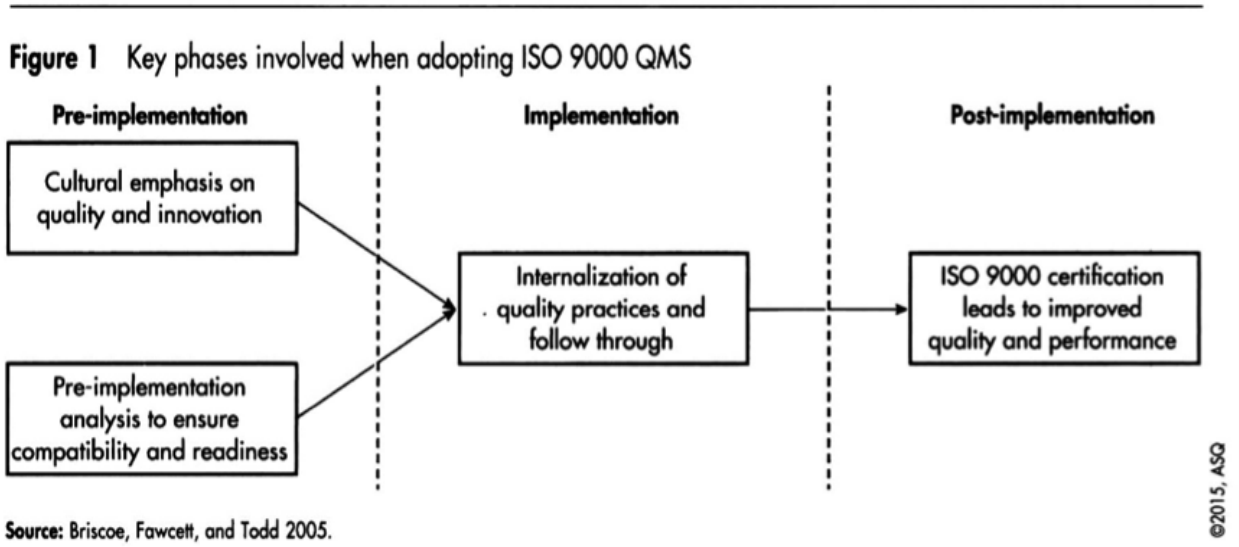

Figure 3.2: Key phases involved when adopting ISO 9000 QMS (Briscoe et al, 2005) (*Ong et al., 2015)*

Alič and Rusjan (2010b) also describe different stages in the implementation process, such as adoption, implementation, certification and maintenance. During these different steps beliefs among employees regarding the QMS have a significant impact on the outcome (Alič and Rusjan, 2010b). Comprehension of ISO requirements as well as the purpose for the implementation is seen as a major factor affecting the beliefs and they tend to be more positive the better understanding they have. To reach this understanding and avoid implementations problems, Ong et al. (2015) promote adequate training of quality practitioners. Furthermore, organizational factors such as management support highly affect the usage and sustainability of the QMS since their attitudes shapes the perceptions and beliefs of the rest of the organization. Hernandez (2010) also agrees stating that:

“The leadership of the top management in the organization requires supporting the implementation of the system as a strategic matter, and is quite relevant to the successful of the implementation process.” (Hernandez, 2010 pp. 465)

To highlight the impact of organizational support and the importance of understanding the ISO requirements to sustain the QMS Ong et al. (2015) show two different paths of adapting to the ISO standard that can be seen in Figure 3.3; Conceptual and operational learning. With the conceptual learning path it is shown that understanding the standard and its requirements will make it easier to comprehend and utilize it, hence avoid problems with implementing and increase its usefulness. The ease of use is strongly connected to the intrinsic motivation of employees to use the system as well as the usability. The operational path shows the positive effects of having strong support for the QMS in the organization, especially from management. Thus, support might not increase the perception of the system’s ease of use; however it will increase the perception the usefulness as well as help to sustain the QMS over time. To conclude Ong et al. (2015, pp 27) state “QMS practitioners' beliefs about the usefulness of ISO 9000 are shaped by the support they receive from their peers and management, as well as from their beliefs about the ease of use of ISO 9000”.

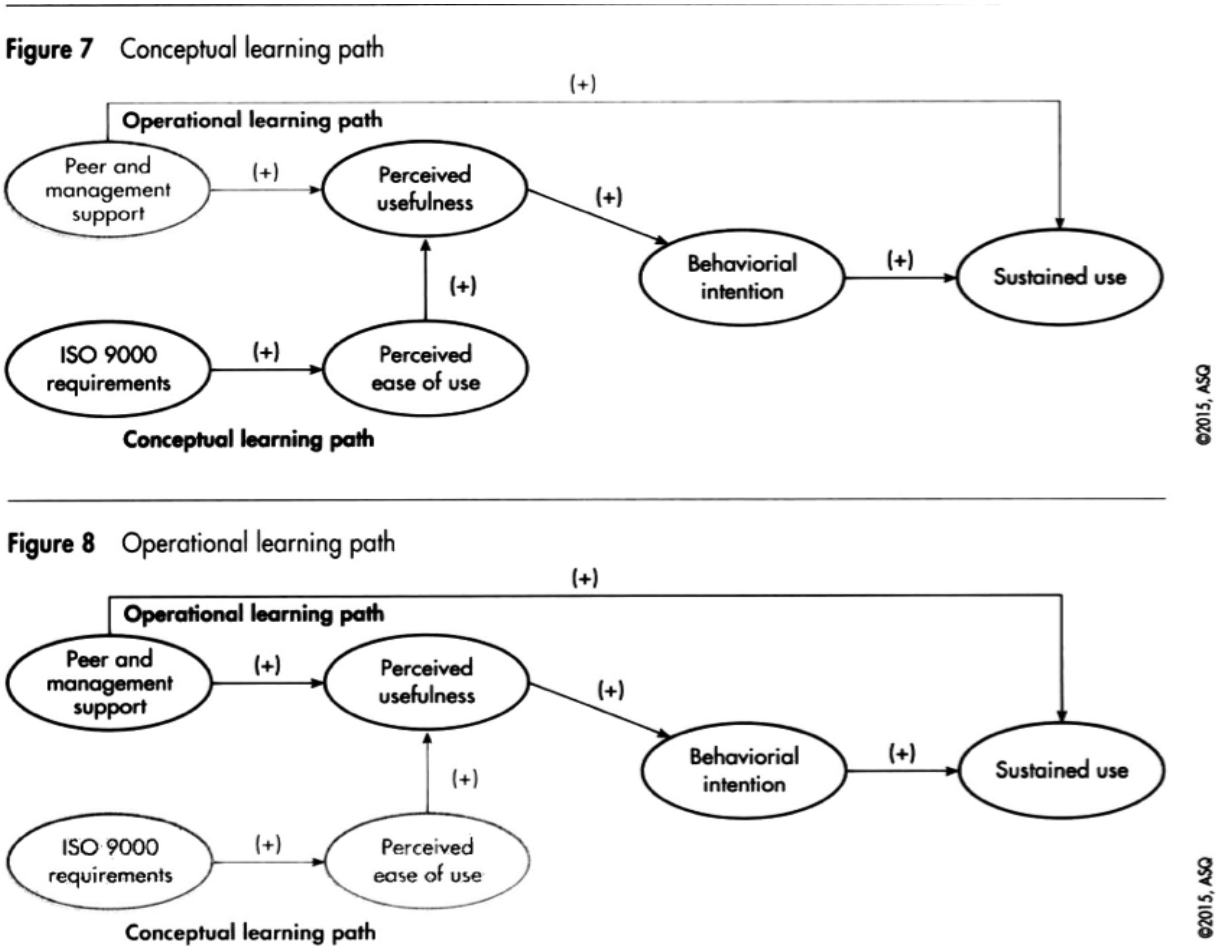

Figure 3.3: Two different paths of adapting to the ISO standard; Conceptual learning path and operational learning path (Briscoe et al, 2005) (Ong et al., 2015)

3.5 QMS implementation and business performance

The theoretical model in Figure 3.4 developed by Alič and Rusjan (2010b) shows what impact a QMS can have in the company. Depending on the integration of the QMS in the organization and its alignment with strategic goals, the contribution to business performance can vary considerably (Alič and Rusjan, 2010b). Companies that mostly seek a certification do not get the same improved business performance as the ones that are driven by internal improvement reasons. The key often lies in desiring an efficient QMS and not only put the QMS in place in order to acquire a certification. In companies with internal motivation one can often find strong management support for the QMS, and they are seldom satisfied with merely fulfilling the requirements set by ISO. The goal is usually to go beyond that and have the quality goals linked to the strategic goals of the company. By aligning the QMS and the quality policy with the company's vision, mission and strategies the QMS can contribute to the business performance in a better way. This is also something that will lead to continuous improvements. By understanding the three different outcomes of the QMS shown in the model in Figure 3.4 it becomes more clear what companies need to do in order to reach certain outcomes with their QMS.

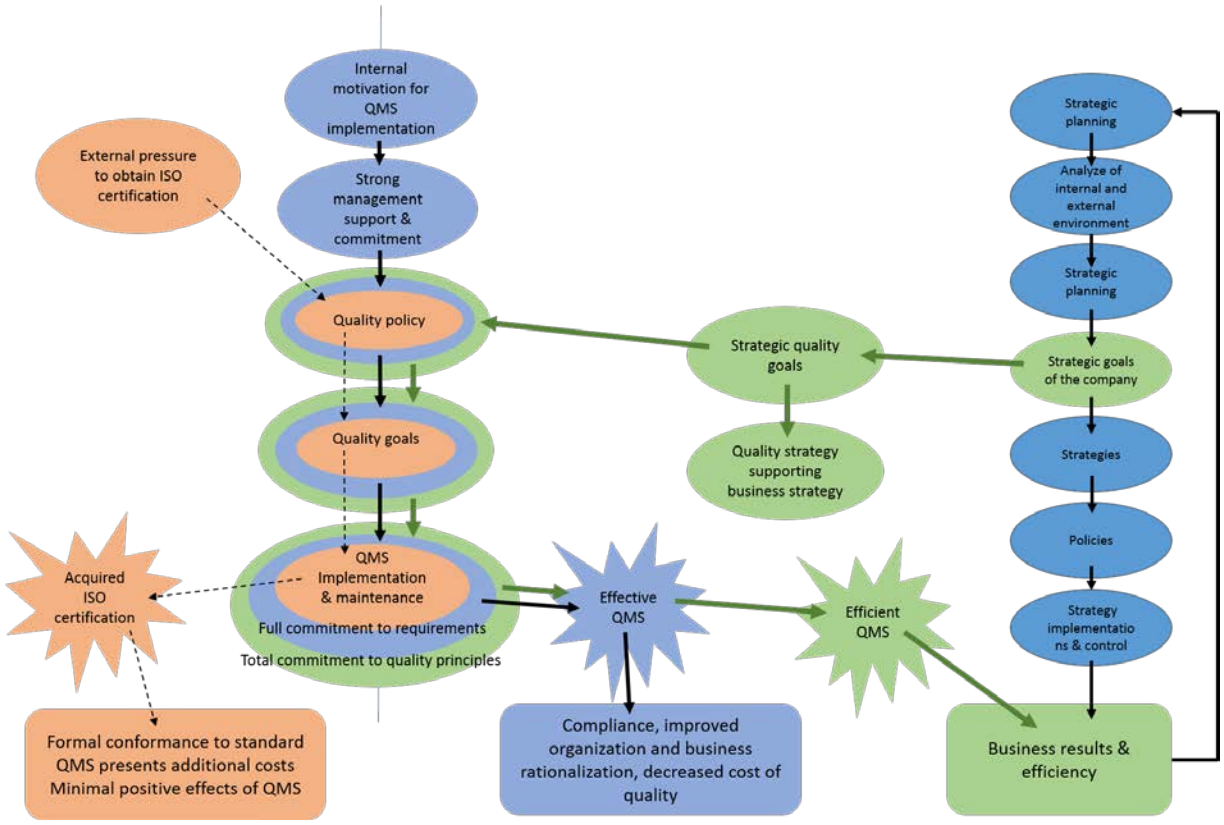

Figure 3.4: Theoretical model showing three different outcomes of having a QMS, depending on the level of integration in the organization (Alič and Rusjan, 2010b).

It is important to emphasize that a QMS cannot solve an organization's problems by itself, but rather help to identify error and waste and provide the opportunity to work more efficiently (Papassavas et al., 2015). The QMS will highlight different areas that in turn could provide an organization with the opportunity to reduce variation in the execution of processes, thus improving quality (Adanur and Allen, 1995). To reach high performance it is not enough to aim at fulfilling requirements set by ISO, but rather to go beyond what is demanded and capitalize on that (Prajogo, 2011), by doing so the QMS can be used as a foundation for continuous improvement (Adanur and Allen, 1995).

3.6 Sustaining a QMS

In order to get the QMS to cater the needs of an organization and gain the most benefits from having it, it needs to be a living system that evolves and not be seen as a collection of documents. The system should be a part of the actual organization and change with the business (Rosam and Peddle, 2009). As stated by Ong et al. (2015) the performance of the ISO 9000 QMS depends on the people using it, meaning that they are the ones that need to believe in its benefits and change their way of working. Sustaining the QMS over time therefore relies on the improvements of individuals' perceptions of the QMS and what it can generate (Taylor and Wright, 2003).

3.6.1 The importance of audits

Auditing the QMS on a regular basis helps the system to stay alive (Rosam and Peddle, 2009). An audit is when internal staff or an external auditor reviews the QMS with the aim to assess its performance and identify improvement areas. Mouritsen et al. (2000) use the analogy of a well-oiled machine to explain the function of an audit, where the ISO management system acts as a "managerial technology" which enables the machine to run better. In this perspective auditing is the same as testing and checking the machine to ensure it functioning in a desired way. By performing audits organizations can identify and correct non-conformities, hence improve performance

Depending on the drivers for implementing a QMS, companies have different purposes and expected outcomes of the internal audits, hence utilize the audit to different degrees. Companies that implement ISO standards mainly to get certifications tend to perform internal audits to maintain the certifications, which seldom lead to improved efficiency and effectiveness in the organization. Consequently focus lies on checking for non-conformities. As stated by Dittenhofer (2001) in Alič and Rusjan (2010a) using internal audits with this purpose often leads to extra bureaucracy.

3.6.2 How to make audits attractive

A way to make internal audits attractive and beneficial is to use them for address manager's already existing needs (Alič and Rusjan, 2010a). Focusing on prevention can assist in shifting the purpose of internal audits from checking compliance to see it as a beneficial management tool resulting in continuous improvement. This can also identify potential corrective actions and preventive actions (CAPAs), hence lead to improvements both for the QMS as well as for the business' overall performance. Audits that focus on being preventive instead of only inspective

are often found in companies with a mature quality culture and an internal motivation for the QMS. This motivation and believe in the QMS seem to result in a wider view of internal audits making it more strategically integrated. In these organizations quality objectives are often linked to the strategic business goals (Alič and Rusjan, 2010a). The model in Figure 3.4 shows possible business benefits of internal audits by showing the importance of connecting strategic goals to the QMS and the internal audits. The model also shows the relations between motivation, implementation, expected benefits, objectives and results, which can help increase the understanding and motivation among managers. The developed framework can be beneficial to use in order to test what benefits the company can expect with the actual approach to the QMS and internal audits. It can also increase motivation which would bring even more benefits and integrate the QMS in a more strategical way (Alič and Rusjan, 2010a).

According to Alič and Rusjan (2010a) it is of great importance to get top management involved in internal audits in order to achieve the most out of it and by doing so they can experience its positive effects and get a better understanding of its value. Hernandez (2010) also stresses that using audits when implementing QMS increases engagement and motivation among employees. To keep a high motivation for the QMS and audits it is important that managers continue to show their support, communicate expectations, treat results from audits in a serious manner, act on findings and do follow ups (Alič and Rusjan, 2010a).

3.7 Attitudes regarding QMS

After interviewing employees in different ISO certified companies regarding attitudes, opinions and support for certifications Boiral (2003) identified three different groups of people; ceremonial integrators, quality enthusiasts and dissidents.

3.7.1 Ceremonial integrators

The majority (40 %) belonged to the Ceremonial integrators, characterized by mainly wanting the ISO certification as a marketing tool and not as a tool for internal improvements. In other words they implemented the quality management systems as a response to external pressure and to keep or acquire new clients, rather than to improve actual quality practices within the organization (Boiral, 2003). Employees felt that the implementation was imposed on them, and usage of the QMS was limited. The lack of commitment for ISO in this group did however not affect the fulfilment of the standard requirements, since the importance of having the ISO certification from a business point of view was well understood (Boiral, 2003). This outlook on ISO 9000 certifications tends to emerge when external pressure on getting a certification is so intense that the stress of getting a quality management system in place overshadows other possible internal benefits that can derive from such an implementation. Due to not fitting the system to the organization's needs it became a superficial adoption that only got attention prior to audits, to ensure that everything was updated and in place (Boiral, 2003). 70 percent of this group worked in service companies which might indicate that the standards still is better suited for manufacturing, due to the fact that it originated from that industry.

“Implementing the standard was done more to prove to outside people that we have good process control than to have good control itself. To tell the truth, the standard wasn’t implemented to

improve our work practices (manager in an ISO 9000-certified industrial SME" (Boiral, 2003, pp.726).

3.7.2 Quality enthusiasts

The *Quality enthusiasts* (36%) had a broader view on the ISO 9000 system and what it can bring to the organization. They shared the previous groups opinion on that certifications can bring commercial advantages, but they do not just look upon it as a marketing tool. To them it was clear that the system was useful for the organization and could result in savings, better management practices, cost reductions etc. Furthermore it raised quality awareness among employees. The structured approach that comes along with the standard also eased the implementation of quality principles such as documenting, traceability, monitoring and also reduced errors.

"The standard has had a positive impact on our practices. For example, it is really important to have an efficient quality control process when we subcontract for pharmaceutical companies that have strict standards. The ISO system helps us to monitor the products better" (manager in an ISO 9000-certified service SME) (Boiral, 2003 pp 727).

In order to reach this level of utilization of the QMS the organization needs to believe that the system is relevant for them and that employees are convinced and support the implementation. To get this commitment is however a difficult task. How the implementation is carried out is also of great importance for its success, which can be seen in the interviews of the study done by Boiral (2003).

"It's the personnel's involvement and motivation that makes the difference (quality specialist in an ISO 9000-certified industrial SME" (Boiral, 2003, pp 727)

3.7.3 Dissidents

The last group called the dissidents (20 %) was clearly and openly against the implementation of ISO 9000, since they felt that the standard was like an "iron cage" hindering them in their work, hence leading to no good. They did not share the belief in that the certification could result in commercial advantages and the impression was that the negative effects outweighed any possible benefits. This lack of commitment and support among employees lead to resistance when adopting the standard. A reason for this can be that the management in these organizations put no effort on adjusting the QMS to the fit already existing practices and show little commitment to the implementations. It was also considered too bureaucratic.

"There are people here who don't follow the procedures and who don't want to write them down. There are others who don't want to see the auditor. Basically, we don't want anything to do with the system" (employee in an ISO 9002-certified industrial SME) (Boiral 2003, pp 728).

"The people here don't even know where the ISO documentation is. They don't need to, because they know what they have to do "(employee in a large ISO 9002-certified service company) (Boiral 2003, pp 728).

Important to mention is that the role in the company the employee held had an impact on their opinion of ISO 9000. People responsible for quality were in general more positive than other managers and personnel. Such an implementation does however not only concern quality management, but due to the fact that ISO 9000 needs to be integrated in the whole organization the involvement and commitment of other roles are vital, making it important to consider opinions, support and resistance within the whole organization in the implementation. However, almost half of the respondents expressing that they were enthusiastic over the implementation was quality specialist, which indicate that the superficial adaption to the standard is probably more common among other people (Boiral 2003).

3.8 Summary of Critical success factors

When organizations implement a QMS and get a certification merely to improve organizational image, they risk not exploiting the QMS to its fullest potential (Boiral, 2003). The QMS itself seem to have little impact on employees in the organization, and not being used as an improvement tool (Sedevich Fons, 2011). Consequently, fundamental areas in quality such as customer satisfaction can end up getting less attention leading to missed profit and negative effects on long-term growth.

Furthermore, employee motivation is of great importance and lack of it can act as a barrier when implementing a QMS (Ali and Kidd, 2013). Boiral (2003) also stresses that commitment of personnel is crucial for a successful implementation. In addition to that Poksinska et al. (2002) mention middle and top management support as crucial factors. Absence of quality motivation and support is often due to lack of knowledge and a poor understanding of the purpose for implementing a QMS as well as its benefits (Sedevich Fons, 2011). Sedevich Fons (2011) also shows that companies that measure the actual outcomes achieved by having and using a QMS tend to exploit the system more frequently. Borial (2012) also stresses that whether a management system is used for marketing purposes or as an improvement tool it becomes what the company wants it to become.

4. COMPANY INFORMATION

This chapter presents the case company, the local market site as well as internal processes relevant for the local Quality Management System. The aim is to provide readers with information needed to understand the context of this research and to create an understanding of the environment where the company is operating.

4.1 General information

Mölnlycke Health Care (MHC), founded in 1894 was originally a weaving mill that produced gauze for the hospitals located in the west region of Sweden. Today, MHC has about 7 400 employees and develops, manufactures and distributes medical devices, biocides and pharmaceuticals to the entire world. The head office is located in the west region of Sweden, in the town Gothenburg, with sales offices and productions sites around the globe.
The medical devices are products for both surgery and wound care. The company's surgical product portfolio includes a wide range of products that are used for protection and infection control of personnel, patients and surfaces in the operation theatre such as gloves, gowns, drapes and instrument drapes. This also includes procedure trays, which are packages containing all the sterile single-use products that are used for surgical intervention. In the wound care portfolio MHC carries a wide range of advanced wound care dressings, wound cleansing products as well as negative pressure wound care therapy and electrical wound care products. When it comes to pharmaceuticals they have products for infection control of personnel, patients and surfaces e.g. antimicrobial hand washes and surgical scrubs.

4.1.1 Regulatory and Quality Affairs

To ensure that the products being produced meet regulations and requirements as well as comply with standards such as ISO 9001 and 13485, MHC has a department responsible for regulatory and quality affairs (called the RQA department). By focusing on quality, the company aims to fulfil following objectives:

"We will improve the quality and efficacy of our products and we will reduce defects in our products and services by means of effective complaint management, product surveillance and corrective and preventive action management, as well as effective and efficient research, development, manufacturing, distribution and supporting processes in order to achieve outstanding solutions for our customers and end-users. We will continually improve our operations and our marketing and sales processes in order to meet and exceed customer satisfaction, maintain compliance and reach business excellence. We will maintain, expand and further improve pragmatic and transparent management systems as the documented evidence of our continual quality improvements."

4.1.2 The Global Management System - Succeed

To manage work related to quality and to achieve the quality objectives stated above MHC has developed a global management system called Succeed. Succeed was launched in 2011 and is managed by the RQA department. The management system describes all the global processes at MHC and is divided into three core processes; Develop Customer Solutions, Provide Customer Solutions, and Manage Customer Needs. In addition to those there are management processes to

govern the core processes and supporting processes such as HR and quality. Succeed is based on ISO standards and other external and internal requirements, and contains policies, processes/procedures, work instructions, internal guidelines and role descriptions. The processes are visually mapped and describe main activities, roles and how the different processes interact with each other.

4.2 The local market site

The local site, named Region North, is responsible for sales and marketing in Sweden, Norway, Denmark, Finland and the Baltic states. It is an umbrella organization that acts as a service function for the countries as well as the link to the global organization. In total they are approximately 90 employees, spread across the different countries, however the main organization is located in Gothenburg, in the same building as the global headquarter.

The site is responsible for ensuring its strategic development by converting the global strategy, with respect to the different countries, and develops it into a strategic long-term plan. The site thereby has the overall responsibility, but it is the countries themselves who execute the plans, launch products, see to that those products are procured and end up in tender contracts. However, the local site needs to make sure that the markets get the right products, at the right time; at the right price and that they have contracts for tenders.

Furthermore, responsibilities include; employee training, and communication of information about products both during personal meetings and in marketing material. The local site should also see to that there are processes for how to deal with things such as pricing, tenders, complaints, validation and approval. They also need to secure that there are processes for how opinion leaders should be contacted to avoid conflict of interest with tenders.

4.2.1 Customers and customer satisfaction at the site

The local site's customers can be divided into two categories: purchasers and users. The purchasers are counties, hospitals and distributors, buying via tenders or orders. The users are the hospital personnel handling the products and also the patients, who are the end users. Every year a customer survey is sent out to customers, with the objectives to better understand the customers when it comes to areas such as drivers for satisfaction, loyalty and performance of MHC over time. The findings from the survey point to that the customers' key priorities for health care suppliers are; that they are compliant to regulations, allow easy ordering and deliver as promised. Their drivers for satisfaction were found to be; responsiveness to which enquires are met, product support given by sales representatives and combined with training and clinical knowledge, and lastly the ability from sales representatives to react proactively to changes. If these drivers are delivered by the company these are likely to ensure advocacy by the customers.

According to the survey MHC is highly appreciated as a supplier, hence high performance scores from both users and the purchasers. Two out of three gave MHC a score of 9-10. MHC is considered a high end brand, but from the survey it can be seen that the cost-efficiency relationship is portrayed in MHC's advantage, with a 7.55 score out of 10.

4.3 Processes for the QMS

The local site operates as its own organization in many aspects, with a lot of different processes and activities. The following processes have, together with the general manager at the site, been pinpointed as the most crucial for quality and the ones that primarily will be included in the local QMS. To get an understanding of what the site does on a regular basis and to be able to analyze the current state the following processes will be described: tender process, sample handling, marketing approval process, complaints handling, market distributors' agreement, field safety, corrective actions and supporting processes.

4.3.1 Tender process

The tender process is one of the most important processes at the local site. To quote an employee "Our whole existence is made up by the tender process". This is due to the fact that they operate in the healthcare industry which is built upon procurement. A tender is a process used by the government or publicly owned instances when they are procuring goods and services and it is regulated by laws, in Sweden it is covered by "Lag (2007:1091) om offentlig upphandling". All the goods bought for public hospitals in Sweden go through a tender process in order to ensure that every company is treated equally. The Swedish law states the following Principles of public procurement (directly translated to English):

- The contracting authorities shall treat suppliers equally and non-discriminatorily and shall conduct procurements in a transparent manner. Further the principles of mutual recognition and proportionality shall be regarded for the procurement.
- The contracting authorities should take into account environmental and social considerations in public procurement on the nature of the contract so warrants. (SFS 2010: 571).

The process at the local site and especially the Swedish part of the organization, can be divided into four steps; pre-tender phase, the tender process, post-tender and capitalization. In the pre-tender phase the focus is on influencing the tender specifications before it gets published. This determines to what extent MHC's products will match the tender. Since specifications cannot be changed after the tender is published it is important for the account managers to be proactive to ensure that tender demands become beneficial for MHC. The tenders often consist of "need to-" and "should- demands". In order to be considered for a tender all the "need to" demands must be met, but if you also fulfil "should"- demands it can result in extra points which will increase the chance of winning. Since MHCs products compete on functionality rather than price it is beneficial to get a tender where they can fulfill many "should-demands".

When Region North has registered for a tender, step two of the tender process begins. During this phase pricing of products is decided upon and documents needed for the tender are sent in. These documents can be everything from quality and environmental certifications, code of conduct, economic safety to a text that specifically answers the tender requests. Depending on what county and what kind of procurement it is the documentation requirements varies. What to send to which tender and how to handle the documentation was identified as a weak link in the process since there only is one employee in the Swedish organization with this knowledge.

After everything is sent in the post-tender phase begins. During this time it is decided who of the competitors that will "win" the tender. Once a deal has been made the last part if the tender

process can start, were they capitalize on what they have “won” and also strategize for the future. The strategy is created by the sales manager together with a key account manager and it entails plans for how to sell the most products. A contract from a tender runs over four years in Sweden, and since there are 21 counties with 15 tender processes this work is continuously done over the year.

In Succeed there is a global process for tenders that the site seem to work according to. There is also a lot of developed training material explaining how the site works with tenders. Where to find this material is however less clear since each employee involved in the tender process has the material in their own personal storages, such as computers, and there is no common place where everyone can access it.

4.3.2 Sample handling

A sample is a test product given to the customer by a company to promote it as well as to give the customer the opportunity to try it before buying. The sample can be either full size or a smaller version of the real product. For Region North sample handling is a supporting process to the tender process. Account managers in the different countries are meeting customers on a daily basis to present products and increase sales. In order to ensure that samples for clinical use are being handled in an appropriate way MHC have developed a guideline that outline the recommended way of handling samples for clinical use from sales organization to customer.

By following the guideline regulatory requirements are met. It ensures that preparation and packing of samples for clinical use are carried out in an appropriate environment in line with existing procedures and that they get adequate protection during transportation and storage, thus to avoid contamination. Furthermore it makes sure that samples are traceable which is important if a field safety corrective action (FSCA) is necessary and the product needs to be recalled. When samples are intended only for demonstration purposes there are no specific requirements for the products. However, they shall always be labelled “SAMPLE - NOT FOR CLINICAL USE” to minimize the risk of it being used on patients. This guideline is about to turn into a procedure, hence something that the site needs to follow.

Both the surgical and the wound care divisions are aware of the guideline regarding samples. However the way samples are handled at Region North differs between wound care and surgical products. Region North have a central warehouse in Europe where all samples are ordered from. By doing so it ensures quality in many aspects, the correct version is sent out and hygiene requirements are being followed. Due to that they need to have traceability in everything used for clinical practice the surgical department have developed a process where samples are sent directly from the warehouse to the customer by express delivery, meaning that traceability is controlled from the warehouse.

The wound care department also orders samples from the central warehouse, but the process used for surgical product is only applicable for wound care products when they plan larger tests together with customers. This has to do with that each dressing has a high cost and if full cartons are sent out of those products to the customers every time it would get very expensive. To address this and follow the guideline they have developed a process where they write down necessary information about the samples in a book. This however has been received with some

resistance. In order to be fully compliant to the internal guideline provided by HQ there need to be a system that works in practice. Account managers already have a CRM system in their iPads where they need to document a lot and feel that this sample process increases the administrative tasks too much. Currently there is an investigation going on to find a better system.

4.3.3 Marketing Approval Process

Marketing plays an important role for any selling organization. At Region North it is supporting the sales process with everything from material for new product launches to material for the tender process. The site has a regional marketing team as well as marketing personnel in the different countries. The regional team is responsible for the strategy and the local personnel for execution. Much of the material that is used at Region North comes from the global marketing department. This ensures that material is correct from a regulatory standpoint and also that the company guidelines for e.g. branding are followed. To make sure that all the material that goes out from MHC is correct there is a newly developed global process in Succeed called “Update or Develop Marketing Material” that should be followed by the whole organization.

4.3.4 Complaints handling

Since MHC is a major provider, manufacturer and distributor of healthcare products to hospitals and healthcare organizations, they sometimes have to deal with complaints. A product complaint can be any written, electronic or verbal communication that declares defects related to the identity, quality, durability, reliability, safety, effectiveness or performance of a product after it is released for distribution. Globally, MHC has a process for handling complaints and all markets shall be aware of the process to ensure it is handled in the right way in the whole organization. The process can be found in Succeed, where all employees have access and there is currently an initiative from Global RAQA to get all employees to complete a Complaints handling training carried out through the learning platform LMS. The training is a self-instructed interactive web course taking a half hour with the objective to:

1. Understand what a product complaint is
2. Understand why it is important to report a product complaint
3. Know your responsibilities and how to act on product complaints
4. Know how and what to report about product complaints

If the complaint is regarding a product the information can be in the form of a mail, an email, a physical product being sent to the site, or a phone call. If there are service complaints they are usually reported by mail, email or a phone call. The complaint is then registered in a software system, then the complaint and the potential product is sent to vigilance, who coordinate it and the investigation is then done by the manufacturing department. Once the analysis is done Region North gets the answer and conveys it to the customer. This is a time consuming activity since it can be difficult to find a root cause and explain that in a customer friendly way.

To control their complaints, Region North tracks all of them in a monthly report. They use an excel sheet that shows the status of the complaint, for instance information about when they got registered etc., to ensure that the complaint is answered as soon as possible and to make sure that no complaint is forgotten.

4.3.5 Market distributors agreements

In Sweden, Region North has around 40 distributors, organized into 4 clusters; medical, county councils, municipalities and private. Generally speaking the Swedish market is dominated by a few big distributors, resulting in that 90% of total sale derive from 10 distributors.

The Swedish marketplace is fairly matured and is not characterized by rapid changes. The majority of distributors have been distributors for a long period of time and as of today all bigger ones already sell MHC products. New distributors that show an interest in selling MHC products are of interest, but there is currently no effort put on actively seeking new distributors, as compared to other markets such as Africa and the Middle East. The business is very much about retaining good relationship and to build trust. Activity plans are often carried out together with distributors and MHC offers adequate training regarding their products in order to strengthen sales performance.

In Succeed there is a process for how to choose and evaluate new distributors called "Select Market Distributors". This process is followed by Region North when applicable; however the impression is that the contract from Succeed, which they are supposed to use with distributors, often feels overly complicated and that the resources provided to reach an agreement are insufficient. Even though the contract touches upon important areas such as how to handle product complaints, adverse events and recalls as well as commercial requirements such as prices, campaigns, activities and sales statistics it is not adapted to fit the needs at Region North. As of today the contract consists of 19 pages with different points that both parties need to agree upon and are designed in such a way that it can be suited for all kinds of markets.

4.3.6 Field Safety Corrective Action

Field Safety Corrective Action (FSCA) is a global procedure in Succeed that needs to be followed. The process is used if there is a product on the market that possesses a serious non-conformity and all products need to be recalled. If there is a situation where a recall has to be made, the site has to provide support to the global office, which in turn is responsible of the recall process. This support is given by the product managers at Region North and they provide the global Vigilance team with information regarding for example; what customers that might be affected by the recall as well as their email- and contact information.

When Region North has done this it is the Vigilance team that takes over coordination and traceability. They prepare a letter with information to the customers in English and Region North is responsible to translate it to the local language. The Vigilance team then traces down the recalled products at the customers and sent out the letters and handles the process further.

4.3.7 Supportive processes

The site also has many supportive processes such as; IT, HR, Supply chain and Finance. For the most part of these processes Region North follows the global processes and they do not have to be localized, and are therefore not addressed in this research.

4.4 Local Market QMS assignment policy

The local market QMS assignment policy, used during the gap analysis, was developed by the global quality department to ensure that local sites comply with internal and external requirements. The policy is built on ISO 9000, ISO 13485 and the global QMS Succeed. It should be followed by all local market sites and is helpful when developing and implementing a QMS. The policy addresses nine different areas; General requirements, Local requirements and regulations, Quality management system, Human resources, Distributors, Subcontractor and Suppliers, Customers, Contracts and Pricing, CAPA and Complaints Handling, Market communication, Information Technology.

The general requirements in the policy states that the site should have an implemented QMS and continuously improve their business. This should be controlled and maintained by the local site manager. The site should also have processes in place and responsible personnel in connection to management reviews, recordings, solving non-conformities and conducting local internal audits, should be appointed. The global processes should be followed to the extent that it is possible, and if local procedures need to be developed, they should be taken into consideration to ensure compliance. In 2014, general managers, in all local markets signed a contract stating that the sites should be compliant to the Local Market QMS assignment policy

5. EMPIRICAL DATA

In this chapter empirical data relevant for the analysis is presented. It enfolds the performed gap analysis, the benchmark with other local market sites and a compilation of interviewee responses regarding QMS motivations at the local market site.

5.1 The Gap Analysis

To understand the current situation at Region North and determine how well they comply with the local market quality management system assignment policy and relevant ISO requirements, a gap analysis was performed. This subchapter aims to present the identified gaps in the areas of quality management system, human resources, distributors, CAPA, complaints handling, marketing communication, FSCA and IT. The gaps are named with letters from the Latin alphabet combined with numbers to distinguish different areas and gaps from each other, e.g. gaps regarding the Quality management system are named A1-A7. These names will be used throughout this report. The complete gap analysis report can be found in appendix B. Actions together with prioritizations for closing the gaps are presented in Chapter 6.

5.1.1 Quality management system

Since the QMS is not yet implemented at the local sites there are several identified gaps related to the QMS itself that needs to be addressed in order for the site to be complaint to ISO 9001:2008.

A1	**No local quality manual**
A2	**No quality roles appointed**
A3	**No management reviews**
A4	**No quality goals**
A5	**Little awareness of the QMS assignment policy**
A6	**No process for document control**
A7	**No local internal audits**

5.1.2 Human Resources

The Human Resource (HR) function at Region North constitutes of one full time employee. In addition to HR responsibilities this function was previously also responsible for the quality tasks at the site. In recent years, this position has had a high turnover in personnel, which in turn has affected tasks such as ensuring updated job descriptions, which is requested in order to comply.

B1	**Outdated job descriptions**

5.1.3 Distributor, subcontractor and supplier

Region North has few suppliers, that has no or limited impact on quality. When it comes to distributors they have a greater impact on customers, thus these gaps hold a higher priority. The following gaps need to be closed in order for the site to meet the requirements, hence deliver the best possible quality.

C1	**No local process for controlling suppliers**
C2	**Uncertainty regarding who should sign distributor contracts**
C3	**Contracts in Succeed not always used**
C4	**No list of distributors**

5.1.4 CAPA and Complaints handling

All product and service complaints are handled according to the Succeed Non-conformity Management Process. There is no need for a local procedure and people share their experience orally. Every month the Complaint coordinator provides a report with all registered complaints in SAP, along with their statuses and other related information. However, the complaints training provided by the global office has not been completed by all employees at Region North yet. When it comes to the CAPA process there is a gap regarding, probably due to that the site has not worked with CAPA's in a structured way prevously. The closure of these gaps will ensure excellent complaints handling by the site, thus have the impact to increase customer satisfaction.

D1	**Poor knowledge of CAPA**
D2	**Insufficient complaints training**

5.1.5 Marketing communication

When it comes to market communication, Region North is well aware of the newly develop Marketing Communication Process accessible in Succeed. There is also a willingness at the site to improve within this area. Due to the fact that Region North has many different markets under its umbrella the marketing manager has initiated a project aiming to make the process more applicable for Region North. This work will result in a PowerPoint presentation explaining the process in a more practical and relevant manner.

E1	**Marketing approval process**

5.1.6 FSCA

The understanding is that Region North follows the global recall process. Even though the process seems to run smoothly no one is appointed responsible for it. Traditionally the product managers have been in charge of recalls in their product range. Since recalls are a rare there are no local procedures on how to proceed and the site relays on the global process and support from the Vigilance team.

5.1.7 Information Technology

In the area of information technology no non-conformities were found. Region North is compliant with the IT process in Succeed and the Software Validation Policy.

5.1.8 Other gaps found

During the investigation of the current state of the site it became apparent that sample handling is an area where the site can improve. The guideline provided by HQ is as of today not followed in full, due to that it is very time consuming and requires a lot of administrative work from the sales people.

O	Sample handling

5.1.9 Summary

To summarize the following can be said; Region North has the willingness to be compliant with the "Local market QMS assignment policy" as well as to improve their business overall. There are some gaps that are more urgent than others and this will be analyzed in the next chapter.

5.2 Quality Management Systems at local markets sites of MHC

To learn from other local QMS implementations at MHC an internal benchmark was performed with the sites in Iberia, France and Canada. The objectives were to investigate the reasons for implementing a local QMS, its development and implementation.

5.2.1 Motives, development and implementation

The different sites all felt the need to implement a QMS due to external pressure for certification; but some internal drivers were also identified. At the Canadian site there was a need for a local QMS in order to be compliant with regulations in Canada but they also sought a better structure regarding internal documents, hence improve efficiency. The site in Iberia already had a QMS but it was considered insufficient and they wanted to improve it in order to differentiate from competitors. They also felt that it could improve employee commitment. The French site wanted an ISO certification in order to be more attractive as a supplier but mostly to be compliant with regulations in France.

Regarding the development of the QMS, the sites in France and Iberia developed it based on ISO 9001:2008 and ISO 13485. They started their QMS work by defining and writing procedures and objectives. After that, personnel received training in the procedures, where to find the QMS, why it was important as well as in their responsibilities. In Iberia the implementation of the QMS was done gradually in order to avoid it becoming overbearing to the employees and have a negative impact on the site.

The site in Canada used guidelines from the official regulation body in Canada, called Health Canada, and used an external consultant in the development and implementation process. To

improve and make the site compliant with Canadian regulations they too performed a gap analysis and used that as a base for the development of the local QMS. They started out by solving non-conformities to the regulations from Health Canada. Even though the Canadian site tried to close their gaps themselves many of the non-conformities also needed to be handled by the global organization. Mapping of processes and the implementation took almost a year for this site.

At all the benchmarked sites the QMS can be accessed through an online system called SharePoint. In Canada they also have a hard copy at the quality manager's desk. New procedures are implemented gradually and the QMS is under continuous improvement. According to the quality managers in Iberia and Canada their QMS' are used daily by the employees.

5.2.2 Employee opinions

At the Iberian site the employees had no formal introduction to the QMS. Since it is such a small site it was decided that there was no need for it. Therefore the local QMS was met with confusion among the employees at first. The quality manager said "In the beginning they were lost about the true meaning of a QMS but gradually they started to understand what it is, how it works, where to search, what is important etc.". In Canada there was more of a sense of urgency among the whole organization, due to an audit showing non-conformities. The QMS were therefore received with excitement from the employees because they understood that it could help them with the site's quality issues.

5.2.3 Effects from implementing

In Iberia the effects of the QMS were not measured but the quality manager described the changes at the site in the following way "People believe in the QMS now, they don´t think that it is only something that needs to be done to obtain a certification, it is something that really helps and supports them, our company and their sales". The changes that have been made are for instance new processes for both sales and marketing that aim to make the site's daily work easier. There is also less variation in how the business is handled and a perceived marketing benefit to have a certification. They try to promote it as a unique selling point and hope to win tenders with it. Today the system is stable, used by everyone and has the support of both managers and employees.

In Canada they could easily measure the success of the QMS due to that they had an external inspection that showed non-conformities prior the QMS implementation. The quality manager said that "In 2013 we got our second audit and I'm happy to say that it didn't show any non-conformities, just two observations". For Canada the implementation became very successful for the company, hence the employees were motivated to use it and keep it updated. They also understand that they have to follow regulations, both external and internal.

The French site got their ISO 9001 certification due to the QMS, which was the main objective for implementing it. The person responsible for the implementation moved to a global position within the company after the implementation and there was no new quality manager appointed until recently. This affected the maintenance of the local QMS and the system is not considered to be alive at the moment.

5.2.4 Lessons learned

According to the quality manager in Iberia, she would not have done anything differently when it comes to the implementation of the actual QMS. However, she stressed the fact that it is important to make employees understand why the implementation is taking place. She focused on making it clear that a QMS will help to improve their way of working and will be useful for retaining and getting more customers. She also highlighted the fact that a QMS is very important for sales and marketing since it helps when "...they receive, record, and treat offers, it also drives the satisfaction survey related with marketing up, it makes the process for product complaints related to sales clear, there are a lot of important points in quality related to sales and marketing".

The quality manager in Canada talked about the importance of audits, and stated "Having internal audits is something that I think every local site should have". The internal audit that the global office performs keeps the system alive and provides opportunities to improve processes as well as the business. They also provide time to focus on quality and improvement work. The quality manager also mentioned that it is important to "celebrate success".

Except from the current quality manager in France, not many employees at this local site use the global QMS Succeed. He said that in order for the global and local QMS' to be used more by local sites there "Needs to be opportunities to archive it properly for local sites to use it". The quality manager also mentioned that it is important to remember whom the QMS is supposed to support, stating that "Marketing personnel is not the worst, but for salespeople it does not come naturally". There is a need to explain to the employees why they would need a QMS and also what it could provide. For marketing personnel, the quality manager pointed to that there "needs to be proven results and also realization that working with quality can make their life easier, their worry is time, for instance graphic chart takes time…".

For sales people it is important to "have clear guidelines and benefits to encourage them to want to do it and it needs to ease their work and not feel as a constraint". The French quality manager encouraged that when developing a QMS or making any changes it is important that the change agent "go and meet people, have a supportive mood, and identifies fear". A tip from the quality manager was to ask people for instance "what are your three worst topics for the moment? Then say how the QMS can help".

To get people involved the change agent needs to be concerned with what is troubling the employee at the moment and build on that. Just telling people what will change and what will improve in the future will not be as effective as focusing on the current state, according to the quality manager. By focusing on the current state, the employees can be incorporated in the development and by that help to achieve the improvement for the future. To sum up the quality manager says "one needs to turn them [the employees] around and make them understand how it actually will help them, put extensive resources on training and make sure to explain why".

5.2.5 Quality mindset

The knowledge of quality and quality work was varying at the different sites. According to the quality manager in Iberia the employees were aware of quality and how it affects their work prior to the implementation. The knowledge about Succeed and the global quality policy were however not extensive before the local QMS implementation. The QMS have now increased their knowledge regarding quality and continuous improvement. It supports them in their work and they feel more involved than before. Unlike Spain, the local market site in France did not have an extensive knowledge of quality at the site prior to implementation. After the implementation the employees got more involved but since the main goal with the QMS was to achieve an ISO certification little effort was put on maintaining the quality awareness.

5.3 Quality Awareness at Region North

Region North is always striving to improve their business by setting up local targets that they follow up and take actions upon. Even though they have not implemented a local quality management system at the site yet, the measuring of business objectives already leads to qualitative improvements. It is apparent that the site wants to improve their business and provide the best possible service to their customers. Customer surveys are carried out periodically to measure performance and customer satisfaction. The results are often compared with results from previous surveys, and thus becomes a way of measuring improvements.

Even though Region North has a desire to deliver high quality to their customers, quality in their processes has gotten little attention until now. This is noticeable by this quote from the general manager at Region North "I have never received an introduction to the Quality Policy, and I have not introduced it to anyone either". The site has no stated quality goals but the general manager talks about quality objectives connected to the following areas:

- Product evaluations
- Marketing-follow up
- CRM-follow up
- KPIs for product introductions

She continues by explaining that "Quality in meeting customers is to deliver the best possible customer experience in terms of service, logistics, training etc. This can be achieved by educating and providing employees with the right tools”.

For most of the employees at Region North the quality awareness and how it affects processes is in the same state as the general manager’s. An employee states the following: “Succeed has only been used by a few, some have never even been in it and looked at the processes presented there” and another employee says “What Succeed means for me… well I’m never in there”.

Since Region North operates in the healthcare industry there are a lot of requirements to fulfil, but there has been no external pressure for implementing a local QMS or getting an ISO certification. Instead, the site has relied on the global certification but since it has been proven that a local certification now is needed this issue has become a priority.

5.4 Motives for implementing a Quality Management System

The importance of employees' thoughts and feelings about upcoming changes cannot be emphasized enough. With the coming implementation of a QMS at Region North the employees were asked what could motivate them to implement and then use it.

5.4.1 Internal motives

The first thing that was noticeable was that everybody stated that it would be motivating to work with the system if the QMS could ease their workload and free up time. An employee stated that "if you can get the system to make it easier for me and make it faster for me to work it would definitely be motivating". Some employees also connected it with business goals stating "It would be motivating since I could have more time to work with other stuff. It would be amazing if everybody knew what to do and who did what, it would create a calmness and responsibility that would allow us to focus on what we are actually here to do, which is to sell more". On the same note another employee said that "if I can see that it could affect my business in a positive way then it's also incredibly motivating, as I am result oriented. That is almost the most motivating".

Another area of motivation was related to getting structured processes that describe how certain tasks is supposed to be managed, related to time and order. An employee emphasized that "It should be easy to find and to search for relevant processes that are well written and provides an oversight to what should be done. It should help with the daily work and it should not be hard to find the stuff that is needed". Today they feel frustrated when they know what they should do but are not given the proper amount of time to follow the process. If the QMS could provide them with processes that make it clear how to do things it would make them more confident in their work.

The knowledge that a process is well designed is also motivating, since this means that wasteful activities are avoided or removed. An employee express that "It's motivating that there may be a QMS, where the most efficient process is calculated. It feels good to work with an optimal process. No one should do a lot of unnecessary things, and a process may lead to that you don't have to do a lot of things in vain, because the process is well planned and optimized".

Another important area that many of the employees talked about as motivating for the upcoming implementation was to make the organization more robust and less people dependent. An employee stated, "If certain people here were to go into the hospital or something, the entire business would fall apart". Another said, "If something happens to someone, for example, an accident, we might have to close down! It is a fact that you need these procedures written down to make sure that we are not only relying on only one person". The following example given by one of the employees sums up the situation." For the tender process you have to rely very much on the documents being submitted, and if anything is missing then we may not be considered for the tender. You have to rely very much on people around you and there is no way for me to check if everything has been included. If my colleagues that possess this knowledge about tender requirements been unattainable, I myself would have had no idea what to do".

According to a manager at Region North they are struggling with sub-optimization. He stated, "I believe that if we would implement a QMS we could be better at everything. Today we sub-optimize a lot and we learn a process in one way, and then somebody new comes along and learns it in a new way. We would get a more united quality and it would be easier for people to join the organization". A new employee also stated “As a new employee and also being new in the medtech industry, it is a little unclear who does what, who to turn to, and how the communication paths are made up… so if you through a QMS can get input that you are on the right track and make sure you do not miss anything, it would be good. You want to succeed for the company, but also for yourself”

Employees also felt that the QMS could work as a communication tool and see that as a motive for implementing. An employee said, “If something that is beneficial for quality is made in one country it would be good for the rest of Region North to use that as well, we do not want to invent the wheel again”. It could also provide knowledge of for instance where in a process a specific project is and that would ease communication barriers.

5.4.2 External motives

Since there is no requirement to have a local ISO certification in the countries where Region North operates, it was not mentioned as motivating factor for implementing the QMS. However, the business director stated that "If the tenders in Stockholm would start demanding ISO certifications I can promise you that it would speed things up here at the office".

Due to the fact that Region North is run as its own organization, pressure from the global organization can in some ways be interpreted as external pressure for the site. They monitor external changes and new stringent regulations from authorities and customers and translate it into internal requirements that the local sites should follow. As a result of this is they recently updated the process for “Update and develop marketing communication”. The global office was noticing that the European regulations were getting stricter, as a reaction to US regulations. This then called for an update to the global process, which in turn became an internal requirement. The employees of Region North understand the importance of following the global requirements and are in some ways motivated by that.

5.4.3 Concerns with the upcoming QMS implementation

There are some concerns regarding the upcoming implementation at the site. Many of the employees fear that the QMS will lead to additional administrative work. When asking if they have any concerns regarding the QMS an employee gave the following answer "Yes, and that is that there will be an additional task. Another must, on top of everything else. That it does not lead to that it will be easier for me to work, improve my business, easier to find things and so on. If I do not experience that, then I probably feel that it just will be an additional thing to do that won’t give me anything”. Another employee stated that "My only fear is that it will be too complex, we get so much information from so many places, we already have like 27 different log ins as it is...! It should not be to complex and bureaucratic, then it won’t be used”. The employees also mentioned that if the system is not updated or properly sustained it will become a burden for them. There needs to be a proper and efficient way to update it or else it will not be used. The system needs to be relevant for the site and it should not make their work more complex than it is today.

6. ANALYSIS AND DISCUSSION

This chapter aims to analyze the identified gaps and actions with the help of the theoretical framework. Furthermore, it presents an analysis of the level of motivation towards the QMS' implementation. The chapter also includes discussion points and ends with recommendations for further research.

6.1 Analysis of gaps and actions

In this chapter the identified gaps are addressed and related actions evaluated with an impact and effort matrix. The gaps are evaluated based on the requirements in ISO 9001:2008, since it will guide in setting up a well-functioning QMS (Evangelos et al. 2009). Comparing the gaps with the ISO standard will also provide a better understanding of the situation and what needs to be addressed to get closer to a certification. Furthermore, the actions will be connected to the potential areas of benefits presented by Alič and Rusjan (2010b) in Chapter 3, and supported by other relevant literature from the theoretical framework. The gaps are presented in the same order as in the previous chapter and they all follow the same structure, including a brief presentation of the gap, explanation of the rating in the matrix along with findings from the literature. The compliance to ISO is also presented and lastly the action for how to close the gap is presented.

6.1.1 The construction of the Impact and Effort matrix

The gaps presented in the last chapter have some different characteristics. To be able to compare them and guide the company regarding prioritization an impact and effort matrix was used. Impact was evaluated by considering the effects the action would have on customers, the whole company of MHC and the site, see Figure 6.1. These areas were chosen with the reviewed literature in mind. Customer satisfaction is highlighted in almost all of the reviewed literature as the most important criteria for excellent quality. Secondly, since much of the literature highlight the importance of tailoring the QMS to its future users, the company and the site was also chosen as stakeholders. Each area got a score from 0-3 and was combined to a total impact score. The same structure was used for evaluation of effort needed. The three factors that was evaluated were people involved, time needed and additional cost (e.g. external consultants needed).

Impact	Effort
Customer	People
Company	Time
Site	Cost

Figure 6.1: Description of matrix' evaluation criteria

As stated above the areas were scored from 0-3 with 3 being the highest, thus if a gap has the score 9x9 it demands the highest effort and holds the highest impact. The criteria and the score

limits were developed in collaboration with MHC in order to be relevant for the organization and can be seen in Figure 6.2.

Impact		Effort	
0	No impact	0	No effort needed for closure
1	Little to some impact upon closure	1	Effort for 1-3 persons, 1 day needed, small amount of money required
2	Medium impact upon closure	2	Effort for 3-5 persons, 1-3 days needed, medium amount of money needed
3	High impact upon closure	3	Effort for more than 5, more than 3 days needed, high amount of money required

Figure 6.2: Description of matrix' evaluation criteria

6.1.2 The Impact and Effort matrix

The evaluation was performed by employees of the quality department, which makes the matrix reliant on their perceptions and interpretations. The evaluation form can be found in appendix C and the matrix is presented below in Figure 6.3. It shows the spread of actions based on their impact and effort-scores. Furthermore, the size of the bubbles shows to what extent the gap and related action can be found in the ISO 9001:2008 requirements. This correlation is based on the authors' interpretation of the standard. The larger the bubble, the stronger the correlation to the standard is thought to be, see Figure 6.4. Closing those gaps will thus take the site closer to an ISO 9001:2008 certification. To clarify, chapters in this report will be referred to as chapters, whereas the ISO standard will be referred to as sections.

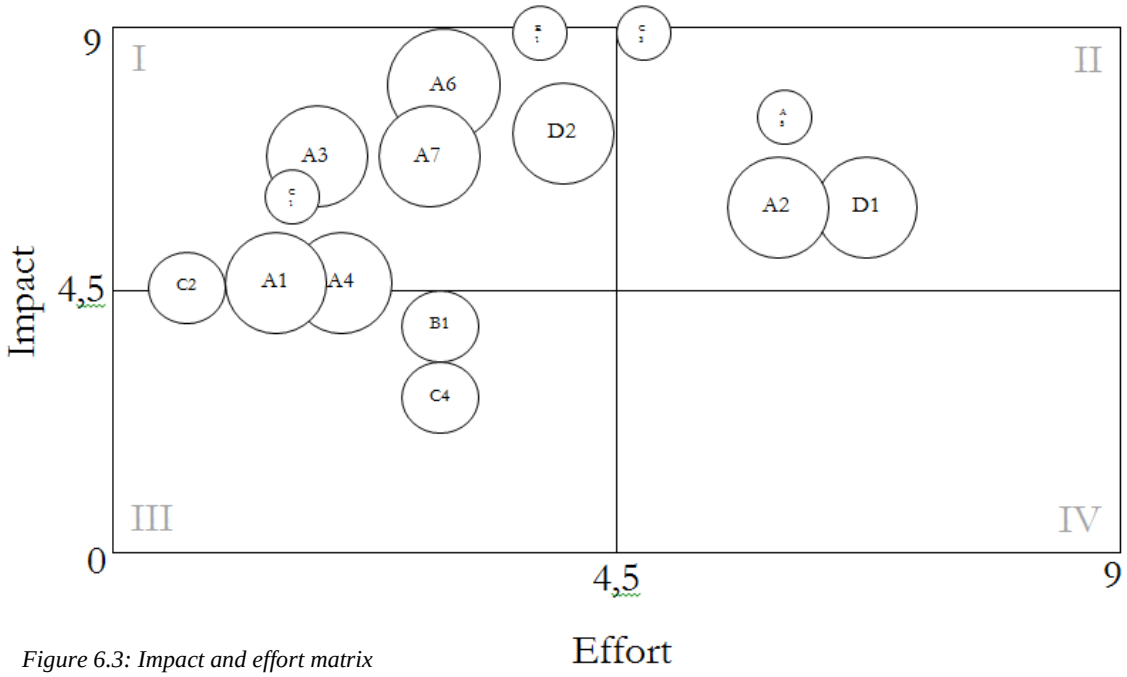

Figure 6.3: Impact and effort matrix

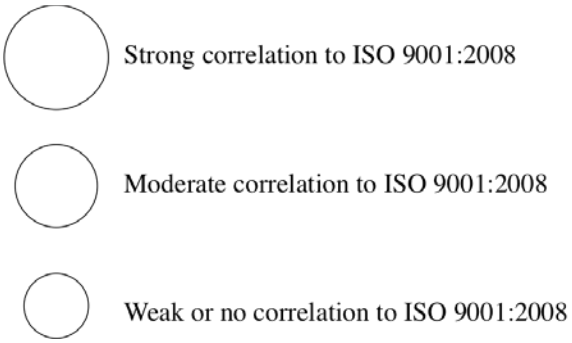

Figure 6.4: Explanation of the circle size, the bigger the bubble the stronger correlation to ISO 9001:2008

The matrix is divided into four quadrants.

- The first quadrant holds actions that if performed will provide the customer, company and site with many benefits and thus holds a high impact. The actions in this quadrant demand relatively low effort to be completed. Actions located in this area should have high priority since they are relatively easy and will bring benefits fast.

- The second quadrant holds actions that hold high impact and demand high effort as well. These actions should be taken one at a time since they are more demanding than others and if too many of these at the same time will prove too much work.

- The third quadrant contains actions that require low effort and also brings low impact. The gaps in the quadrant are easy to close but also will not be that noticeable when closed. These actions should be performed when there is time.

- The fourth quadrant holds actions that demand high effort but entails low impact hence can be seen as somewhat redundant. Actions that are in this quadrant needs to be carefully considered before started. They demand high effort but bring a low impact, thus the necessity of closing the gap needs to be evaluated. These actions should not have high priority and should be performed when there is time and other more important gaps have been closed. There is however no gaps located in this quadrant during this analysis.

6.1.3 Actions - Quality Management System

A1	**No local quality manual**	**Develop a quality manual**

Today, the site does not have a local quality manual. To create a local quality manual will have medium high impact but does not require much effort. Since having a quality manual is a requirement to be eligible to receive an ISO 9001:2008 certification (seen in section 4.4.2 regarding documentation requirements) as well as a demand from MHC, this gap must be closed.

Having a manual is an appropriate way to internally present information about the sites business and quality related issues. Since the manual also aims to show main activates and processes it is also a good way to get an overview of the business, hence improve communication at the sites as

well as to the HQ. Alič and Rusjan (2010b) identifies improved communications and better business overview as potential benefits coming from focusing on internal processes as is done when creating a manual.

Since the closure of this gap was a crucial it was decided that the creation of the local quality manual should be a deliverable from this research project.

A2	**No quality roles appointed**	**10% resource is coming**

Region North does not have a specific person whom is appointed to be the quality representative. Closing this gap will have a great impact according to the matrix but in turn also demands high effort since resources needs to be allocated.

Closure of this gap is crucial for the success of the QMS implementation. Turusbekova et al. (2007), Hernandez (201, Ong et al. (2015) and Boiral (2003) all agree upon the importance of having an appointed person responsible of quality. This person is crucial for ensuring that quality related issues are addressed continuously and that the QMS is maintained. This is as also emphasized in Chapter 3.4 where important quality roles and their necessity for keeping a system alive are discussed.

This action can lead to benefits from all of the perspectives presented by Alič and Rusjan (2010b). Having someone focusing on quality will enable continuous improvements to processes. This can in turn lead to improved service quality, hence more satisfied customer which can lead to achievement of economic goals etc.

Closing this gap is also a requirement for obtaining an ISO 9001:2008 certification. In section 5.5.2 in the standard it is stated that there needs to be a management representative for quality appointed. It is also stated in ISO 9001:2008 section 5.1 that management have the responsibility to ensure that there are resources set aside for having a quality representative, and by that show their commitment to the system.

All benchmarked sites that have a QMS in place have allocated resources for a quality representative in their budget, hence something that should be possible for Region North as well. This action needs to be addressed on higher management level, and is therefore only highlighted in this report.

A3	**No management reviews**	**Include in management meetings**

There are no management reviews for quality today. According to the matrix this gap requires low effort and gives high impact. The review can be incorporated into already existing management meetings, thereby the low effort, and is needed to be able to keep the system up to date and also to improve processes as needed. By incorporating the review into an already exciting daily operation and practices the transition can be easier according to Turusbekova et al (2015).

By reviewing process performance on a regular basis, the process can be optimized since potential improvements are likely to be found. According to Alič and Rusjan (2010b) focusing on internal processes leads to process improvements and quality enhancements. The improvements also have the potential to generate more satisfied customers due to optimized and improved processes.

Having management reviews is a demand from ISO 9001:2008 and it can be found in many of the chapters in the standard. Section 5.1 states that it is the management that have the responsibility for executing the reviews and what it entails is stated in Section 5.6. Section 4.2.4 in the standard explains how records of the reviews should be kept and section 6.2.2 describes potential areas where the review can help identify improvement with regards to for instance competence of the employees.

Since this project will not take part in the implementation phase the management team at Region North will carry out this action with the support from the QA department. Because this will add additional work for the management team motivation becomes an important factor for sustaining it. If the benefits and the purpose are well understood it will provide more motivation for the reviews. Canada can be used as a great example on how to benefit from management reviews. The reviews keep their system alive and provide opportunities for improvement. There is also a procedure in Succeed that could be used as a guide.

A4	**No quality goals**	**Decide upon goals (measureable)**

Since quality management has not been in focus at the site before, no clear goals for how to improve quality have been set.

According to the matrix, the creation of the goals will not be too demanding, having a relatively low score for effort, however great effort should be made to ensure clarity and suitability. The goals have the possibility, if properly created, to have a moderate impact on the site, according to the matrix. To get the employees at the site to work towards the same future state it is important to have common goals that are relevant to their business. When setting quality goals, it is also important to make sure that they are measurable, so that improvement can be monitored. As can be seen in Figure 3.4 made by Alič and Rusjan (2010b) aligning quality goals with the motive for implementing the QMS can greatly affect the outcome.

Measuring goals can be seen as a tool for basing decisions on facts, which is a foundation in the ISO standard. Having quality goals as objectives is also a demand form ISO 9001:2008. In section 5.4.1 of the standard it is stated that it is the management's responsibility to develop and communicate the goals to the organization. By making the management team develop the goals, they will also be anchored in the top management's objectives for the business, hence ensure their commitment.

The management team therefore needs to sit down and develop site specific quality goals and communicate them in the organization. Both Bergman and Klefsjö (2011) and the employees of Region North emphasized the fact that it is important to remember who is affected by the

change, and to tailor it to fit the specific situation. To make the QMS as beneficial as possible Region North should therefore first agree upon a desired outcome of the QMS and have that in mind when deciding upon goals. Setting and working towards quality goals can also assist in reaching improved financial performance, since it brings focus in continuous improvements. In order to align with the quality goals of the entire company the management team should start by looking at the global quality objectives. In order to make the goals relevant for their site they can also look to what other local market site at MHC have stated as their quality goals. Furthermore, aligning quality goals to the strategic goals of the company is seen as an important factor in making the QMS as beneficial for the business as possible. Furthermore, the goals need to be communicated and followed up regularly in order to benefit.

A5	**Little awareness of the QMS assignment policy**	**Training of employees**

The QMS assignment policy is not something that is well known at the site. Few employees have received training in it and some are not even aware that it exists. To be aware of quality policies is of great importance in order to act in line with the corporate vision. Since the global quality vision emphasize continuous improvements on MHC's services and products, this is relevant for Region North as well.

This gap ends up in the high effort and high impact quadrant. Since it is important to act in line with the corporate vision the gap has received high scores for impact on the business and it is believed to affect the business positively if the policy is well known. It will also take a lot of effort due to that there have been little to no training with regards to quality at the site. This means that many needs to be involved in training which will require a lot of time.

According to the customer survey, Region North has very satisfied customers, and they focus on continuously improving their services. However, closing this gap will also provide an understanding and necessary knowledge about how to use the global management system. The closure also has the possibility to reduce communication barriers between Region North and the global quality department, which can lead to benefits in terms of learning and development, as discussed in Alič and Rusjan (2010b).

This gap is not connected to any requirement from ISO, thus has no effect on the site receiving the certification or not. It is an internal requirement only.

To close the gap quality training should be performed. This training is given by the quality department.

A6	**No process for document control**	**Use global/develop process**

Today the site does not have any documented process for document control and no general structure. Closing this gap will have a high impact at Region North as well as for global RAQA since it will ensure that important documents are controlled and accessible. Since it does not demand much effort according to the impact and effort matrix this is a beneficial gap to address.

Closure of this gap has clear benefits related to the customer perspective in Alič and Rusjan (2010b), since it entails the control of documents which for example can contain important information related to customers. Having a process for document control can also provide some of the benefits identified in the area of learning and development, with regards to knowledge sharing and transferability.

Managing quality documents, such as contracts, in a controlled way is a requirement according to both ISO 9001:2008 sections 4.2.3 and 4.2.4, and the internal QMS policy. As highlighted in the theoretical framework this is necessary in order to be able to show other stakeholders that the organization have a working quality assurance system and prove that they work accordingly.

To close this gap relevant documents must be identified and a proper storage procedure decided upon. In Succeed there is procedure and a form for document control that can be used at the site as well. Region North's management team will decide upon a suitable solution, with support from the global QA.

A7	**No local internal audits**	**Perform after QMS implementation**

Performing internal audits is a way to control non-conformities and a necessity when having a QMS. Since Region North has no QMS, there has been no need for internal audits at the site, which explains this gap.

The closure of this gap holds a high impact for the site, due to that audits will identify potential areas for improvements, both for the site, the company and their customers. It ends up in the first quadrant thus requires low effort for closure. This has to do with the fact that audits are regularly performed at other parts at the company and the experience for how to perform them is high. The audits are only performed a few times a year, thus does not require much time.

As stated in the theoretical framework, audits can be used as a tool for continuous improvement, and is according to Rosam and Peddle (2009) and Mouritsen et al. (2000) a way to keep the system alive. If utilized to its maximum it can result in benefits presented by Alič and Rusjan (2010a, 2010b) regarding learning and development, and assist in making the organization reach economic goals. Performing audits is also a requirement in ISO 9001:2008 section 8.2.8.

Due to the initiation of this project Region North has now been put on the corporate audit program for 2015, and therefore needs to find a solution for how to manage internal audits moving forward. Initially there will be some support from global QA to manage these audits, and inspiration for how to handle it can be taken from the sites in Singapore and Australia as well as from the process in Succeed. How to handle these internal audits over time is up to the future quality responsible to decide. The local market site in Canada, who performs internal audits on a regular basis, has experienced great benefits by performing internal audits and strongly recommends using it to keep the system alive, hence improve the business.

6.1.4 Action - Human Resources

B1	**Outdated job descriptions**	**HR has initiated update**

Due to missing a HR responsible the last year, employee job descriptions are outdated and do not reflect the work that the employees are doing. In recent years there has been a high turnover of employees in the HR role, which also explains this gap.

This gap does not count as having a high importance in the matrix, however something that the employees of the site highly requested. According to the matrix it does not require much effort to close the gap. The reason for having updated and accurate job description is to create a transparent environment where everybody is aware of their responsibilities and knows who does what at the site. This also connects to possible benefits found in the learning and development perspective in Alič and Rusjan (2010b).

In ISO 9001:2008 section 6.2.2 it is stated that in order for an organization to obtain a certification competence, training and awareness must be evaluated. In chapter 5.5.1 it is also stated that management is responsible for ensuring that the right competence is in the organization. It is also important to understand how different activities are interconnected and how different roles can contribute to reaching the quality goals.

With the help from management the newly appointed HR manager has initiated work for improving HR related areas at the site, and will also address this gap.

6.1.5 Actions - Distributor, subcontractor and suppliers

C1	**No local process for controlling supplier**	**No need for local process**

There is a local process for controlling suppliers at the site, but since they have such close connection to the HQ, by being located in the same building, most of the sites suppliers are included in the HQ's contracts regarding subcontractors and suppliers, which mean that the HQ controls them.

Other suppliers that could affect quality of their service, and that they need to have control over is mainly those regarding logistic. This issue is currently presented to the logistics manager at Region North, who needs to make sure that they have a certain procedure and work accordingly. This gap is located in the first quadrant and should be addressed as soon as possible.

There is a global procedure called “Evaluation and approval of supplier in Succeed” that can be used as well as a local evaluation form (F008) to start evaluating current suppliers. This is also used by other sites and has proved useful.

C2	**Uncertainty regarding who should sign distribution contracts**	**Check with legal**

There is confusion at the site as to who should sign contracts.

To ensure that someone with the right authority sign contracts is vital, since it ensures validity of the contract. Since it affects many stakeholders this issue has a very high impact. Raising this issue to the general manager and the one responsible for these contracts will hopefully solve it.

Responsibility and authority is also discussed in ISO 9001:2008 section 5.5.1 where it is stated what management is responsible for clarifying it.

This gap can be closed easily by checking with the legal department who has the authority to sign and who does not.

C3	**Contract in Succeed not always used**	**Initiative to formulate a more suitable contract**

It is evident from the interviews that the site struggles to get distributors to agree upon the global MHC contract and therefore it is not always used. The contract is not designed specifically for Region North, which sometimes makes it overly complicated and often result in very cumbersome negotiations. Furthermore, the distributors are often large companies themselves that can withstand pressure from MHC, and they often already have their own contract that they want to use.

Closing this gap demand great effort, but it will also have a huge impact since it ensures that the site fulfils its obligations if something were to happen, e.g. that distributors assist in recalls or register complaints in an appropriate manner.

To increase awareness and create a common understanding for why the contract is importance there might be useful to educate distributors in the requirement put on them from authorities; this can also lead to the benefit found in Alič and Rusjan (2010b) where they mention improved communication with suppliers as a possible benefit in the area of customer perspective.

Contracts are seen as quality records and should therefore be handled according to the ISO 9001:2008 sections 4.2.3 and 4.2.4.

Reaching agreements with the existing contract require a great amount of work and the perception is that the motivation for doing so is lacking. Due to motivation being a critical success factor for a QMS implementation it is beneficial to try to solve this matter in a different way. The action is therefore for Region North and Global QA to develop a simplified version of the contract together with the legal department, including only the most crucial points that need to be decided on when conducting sales with distributors in their market.

C4	**No list of distributors**	**Print from Cognos, store as quality document**

Today there is no physical list of distributors. To be complaint to ISO 9001:2008 sections 4.2.3 and 4.2.4 a physical list must be stored since it is seen as a quality record.

This action is next to effortless since distributors already are listed in Cognos. It only needs to be printed and stored according to the procedure soon to be developed for controlling quality documents.

6.1.6 Actions - CAPA and Complaints handling

D1	**Poor knowledge of CAPA**	**CAPA training**

The general knowledge at the site of CAPA is considered poor by the employees themselves. To make sure that everybody understands what CAPA is and how the global CAPA process works the global QA department provides trainings to all employees. This trainings has however not been carried out at the site and therefore the knowledge is low.

To close this gap a lot of effort is required, seen as all of the site employees needs to attend, taking both time and employee engagement. However, if the gap is closed it also holds a high impact for the customers, the site and MHC in general since the CAPA process ensures that errors are corrected and quality is continuously developed.

Having a functioning CAPA process means that for example complex problems that have led or can lead to non-conformities affecting patient safety can be solved in an efficient manner. Closing this gap can lead to benefits found in all of the perspectives described in Alič and Rusjan (2010b). The understanding of the CAPA process and the ability to contribute to the reporting of potential CAPAs can, in the most extreme case, safe human lives. It can also lead to improved services and products, hence lead to more satisfied customer. The knowledge of the CAPA process also brings benefits found in the perspective of internal processes since it potentially provides higher productivity and increased visibility of processes.

For the perspective of learning and development the understanding of CAPA can improve communication between the site's employees as well as with HQ. This due to that the employees are aware and have knowledge about the process. The ultimate outcome coming from the closure of this gap is economic growth due to continuous improvement of products and services.

The importance of CAPA is also highlighted in ISO 9000:2008 sections 8.5.2 and 8.5.3 where it is explained and stated as a requirement.

The gap can as described before be closed by training the site in the CAPA process. Since the concept of CAPA is entirely new to many of the site's employees the importance of explaining WHY this is important cannot be emphasized enough. To ensure that the CAPA process is implemented in a proper manner after the training it is crucial to have a person responsible at the site handling and supporting the personnel.

D2	**Insufficient complaints training**	**Do LMS complaints training**

The global process found in Succeed is followed by the personnel working with complaints handling at the site. However, the knowledge sharing is mainly shared face to face, which might

lead to deviation in the process over time. There is training available in the company's LMS called Product complaint training, but this has however not been completed by all employees.

According to representatives from the QA department completing the training is relatively effortless. Closing this gap and improve the quality therefore holds a high impact generated from low effort.

From the theory it is also found that processes are more efficient when everybody is aware of the way a specific task is meant to be carried out. According to Alič and Rusjan (2010b) this relates to the perspective of internal processes, when procedures are determined and more visible the process and in the end the whole organization becomes from efficient.

Ensuring control of nonconforming products is a requirement from ISO 9001:2008 found in section 8.3.

To ensure the quality regarding complaints handling it is important that everyone is aware of how to register and handle complaints and understand why it is important to follow the global process. Since there is a desire from HQ that everyone should do the Product complaint training in LMS the site's management team needs to make sure that all employees do it.

6.1.7 Action - Marketing communication

E1	Marketing approval process	Actions taken already

There is no marketing approval process in place today at the site. This can cause problems due to that the communication going out from the site is not quality controlled, hence incorrect information might reach a potential customer. Due to the industry that the site operates in, claiming something that is untrue can get devastating consequences.

This action holds the highest impact value since it affects both the customer, Region North and MHC. The closure of this gap will ensure more satisfied customer since the marketing material will not claim something that is untrue, thus relating to the customer perspective of the QMS bringing more satisfied customers talked about in Alič and Rusjan (2010b).

To mitigate the risk of incorrect marketing material the marketing managers at Region North have already taken the initiative to make the process applicable to their business, hence translate it to work instructions that they will train the marketing people in to ensure compliance. The importance of making it work in practice and tailor it to daily operations is supported by the literature in Turusbekova et al (2015).

This training is currently going on at the site and the material developed will be used in the QMS. Once again it is important to sustain this change by making sure that management continues to emphasize its importance and check that it is done accordingly. Since the site has several markets with different languages it is also important, from a global perspective, to create an understanding of each other’s needs and challenges as to find a solution that can be sustained over time.

6.1.8 Other actions

O	Sample handling	Discussion needed

Another issue that came up during the gap analysis was that there was a need to create a sustainable solution for the sample handling process. Today there is a guideline developed that should be followed but according to the employees at the site it usually is not. As always when it comes to processes and systems, it is seldom the individual's fault but rather the systems that needs to change.

Since there is room for improvement and the awareness of it is high, this needs to be solved on a higher level. To ensure that employees will follow the guideline it is important to provide them with a suitable system that works in practice. Merely pushing them to "just follow" the current guideline without giving them the tools to do so might create a sense of urgency to change but it will surely not increase their intrinsic motivation to do so, nor create a positive attitude towards the QMS.

To be able to make the process work for the employees an investigation regarding a new system is currently ongoing.

6.1.9 Analysis of the actions and the matrix

To be able to prioritize the actions the impact and effort matrix, seen in Table 6.3, can provide some assistance. The first thing that is noticeable from the matrix is that the actions needed for closing gaps regarding the QMS (named A) all will bring high impact. Many of them are also located in the first quadrant meaning that they require a low effort. Since the site has not had a QMS before it is not unusual that there are many gaps in this area. The actions for the gaps located in the first quadrant should all have a high priority since their closure is essential for the development of the QMS. Two of the actions are located in the second quadrant, which means they have high scores both on impact and effort. To manage the closure with a moderate effort level it is recommended to address these gaps one at a time. From the literature described in chapter 3.6 regarding audits and also in the benchmark in chapter 5.2 the emphasis on closing gap A7, regarding internal audits, can easily be understood since it will bring many benefits. The closure of this gap should therefore have a very high priority as soon as the QMS is in place.

The gaps regarding distributors, subcontractors and supplier (named C) are scattered all over the matrix. The priority for them should therefore be to start with the action that will bring the highest impact which is C3 regarding customer contracts. These actions demands relatively high effort to be closed but since it holds such high impact it should have high priority, possibly the highest for all of the actions found in the second quadrant. To close gap C3 will as explained in subchapter 6.1.3 involve many employees and is therefore deemed as demanding. For other gaps there are less effort demanded for their closure, mainly because they don't involve as many employees.

The gap that yields the most effort in the matrix is D1, which is the gap regarding CAPA knowledge at the site, due to that it will involve all employees. This gap might be good to

combine with gap A5, regarding employee training in global quality, since all of the employees will be gathered for the closure of that gap as well. Since the site have good knowledge of complaints, regarding the gap named D2, the related action will upon closure not bring much change to the site, but it will ensure that everybody at the site can contribute to the complaint handling process, hence make it even better.

The gap regarding marketing approval, named E1, is also located in the first quadrant, hence have high impact will low effort. This gap together with C3 (regarding distributor contracts) holds the highest impact on the customers, company and site. E1 has the effort level of 4 which is relatively low and upon closure should hold a high priority.

6.1.10 Summary of the actions

No general patterns can be found in the matrix, but it is clear that closing the gaps will in almost all cases bring a relatively high impact to the three chosen stakeholders. For actions having an impact level of 7-9 their closure affects all three areas, and these actions should in most cases have a higher priority than the rest of the gaps. Many of the gaps also demand low effort levels as can be seen in the matrix. This might be due to that the site has not focused on quality in the QMS structure before and that the awareness of that has been low. If there had been more awareness of quality management many of the gaps might not exist at all. Additional factors that might have led to that quality management has not been prioritized might be related to that the site has a history of performing well and has limited external pressure to get a certification.

When creating a plan for the implementation of the QMS and closure of the gaps the matrix is a good tool to ensure that the correct action is prioritized, however there are more things that should be considered. To ensure a successful implementation all affected stakeholders must be engaged in the process. As shown in Chapter 3 their motivation is a factor that in many ways determines the outcome of the QMS.

6.2 Motives for implementing a QMS

Motivation regarding ISO implementations is well researched in literature and the importance of it cannot be emphasized enough, as can be read in theoretical framework. For Region North the initiative to implement a QMS came from the management team together with RQA, thus having a top down approach. It was therefore not something that was requested by the employees. Due to the fact that motivation is identified as a critical success factor in the literature review for QMS implementations it is important to acknowledge the situation at the site and properly identify what could motivate the site to work with a QMS.

6.2.1 Identification of the motives

The interviews showed that it is motivating to have a QMS at the site if it will lead to; more efficient work procedures, more structure, and also make it more clear who is responsible for what. All of these factors can be looked upon as internal motives, which according to Sampaio et al. (2009) in Chapter 3 can result in organizational improvements. Furthermore, if the QMS would allow the employees to focus on their daily tasks, which is selling products and serving customers, it is considered extremely motivating by many of the employees. Focusing on internal processes might also lead to that they do tasks in the best possible way, which is also expressed as a motivating factor. Alič and Rusjan (2010b) also highlight the benefits regarding improved internal processes. If the QMS can ease the inductions process for new hires when it comes to introduction of tasks and confirmation of doing things accordingly, it is considered motivating too.

Furthermore, the opinion among employees is that a QMS could help to improve communication and knowledge sharing as well. It becomes clear during the benchmark that there is a lot of material that already has been developed both at Region North and at other sites that could be adopted and used by the site. A manager expressed that he hopes that the QMS can lead to that they do not have to invent the wheel over and over again. Increased communication is one of the possible benefits from implementing a QMS according to Alič and Rusjan (2010b). They call it “Increased transfer and dissemination of knowledge among employees”. This benefit should be conveyed to the employees in order to motivate them to start working with the QMS.

The opportunity to reduce wasteful activities at the site due to getting more structured processes in place is a great motivator for many of the employees and was often expressed during the interviews. Reducing waste is also found as a potential benefit in Sedevich Fons (2011) since it often leads to cost savings. Even though many of the motivating factors that are brought up could lead to cost saving opportunities indirectly, an interesting reflection is that none of the employees talks about wanting the QMS for cost saving reasons. In chapter 3 it can be seen that there are many ways to be able to save money, for instance by making the organization more effective by structuring the processes. Alič and Rusjan (2010b) also identify “Achievement of economic goals and improved financial performance” as one of their four areas where the QMS will create benefits if implemented. This might however be more motivating for the management team than for the employee.

In both Poksinska et al (2002) and Priede (2012) commercial potential from a certification is greatly emphasized as a common driver. At Region North a certification is not sought at the

moment. The impression is that it is not important from a customer point of view and that it would not improve the sites image to any extent at the moment. It is therefore crucial to identify other drivers that will motivate the employees, such as the benefits for the internal organization and their daily activities.

In the reviewed literature it is evident that an ISO certification is one of the most common drivers for implementing a QMS, however many also highlight the risk of merely implementing the QMS to obtain a certification. Brown et al (1998) also talks about how different drivers will lead to more or less success. In the research they point to that those organizations that just get certified for external pressure will enjoy less of the benefits compared to organizations that believe that the certification (or implementation) will lead to a better way of working, such as Region North. Sedevich Fons (2011) is another researcher that has found that external drivers lead to a superficial adoption of the QMS, hence not reaching its full potential. Since Region North does not have many external drives they will have to focus on the internal motives, hence have a greater possibility to gain more benefits from the QMS. However, some external pressure has been proven effective for an implementation, as discussed in Prajogo (2011) in chapter 3. When there was external pressure put on the benchmarked sites they became more motivated to start the QMS work. For Region North the implementation should be seen as preventive work as oppose to the reactive work the other sites had to do.

Sampaio et al (2009) also divide the drivers into internal and external ones. From the benchmark it could be seen that the Iberian site sought the certification due to customer pressure and raised competition, both categorized as external drivers. Compare to the Canadian site that needed structure, thus having more internal motivation. However, the need for structure initially came from an external audit, but then evolved into internal motivation. Region North wants, if connecting their identified drivers with what is said in literature, to use the implementation for internal benefits, since it does not need a certification at the moment.

6.2.2 Implementation attitudes

Boiral (2003) looks at organizations where the implementation of a QMS has taken place and identifies different groups of people depending on what opinions and behavior they have. To be able to prepare and plan the implementation in the best way possible at Region North it can be beneficial to identify different groups and understand how people might react early on. By doing so they can ensure that proper precautions are taken. To look at the benchmarked sites and understand what happened there can also be helpful.

The group that Boiral (2003) calls dissidents, that have a strong resistance towards the QMS, have not been found anywhere at MHC during this research. At MHC quality is a crucial value and a very central concept at the global organization. This might lead to that the employees value quality and do not oppose an introduction of a QMS that could improve quality. Since a QMS should be used as a foundation for continuous improvements, having that value and mindset, can according to Adanur and Allen (1995) results in a better QMS. From the benchmark there is however two sites that showed obvious signs from the other two groups identified in the article. The French site could be said to have more similarities with the group “ceremonial integrators” and the Canadian site is more of what Boiral describes as “quality enthusiast”.

Considering what is known about Region North's drivers for the QMS from the interviews and observations, described in subchapter 6.2, the impression is that they might end up between the Canadian and the French site, if the identified drivers remain over time. Region North's drives can be summed up in the will to be and do better, hence get even more satisfied customers. However, since there is no external pressure stemming from customer or regulations, sense of urgency can be lacking and in some ways decrease motivation. To ensure that the implementation and possible certification have an even more successful outcome the recommendation is to encourage the traits of Boiral's (2003) quality enthusiasts such as viewing the QMS as a tool for gaining benefits beyond those for marketing. Since their motivation does not originate from only wanting a certification they would according to Brown et. al. (1998) gain more benefits from having a quality enthusiastic mindset. By also understanding the benefits with the QMS implementation they could get a more integrated and efficient QMS, resulting in improved business results. This is explained further in the model depicted in Figure 3.4 by Alič and Rusjan (2010b).

6.3 Summary

In order to make sure that a QMS implementation is successful and the organization gets the possible benefits out of the system there are some evident factors that are important to consider. The first factor is the reason for wanting a QMS and the often following ISO certification. The literature review presented in this report clearly highlight the fact that a QMS and certification that aims to serve as a marketing tool, to show the surrounding that a quality assurance system is in place, will most likely not be used internally. Neither will it improve quality practices affecting daily operations, found in both Psomas et al, (2010) and Brown et al, (1998). It can of course generate new clients, but by creating an awareness of what a QMS actually can bring to an organization the benefits will be many more. A common opinion in the theoretical framework, Chapter 3.5, is also that motivation among employees regarding the QMS implementation plays a vital role in its success, found in for instance in Taylor and Wright (2003). If an understanding of the reason behind implementing it as well as possible benefits for the daily work is clearly communicated the chances of making it into a living system instead of a shelf warmer is much greater.

Since Region North has, as stated in Chapter 6.2, limited external pressure for an implementation and even less to get an ISO certification the driving forces for implementing is internal. Through interviews with the employees of the site it was identified that there is a desire for more structure and to feel confident that tasks are executed according to global processes and guidelines. There is also an emphasis on that they do not want vital information and knowledge to be limited to certain persons, but rather be accessible through a QMS to ensure that a crisis is avoided if someone gets sick or leaves the company. To build upon this internal motivation and the belief that the QMS will improve their business are therefore of great importance.

However, even though these internal drivers are fortunate, the lack of external pressure can result in that there is little sense of urgency to change and that other things get higher priority. To make sure this intrinsic motivation stays among the employees it can be good to think of how to handle the change and the implementation before it starts. To understand the usefulness with the QMS it

is important to understand the requirements and the purpose of implementation, which is described in the literature review. To get successes early in the implementation can prove to be crucial for the site in order to increase motivation for the project. Region North can benefit from starting off with implementing and changing something that will create positivity around the change, for instance gap B1 “Update job descriptions”. It is also important to get the employees involved in the implementation and make them think about how they can assist in making the changes happen, gap B1 is suitable for this since it affects all employees and they can be in control due to that it is their respective job description. In doing so it becomes easier to understand what role they have in the whole change process, they get the feeling that they can take part in the process and not get hopefully feel that the change was not imposed on them.

By using the theoretical model by Alič and Rusjan (2010b) chapter 3.5 that describes the impact a QMS can have on a company’s performance depending on how much the system is integrated, it becomes evident that MHC and Succeed are not yet in most efficient zone. Succeed is for example not yet used by all employees, hence does not give the company all of the possible benefits. Region North will use many parts of the global management system, and since the site still is in the pre-implementation phase it is still possible to affect the outcome and the effectiveness of their adapted QMS. Setting quality goals and policy is for example of great importance and when constructing them should be beneficial to have Alič and Rusjan’s model in mind. By aligning the site’s policy and goals with the global one’s the site will have the potential to use the QMS for more than just compliance. The model also visualizes the importance of management support and commitment, to gain more benefits and utilize the management system properly.

To understand that the QMS needs to grow with the business is vital (Rosam and Peddle, 2009). The system needs to be kept alive in the post-implementation phase and get the attention that it needs and the employees need to be reminded of its importance. Management reviews and especially internal audits will come to play an important role for the awareness, together with communication. In the research, in Hernandez (2010) and Poksinska et al. (2002), top management support is called out as a fundamental factor for successful quality initiatives, and thus something that the site management team must agree upon.

7. CONCLUSION

The purpose of this research was to assist a local site in becoming compliant to the company's internal quality requirements and to bring the site closer to an ISO certification. To do this awareness of quality had to be raised and critical success factors regarding QMS implementations had to be investigated. During this research two questions has been used for guidance, and answers to them will be presented in this chapter. Furthermore, an introduction to the QMS draft will be given.

7.1 Answers to research questions

Here follow the answers to the two research question that have been used to guide the project.

7.1.1 RQ 1: What is required to adapt a global quality management system to a local site?

First of all, the global organization's QMS needs to be well understood and processes relevant for the local site identified. It is important to understand why the local site wants to implement a QMS, what local processes that are important to include as well as adapting the global processes to fit the specific needs of the site. If an ISO certification is sought the requirements found in the standard should also be used to guide the adaptation.

Furthermore, the current situation at the site needs to be mapped and well understood. To identify what steps needs to be taken to reach the desired state a gap-analysis should be performed. The gaps must be evaluated and the reason behind them clarified. To illustrate why the reason matters examples from the case company can be used. By looking at the gaps; C3 Contracts in Succeed not always used, and E1 Marketing approval process it is easy to see that there can be many reasons behind a gap. For C3 the site had tried to use what the global QMS offered but since it did not it suit their needs, it will be restructured for the creation of the local QMS. Gap E1 showed that the need for this process had not been expressed before, hence a new process needed to be developed.

Even though the global organization's QMS should be followed, it is important to make the processes relevant for the sub-organization. Many processes are on a global level and will therefore not always be relevant in full. The conclusion is therefore to use what is relevant, adapt what needs to be adapted and develop new procedures when necessary. There are many processes for the global QMS that the site can use without adapting, for instance for closing gap A3 No management review. Here the site can use the global process and incorporate it to their daily work straight away, but as described there are other gaps that needs adapting, such as gap C3 and E1.

When all the gaps have been identified, a plan for closing them needs to be created. Since resources are often limited, gaps need to be prioritized. By mapping the site's gaps in an impact-effort matrix the employees involved can get better understanding of what needs to be done and how to prioritize.

The success rate of a QMS implementation is not only about closing identified gaps. In the literature review it was found that the success is greatly impacted by the drivers for wanting it,

which make them crucial to understand in order to get the desired outcome from having it (Prajogo, 2010). By looking at the benchmarked sites, where the drivers for implementing a QMS were very different, Prajogo's theory could be confirmed. At the Canadian site the QMS was appreciated and seen as a natural part of improving the organization, whereas the French site only wanted it because of the ISO certification, which made it more of a burden.

Except from understanding drivers and set the right expectations, top management support is crucial to ensure the long-term success of the QMS. Hernandez (2010) and Poksinska et al. (2002) even considered it a requirement. Management support ensures that enough resources are available and that the implementation gets the attention that it needs. Without that support the implementation risks being ceremonial, hence the QMS will not be utilized to its full potential. During the research the importance of this was emphasized when talking to management and the implementation seemed to be well anchored, since the initiative to implement the QMS came from the manager at the site.

Today there is limited research about the subject of adapting a global organization's QMS to a single site. This research provides a path for how to proceed in similar situations including; current state analysis, internal benchmark, gap analysis and impact-effort matrix. It was seen as a useful strategy at the case company and helped them to gain relevant knowledge for developing and adapting a suitable local QMS.

7.1.2 RQ2: To what extent is the case company ready for the implementation?

In the literature review it was found that both knowledge about QMS and motivation had a prominent effect on the outcome of QMS implementations. This was also confirmed in the performed benchmark, where the implementations were more or less successful depending on the prerequisites at the site. By understanding the drivers found in an organization, better precautions can be taken to ensure that the desired outcome is reached. It is shown in the theoretical framework that organizations tend to get the QMS that they aim for, see Ong et al. (2015) and Alič and Rusjan, (2010b). By having knowledge about what impact the outcome already in the pre-implementation phase organizations will have the opportunity to create a QMS that will fit its needs and expectations.

During this research much effort was put on creating an understanding of the drivers for implementing a QMS at the site, as well as to increase employee motivation to incorporate it into daily operations. According to Ali and Kidd (2013) the latter is of great importance, since lack of motivation can act as a barrier for the implementation.

Sharing this research with the site through meetings, presentations and this report increased employee motivation and readiness. The lack of external pressure has in the researched organization lead to that internal hopes for the QMS have arisen and become more prominent. This knowledge will help the management team to better explain why a QMS might be beneficial for the organization and lead the motivation towards the internal benefits that have been found in the literature review. By motivating the employees in the correct manner and allocate enough resources to implement the QMS in a desired way the chances of success are increased. As a result of this research, the case company allocated a 10% resource to drive the implementation.

The findings confirm much of what has been stated in the literature and also highlight what an organization, where there is little external pressure, can do to motivate its employees to create a proactive change. It is important to convey that a QMS will not solve an organization's problems all by itself (Papassavas et al., 2015). However, it has the ability to structure and create an environment beneficial for continuous improvements.

7.2 Development of a QMS for a local market site

The following picture, see Figure 7.1 gives an understanding of how everything is connected. Standards, motivation and corporate requirements will together lead to an implementation plan which in turn result in the finished QMS. The research questions have guided the research in the right direction and by answering them the information needed to create the first draft of the QMS for Region North were gathered. The draft is found in appendix D.

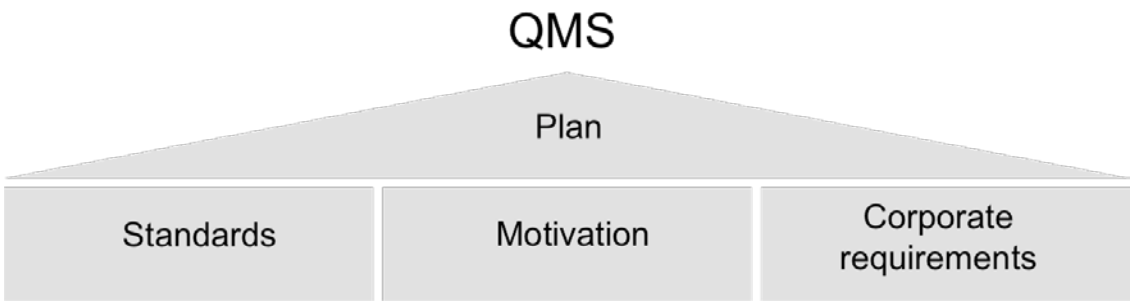

Figure 7.1: Description of how the different factors are connected

7.3 Further research

In the previous research about QMS there is very few that focuses on this particular issue of implementations on sub-sites. It would be interesting to further investigate if more companies have made similar transformations to their main QMS. This research could possibly give insights; not only as to how a company could adapt a global system and make it more applicable to a single site by identifying relevant parts, it could also help companies make their QMS' more applicable to their whole organization.

QMS along with many quality practices have been much applied in manufacturing industries, but there is not as much research on tangible positive outcomes from using quality practices in service organizations. A subject for further researched could therefore be to study the effect that QMS can have on sales and marketing organizations. To study an organization for a longer period of time to measure outcomes would also be interesting.

The integration of QMS to other systems was not studied in this research but that is an interesting subject for further investigation as well. The integration between QMS and customer

relationship management (CRM) systems would be very interesting to research, especially from a sales and marketing perspective where CRM are vital to their organizations.

Another interesting subject would be the actual use of the QMS and the integration to the whole organization. The model by Alič and Rusjan (2010b), chapter 3.5, shows three different levels of integration, the possible usage of the QMS in different levels and then discusses how that affects the effectiveness of the QMS. Boiral (2003) discusses different attitudes towards QMS and the linkage between the two articles could be an interesting start for the research. How the personnel see the QMS is often connected to the outcome and the gains from the system and to investigate many companies and employees from different departments and of different rank could possibly give a true picture of the real use of QMS'.

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Appendix

A. **Interview Guide**

This guide was used to guide the interview. Depending on the interviewees answers additional questions was added ad hoc.

Describe who we are and where we are coming from.

- Describe the project in short.

Questions:

- Who are you and what is your role/position at the company?
- (Describe a normal day at work?)
- Could you in as much detail as possible describe the ….. process?
    - Could you illustrate the process?

- Are there any parts of your process that you feel could be improved/removed? Eg. areas where you feel less confident following company standards, document handling issues etc.

- Any other processes that you feel can be improved/benefit from more structure?

- How do you define quality? Can you please define good/bad quality in your process/daily work?
- What would you say is the biggest motivator to have a QMS and in the future a ISO certification? Do you think region North can benefit from having a QMS?
- Do you think that your organization will benefit from the implementation of the QMS?

B. Gap analysis

GAP ANALYSIS AT REGION NORTH 19/4 2015

Participants:	[redacted]
Purpose:	To initiate a Quality Management system (QMS) implementation by performing a gap analysis towards the "Local market QMS assignment policy"

SUMMARY

Region North has the willingness and commitment to be compliant with the "Local Market QMS Assignment Policy" as well as to improve their business. Applicable global processes are known and understood in many cases, but no local procedures exist and evidence of implementation is difficult to find except for the Product Complaint handling process.

Management commitment regarding quality and structure is identified by the staff which is an important pre-requisite for a successful implementation of a QMS. However QA resources are also a key success factor and needs to be solved.

Motivators to implement a local QMS are according to employees to work more efficient, have a good structure and to easier access documents and information. Also to avoid being dependent on certain persons who knows the process by heart. It is expressed as a way to clean up.

Even though an ISO certification is not a priority at the moment it should be a possibility for them in the future, hence it will be taken into consideration during the QMS development. Another requirement for the QMS is that it should be user friendly and supportive, as to make into to a living that the region will use.

1. BACKGROUND AND OBJECTIVES

This Gap analysis is a part of larger ongoing project aiming to prepare Region North for a local QMS implementation. The goal with the analysis was to assess compliance to global procedures, identify local processes and to set a strategy for the coming implementation together with the Region North General Manager, Katriina Öberg. Focus was on identifying gaps as well as to agree upon what actions to take. It was not intended as an audit but rather as an improvement tool.

The Gap analysis was performed at the Region North office in Gothenburg and data was gathered mainly through interviews with appointed representatives at Region North as well as from the Swedish regional office. It was carried out by Anette Stenson, Global QA Commercial Manager, with assistance from two master thesis students from Chalmers, Malin Lindgren and Patricia Mattsson.

Since the The Local Market QMS Policy should be applied in the region it was used as a reference, hence the structure of this report. The policy was developed for local Sales & Marketing sites with the purpose to make them as "lean" as possible and to make local markets focus on the areas in Succeed and ISO standards that are applicable to them. Local market sites often differ a lot in terms of size, activities and structure as compared to the global organization and manufacturing sites, meanings that many parts in Succeed are not relevant.

2. QUALITY MANAGEMENT SYSTEM

Since there is no Quality Management System in place at Region North yet there are a few gaps in this area:

GAPS	**ACTIONS**
There is currently no Local Site Description that describes the local organization and its activities	Malin and Patricia will start working on a draft for this document and present it for Region North Furthermore local processes should be mapped and described. A key process that should be developed is the Tender process

There is little knowledge and awareness of the Quality policy developed for the local sales and marketing sites. Lack of Succeed training is mentioned as one reason.	Make sure all employees get necessary Succeed training
No Market Quality Manager (MQM) is appointed	Working on an agreement with Global QA to get support from them in this matter. Still important to assign a responsible QA person in the management team to ensure a successful implementation
No concrete quality goals are formulated and measured	The management team needs to agree on suitable goals and make the rest of the organization aware of them.
Management reviews[1] need to be performed on a regular basis (twice a year)	Add as a point in the already existing management meetings. Global QA can assist in how to perform them accordingly. Fixed agenda to be used.
The market site needs to make sure they have a documented procedure for how to handle document control[2] of the local QMS	Refer to Succeed procedures when applicable and identify local quality records, storage time etc.
Document control needs to be improved to ensure we are in control and have evidence showing that we are compliant	Need to identify quality documents and to decide where to store them and for how long.

[1] In a management review the status of the QMS, quality goals etc. are highlighted and improvements areas discussed and decided upon

[2] Including how to write procedures, approve and store quality system records e.g. customer contracts, training records, minutes of management reviews, internal audit reports, non-conformities etc.

	Eg. in a binder where it can be easily accessible if needed. Check with T014, F002 forms, contains process for approval
A validation process for the QMS-documents is not yet developed	Can probably be handled by Global QA and IT
Local internal audits are currently not performed, since there have been no internal audit plan and auditor at Region North.	Region North is on the Corporate audit program 2015 and should therefore try to find a solution for how to manage audits moving forward. See QA resource gap.

Even though there are no concrete quality goals stated, the GM expressed their quality objectives as Quality in the meeting with customers and to give the best customer experience. Region North also follow up objectives set in the Marketing Plan which can be seen as a way to continuously improve.

3. HUMAN RESOURCES

The Human Resource function at Region North constitutes of one person. In addition to the HR-tasks this role has previously been responsible for QA at the site. In recent years this position has had a high turnover in personnel, which has affected work with quality management and postponed the quality management system implementation first initiated in 2014. As from [date] [name] has filled the position as HR-responsible at the region but the QA task will no longer be included in this position.

GAPS	**ACTIONS**
Many job descriptions seem to be insufficient or even missing.	Review and update job descriptions where it is needed and make sure they are reviewed in the PPR.

Key quality roles according to local QMS are not appointed	The management team should appoint a Market Quality Manager (MQM), Management representative and CAPA handler. Global QA might support in this.

Training and competence: Marketing Competence/Capability assessment has been done for all sales staff and training program are developed depending of the outcome. The question is if this will be done on a regular basis. No PDP were reviewed due to confidentiality

Complaint Coordinators are appointed and they are all doing a good job and know what should be done, despite the fact that the task is not stated in their position descriptions. There are 12 different complaints handler for 7 countries (to be confirmed). Each complaint handler is responsible for a range of products. Service complaints are handled by Customer Service in Waremme.

4. MARKET DISTRIBUTORS, SUBCONTRACTORS/SUPPLIERS

The responsible person for distributors is aware of the Global Select Market Distributor Process and seems to have a good relationship with the main distributors. Due to business reasons the recommended way of working is not always applied. The time and efforts this work entails is currently not available at the site, leading to that the distributor contract template from Succeed is not always used and old contracts not updated.

Region North is working on establishing distributor contracts according to Succeed with all their distributors. Due to the fact that the larger distributors often have a lot of power in negotiations as well as their own contracts it has proven difficult to get an agreement on current contract. The impression is that the contract often feels overly complicated and that the resources provided to reach an agreement are insufficient.

GAPS	**ACTIONS**
Region North (Sweden) does not use the Succeed distributor contract with all distributors	A simplified version of the contract could be created together with legal, including only the most crucial points that need to be decided on when conducting sales with distributors

There is a slight confusion regarding who is supposed to sign contracts with new distributors.	This needs to be decided by the management team as well as with Legal. Check what has been decided on a Global level
A list of all distributors should exist, as of today they have them listed in Cognos	A list should be stored together with other quality records
No procedure concerning how the site ensures control of suppliers/subcontractors exists	Refer to global procedures and use the local evaluation forms to start evaluating current supplier that might have an impact on product/service quality

7. CAPA AND COMPLAINTS HANDLING

All product and service complaints are handled according to the Succeed Non-conformity Management Process. The work seems to be done in an efficient way and there is no need for a local procedure. Employees tend to share experience orally and learn from each other. To have control over all registered complaints in SAP and their status the Complaint Coordinator puts together monthly report. This gives an outlook on all opened complaints and is a way to measure “time for closure”.

GAPS	**ACTIONS**
There is little or no awareness of CAPA and the global CAPA process	To understand what CAPA is and how to act when identifying potential or existing non-conformities Region North should have training in the Global CAPA process
No CAPA handler	After the CAPA training a local CAPA handler should be appointed.

Product complaints training is not yet done by all employees	The management need to make sure that all employees do the Product complaint training in LMS

To ensure that Region North continues to handle product complaints as well as today it could be a good idea to include product complaints in the introduction package for new employees. It is also necessary to get a backup-system regarding Complaints coordination in place eg. by appointing a deputy.

8. MARKET COMMUNICATION

New process is under implementation; Region North are well aware of the newly develop Marketing Communication Process accessible in Succeed, and there is a willingness at the site to improve within this area. Due to the fact that Region North has many different markets under its umbrella the Marketing Managers has initiated a project aiming to make the process more applicable for Region North. This work will be presented in a power point presentation explaining the process in a more practical manner.

GAPS	**ACTIONS**
Local process under construction	The process will be included in the local QMS

9. FSCA - Field Safety Corrective Action

The understanding is that Region North follows the global recall process. Traditionally the product managers have been in charge of recalls in their product category. Since recalls are rare at Region North there are no local procedures on how to proceed and they can rely on the global process with support from the Vigilance team.

GAPS	**ACTIONS**
No identified gaps, the recall process seem to be handled in a good way	However, it might be beneficial with a checklist/work instruction on what needs to be done locally and ensure proper transfer of responsibilities in case of changed roles/position (Andreas?). Position descriptions to be updated as well.

10. INFORMATION TECHNOLOGY (ref. Succeed)

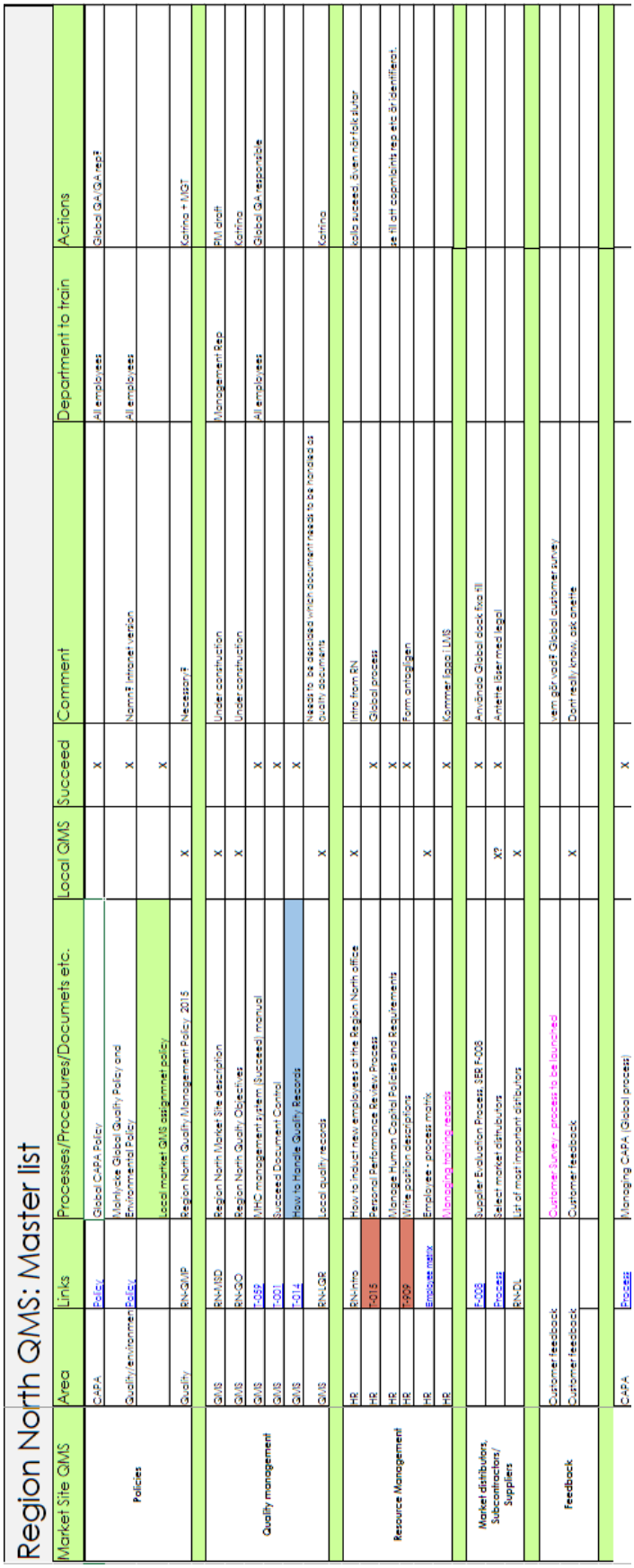
The market site complies with the IT process in Succeed and the Software Validation Policy.

C. Evaluation form

GAPS	IMPACT				EFFORT				ID
	Customer	Global RAQA	Region North	**Score**	People	Time	Money	**Score**	
No Local Site Description	1	2	2	5	1	1	0	2	A1
No Market Quality Manager (MQM) is appointed	2	2	2	6	2	2	2	6	A2
Management reviews	2	2	3	7	1	1	0	2	A3
No concrete Quality goals are formulated and measured	2	1	2	5	1	1	0	2	A4
There is little knowledge and awareness of the quality policy developed for the Local sales and marketing sites. Lack of Succeed training is mentioned as one reason.	2	3	2	7	3	3	0	6	A5
No (Local) document control process for Quality records	3	2	3	8	1	2	0	3	A6
Job descriptions are not updated (Key roles identified)	0	1	2	3	3	1	0	4	B1
Local internal audits are currently not performed	2	2	3	7	2	1	0	3	A7
Region North (Sweden) does not use the Succeed distributor contract with all distributors	3	3	3	9	1	3	1	5	C3
There is a slight confusion regarding who is supposed to sign contracts with new distributors.	2	1	2	5	1	0	0	1	C2

A list of all distributors should exist, as of today they have them listed in Cognos	0	2	1	3	1	2	0	3	C4
No procedure concerning how the Site ensures control of suppliers/subcontractors exists	2	2	2	6	1	1	0	2	C1
There is little or no awareness of CAPA and the global CAPA process	2	2	2	6	3	3	0	6	D1
Product complaints training is not yet done by all employees	2	3	2	7	3	1	0	4	D2
Not following the marketing approval process (is under construction)	3	3	3	9	2	2	0	4	E1

D. Draft of a Local Quality Management System



Region North QMS: Master list

Market Site QMS	Area	Links	Processes/Procedures/Documets etc.	Local QMS	Succeed	Comment	Department to train	Actions
Policies	CAPA	Policy	Global CAPA Policy		X		All employees	Global QA/QA test
	Quality/environmen	Policy	Malmö/ske Global Quality Policy and Environmental Policy		X	Namn fl intranet version	All employees	
			Local market QMS assignment policy		X			
	Quality	RN-QMP	Region North Quality Management Policy 2015	X		Necessary ?		Kolrina + MGT
Quality management	QMS	RN-MSD	Region North Market Site description	X		Under construction	Management Rep	PM draft
	QMS	RN-QO	Region North Quality Objectives	X		Under construction		Kolrina
	QMS	C-059	MHC management system (Succeed) manual		X		All employees	Global QA responsible
	QMS	C-001	Succeed Document Control		X			
	QMS	C-014	How to Handle Quality Records		X			
	QMS	RN-LQR	Local quality records	X		Needs to be created when document needs to be marked as quality documents		Kolrina
Resource Management	HR	RN-intro	How to induct new employees at the Region North office	X		Intro from RN		kalla succeed, Sven när folk slutar
	HR	C-015	Personal Performance Review Process		X	Global process		
	HR	C-009	Manage Human Capital Policies and Requirements		X			se till att copmlaints rep etc är identifierat
	HR		Write position descriptions		X	Form antagligen		
	HR	Employee matrix	Employees - process matrix	X				
	HR		Managing training records		X	Kommer läggi LMS		
Market distributors, Subcontractors/ Suppliers		R-008	Supplier Evaluation Process, SER R-008		X	Amändas Global dock fixa till		
		Process	Select market distributors	X?	X	Antette låter med legal		
		RN-DL	List of most important distributors	X				
Feedback	Customer feedback		Customer Survey - process to be launched			Vem gör vad? Global customer survey		
	Customer feedback		Customer feedback	X		Dont really know, ask anette		
	CAPA	Process	Managing CAPA (Global process)		X			

Part of the Local Quality Management System draft.