THE DEVELOPMENT OF A QUALITY HANDBOOK AS A TOOL FOR A QUALITY MANAGEMENT SYSTEM

Case ProMedical Ltd

Reetta Emilia Sallinen

Business Administration Bachelor's Thesis

International Business

SAVONIA UNIVERSITY OF APPLIED SCIENCES
SAVONIA BUSINESS
Degree Programme

International Business

Author

Reetta Emilia Sallinen

Title of study

The Development of a Quality Handbook as a Tool for a Quality Management System: Case ProMedical Ltd

Type of project	Date	Pages
Thesis	12.11.2011	46 + 2

Supervisors of study	Executive organization
Risto Kiuru Anneli Juutilainen	ProMedical Ltd

Abstract

The objective of this thesis was to develop a quality handbook for the case company Pro-Medical Ltd as a tool for implementing a quality management system inside the company. ProMedical Ltd is an organization that imports and markets medical equipment to Finland. The need for a quality handbook was generated from the company's own decision to develop its functions.

Two aims were formed based on the objective. The first goal was to examine theory about quality management systems and the construction of a quality handbook from the point of view of an SME in order to create a basis for constructing a proper quality handbook for the case company. The second aim was to discuss the impacts of the quality handbook for the company. This was carried out by examining overall benefits, by evaluating if the development goals for the company's quality system could be achieved and by assessing the impact of a quality management system in relation to the highly competitive industry, in which the case company operates.

The research was conducted by gathering relevant theoretical information about the topics. The analysis dealt with these findings and the observations that were made during the construction of the quality handbook in the company. The thesis formed a stable ground to create the quality handbook. The research aims resulted in obtaining crucial information for the further implementation of the quality management system. Additional research later on would provide even more precise results of the benefits of a quality management system to the case company.

Keywords

Quality management system, quality handbook, SME

Note

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

1 INTRODUCTION

Companies who seek to operate in the most efficient way are increasingly developing quality management systems. The systems are created in order to improve the current processes and policies of the company and potentially to generate a higher profit in the long term. (Summers, 2005, 5.) It is not only large multinational manufacturers that strive to enhance their operations with quality management, as companies from all fields and of all sizes are starting to create interest towards maintaining quality (Waller & al., 1993, 10). As a part of a designed and implemented quality management system, some organizations create a quality handbook, in which all activities of the company are presented. Despite of having many roles depending on the usage of it, a quality handbook represents the quality management system, and functions as a guide to the operations of the organization. (Waller & al., 1993, 11.)

A Finnish SME ProMedical Ltd, operating in the medical equipment industry, has opted to implement a quality management system to improve its operations. The company is small and therefore does not pursue an official certification with its quality management system. However, the company considers it important for its success in the competitive industry to possess a quality handbook that can be presented to customers as well as to providers of the products imported by the company. The quality handbook is written by a student of Savonia University of Applied Sciences during a 5-month-long internship they completed in the case company, and the thesis is created as a tool for developing the quality handbook and a quality management system for the organization. The need for both the handbook and the system is a result of the case company's decisions to develop its functions in terms of management and operational processes and to ensure continuance of the development. The system is implemented with the help of the quality handbook and the conducted research of the thesis. As mentioned, the handbook is also created to serve as a guide to the case company's operations for its customers and producers.

The background for the thesis comes from the process of creating the quality handbook for the case company. There are two aims for this work. To present the objectives of the thesis clearly, the following structure is formed:

1. The first goal is to examine quality management systems and the construction of a quality handbook from the point of view of small- and medium-sized enterprises. The theory about these topics is gathered in order to construct a proper quality manual.

2. The second aim for the thesis is to discuss the impacts of the quality handbook for the company. This is done in three ways. First, the overall benefits of the quality handbook are analyzed with relation to theoretical findings on the subject. Second, the thesis evaluates whether or not the development goals that the case company has set for its quality system can be achieved. These goals were introduced in the former chapter. The analysis is done with the help of relevant literature and the observation that occurred during the construction of the quality handbook in the company. Third, the impact of a quality management system in relation to the competitive industry the case company operates in is examined to provide a more profound image of how the company may benefit from the handbook.

With these research topics, the thesis gives a theoretical basis for the construction of the quality handbook and provides the company with knowledge of what benefits it may gain with the implementation of a quality system and how it may gain them. The case company requested that the thesis includes research on the benefits, as the company may use this knowledge when implementing the quality system. It was also considered motivating for the further development of the quality system, once the potential impacts are recognized. Nwankwo (2000, 94) also finds that advantages of quality assurance for small businesses and how to gain them should be more researched, as companies often find it difficult to assess them. They also lack the time for performing this analysis (Nwankwo, 2000, 94). The research questions were chosen, because growth and development in small companies, such as in this case company,

are strongly related to a balance of the owner's intentions (development goals of the case company), the ability of the business (small size of the case company, which is evaluated when the relationship between small organization size and quality management is discussed) and the opportunity environment (industry where the case company operates in) (Morrison & al, 2003, 423). Thus, for the evaluation of the impacts of quality approaches, it is necessary to view these aspects in particular.

The content of the thesis is the following. Chapter two introduces the case company, ProMedical Ltd, in detail. Chapter three follows by providing a theoretical background for the construction of a quality management system and the quality handbook. The section begins with a theoretical discussion on what service quality is and how it can be improved. The discussion continues with reviewing literature on what project management is like in smaller companies. This is essential information for the development of a handbook, as it is a conducted project in the case company. The examined theory helps to evaluate the progress and success of it as a project. Next, the thesis examines quality management systems on a general level, presenting also the concepts of standardization and certification briefly. The chapter also introduces some barriers to quality systems. The thesis finishes the theoretical review of quality systems by discussing the relationship between quality management and small companies, followed by an investigation of the proper ways of constructing quality handbooks with references to relevant literature. Chapter four moves on to evaluate the impacts of the quality handbook on the case company. After that the thesis proceeds to chapter five to describe the quality handbook process that occurred. Following this, the discussion section evaluates the connections between the process and the theoretical findings, and presents the aroused consequences. Conclusions are presented at the end of the thesis. This section presents final comments on both the quality handbook and the thesis as a process. References and appendices can be found at the end of the paper.

2 THE CASE COMPANY - PROMEDICAL LTD

ProMedical Ltd is an organization that imports and markets hospital equipment and devices. The organization was founded in 2002 and is based in Helsinki, Finland. The company was created in cooperation with another company operating in the same field. Ab Medesco Finland Ltd and ProMedical Ltd cooperated successfully, which gave them an idea to merge the two companies together. As a result of the fusion, a new company was founded, and it was left with the name ProMedical Ltd so that the company would maintain the recognisability it had already gained in the market. During 2011 the company bought rest of the shares owned by Ab Medesco Finland Ltd and gained full ownership. (Pulliainen, 2005, 3.)

The product range of the case company consists of ultrasound equipment, hospital instruments, urologic machinery, surgical equipment and products for pain relief. The vision for the company is to provide its customers high quality products and good service in training, sales and deliveries. The strengths of the organization include personal selling, good service and well founded customer knowledge. (Pulliainen, 2005, 5-6.) The customers of the company include central hospitals, private hospitals and private clinics (Pulliainen, 2005, 12).

The staff of ProMedical Ltd includes the CEO, two sales representatives and a development manager. The sales representatives and the CEO perform a lot of field work as they visit customers regularly, while the development manager operates mainly at the office premises in Helsinki. The case company cooperates with medical equipment producers from all around the world, although mainly from Central Europe. The producers are employed from expeditions that are arranged in the industry and through networking. (Pulliainen, 2005, 11–12.)

3 THEORETICAL BACKGROUND FOR THE DEVELOPMENT

In this section of the thesis, several theoretical sources are discussed to provide a profound basis for initiating a quality management system in the case company. The aspects are to be recognized and understood by the company before it engages in the development process. As mentioned in the introduction, literature on project management aids in approaching the handbook as a project, whereas recognizing barriers of quality management systems shows the company what it should not do in the process.

3.1. What is quality?

Quality in both internal and external operations has become a necessity for the success of a business. However, in order to begin to proceed with quality issues one must understand the concept of quality. Definitions vary depending on the view quality is approached with (Schneider & al., 2004, 10), but in the world of business, quality is determined by the user of the product or service (Srinidhi, 1998, 43; Schneider & al., 2004, 10). This definition of quality, appropriately named by Schneider & al. (2004) as “user-based approach”, suits well when service quality is examined, because services are not tangible. In other words, they are exactly what they are perceived as. (Schneider & al., 2004, 10.) Quality can also be determined more specifically than with the ending result of a product or a service. It can be examined in a more objective manner by focusing on the specific areas of producing the service or product. (Schneider & al., 2004, 10.)

When quality is examined more thoroughly, one can distinguish a concept of service quality, which is particularly important for companies, providing some kind of a service, to consider. Service quality is defined by how a customer perceives the service performance of a business (Kuei & al., 1997, 24). Berry & al (1990) present five factors that impact on how service quality is perceived. The appearance of physical facilities, equipment, personnel and communication materials are the attributes customers pay attention to when they evaluate a service. In this case, a quality handbook may be classified as a form of communication materials. Customers also consider the company’s

ability to perform a service as accurately as promised as well as its level of willingness to help the customer. In addition to these, customers evaluate the knowledge of employees, their trustworthiness and confidence, and the individual attention an organization gives to them. (Berry & al., 1990.) Assuming these are the core attributes customers take into consideration when evaluating the level of quality, it is important to focus on them in quality management.

In order to keep customers, an organization has to frequently develop the above mentioned features. For a company offering a service, this may be in the form of service quality improvement. While the development process has to be incorporated in the company's own way of operating, there are a few imperatives, suggested by Berry & al. (1994), companies may focus on when improving service quality. Listening customer's suggestions for improvement is vital, as they are the receiver of the service. Service quality may be improved by assuring service reliability and accuracy as well as by providing functioning basic service, instead of making great promises and not fulfilling them, as this is more valuable for the customer. Surprising customers with superior service when possible and maintaining good team work inside the company are imperatives for service quality improvement as well. In addition, companies should ensure efficient leadership, as this is essential for the development. Once the thesis moves on to examine quality management systems, it is noticed that service quality improvement and quality management are closely related to each other.

3.2. Project management in small companies

To begin this section the characteristics typical for SMEs, specifically those that are related to project management, are reviewed first. Ghobadian & al. (1997, 128) present that in small companies operations and the behaviour of employees are highly related to the owner's way of working and their outlook. This suggests that projects that are undertaken in small companies are determined by the owner, even if the whole organization participates in them. Typical characteristics of small companies also include a short decision-making chain and a simple way of planning (Ghobadian & al., 1997, 128). This

correlates with the statement that project management is determined by the owner's outlook on the company, as he is often the only one who decides which way the company should take. Heuristic strategy planning, result-oriented processes as well as informal procedures in evaluation and control are typical in small companies as well. (Ghobadian & al., 1997, 128.)

A research conducted by Turner & al. (2009, 290) concludes that smaller companies apply smaller projects. The same study explores that the most important tools for small companies to consider when managing projects are resource scheduling, work breakdown, milestone planning and quality management (Turner & al., 2009, 290). Clear objectives and goals for the process, efficient resource allocation and consulting customers, as emphasized also in service quality improvement, are factors impacting project success in small companies (Turner & al., 2009, 292).

The assumptions from these findings help to form relevant project management principles. The typicality of simple planning in small companies is related to one of the major tools of project management, milestone planning. It is easier to break down working processes when plans are kept simple, whereas complex strategic choices would most likely be rather difficult to allocate into operational procedures. Simple planning also helps when clear goals are needed for projects. Clear objectives are also easier to determine when there is only one person making decisions in the company, which in SMEs is the owner. However, the informality that governs most procedures in SMEs can hinder an effective resource allocation or even the overall planning of a project. Informal may often signify that not everything in the company is, for example, documented or reported accurately, and therefore locating and using necessary information for projects can be challenging.

3.3. Quality management systems

A quality management system refers to a program an organization engages in to improve and to maintain the quality of its activities. Creating a more suitable organizational structure, planning and implementation, resources and documentation should all be taken into consideration, when a quality management

system is introduced. Many have a false assumption that quality systems are the concern of only large corporations. Instead, companies of all sizes are encouraged to control their quality level. (Suomen Standardisoimisliitto, 2003, 17.)

Advantages of employing a quality management system are many and depend on the company and how efficiently they implement the system. (Suomen Standardisoimisliitto, 2003, 19.) The Finnish Standards Association (2003, 23) reflects that in order to gain benefits from a quality management system, a company must ensure the involvement of both the management and the employees throughout the process. Cheng & al. (2007, 65) support this by stating that continuous interest and commitment of management are imperatives for a successful implementation. Not only does management provide the vision that reflects the service and its quality, but it also offers personal input on how the service can be made as efficient as possible. In addition, management encourages employees to perform in a way that represents the best possible quality of the service. (Cheung & al., 2010, 261.) The point being assumed here is that quality issues require strong leadership.

Employing a quality management system is not an easy route for development, and without proper implementation it may fail to bring the real benefits for an organization. A quality system may result in a bureaucratic mess that only complicates business activities. Steve Denning, an author of six business books and a consultant to companies all around the world, criticises some quality management systems for their lack of customer focus, in *Forbes* magazine (Forbes, 2011). The idea behind his argument is that quality is defined by the customer, which was also the assumption from previous findings. When customers' expectations are exceeded, they will consider the products or services as good quality. This in mind, customers should be the most important focus when proceeding with a quality management system. The process is commenced by discovering *what* it is that customers want and is ended by making them satisfied. It is also advisable to ask customers about areas of the business they would like to know more about. These investigations can be made for instance by conducting a customer satisfaction survey. To empha-

size the importance of customer perspective in quality management systems, and to get a wholesome image of how the system should flow, a model of it is presented below (FIGURE 1.). The model is from the book ISO 9001 Pk-yrityksille – mitä tehdä by the Finnish Standards Association (2003, 38).

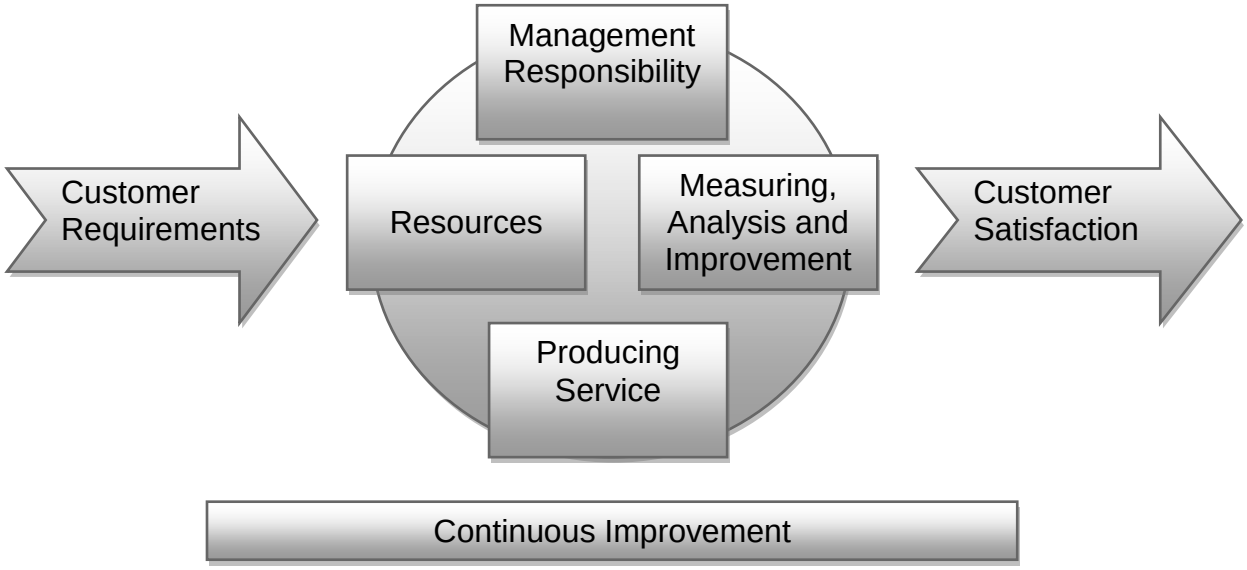

FIGURE 1. Quality management system *(*Suomen Standardisoimisliitto*,* 2003, 38)

As can be seen from the model, the process begins and ends with a customer perspective. By interviewing customers, a company finds out their needs and may use this as an input for the process. Producing the service is the main procedure, including all actions to develop a finished service. The model also includes “measuring, analysis and improvement”, which refers to any information the company needs in order to produce an offering. For example, feedback from customers can be an extremely useful source of information. It cannot be emphasized enough how important it is that management is involved in the process. The responsibilities of management include for example allocating resources. “Resources” in the model refers to the need for an organization to reserve resources for the quality management system in terms of employees, premises, financial resources and materials. Finally, “continuous improvement” indicates the importance of maintaining the quality that is accomplished during the process. (Suomen Standardisoimisliitto*,* 2003, 38.)

Standards

Companies seeking to certificate their quality management systems are required to follow an official standard. While applying standards is useful and structured, organizations must remember that they are created for guidance. As Green (1996, 24) states, it is unnecessary to implement all requirements of international standards particularly in small businesses. It is the responsibility of the company to exploit the standard to a certain level to improve the way it functions (Waller & al., 1993, 27). The ISO 9000 standard is an international series created by the committees of International Organization for Standardization (ISO) (Suomen Standardisoimisliitto SFS, 2001, 9). ISO standards are designed to improve the sales of products and services with the requirements of quality management systems. While the ISO 9000 standards are updated according to changing markets, they are used by many companies as a base for their continuous improvement (Summers, 2005, 35). Principles of the ISO 9000 standard that make up a quality management system are customer-focused organization, leadership, involvement of people, process approach, systems approach to management, continual improvement, factual approach to decision making and mutually beneficial supplier relationships. ISO 9000 standards also emphasize the importance of clear documentation during the process (Summers, 2005, 38). If all these areas are successfully implemented during the quality management system, an organization should be able to improve and maintain the quality in its operations. (Summers, 2005, 36.)

Certification

If a company wishes to register, they must complete the quality management system with a certification. Organizations may apply standards without an official certification process, but some have considered it a major advantage to register as a business, who has dedicated itself to quality management. (Suomen Standardisoimisliitto, 2003, 25.) Certification means that a quality management system is evaluated by an external, official registrar. By observing the employees of an organization the registrar ensures all areas of the standard are fulfilled and the company operates in ways their quality handbook indicates. The registrar then decides whether or not the company is worth the certification of quality management. There are advantages to certifi-

cation and one of the most significant is increased revenue, as being accepted by an international quality standard gives the organization recognition and an opportunity to expand geographically. In addition, some customers may require the certification of a quality standard from the company. However, the process is costly and requires a significant investment in time and effort. Therefore, a business should consider whether or not it in fact needs to be registered to succeed in its market. (Summers, 2005, 39-40.)

Barriers of quality management systems

A quality management system may also create more harm than benefit for a company. As it was indicated in the previous chapter, it may only result in more complexity in business activities. Quality management systems have also been criticised for the usefulness of them. There are companies who have been through a standardized certification and still produce and provide poor quality. (Bell & al., 2011, 725.) One may assume that this drives companies to question whether or not to engage in such a demanding process. In addition, it may impact the degree of motivation a company has for the development.

The importance of management involvement was already emphasized and a lack of it is a barrier to quality management systems (Srinidhi, 1998, 68; Psomas & al., 2010, 442). Psomas & al. (2010, 442) point out that lack of leadership may lead to insufficient allocation of responsibilities and authorities for the process. The same study also finds quality management systems may suffer from too great expectations as well as from a lack of full commitment to the process (Psomas & al., 2010, 442). Srinidhi (1998, 67) notices if a company is structured departmentally, an overview of the development process may be difficult. Departmental managers may fail to see how the quality level of their department impacts the whole organization. Therefore, the point being assumed here is that cooperation between all departments is necessary for a functioning quality management system. In addition, companies often find it challenging to change the way of organizational reporting in the short time an initiative to a quality management system begins (Srinidhi, 1998, 68). Companies may have troubles finding resources and time for additional inspection of

processes. A lack of a decent information system ensuring an information flow throughout the organization may also hinder the system. This often occurs in companies which have expanded through acquisitions, where communication is more challenging than in organizations with no subsidiaries or departmental units. Lack of communication may be somewhat substituted by strong management, but this does not guarantee the success of a quality system. (Srinidhi, 1998, 68.)

3.3.2. Relationship between small firms and quality management

As the economy faces a crisis once again, small businesses are put in focus. Large businesses are unlikely to employ new staff until the economy fully recovers from the downturn. Therefore, growth will most likely occur in small- and medium-sized businesses, where the importance of quality management continues to increase. (Bell & al., 2011, 733.) In addition, Morrison & al. (2003, 417) state that small businesses concise the largest portion of the world economy, further increasing the need to study quality issues for the small business sector. Ghobadian & al. (1997, 130) evaluate, however, that the need for organizational changes, for example in quality management, may be difficult for the leaders of small companies to detect. Nevertheless, particularly in SMEs, not only the management takes part in the development process, as the employees often bring out their suggestions on it as well (Ghobadian & al., 1997, 132). This suggests that the management may not be, and usually is not, the only responsible one for recognizing the need for a change.

While the need for development may be recognized, the processes often seem intimidating and too much of an investment for a small company, as quality management requires consideration on so many levels. Creating management structures, following requirements from various directions and formalizing all procedures challenge the organization in a new way. In addition, as the quality system proceeds, a company has to correct activities which are discovered insufficient as well as audit the improved system regularly. Due to all these procedures, the system may require too much investment from a small organization. (Waller & al., 1993, 20; Ghobadian & al., 1997, 133.) The

Finnish Standards Association (Suomen Standardisoimisliitto, 2003, 24) advices companies to evaluate their resource structure in order to decide if they should build a quality management system internally or outsource the task instead. Many companies use outsourced professionals, but that requires a substantial investment in money. As small firms often have little opportunities to finance this (Ghobadian & al., 1997, 133), they must consider a suitable pathway to implement a quality management system.

Not only do quality management systems intimidate small firms, but McTeer and Dale (1994) also suggest that most companies experience problems with managing them because of lack of time and knowledge. The inability to perform the task themselves is the reason SMEs assign the task to an outsider. A study about small- and medium-sized enterprises and quality management conducted by Brown & al (1998) found these reasons for using external professionals as well. Nwankwo (2000, 96) also concludes that ignorance about quality assurance inside SMEs leads to an insufficient process. The point being assumed from all these statements is that a SME should commence the process by learning about a proper application of a quality management system, before engaging into one.

Although there are studies examining the relationship between small- and medium-sized companies and quality management systems, there are very few empirical researches on the subject (Anderson & al, 1999, 863). Thus, it is difficult to provide statistical information about the relationship between the two. This may impact the perception many leaders and employees have about employing a quality management system. Motivation may also be affected, as creating a quality management system or even a quality handbook inside a small organization is often associated with high costs and no visible results (Anderson & al, 1999, 862). Moreover, employees of small companies are often only concerned about their daily tasks and short-term goals, rather than what long-term benefits quality systems have to offer (Ghobadian & al., 1997, 133). If the management of a company fails to communicate the long-term value of a quality management system to the employees, the effectiveness may suffer, as the employees are not motivated to participate fully on the qual-

ity initiatives. (Anderson & al, 1999, 875.) Taking these findings into consideration, one may assume that a company has to invest in motivating the entire company with the potential benefits the system can bring.

It is imperative for small companies to focus on effective management systems. Bell & al (2011, 733) emphasize the need particularly as companies choose their major manufacturers. Quality management includes gathering information on what is required from the producers and what is perceived as good quality in their case. The reasoning for an efficient management system is that some large manufacturers may have components or parts of its service that are of poor quality. Unless this is monitored by a small company, particularly with its major producers, there may be a substantial negative impact on the company's sales (Bell & al., 2011, 733). Although risk-free relationships with producers cannot be guaranteed with the utilization of a quality system, it can provide a better way of monitoring for a SME, and thus prevent substantial losses from occurring.

A positive impact of a small organizational size on development processes is the absence of bureaucracy in the company. Small companies benefit from a more flexible structure, in which decisions are made together, making the design and development of new operational processes as a part of the quality management system much easier (Ghobadian & al., 1997, 127). Ghobadian & al. (1997, 128) also suggest a small company size makes managerial processes less complex, which impacts the control of quality systems positively as well. In addition to this, the change through quality management is more fluent for smaller companies, because there are only a few employees to train for new changes (Ghobadian & al., 1997, 132).

3.4. The construction of a quality handbook

When a quality management system is planned and implemented, an organization must document everything in a quality handbook. However, the order in which these two are synthesized varies. For example in the case company, the quality handbook is written first and then used as a guide to implement the quality management system. This way the system is done in order. (Waller &

al., 1993, 40.) It is also an efficient way to detect areas that need improvement. The content depends on the system and what the organization considers important to include in the handbook. Waller & al. (1993, 39-40) present one way to construct a quality handbook.

- Quality policy manual

  A policy manual is the first section of the quality handbook and created to present all policies on quality and strategy that the management has developed or develops during the process. The content of a quality policy manual includes an introduction and policy statements. In the introduction, the reader should discover the standard used for the quality management system, the way it is organized and who is in charge of maintaining it. Policy statements inform the reader of the strategic goals and visions of the company. The customers are interested in knowing this, as the strategy should strive for satisfying their needs. (Waller & al., 1993, 48.) It is also important to present the organizational structure of the company, for example in the form of an organizational chart. The structure may be changed during the course of the quality management system, if it is discovered insufficient. (Waller & al., 1993, 52.) Management responsibilities and reviews are to be presented in this section of the quality handbook as well (Waller & al, 1993, 48).

- Quality procedures manual

  A procedures manual represents the operational side of a company's functions. The reader is informed of how processes are developed and executed in detail. (Waller & al., 1993, 65.) Organizing procedures in timelines or departments is a structured method of forming a procedures manual, giving the reader a clear image of how the organization functions (Waller & al., 1993, 68). The reader should also discover the various jobs of the company and how they are fulfilled (Waller & al., 1993, 78).The criticality of a quality procedures manual is that the outcome of a quality system depends on how clearly and in detail the section is researched and created (Waller & al., 1993, 67). The content varies according to the functions of the company, which along with the

other requirements for a procedures manual demand full commitment from the staff and critical observation throughout the process.

- Workplace references

  This section of a quality handbook should include all documents employees need to fulfill their tasks, such as work instructions, technical manuals and codes of conduct. The purpose behind workplace references is to make a company as efficient as possible dealing with its informational documents. (Waller & al, 1993, 85.) The section is created primarily to the existing staff of the company and to new employees, so they know where to locate and how to use the information concerning their daily tasks. The quality handbook may present the documents in writing or as an appendix. (Waller & al. 1993, 86.)

When writing a quality handbook, one must consider the importance of style and design. It is equally important *how* the handbook is written than *what* is written in it, as it indicates the investment and effort that has been put into it (Waller & al, 1993, 103). A quality handbook must be easy to read, clear and attractive. If the reader, whether it is the customer, producer or the company's own employee, understands little or nothing of what the book has to say, they are going to get frustrated. This only takes away from the benefit that can be gained with it. (Waller & al, 1993, 117.) Some important rules when writing a quality handbook are using common and understandable words, explaining technical terms, being consistent, using short and simple sentences and writing in a positive tone. Along with good editing work, all these impact the way the reader approaches the quality handbook. (Waller & al, 1993, 104-111.)

4 THE IMPACTS OF THE QUALITY HANDBOOK

The impacts of a quality management system vary between companies, and they are highly related to how the system is implemented. This section of the thesis starts with discussion on the benefits the case company can gain with a quality handbook and through employing a quality management system. The benefits are a result of analyzing both theoretical findings and the observation that was performed inside the case company during the construction of the quality handbook. The section continues with an evaluation of whether or not the development goals the company has set for its quality management system can be achieved, and in what ways they can be proceeded with. This is also done with the help of theoretical sources. The last part of the section consists of discussion on the impacts of a quality management system in relation to the competitive industry the case company operates in. As it was mentioned in the introduction, all these aspects are examined to support the case company as it begins to implement a quality management system with the quality handbook.

4.1 Benefits of the quality handbook

Through a quality handbook, companies increase quality awareness among clients, as they are introduced to the services of the organization and what the quality level of those services is (Waller & al, 1993, 46; Brown & al, 1998, 279). In this sense, a quality handbook is a powerful marketing tool. Even if certification is not needed, as it is not for the case company, a quality handbook enhances the image of a company substantially. (Green, 1996, 24.) Nwankwo (2000, 95) supports this by stating that quality approaches bring a significant input on the marketing of a business. The majority of the case company's current customers send requests for a quality handbook as evidence that the company has engaged in a quality management system. Once an organization provides customers what they ask for, customer satisfaction is increased (Milena & al., 2010, 920). Thus, for the future success of the business deals the case company makes, it is a great advantage to create a quality handbook.

Waller & al. (1993, 47) suggest a quality handbook makes a significant impact on the selection and the management of producers, as they receive insight to the policies of the organization through the handbook. Milena & al. (2010, 920) reflect that overall communication and understanding between companies and their suppliers are improved, particularly when the supplier wants to know more about the company. Guilhon & al. (1998, 696) also state that quality approaches help refocusing the activities that are outsourced by the company to its producers. The case company's future goals include developing the relationships it has with its producers. According to the presented findings, a quality handbook and a quality management system provide an opportunity for the company to reach for this objective. Another aspect for the case company to consider is that global markets are constantly growing in terms of producers. New manufacturers of the products imported by the case company are established in Europe, but especially in China and in the Far East. (Pulliainen, 2005, 5.) Therefore, the regulations and the ways of working in different countries are to be taken into consideration. A quality handbook ensures this and a more fluent cooperation by presenting how the company operates.

In addition to customers and providers, a quality handbook benefits the employees of the case company itself. By obtaining deeper knowledge of the company's operations, they are able to perform better at work in case instruction is needed. (Waller & al, 1993, 45.) Nwankwo (2000, 94) also finds better understanding of operations as one of the advantages of quality management systems. Internal operations are improved as communication and ways of working run more smoothly and the entire organization is informed of the correct ways of working. Not only does the flow of information improve, but the employees are also more informed about the short- and long-term goals of the company (Guilhon & al, 1998, 696). Often this adds to the motivation of employees and their ability to innovate. (Summers, 2005, 10; Milena & al., 2010, 921; Guilhon & al., 1998, 696) Once employees are in control of their work and know what they are doing, they are more involved (Cheung & al., 2010, 262). Cheung & al. (2010, 263) suggest employee involvement has a positive impact on customers' perceptions about quality. Referring to these findings, one may assume a positive customer perception increases the offering's qual-

ity. Thus, the case company may focus on maintaining employee involvement as one method of building good quality services. In addition, a quality handbook ensures a correct and efficient training of new employees. They are inducted to their new positions by following the information in the quality handbook. (Green, 1996, 24.) Moreover, unnecessary procedures can be detected during the creation of the quality handbook and deleted from operations. The point being assumed here is that the case company can reduce its costs by doing so. (Milena & al., 2010, 920.) However, Nwankwo (2000, 95) reminds that although cost reduction is an attractive reason for implementing a quality management system, this may not compensate the cost involved in the process. Referring to this, it is necessary to evaluate both the investment and the cost benefits.

Quality management standards follow a customer-oriented approach, as including needs of customers in the process increases organizational effectiveness (Summers, 2005, 4). By adhering to this and developing a greater focus on its customers, the case company may be able to generate more revenue in long-term. However, Nwankwo (2000, 93) reminds external factors, such as customer benefits, should not be considered alone, as quality management provides a company an effective management tool for operations as well. One may assume that by examining all potential benefits, the case company is more likely to achieve the full potential of this process. Summers (2005, 5) reflects that creating a quality handbook enables a company to examine its position in the industry and market. Observation of the company's own position, for example in terms of market share and current state of competition, brings insight to where it stands and the process of improving its activities becomes much easier. Concluding these findings, the case company increases organizational effectiveness with its quality approaches in various ways.

4.2 Development goals

Whether or not the development goals of the case company can be reached through a quality management system is difficult to determine. However, Srinidhi (1998, 40) suggests the chances of achieving noticeable results are increased if the goals of the quality management system are linked to the

overall strategic plans of the company. Srinidhi (1998, 42) presents “Strategic Quality Management” in his research, which refers to an integration of the quality principles and the vision of the firm. According to the research, strategic planning includes possessing a clear vision, a developed change methodology for achieving the vision and planned mechanisms for the change (Srinidhi, 1998, 41). Cheng & al. (2007, 70) also discover connecting the objectives of the quality management system to the already existing strategic goals and vision as one of the key components of a successful change. Nwankwo (2000, 95) supports this by studying that a quality management system requires a clear strategic perspective to work. Both of the studies also emphasize the involvement of management in the strategic planning process (Cheng & al., 2007, 71; Nwankwo, 2000, 95). Srinidhi (1998, 43) also reflects that strategic quality management is applied by using researched management methods. The point being assumed here is that effective leadership is vital in the strategic planning process.

To demonstrate how the case company integrates its quality development goals and its strategic planning, a table consisted of both the quality management system goals and the company’s strategic goals is presented below (TABLE 1.). Both sets of goals have been determined by the CEO of the case company in the business plan (Pulliainen, 2005) and confirmed during meetings for the quality handbook.

TABLE 1. Quality management system goals vs. strategic goals

Quality management system goals	Strategic goals
	Development of management
Development of operational processes	Development of operational processes in terms of finding new producers
Differentiation by developing product offering	Fixing weaknesses
Continuance of development	Customer-oriented operations
	Extending the business, e.g. by employing a third sales representative

As can be seen from the table, the goals for the quality management system are quite general, whereas the strategic goals of the case company are defined more specifically. From the quality management goals, particularly continuance of development and development of operational processes are related to the strategic plans of the company. Differentiation and extension of the business are good strategic choices for the continuance of developing a business. Operational development can be achieved through improving the ways how the case company finds new partners and through fixing weaknesses. In addition, as it has been indicated in the reviewed theory, the entire quality management system should follow a customer-oriented approach, which is one of the strategic goals for the case company's operations as well. However, it appears that the development of management is not considered in the strategy. Referring to the findings, the case company may have to incorporate management development into its strategy before it can start improving it through the quality management system. The point being emphasized here is that a lack of detailed strategic planning in the quality management system may prevent the development all together. Therefore, it is vital that the two of these are linked. In addition, it is more likely that if quality management is based on the strategy of the company, the overall direction of the company becomes clear for both the management and the employees to follow.

One if not the biggest impact on the success of reaching the development goals the case company has set is how motivated the management is to implement the quality management system (Milena & al., 2010, 918). Several studies indicate that management must be visibly involved in the process and to themselves operate according to the quality policies they have set. If the management shows no motivation and no importance towards the quality management system, this may impact the impression employees have about the whole process. No one in the company is motivated to proceed with it. (Cheng & al., 2007, 65; Psomas E.L. & al., 2010, 451) Whether or not this has happened in the case company can be determined by examining where the idea for a quality handbook originates. Although creating a quality handbook is the requirement of many of its clients, the case company chose to begin the process to develop its operations. In other words, the quality handbook is not

a forced assignment for the organization, but the owner's decision to make improvements in the quality of services. Studies suggest that internal motivation towards implementing a quality management system has a major impact on the success of it (Milena & al., 2010, 918). The point being assumed here is that if the case company adheres to this, it may be able to improve its operations.

The probability of reaching the goals also depends on how the case company implements internal audits after the quality handbook is finished. Internal auditing is one of the major activities of quality management standards and required for a successful execution (Milena & al., 2010, 917; Cheng & al., 2007, 71). Researchers suggest it is not enough to employ a quality management system or write a quality handbook, as the company must also conduct regular, internal audits in order to gain noticeable improvement from its quality system (Milena & al., 2010, 918). As the case company does not aim for certification, it has no formal obligation to internally audit if it has reached its development goals, and the motivation for this must be generated from the company's own interest. Therefore, the success of reaching the development goals in relation to internal auditing depends on the company's devotion to engage in this activity. Nwankwo (2000, 94) suggests an additional point of view by stating that external assessment is a necessity in proper quality control, and employing quality management systems only in the internal level is most likely not efficient enough. The point being assumed here is that in addition to internal auditing, the case company would also need an external source to evaluate the development process in order to achieve results from it.

Monitoring is also crucial for the continuance of development in the company's operations. Measuring outcomes is a large part of quality systems, and used to ensure sustainable efficiency (Cheng & al., 2007, 71). The continuous development required in a quality system enhances professionalism inside the company (Nwankwo, 2000, 94). Thus, continuance of the development is a long-term goal and strategically wise for the case company to include in the goals of the process. Importance should also be placed on frequent updating of the documentation of the quality management system. As information tech-

nology evolves, companies are forced to change working habits and instructions. (Bell & al., 2011, 733.) Updating this information in the quality handbook is crucial for the case company's continuance of development.

The success of improving operational processes in the case company is highly related to the availability of resources for the task. Forsman (2008, 611) evaluates that if a company underestimates the resources needed to develop new operational procedures or to enhance existing ones, it most likely does not succeed in its task. Small companies in particular may have the ambition, but they lack the appropriate amount of resources for their development. Concluding these statements, it can be suggested that the right balance for successful change in operations should come from the definition of the project goals and the identification of the needed resources for it. Cheng & al. (2007, 71) also find it imperative to secure resources for the new system as well as allocating them to correct development procedures. Psomas & al. (2010, 453) support this by concluding in their study that an efficient development system calls for the reservation of financial resources for the process. During the process of writing the quality handbook, the case company was yet to identify the resource allocation for reaching its development goals. Referring to Forsman (2008), Cheng & al. (2007) and Psomas & al. (2010, 453), it can be argued that this may be a major disadvantage for the development.

4.3 Relationship between the industry and quality management

Psomas & al. (2010, 453) find it critical for any service company conducting a quality management system to consider the features of the external surroundings in which they operate. Taking this into consideration, inspecting attributes of the medical equipment industry gives the case company a better chance to build an efficient quality management system. In addition to this, quality is everything in the medical equipment industry. For the purpose of treating humans, the products must be perfect and if they show any sign of malfunction, they are not bought. The functionality of products has to be supported with a trustworthy image of the company as well. In an industry where these become

of great importance, quality issues are necessary considerations for any company, who enters the market. (Pulliainen, 2005, 5; Srinidhi, 1998, 42.)

The case company operates in a dynamic industry that faces new developments continuously (Pulliainen, 2005, 4). The fast-evolving nature of the industry opens new opportunities for companies to expand their operations, but at the same time they are challenged with substantial developing procedures. This in mind, the case company must develop its product range and services in order to succeed. A quality management system provides a good opportunity for this, as the system requires regular auditing of operations. Long-term planning in an industry that develops and changes so often may be pointless and therefore, the frequent auditing of a quality management system is most likely more efficient.

The medical equipment industry is relatively concise, because there are only a certain amount of customers, who in this case are central hospitals, health centres and private clinics (Pulliainen, 2005, 4). As the customers of the field consist of state owned institutions, the payer is the municipality or the government. In Finland, companies can trust that the payments are received accordingly. Therefore, one may assume that the case company faces very little or no credit loss from its sales. Theoretically this implies that the risks lie in the company's own operations. If internal operations of the case company are controlled through a functioning management system, the risk to fail becomes nearly non-existent. However, an efficient quality system is required for the organization to reach such a comfortable level. Only creating a quality handbook is not enough, as the case company must also continue with the help of it to monitor and develop its activities. The importance of this was already stated as continuance of the development was discussed.

Typical for the medical equipment industry is that the trading is regulated. Because of the fact that customers are mostly state owned hospitals, the business is formed on the basis of statutory competitive bidding. In practice this means it is mandatory for customers to perform offer competitions for new products. This gives small companies, such as the case company, a chance

to compete in the market. (Pulliainen, 2005, 4.) However, to be able to compete with larger competitors, the case company must have the expertise to participate in the competitive bidding of the market. Without the know-how and efficient operations, the company is unlikely to succeed in the market. The organization can produce a competitive edge and survive in the competitive surroundings with its quality management system. Lundmark & al. (2006) find that companies motivate themselves to implementing quality systems with the opportunity to increase market share. With increased efficiency and innovation the case company may participate in the formation of new and improved services in the industry and possibly gain more market share.

The International Standardization Organization (ISO) has developed a quality management standard that is specifically designed for the medical device industry. The standard gives organizations in developed countries an opportunity to reflect on their regulations and to improve them. As for organizations from countries where the regulations have not yet been developed entirely, the standard represents an excellent model for the design and implementation of them. (Gasiorowski-Denis, 2003.) A quality handbook is a suitable start for the quality improvements inside the case company, but if it wishes to grow in size in the future, it may consider adopting the quality management standard designed specifically for companies in this field and certify its business.

In addition to the ISO standard, the industry has developed a Global Harmonisation Task Force (GHTF) which consists of representatives from the medical equipment industry. The goal of the cooperation is to facilitate international trade in the industry by promoting regulations and requirements of various markets. GHTF provides documents and guidance for companies in the field and especially ones that are planning to globalize their operations. (Lalis, 2007.) Considering the development plans of the case company, it may benefit from the documents of the GHTF to improve the ways it manages international trade and potentially to expand its sales area geographically. The ISO standard for the medical equipment industry and the Global Harmonisation Task Force were introduced for the case company to gain more knowledge of the opportunities that lie in quality management.

5 THE QUALITY HANDBOOK PROCESS

In this section, the process of making the quality handbook is described by presenting the various tasks executed in the case company. As mentioned in the introduction, the quality handbook was formed during the internship the Savonia student completed in the case company.

Determining purpose and objectives

The first task in the process was to determine clear objectives and the purpose for the quality handbook, as without them the process could not begin. The case company has been operating since 2002 and has not yet managed to expand as it has envisioned in its strategy. Therefore it chose to engage in a quality management system, which begins with writing a quality handbook. The case company set development goals for the quality management system in order to structure its operations, to improve their functionality and possibly to gain an opportunity to expand. The goals were communicated to the employees of the company and included development of management, operational processes and ensuring continuity of the development after the quality handbook. The organization wanted to develop the quality handbook also in order to create a tangible document, from which the strategic and operational policies and procedures can be read. This has its basis on the quality handbook requirements the case company continuously receives from external sources.

Determining methods and responsibilities

The next task was to determine the method of constructing the quality handbook and to assign responsibilities for the process. These were determined in a meeting that was held with the management of the case company. As a method, it was considered easiest for the implementation of the development process to first inspect the company activities thoroughly and detect the weaknesses through the quality handbook. In other words, the handbook would serve as a guide for implementing the quality management system. Because of this, it was decided that the quality handbook would be constructed using an ISO 9000 standard as a model so that the structure and the content would focus on finding the fundamentals of the business. The standard also

includes steps that assist in the process once the handbook has been finished. These include management review, quality records, quality audits and corrective action. Holding on to these tasks regularly, the company ensures that it correctly maintains the quality management system. (Waller & al, 1993, 182.) The equivalence table to the ISO 9001:2000 standard, where one can see which areas of investigation are included in the case company's quality handbook can be found from appendix 1. The responsibility of the entire project, in terms of researching and developing the handbook, was given to the student. However, to ensure a truthful handbook it was regarded necessary that the student approached the staff of the case company when information about the organization was needed. The case company did not assign responsibilities for the further implementation of the quality management system. The quality handbook was chosen to be written in both English and Finnish so that it could be presented to both the producers from other countries and the customers from Finland. During this process it was also chosen that the quality management system will not be certified in the near future as the company did not find it necessary for its current situation.

Time scheduling

The next task included determining a preliminary time schedule for the process. The case company did not set a particularly detailed schedule for the quality handbook. However, it was to be written during the internship the student completed in the company and as the thesis was formed. Therefore, the project was to be completed in 5 months, giving it a deadline to the end of October, 2011. The time schedule was not developed further during the process.

Collecting information

The next task was to begin developing the handbook. This task involved forming an understanding of a proper content of a quality handbook, the organization and the ways it operates. It was also important to have a clear concept of what quality management systems are about. Thus, a lot of information was to be gathered. Information about the case company and its operations that were to be documented in the quality handbook as well as information about creating quality manuals were collected in the following ways:

- At first, interviews with the entire staff were conducted. For small companies, conducting interviews is an efficient method of collecting information (Waller & al, 1993, 156). The case company consists of only 3 employees and the CEO. Therefore, individual interviews suited best for this quality handbook. The interviews consisted of questions such as what are their tasks to perform, what kind of responsibilities each employee possesses and if the staff has any problems or suggestions for improvement. As the interviews were conducted, the interest and motivation of the staff towards the quality handbook process were also revealed. Limited knowledge of quality management and the long-term goals that could eventually bring benefits for the company motivated the employees to proceed with the task. The interviews took place at the beginning of the process, where the participants still had a relatively limited image of the specific content of the quality handbook.

- To get the most out of the data collection process, the employees were also asked to write a description of their working processes, which verified the answers they had given during the interviews. According to Waller & al. (1993, 157) this ensures that factual responses are received and there is no room left for misinterpretations.

- In addition to interviewing and written descriptions, the business plan of the case company that was written by the CEO helped to gain insight to the aims and objectives of the company. According to Waller & al. (1993, 79) factual descriptions of the procedures are formed, if they are written with assistance from the people who carry out those procedures. This was also taken into account in the writing process.

- Gathering information about the case company was naturally not enough to create a quality handbook. It was essential to study guidebooks about how to write a quality manual and how it would help in the quality management system. The most knowledge on the fundamentals of creating a quality handbook was gathered from the guidelines written

by the Finnish Standards Association (SFS) “ISO9001 Pk-yrityksille – mitä tehdä” and the book of Waller, Allen and Burns “The quality management manual: how to write and develop a successful manual for quality management systems”.

Determining content

The next task in the process was to write a draft of the quality handbook and to determine the content of it. During this task, the level of commitment to the ISO 9000 standard was also identified. When determining the content it was particularly important to consider first what the main operations inside the company were. The content of the case company’s handbook was formed with the help of the ISO 9000 standard and the model presented earlier in this thesis, which included a clear description of both strategic and operational sides of the company’s operations. The content is described in this section and to get an overview of it, the table of contents of the quality handbook can be found in appendix 2.

- An introduction to the organization and its history begin the handbook. In addition, the services are described briefly. The company considered it important to describe its product groups and their manufacturers in detail. Contact information of the manufacturers was also added to demonstrate reliability. As the quality handbook proceeds, strategic policies of the case company are introduced. Planning and management of the business are presented, including information about the vision and policies on quality, environment, safety and health. In this case, specifically quality policies and environmental policies are of great interest to the customer, and therefore important to include in the handbook. Next, control procedures of the company are introduced. For the reader to gain knowledge of the job positions in the case company responsibilities and authorities are introduced and an organizational structure is shown. Following this, the quality handbook gives insight to operational control and monitoring in the case company, which lets the reader know about meetings and the information flow. Resource management is also presented. The section includes critical information on

how the company's producers are chosen. Therefore, it is a great source of information for the manufacturers interested in cooperation with the case company. In addition to this, facts on purchases, human resource management and physical structure of the resources are presented.

- The operational procedures are introduced next. Control of deliveries includes information on how the case company deals with sales, procurement of materials, warehousing, transference of products to customers, after sales operations and reclamations. The reader learns how the company operates, for example, in terms of delivery times and what happens after the purchase has been made. The last two chapters of the handbook describe how the case company evaluates its business activities, how the activities are monitored and how the development of the activities is designed and implemented.

- During the process it was chosen that workplace references are left out of the quality handbook. The case company's management considered it unnecessary to present them to the appointed audience of the handbook. However, to cover the documentation policies of the company, which some readers wish to know about, the quality handbook includes information on how the company performs its documentation. It is also vital that the case company reflects on the documentation system it currently has, and improves it if necessary as a part of the development of operational processes.

Determining internal auditing

It is to be reminded that the quality handbook process is not the aim for developing the operations in the case company. Instead, the creation of the book including the help of the investigation in this thesis allows for the company to begin its development procedures with the quality management system. Because of this, the process included a task of determining the future of the internal audits once the quality handbook is developed. This was left as the responsibility of the organization. It was important that the case company set

long-term plans for measuring and analyzing if the quality management system gains the benefits that the company has aimed for. Developing the handbook with the assistance of an ISO 9000 standard assists the case company in applying its quality management system over time. The company set a schedule of performing audits frequently when the quality system is commenced. The resources for the quality management system were yet to be identified or allocated during the quality handbook process.

Finalizing the process

The process continued with observing the case company and writing the quality handbook. By the end of the process, few drafts were given to the CEO for them to check the handbook supported the current strategy and processes. The quality handbook was finished according to the initial schedule at the end of the internship, and the investigation included in the thesis shortly after that. Below one can see a simplified outline (TABLE 2.) of the quality handbook process and at which stage the presented tasks occurred. The table also presents the construction of the thesis.

TABLE 2. The process

June 2011	Internship in case company begins
	Topic for thesis outlined
	Determining methods for construction of quality handbook
	Assigning responsibilities
	Determining preliminary time schedule
July 2011	Theoretical research conducted
	Interviews for staff conducted
August 2011	Writing thesis and quality handbook
September 2011	Determining internal audits
	Writing thesis and quality handbook
October 2011	Finalizing quality handbook
	Internship in case company ends
November 2011	Finalizing thesis

6 DISCUSSION

The theory presented in the thesis regards management involvement as one of the most important for small firms to ensure while implementing quality management. During the unfinished process in the case company there was some uncertainty if the handbook would be finished on time, due to the fact that occasionally the management could not participate on the process as actively as it was needed. The small size of the company forces so many responsibilities on all employees that they were simply too busy to be highly involved in the process. Thus it was also concluded that the input of a student was much needed. However, the responsibility of the task is not to be left entirely to an outsider, as the theoretical findings emphasize as well. It was regarded that the flow of the process and potentially the ending result also would have been more sufficient, if the management had been more involved. The findings, starting from imperatives of service quality improvement and continuing to implementation of quality management systems, strongly claims that a development process does not function without the commitment of owners. Therefore, for future implementation of the quality management system also, the case company must ensure the involvement of management for the entire process.

Like any project, a quality management system requires basic tools of successful project implementation. Project management in SMEs was reviewed at the beginning of the thesis, and some relation to the construction of the quality handbook for the case company was found during the process. The objectives for the quality handbook came primarily from the CEO of the case company, which correlates with the fact that operations of SMEs are strongly related to the owner's outlook. An informal nature of operations, subject to the case company as well, was considered a small burden during the process. As the process was planned, resource allocation was not clearly determined. Although it was not vital to allocate financial resources for the quality handbook process, this plays a major role in how the quality management system in the future turns out. As it was pointed out in the theory, informal procedures in small companies often result in unstructured reporting and documentation methods. Although there were no clearly documented files about the proce-

dures and policies in the case company, collecting information for the handbook was not found particularly challenging. Instead, interviewing and own documentation were found as appropriate methods. However, it was necessary to check the documented procedures several times to ensure that they were correct, which overall added to the working process. Milestone planning and work breakdown structure are mentioned as important features of project management of small companies. As can be seen in the process description, the project in the case company was not broken down with a distinct schedule or milestones, which disabled a structured flow of the process. In addition to the few cooperative meetings at the beginning, clearly scheduled meetings throughout the process would have ensured that all participants were on the same page about what the quality handbook process should comprise, increasing its fluency.

As the imperatives for service quality improvement are reviewed, it is sighted that the importance of listening to customers was lacking in the case company. Although the company stays in close contact with its clients before and after sales, it would have received useful information for its development process through a customer satisfaction survey. Once the quality handbook was finished, it was considered that the process should have begun with such a survey. Although the handbook was nevertheless constructed, the survey is necessary for a customer-oriented quality management system. Thus, it is highly recommended that the company implements it. Building quality systems on customer needs is also emphasized in the investigation for the impacts of the quality handbook, which further supports the need for a survey. Improving service reliability and accuracy, also included in the imperatives, may be achieved through the development goals the company set for its quality management system. A quality handbook may also assist the case company with the imperative of providing basic service, as through the construction of the handbook, main functions of the business and their improvement are focused on.

Some relation to the discussed barriers of quality management systems was found in the development process of the case company. A departmental struc-

ture as a barrier was not relevant to the company's operations, as this structure does not exist in the case company. Instead, all employees work with the same issues, and are therefore well-informed about current issues. It was discovered that the flow of the quality handbook process benefited from this non-departmental structure. Lack of an information system as a barrier did not relate to the case company either. During the process it was noticed that the organization practiced strong communication in its operations. On that account it was concluded that if the information flow functions during the quality management system, the company will not be burdened by this. However, the relative lack of management involvement was considered a barrier in the process, as it was already pointed out. Like all organizations, the case company too may have practical difficulties in changing its organizational reporting in a short period of time during the quality management system, but the small organization size is advantageous as new transitions are more easily introduced to a smaller crowd. As can be seen in the description of the process, the company did not allocate responsibilities or authorities for the quality management system. The quality handbook was assigned to an outsider of the company, but the later implementation of the quality system was yet to be assigned to someone in the company. Referring to the theoretical findings, this can be an obstacle for a successful implementation.

Small organization size, which was discussed earlier in the thesis, contributed to the case company's process in several ways. Inability to perform the task themselves due to lack of time and knowledge were the very reasons the case company assigned the development of a quality handbook to an outsider. Because of the large investment quality systems require, it was vital to find the most efficient way of constructing the handbook with the investment the company was able to make at the time. The research also found that lack of empirical studies about the effects of quality management on small firms may impact the motivation of organizations to implement them. During the process in the case company, it was noticed that the employees including management had very little knowledge about quality management systems and the impacts of them. However, this did not restrain the company. Instead, the management as well as some staff members were more eager to learn how

they could benefit from quality approaches. The findings support this in that knowledge of quality management must be gained before engaging into the process, which was ensured with the research in the thesis. In addition, similarly as the previously presented studies found, employees of the case company were more motivated to build the handbook, as they were informed of the long-term value of the process. The importance of a quality system in maintaining fluent relationships between companies and manufacturers was found particularly innovating in the case company. The company functions through its producers and whether or not they operate efficiently has a major impact on its sales. This in mind, the staff was motivated to construct the handbook to begin improving these relationships. Lack of bureaucracy, subject to SMEs and also to the case company, contributed to the process positively. The design and development of the quality handbook became much easier as the ideas were formed freely, instead of according to a structured, hierarchical management.

7 CONCLUSIONS

It has been interesting to come to find how much the development of a quality handbook has impacted the outlook the case company has on implementing a quality management system. The initial expectations of the company have become more realistic, because the process made the participants acknowledge that implementing a quality system in a small company is challenging and needs far more effort than writing one quality handbook. It is the responsibility of the company to ensure it receives as many advantages as possible after the quality handbook is written. The development has given the company an opportunity to develop a change movement, which it has not had time for before this process. The company may exploit the quality handbook as well as the information provided in this thesis to construct a functioning quality management system. It was evaluated that, as a whole, the process helps with managerial decisions, ensures a structured flow of the quality management system and above all, has acted as an awakening to the proper ways of applying the system in a small company.

The thesis was intended to be a research for the creation of the quality handbook and the implementation of the quality management system. While the thesis was found useful for both, it was concluded that without daily observation inside the company throughout the process it would not have been possible to make such profound evaluation on the research questions. As it was indicated, the case company wished for the thesis to study the impacts of the handbook and the future of the quality management system, particularly in terms of the development goals, from a theoretical and analytical point of view. Through the inspection of potential benefits, the case company gained reassurance of the impacts a quality handbook has on its customers, producers and internal operations. Through the evaluation of the future of the development goals and the relationship between the industry and quality management, the company came to realize the importance of quality management, which impacted the quality handbook process in a positive, motivating way. Theoretical findings increased the interest of the case company to continue with its quality management plans. Examination of benefits also raised awareness towards new development areas that the management has not yet been

aware of. The company realized it was lacking on some crucial operational processes, such as an efficient customer feedback system. A lot of the operations in the case company were thought of and designed, but concrete implementation of the procedures was lacking. In other words, there was a thought but no action. Thus it was concluded that through the quality handbook the company was able to truly see what areas of its business were lacking and could begin to implement the action plans. In addition, the importance of auditing and measuring the achieved results became clear for the company when the development goals were evaluated.

Research reliability

The reliability of this working process is relative, because the evaluation is based on a specific case company, its ways of operating and the industry it functions in. The theoretical basis for the construction of a quality handbook and the evaluation of potential impacts on the company are nonetheless strong, and the conclusions provide a lot of useful information for the case company. The observed information about the case company is supported by relevant theoretical sources, and thus the study findings are credible and the ending result of this particular study is valid. To further increase validity of the analysis, the case company could implement another study in a few years, where the applied quality management system is examined. This way, actual impacts that have occurred could be realized and the research would be complete. The information in the thesis, particularly concerning effective implementation of quality management systems in SMEs, is applicable for other small companies planning similar developments. Nevertheless, as it was done in this process, other companies should adjust the gathered findings according to their own operations and needs as well.

Own working process

My own working process has been a challenging experience. Both the construction of the quality handbook and the research made for this thesis has required a lot of persistence on my part. Looking back to the process, I consider that it could have been more structured and fluent if there had been a project manager within the company, who could have given their input on the

work throughout the task. Assigning full responsibility to me in terms of both design and development of the handbook perhaps took away from an efficient process flow and a better ending result. Together with a project manager, I could have created a more detailed research, hence more benefits for the case company.

The need for analytical skills in the process was substantial, because connections between the theory and the practical experience in the case company were to be found in order to answer the research questions. I would not have been able to construct the quality handbook for the company without making the research for a professional quality manual first. The evaluation of the impacts that the quality handbook has on the case company was challenging, because I did not have the experience from the industry and how such companies function. Therefore, it was vital to do a lot of interviewing and observing inside the company to get the needed information.

Throughout the whole process my expertise on quality management systems developed substantially, which impacted the ending result of the quality handbook. Just like the case company, I began the process with less than enough information about constructing quality manuals and how quality management systems are supposed to work. Now after the handbook has been written, I have come to find that my knowledge in this area increased significantly. I consider it to be an advantage for me in the future, if my future employer is planning quality initiatives in their company.

The relation of this assignment to my personal study plan of international business is also impressive, because the case company practices international trade and this aspect was also taken into consideration during the process. By developing a quality handbook for the company, I was able to observe how an international SME functions in practice and relate this information to what I have learned during my entire education.

REFERENCES

Anderson M., Sohal A., 1999. A study of the relationship between quality management practices and performance in small businesses*, International Journal of Quality and Reliability Management*, 16:9, 859-877

Bell M., Omachonu V., 2011. Quality system implementation process for business success*, International Journal of Quality and Reliability Managemen*t, 28:7, 723-734

Berry, L.L., Parasuraman, A., Zeithaml, V.A, 1990. Five imperatives for improving service quality, *Sloan Management Review,* Summer, 29-38

Berry L.L., Parasuraman A., Zeithaml V.A., 1994. Improving service quality in America: lessons learned*, Academy of Management Executive*, 8:2, 32-52

Brown A., van der Wiele T., Loughton K., 1998. Smaller enterprises' experiences with ISO 9000*, International Journal of Quality and Reliability Management*, 15:3, 273-285

Cheng M-I., Dainty A., Moore D., 2007. Implementing a new performance management system within a project-based organization: a case study*,* I*nternational Journal of Productivity and Performance Management*, 56:1, 60-75

Cheung M.F.Y., To W.M., 2010. Management commitment to service quality and organizational outcomes*, Managing Service Quality*, 20:3, 259-272

Denning S., 2011. Quality management gets strategic and discovers (gasp!) the customer*, Forbes magazine* [electronic newspaper], read 1 July 2011, available from:
http://blogs.forbes.com/stevedenning/2011/04/13/quality-management-gets-strategic-and-discovers-gasp-the-customer/

Denning S., 2011. Contributor profile, *Forbes magazine* [electronic newspaper], read 20 October 2011, available from:

http://blogs.forbes.com/people/stevedenning/

Forsman H., 2008. Business development success in SMEs: a case study approach*, Journal of Small Business and Enterprise Development*, 15:3, 606-622

Gasiorowski-Denis E., 2003. Quality management systems for the medical device industry*, ISO Insider* [electronic newspaper], read 18 September 2011, available from:
http://www.iso.org/iso/medical_device_ims6_2003.pdf

Ghobadian A., Gallear D., 1997. TQM and organization size*, International Journal of Operations and Production Management*, 17:2, 121-163

Green D., 1996. *The complete ISO 9000 manual: A practical guide to a quality system, policy manual, core procedures and forms,* Kogan Page Ltd, London

Guilhon A., Martin J., Weill M., 1998. Quality approaches in small or medium-sized enterprise: methodology and survey results*, Total Quality Management*, 9:8, 689-701

Kuei C-H., Lu M.H., 1997. An integrated approach to service quality improvement*, International Journal of Quality Science*, 2:1, 24-36

Lalis G., 2007. Cooperating for safety, quality and performance of medical devices, ISO Focus, *ISO Focus* [electronic newspaper]*,* read 18 September 2011, available from:
http://www.iso.org/iso/iso13485_focus_07-02.pdf

Lundmark, E., Westelius, A., 2006. Effects of quality management according to ISO 9000: a Swedish study of the transit to ISO 9000:2000*, Total Quality Management & Business Excellence*, 17:8, 1021-42

McTeer, M.M., Dale, B.G., 1994. Are the ISO 9000 series of quality management system standards of value to small companies? *European Journal of Purchasing and Supply Management,* 1:4, 227-35

Milena A., Rusjan B., 2010. Contribution of the ISO 9001 internal audit to business performance*, International Journal of Quality and Reliability Management*, 27:8, 916-937

Nwankwo S., 2000. Quality assurance in small business organizations: myths and realities, *International Journal of Quality and Reliability Management,* 17:1, 82-99

Morrison, A., Breen, J., Ali, S., 2003. Small business growth: intention, ability and opportunity, *Journal of Small Business Management*, 41:4, 417-25

Psomas E.L., Fotopoulos C.V., Kafetzopoulos D.P., 2010. Critical factors for effective implementation of ISO 9001 in SME service companies*, Managing Service Quality*, 20:5, 440-457

Pulliainen Aki, 2005. *ProMedical Oy Business Plan*

Schneider B., White S., 2004. *Service quality: research perspectives,* Sage Publications, Inc., Thousand Oaks

Srinidhi B., 1998. Strategic quality management*, International Journal of Quality Science*, 3:1, 38-70

Summers D., 2005. *Quality management: creating and sustaining organizational effectiveness,* Pearson Education, Inc., Upper Saddle River, New Jersey

Suomen Standardisoimisliitto, 2001. *Laadunhallintajärjestelmät, vaatimukset*

Suomen Standardisoimisliitto, 2003. *ISO9001 Pk-yrityksille – mitä tehdä: ohjeita tekniseltä komitealta ISO/TC 176*

Turner J.R., Ledwith A., Kelly J., 2009. Project management in small to medium-sized enterprises: a comparison between firms by size and industry*, International Journal of Managing Projects in Business*, 2:2, 282-296

Waller J., Allen D., Burns A., 1993. *The quality management manual: how to write and develop a successful manual for quality management systems,* Kogan Page Ltd, London

APPENDICES

Appendix 1. Equivalence table to ISO 9001:2000 standard

ISO 9001:2000 standard	ProMedical quality handbook
5 MANAGEMENT RESPONSIBILITIES	
5.1. Management commitment	3.2., 4.2., 4.3.
5.2. Customer-focused approach	4.2., 6.1.
5.3. Quality policy	3.1.1.
5.4. Planning	3.2.
5.5. Responsibilities and authorities	4.2.
5.6. Management review	
6 MANAGEMENT OF RESOURCES	
6.1. Resource allocation	5
6.2. Human resources	5.2.
6.3. Infrastructure	5.3.
6.4. Working environment	5.3.
7 EXECUTING THE PRODUCT	
7.1. Operational procedures planning	3.2., 4.3.
7.2. Procedures involving the customer	6.4.
7.3. Planning and development	8.2.
7.4. Purchasing	5.1.
7.5. Services	6
7.6. Measuring and monitoring	4.3.
8 MEASURING, ANALYSIS AND IMPROVEMENT	
8.1. General	8
8.2. Measuring and analysis	7, 8.1.
8.3. Monitoring deviations	4.3., 8.1.
8.4. Analyzing the data	7
8.5. Improvement	8.2.

Appendix 2. Table of contents in the quality handbook

1. Introduction
2. Products and services
3. Planning and management of the business
    a. Vision
        i. Policies on quality
        ii. Policies on environmental issues
        iii. Safety
        iv. Health
    b. Planning the operations
4. Control procedures
    a. Quality management system
    b. Responsibilities and authorities
    c. Operational control and monitoring
5. Management of resources
    a. Purchases
    b. Human resources
    c. Physical structure
6. Control of deliveries
    a. Sales
    b. Procurement of materials
    c. Warehousing
    d. The transference of Products to Customers
    e. Operations after delivery
    f. Reclamations
7. Evaluation of business activities
8. Developing the business
    a. Monitoring the activities
    b. Development process
9. Table of equivalence to ISO 9001:2000


SAVONIA