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Developing and implementing a quality management system in a startup company

Master of Science Thesis

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Abstract

As a manufacturer of vehicles is it vital to have control over the processes in the company. There are regulations from authorities stating an approved vehicle manufacturer should be able to always produce vehicles according to conformance. Companies who want to produce products of high quality, high safety and want approval often need some kind of quality management system (QMS) since there are regulations and laws that demand special quality control on certain products. To be approved as manufacturer of vehicles is it necessary to be able to guarantee each vehicle is safe and does not deviate from the type approval. The production process shall be the same for every product. A quality management system shall therefore support a company to keep the quality at a constant and high level.

A recently started company called Nimbell is in need of developing the business. The company wants therefore to start a project for developing a quality management system since they had not yet focused on the quality work in the organization. The company has the intention to be an approved vehicle manufacturer in the future.

The purpose with this thesis is to find out how to develop and implement a quality management system in a startup company.

To create a base of understanding of how to approach a QMS implementation project literature studies have been done. Information has also been gathered through interviews with professionals in the consultant management business and benchmarking interviews with other small companies who work with quality management systems.

Based on the literature studies and the findings from interviews a custom made quality management system has been developed, specific to the company's needs and resources. It has been found it is important to build the system from the base and engage people in the implementation to get the wanted effect of a QMS. Keep it simple and understandable from the beginning is important and start analyze a few important processes.

The suggested implementation is divided in steps; the first step which is the focus of the master thesis is a startup phase focusing on learning and preparation. It has been designed to start up the implementation. The second part can be implemented by the company itself with support of developed material. There are recommendations of how the development and implementation can proceed after step one.

It was found that workshops are a good tool for creating involvement in a change process. It triggers discussions which stimulate learning. However, just focusing on discussions leaving out practice is not optimal for learning. The practice should be included in the workshops. In order to put some pressure on the participants to deliver results, gates for delivery shall be set. Having clearer goals would probably make the group more focused on the project and put more resources into it. Clearer goals could therefore have generated more engagement and a faster startup of the project. When processing a project which is separate from core activities, the timing is crucial in a small company. The experience is that the resources are few and the employees have often very much to do due to Nimbell's different projects' deadlines. It was shown that planning is a vital factor for the projects existence and success. The implementation method developed and used for this thesis have overall been applicable for this project. Even though trying to avoid pitfalls one cannot always avoid them

anyway. Gaining experience from complications can be useful some times because it leads to insights which give knowledge of how to improve next time.

Sammanfattning

Som fordonstillverkare är det vitalt att ha kontroll över företagets processer. Det finns lagar som säger att som godkänd fordonstillverkare skall man alltid kunna producera fordon som överensstämmer med den godkända fordonstypen. Företag som vill producera produkter av hög kvalitet, som är säkra och vill ha dem godkända för marknaden behöver ofta någon form av kvalitetssystem. Det krävs att företaget kan säkerställa och kan visa på att man tillverkar typgodkända produkter. För att bli godkänd fordonstillverkare skall man kunna garantera att varje fordon är säkert och inte avviker från den godkända fordonstypen. Ett kvalitetsledningssystem skall därför supportera för att hålla en hög och jämn nivå på kvaliteten.

Nimbell är ett nystartat företag som behöver hjälp med utvecklingen av sin verksamhet. Företaget ville påbörja ett projekt för att utveckla ett kvalitetsledningssystem då de inte hade påbörjat sitt kvalitetsarbete ännu. Företaget siktar på att bli godkända fordonstillverkare i framtiden.

Syftet med det här examensarbetet är att utreda hur man bör gå tillväga för att utveckla och implementera ett kvalitetsledningssystem i ett nystarts-företag.

För att få ökad förståelse i ämnet och om hur man bör gå till väga har litteraturstudier gjorts. Det har följts av intervjuer med konsulter inom verksamhetsutveckling och benchmarking mot andra företag i som varit i liknande situation och som aktivt arbetar efter ett kvalitetsledningssystem.

Med hjälp av den insamlade informationen från litteraturstudierna och intervjuerna har det påbörjats en utveckling av ett kvalitetsledningssystem utefter Nimbells behov och resurser. Det var förstått att systemet måste byggas från grunden och engagera människorna i företaget under utvecklingen och implementationen för att uppnå de långvariga effekterna. Det är viktigt att från början få kvalitetsledningssystemet användarvänligt och lättförståeligt.

Den föreslagna implementationen är uppdelad i steg. Första steget som är fokus för examensarbetet är uppstartsfasen och fokuserar på att förbereda och lära de berörda. Det har designats för att starta implementationen. Den andra delen kan medarbetarna i företaget genomföra själva med hjälp av det material som är framtaget. Det finns rekommendationer för tillvägagångssätt att följa.

Det konstaterades att workshops är ett bra verktyg för att involvera människor. Med workshops fås bra diskussioner vilket stimulerar lärande och ger ökad samsyn. Men att bara fokusera på diskussionerna och utelämna praktik är inte optimalt för lärande. Workshopar skall inkludera praktiskt tillämpning och för att sätta lite press på de medverkande kan man sätta upp delleveranser mot ett mål. Med klarare mål skulle gruppen fokusera mer på projektet och det skulle ge en snabbare uppstart av projektet. Eftersom kärnverksamheten tar upp mycket av resurserna är det viktigt att lägga tidsödande projekt av den här kalibern rätt i tiden så de inte underprioriteras. Uppfattningen är att resurserna är knappa och de anställda som skall involveras har ofta mycket att göra på grund av andra projekt. En välgjord planering är väldigt viktigt för projektets genomförande. Metoden för utvecklingen av examensarbetet har över lag varit applicerbar för projektet. Även om man känner till fallgroparna som finns och försöker undvika dem så kan det vara lärorikt att falla i dem i alla fall. Det ger erfarenhet man får ta med sig och leder till insikt som ger kunskap för framtiden.

Foreword

This is a master thesis report for a master thesis project at Chalmers Teknologiska Högskola. The thesis has been carried out during spring and summer 2011 in collaboration with a startup company named Nimbell AB with roots at Chalmers Teknologiska Högskola.

Researching on site has been beneficial. It has had positive effects on the understanding, on own motivation and the social connection to the people at the studied company. Being part of a group who works towards a shared long term goal has been motivating for me. The experience of working in a small startup company is unique and might not be offered again. For that I am thankful.

What have I learned as a researcher and student from this project?
I have got experience of organizing a reality based project in a, for me, new and special environment. I got understanding in the startup business problematic as well as rooted knowledge in quality management, by practicing and observing. I have got a better understanding of how to drive changes since that was the thesis somewhat have been about. Some sessions have my role been of coaching characteristic which I got interested in for my own coming profession. Since I have been working on my own in the master thesis project I have had own responsibility for the project. I think the own responsibility have been a good experience for me personally.

I want to say thank you to my supervisor at Chalmers, Sverker Alänge, the people at Nimbell and all the interviewed persons who have been helpful. Thank you.

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1. Introduction

This chapter is an introduction to the report and master thesis. It describe, in sequential order, the background, the purpose, the problem definition, the delimitations and the company where the study been done.

1.1 Background

Today's competition is quite tough and the quality of the products on the market needs to satisfy some kind of need expressed by potential customers. There are many definitions of quality which can be discussed but at the end of the day it comes down to selling products to be sustainable in business. Different products can be of different quality but it is essential to produce quality products when dealing with vehicles, which is the case for Nimbell.

Companies who want to produce products of high quality, high safety and want approval often needs some kind of quality management system since there are regulations and laws that demand special quality control for certain products. Examples are vehicles or medical technology (medtech) products. To be approved as manufacturer of vehicles is it necessary to be able to guarantee every vehicle is safe and not deviate from the type approval. Conformity in the production process is vital. A producing company shall have control over its processes to be approved as vehicle manufacturer. The quality management system should reflect the high uniform quality output of the organization's products. The developed quality management system should give support to the daily work at the company to be a high performing organization. Another possible outcome of the project is to develop the organization's structure to the better by visualizing activities for improvements and learn from that.

Often when companies need help with establishing a management system they contact a consultant who facilitates the work at the company. The consultant tries to give energy and knowledge to make the job of implementing go smoother. When this project started, Nimbell had no defined management system. Instead of hiring a consultant the company arranged the task to prepare for an implementation of a quality management system as a master thesis project at Chalmers University of Technology.

1.2 Purpose

The purpose of the master thesis is developing an understanding of how to implement a quality management system in a start-up company. The thesis's aim is to create a solid start that can guide and support the people in the organization towards better learning and development of the business.

1.3 Problem definition

There are difficulties which are required to overcome when initiating this kind of project. There are needs and other aspects which require to be considered to successfully navigate through the development and implementation phase. A great part of the work has been to understand which these difficulties are and how to avoid or handle them. The research questions below have been central for the thesis's scope and they are used to shape the questions for the interviews. Starting with the main question:

- How to implement a quality system in a start-up company?

There are certainly different ways to approach the implementation of a quality management system. The intention is to understand if there are any specific aspects regarding startup companies which lead to the next question.

- Are there any specific aspects to take into consideration as an effect of the company's situation as un-experienced and being in an early development phase?

To perform the implementation in a successful manner it would be good to know what is needed to be considered. Finding out what is usually important to think of could be vital.

- What is generally needed to consider when developing and implementing a quality system?

Since there are different quality system standards, would anyone be better for this project, why the next question is stated.

- Is there any quality system standard more suitable for a start-up company/ new company like Nimbell?

1.4 Delimitations

The main limits are the amount of time and man-hours behind the project. Since it is only one person responsible for the research and implementation, the amount of time can be an obstacle. The time for this project is set to 20 weeks of full time work with a final presentation. The master thesis aim to answer the questions defined in the problem analysis. Other sidetracks can be seen as supportive research for the main problem.

A quality manual should be a living document which is updated and maintained over time. Therefore will not any final, closed document be able to be established for Nimbell. Almost all parts of the QMS are changing over time since the processes are improved over time. The idea is that the quality manual is to be revised once in a while. The result of the quality manual will therefore be a draft, not a final product.

One of the main processes, production, is still very unclear in terms of stakeholders since the final production partner is not yet decided. The production shall be outsourced, that is known. Therefore will the production process be left out from the scoop. There are also other processes which are not considered yet in the development since the recommendations are to focus on a few processes.

1.5 Nimbell – a startup business

The master thesis has been collaboration between Chalmers and a company named Nimbell. Nimbell is a start-up company and is an off-spring from the Chalmers School of Entrepreneurship, CSE, and was founded in the summer of 2009. The main objective is to develop and market their products which primary focus on the Swedish market but intend to target the foreign market as well. At the moment there are two types of electrical vehicles in the pipeline but the main focus is currently on one of them. The target for Nimbell is to release their first product to market during fall 2011. The plan is to expand in the upcoming months in order to ramp up the production of the first vehicles. The production is outsourced to other partners who are also planned to assembly the vehicles in the future.

As a startup business it has not got the economic opportunities to hire costly consultant hours. Nimbell has good connections to the university and therefore became the solution to initiate the work as a master thesis project. Today there are four full time employees who all work at the site in Gothenburg and some employees with special competences. "The organization is consisting of six employed persons, the majority being young professionals. The board of directors constitutes a group of senior industry executives with experience from different industries. The company works

closely with external collaboration partners such as Chalmers and cutting-edge engineering firms" – *Jonas Mårtensson, CEO.*

Nimbell is as mentioned developing new vehicles. A part of their strategy is to get the new vehicle, Trigo, type approved for the international market. To get the type approval, it is necessary the company can show how they in a structured manner developed the vehicle and have conformance to the approved vehicle type for every single vehicle manufactured. A well-structured quality management system supports the product development, product design process, procurement and production of the product.

2. Method

The method chapter describes how the project was performed; presenting a plan, literature studies, interview method and workshops. The project was held to the main plan to approach the problem. As time proceeded, iterations have been made to adapt new findings and insights. The last section is reflection which gives input to the recommendations and further work. Figure 1 below shall illustrate the thesis work procedure.
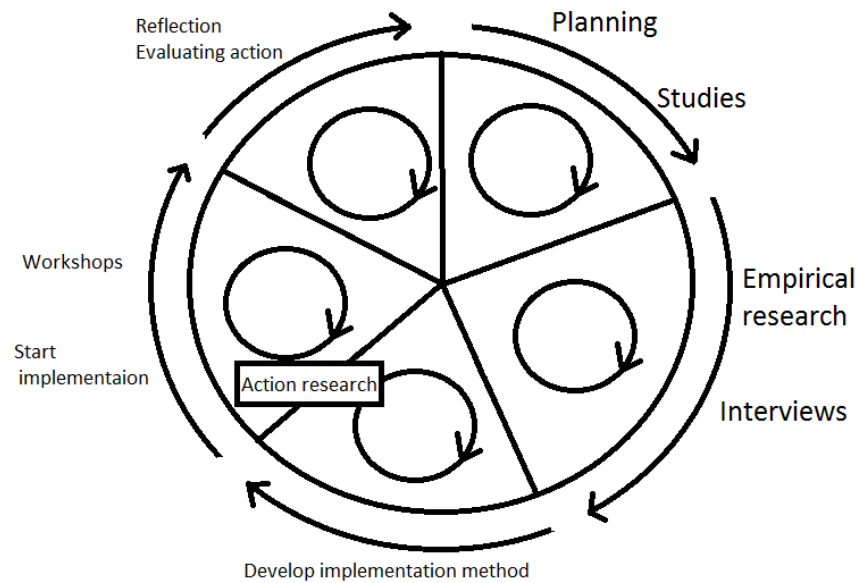
Figure 1 Illustration of the method's activities in a circular arrangement, starting at the top. Each circle inside each section illustrate an iterative action

2.1 Action research at the company

Action research is a good approach for problem solving when the research questions relate to understanding a series of actions. By taking action and directly experience the research environment can the problematic situation be resolved from one's own, known, point of view. Action research creates understanding of changes of processes and stimulates for improvements and learning (Mashhadi 2010). Participation in forums like workshops creates interaction between the participants i.e. the employees. Knowledge and reflections are shared which stimulate the learning process. Each workshop session is an opportunity to learn and gain insights, for all participants. The different participants focus on different things due to different interest and the participants contribute with different aspects which contribute to the system view.

The results of the workshops in the action research have created a foundation for the coming work. The knowledge developed in part 1 is the foundation for moving into the next step, part 2. The learned and developed understanding has resulted in recommendations which can be illustrated as a catalyst or support for taking next step into part 2. Figure 2 illustrate the situation.
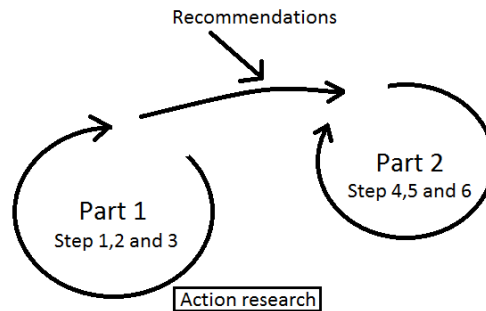
Figure 2 An overall implementation plan with part 1 and 2

The steps in part 1 are described in the action research chapter and the steps in part 2 are included in the recommendation chapter.

A part of the action research was also to start up the draft for the quality manual. It is based on the organizations capabilities and shall be a support in the company's further implementation of a quality management system. It holds documents of what is done today and suggestions of what should be done. The quality manual should be seen a proposal of one way to work.

2.2 Planning

Planning was naturally one of the first steps in the project as well as it is a continuous process during the whole project. In the beginning was a rough plan made with some early to-do-tasks taken from brainstorming session and input from the management at Nimbell and the supervisor. It was important to early get an overview of the topic and to set up the problem definition for the project. Since an implementation work can be very extensive it is also important to set up and define the delimitations for the amount of work and to plan a completion of the project. The delimitations are described in the introduction chapter.

A plan over the coming 20 weeks was made. The different activities were overlapping each other. The included steps were; planning and literature studies, interviews, development and start the implementation. That was a quite rough plan. Each part was more detailed when it was in action.

There is a lot of material available about quality management and standards like the ISO 9000 series which have been useful for a basic understanding of the concept of quality management system. It shall be pointed out the focus has been on the own management system. It is often most risky to look at the standards requirements to fill the gap too early. That is why the requirements for any standard not have been highly prioritized in the thesis work. Most of the search for literature has been made on the database at Chalmers Tekniska Högskola and in company library.

The first interview with a consultant in the field management systems gave basic understanding and an introduction to the management role. Much of the consultant's ideas and opinions have followed the thinking as the project progressed and influenced the planning. The project got influences due to his approach which has been useful.

Scanning for companies in similar situation as Nimbell who can give input to the project was also a part of this phase. The search was primary focusing on young companies with few employees who had established their own management system. The purpose of getting in contact with other companies was of cause to be able to benchmark how this kind of project can be performed and get inspiration. The idea was to get answers to the questions stated in the problem definition.

2.3 Interviews – an empirical research

The approach for making interviews has been dependent on who has been interviewed. All interviews have been semi-structured with focus on a couple of questions derived from the problem definition. There are two categories; professional consultants and companies with similarities to Nimbell, as described above. It has been very similar questions in all interviews but with minor modifications depending on the interviewed person. Some questions to the consultants would not have been as relevant at company visits and vice versa. Instead could the question be changed to be relevant in another perspective e.g. the consultant was asked when companies tend to contact them and then was the companies asked if they hired any consultant for advice. The first interviews were more organized than the later ones which sometimes got into a discussion characteristic where both parts expressed their view of the questions in focus. The positive aspects are that the interviewer who wants to learn and be taught can ventilate his or her ideas and interpretation whereas the conversation gets more interesting for both parts. It is also good to ensure the meaning is understood. On the other hand is there a risk of missing information if the words are put in the mouth of the interviewee.

The interviews had a qualitative rather than quantitative approach since they needed to give an understanding with input from different experts. All interviews were quite extensive, between one and two hours, seeking for subjective answers and had no multiple choices questions. The interviews contain information which will not be presented in the main report due to it is not necessary information for the project. The interested reader can find the interviews in the appendix A.

The project is very much based on the interviews and the information given from the interviews. The result from the interviews is in line with and verifies the literature studies and theory. The interviewed professional consultants had overall a quite similar view of how the challenge could be approached. In general they all advocated the process view and gave the advice to keep the documentation user friendly which means keep down the amount of text and keep all documents at an easy and understandable level. Too often does it become too complicated and then it is very common the only thing the documents become is a bookshelf product of no use (Book 2011). This recommendation has been kept in mind through the entire project.

The interviews with the companies had a little bit of another characteristic. The companies interviewed were all in the medtech business. One company produces dental implants, another with positioning systems for internal human organs and a third company produces synthetic bone material for implant applications. The similarities with Nimbell are still many; there are regulations from authorities, all the companies have few employees and everyone are in the long run aiming for any kind of certification or already got a certification. The interviews with these medtech companies gave good insights of more practical characteristics since they were willing to share their practices in another context.

The recording of the interviews was transcribed directly after the interviews. Some were however summarized at once. Analyzing the seven interviews gave enough information to create an action plan for development and start of implementation of the QMS. The similarities and depth of the information was considered enough to start the next step in the project.

2.4 Develop an implementation method

Since the consultant practiced the involvement with workshops have the same approach been used in this project. The workshops ware planned to be held in steps starting with an introduction workshop and followed with active sessions which made a base for the findings and implemented routines. As planned the workshops were related to each other. The idea was to give understanding in a first workshop and then practice in the following. The workshops made up a journey starting

from nothing to a startup of the implementation, which is called *part 1* in the action research. Part 1 is logically followed by *part 2.* With experience and learning from part 1 should Nimbell be able to manage part 2 which is planned to be performed by the employees themselves. Part 2 is mainly a recommendation since it explains how Nimbell could continue the work.

2.5 Reflection about method

The method is applicable for this kind of startup environment and the circumstances. The first two sections in the method cycle has of course been a base for the project which are quite fundamental for the research and development of the knowledge. Planning is important for visualizing and it gives an overall picture of what is required. The literature studies and the interviews are vital for the understanding and possibility to develop the implementation method and its activities. One can argue the development phase is the planning of transferring the previously gained knowledge into the company, which is actively executed in the next section. Being active at site has therefore been needed for the thesis to understand the activities in the company. To understand the processes it is very relevant to see and study for yourself where the activities are performed. A less successful method could be analyzing the current state and propose a new solution without involving the concerned employees. It is probably not prosperous in the long run since it gives less chance of engagement and further commitment. Therefore the workshop approach has been good since it engages everybody to valuable group discussions from which the group learn and get insights. When visualizing the company situation, it provides a useful base for discussion and reasoning. It has also been an education of e.g. process mapping which is useful in the coming work. The last section, reflection, is in practice the report writing. It is during this time the overall picture is summarized and thought of as its whole. It is now easier to look back and see the consequences of the acting (or non-acting if you like). It is now the knowledge and experiences really root in me. The intention has been to communicate this reflection approach to the people I worked with during this journey. Writing reports can be very good for the reflection process since one is forced to think about occurred activities.

Overall, I think the reflection part is important and is easily missed. Reflecting while you are in the middle of a process is easily forgotten. Just stopping for a while and think of what is happening in the big picture can be helpful. I could have missed that within the sections which are criticism to me regarding the actualization of the method.

So what have I learned as a researcher and student from this project? I have got experience of doing a reality based project in a very special environment. The experience of working in a small startup company was new for me and might not be offered again. I got understanding in the startup business problematic with few resources as well as rooted knowledge in quality management, all by learning by doing. Personally have the experience of having own responsibility for the project has been very meaningful for me. By working on my own I have now got a better understanding of how to drive changes since I practiced it. It was discovered that the engagement and demand from the internal customers is vital for progress in the process development. Resources are needed in form of the concerned employees to design their processes. These people need to be involved in the development. It becomes more difficult to establish new routines if there is lack of commitment of the improvement work and no ownership of the change. Commitment and understanding is increased with participation from the involved people. I have therefore seen myself as some kind of coach or consultant who guided the employees to awareness. Some sessions have my role got the coaching characteristic for example when discussing drawings. My job was then to facilitate the discussion to find a structured manner to name drawings.

Being at the office, in the environment and researching on site has been beneficial. It has enable to see behaviors and problems the environment creates, it has been motivating and provided the social

connections. Being part of a group of people who works towards a common goal is motivating for me. The personal interaction with the employees at Nimbell would probably not have been as intensive if the master thesis project had included another person as well. It would not create the same bonds which are important for a good collaboration. What is even more interesting and important is the attendance of a "quality manager" at the site. According to the CEO, it had an effect on the employees at the company. My attendance at the office was unconsciously reminding the employees of the importance of working with business development and process improvements. It has led to awareness of process development. I think the base for further development of the business is the awareness and understanding of the importance of quality management. Without a person dedicated to these issues, awareness and knowledge among the personnel are important in order to not ignore the focused improvement work.

When I reflect on what the company could have done for me I realize even more that I am the kind of person who needs deadlines and pressure from my environment to work more efficiently. That is an insight on my own personality. A more detailed plan could with more sub goals could have been effective to follow up the projects progress and also create pressure in the organization.

3. Theory

In this chapter is the theory behind the project work presented. It is based on the studied theory, with much influence from the advices and recommendations from the interviews with a group of experienced consultants. The theory consists of studies of quality management including important factors for a successful development and implementation of quality management systems.

3.1 The cornerstones for Total Quality Management

According to the theory of total quality management (TQM), there are core values which are essential to successfully make up a foundation for the quality work as well as for managing changes in organizations. The most important aspect is the *committed leadership* to the quality issues. It cannot be emphasized how important committed leadership is to create culture for successful and sustainable quality improvements. Managers should create commitment and engagement from the people at all levels in the company by being credible, clear and good at communicating. The management should show interest in and support activities regarding quality. The top management should by acting be a role model (Bergman, Bo; Klefsjö, Bengt 2010). On top of that fundamental base are the important values; focus on the customers, base decisions on fact, focus on processes, improve continuously and let everybody be committed. It is of importance the organizations culture is incused by these six values and that they can interrelate to each other (Bergman, Bo; Klefsjö, Bengt 2010).It is also important the management is well aware of and have the right mindset about quality management. It is an ongoing process in itself which shall be improved over time, not a one-time-project (Book 2011). The figure 3 below illustrates the relationship between the important values, the cornerstones.
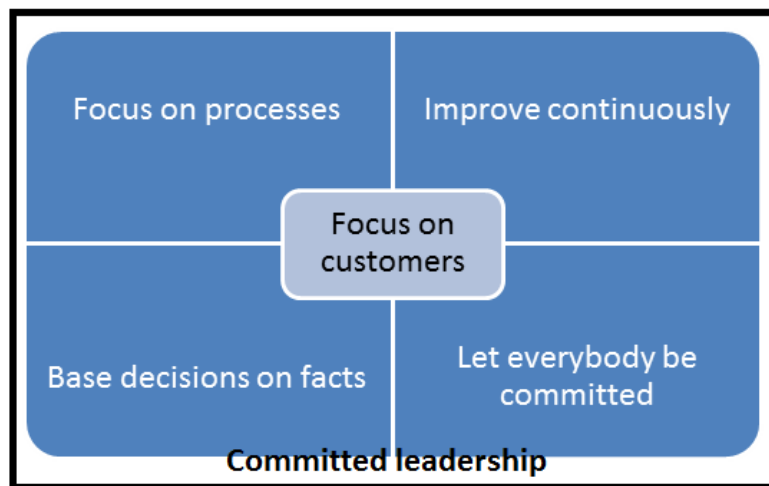
Figur 3 The cornerstones of TQM

Focus on customers means that their needs and expectations are important input to your business and to be able to process that input into something valuable for the customer. Basically is the task to find out these needs and expectations of the customer and then systematically fulfill these needs when developing and manufacturing the product. This is nowadays often expressed in customized products in various product areas.

Customers can be divided into *internal* and *external* customers. If the focus is mainly on the external ones it is easy to forget the internal customers, the employees. With a process view shall the upstream actor satisfy its internal customer with high quality products so the (internal) customer can

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focus on fulfill their own task. The employee has need which is required to be satisfied in order to do a good job. Providing the employees with better opportunities to do a good job and make them feel proud of their work will create a breeding ground for satisfied external customers in the long run. (Bergman, Bo; Klefsjö, Bengt 2010)

Base your decisions on facts. To get reliability towards others it is decisive to be able to show the work which is supporting your decisions. Do relevant research, gather information from relevant stakeholders and use the information to do the right improvements. Since time to market needs to be shorter and the lifecycles of new products are generally shortened it is vital to present a product with conformance to the requirements as early as possible. Basing the decisions on analysis of facts and not on guts feeling shall therefore increase the chance to be successful.

A process is an organized repeatable action whose objective is to create value for a customer, internal or external. A process transforms certain inputs, such as information and material into some kind of output like a service or goods. The purpose of the process is to get as high quality result as possible out from the resources, the input. It is important to understand your processes, knowing the supplier of resources and have clear signals about what is needed in the processes, to minimize resources and to satisfy customers. See figure 4 below.
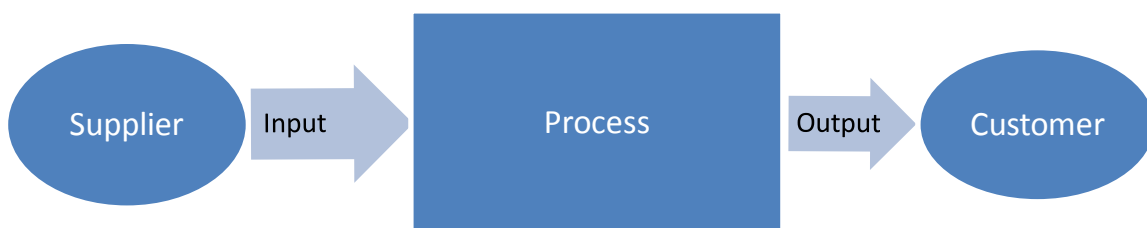
Figure 4 Illustration of process definition

*Process: "*Sequence of interdependent and linked procedures which, at every stage, consume one or more resources (employee, time, energy, machines, money) to convert inputs (data, material, parts, etc.) into outputs. These outputs then serve as inputs for the next stage until a known goal or end result is reached." - (Business dictionary u.d.)

According to Book (2011) and Franze (2011) the *process view* is the best approach when working with a management system. Understanding the concept of processes can give a good platform to take off from. Start to define the business' main structure and be open minded to change it if it does not correspond to the company's situation. The company creates its own logic of processes which each one have their specific output. It is however important to have the right focus. It is easy to bring the requirements (for certification) too much attention and not look to the needs of a management system.

Processes are often categorized into three different types. These are *main processes* (also known as operative processes or core processes), *support processes* and *management processes*.
- Main processes, has the main task to fulfill the needs of the external customers and to improve (add value to) the products provided by the organization. Examples are product development and sales
- Support processes have primary internal customers. These processes shall provide resources and support to the main processes. Examples are maintenance and information processes.

- Management processes whose purpose is to make decisions on the targets and strategies of the organization, implement improvements in other organizational processes. Management processes have, as well as support processes, internal customers. Examples of processes can be strategic planning and auditing.

Improvement continuously is an important element in a successful quality strategy. Stop improving means there is no positive changes which soon lead to being less successful. In TQM is the PDCA-cycle (plan-do-check-act) a central concept for the improvement work, as well as in the ISO9000 standard. The basic rule for continuous improvement is that it is always possible to improve processes, products or services in a way the input resources is reduced, quality of output is increased or cost is lowered. The challenge is to find the right way to change to improve.
Another vital aspect is the mind-set that everything can be improved; get a better match of customers' needs with fewer resources.

The Japanese call it kaizen, which means 'good changes' which equals improvement work. All interviewed persons describe how they do their improvement work in workshops. A couple of persons involved in the process meet under organized circumstances and discuss possible actions to improve the process or business. Together people can be stimulated to bring forward new ideas and get feedback on those from co-workers. Often is there a purpose to share; visions, mental models, knowledge (information) between each other. The outcome can then be a more effective organization with understanding for each other's work and better system thinking. *Workshop* can be defined as*:* training class or seminar in which the participants work individually and/or in groups to solve actual work related tasks to gain hands-on experience. (Business dictionary u.d.)

Let everybody be committed is about creating an environment which gives motivation and encourage employees to active participation in decision making and improvement work. Participation and commitment are achieved through delegation of responsibility and authority. Employees, who are given a chance to do a good job, feel professional pride and get feedback for well performed work will be committed to their job. This leads to improved quality of work (Bergman, Bo; Klefsjö, Bengt 2010).

A part of creating motivation for change is about showing interest in the employee. By asking the employee questions about their job, the conversation can dissolve the defensive attitude that might exist. By enlightening how to realize positive aspects of making the improvement and what is needed to avoid, the drawbacks, gives credibility to the improvement project. "There are many aspects; commitment, setting goals, measure and follow up, communication, engagement, usage of a clear method, continuous risk analysis. But the most important is the change analysis. What is positive, negative and what actions we take. It is vital to be restrictive with spreading the negative aspects, doing that can be devastating" (Nyström 2011).

Related to commitment is the *process ownership.* The process owner is responsible for a particular process i.e. manufacturing. The ownership includes responsibility for improvement work of the process and all resources in the process, including the economic resources. The process owner should create rules, direction and framework for the operation.

3.2 Process management methodology

The importance of adapting to the process view has led to the creation of the process management philosophy and thereby also some methodologies consisting of different steps, although process management can be deployed in different ways. One methodology is presented below. Basically it is made up of four steps (Bergman, Bo; Klefsjö, Bengt 2010)

1. *Organize for improvement*. Start with appointing process owners and a process improvement team. It is not necessary to appoint for every single process in the beginning since it has been shown that the focus should be on a few processes.
2. *Understand the process.* It is needed to understand the process before it can be improved. Define customers, suppliers, input and output (wanted result) to get knowledge about the process. Be systematic when describing the present process. Co-operation with customers and suppliers is a good way to understand their needs and the interaction in the value chain. It is a good idea to *map* the process in a *flow chart.* In a flowchart are the different activities identified and the connection them between can be visualized. The learning and insights that are generated when mapping a process is valuable in itself. The shared visualization of the process (flow chart) make out a good foundation for improvement work since it is a good mutual reference.
3. *Observe the process.* Earlier behavior of the process is used as basis for improvement. To find facts that show on an earlier behavior it is a must to measure the process in different ways. Resource consumption, reliability and customer satisfaction (quality of output) can all be areas for improvement and should therefore be measured. Find improvement opportunities based on the data gathered.
4. *Improve the process continuously.* Adopting a holistic view of the organization is a central factor in process management. Therefore shall the improvements focus on;
   - *quality* (the capability to satisfy customers' needs and expectations),
   - *efficiency* (how well the processes are utilizing the resources in the organization to produce results)
   - *adaptability* (how well the process can be adapted to changed conditions)

Processes are often unnecessary complex due to all changes made over time. Try to simplify and be open-minded. (Bergman, Bo; Klefsjö, Bengt 2010)

3.3 Process mapping

Process mapping is a central tool in the TQM. With a structural analysis of a flow of material or information can it be distinguished how work is actually done from how work should be done in three steps. Visualization of what really occurs in the flow creates an "as is"-map. "As is" shall reflect what is done today. "As is"-state is not optimal. By very small means can another level of performance be achieved called "should be". It refers to what the organization should be able to perform without any extra means. Using the current investments software, people, equipment and processes is it possible to reach another level of performance by for example rearranging the material or information flow.

There is a third step called "could be" which refers to the level of performance an organization can reach by investing extra resources. "Benchmarking" is a major driver of change at this level since it is a lower risk strategy which gives both direction and an indication of goal level. Another approach is "business process reengineering", which however is a strategy with higher risk (Alänge, Sverker WP 1996:01)

Once again, there are different approaches to make a process map. *Flow charts* can illustrate the different activities in the process. *Block diagrams* do also include where in the organization the activity is performed which means the operator or performer is included in the horizontal lanes, sometimes referred to as *swimming lanes*. A banking example illustrated in figure 5 shows how the credit checker is initiating the process, then perform step 1 and step 2. Step 2 generates a document. The supervisor takes over for step 3 and then ends the process.
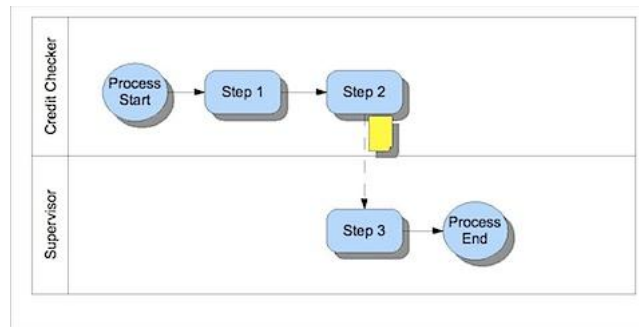
Figure 5 Illustration of a simple block diagram

Let us say it is the "as is" level of performance in the banking example in figure 5. Analyzing the process can result in opportunities for improvements. E.g. the document produced in step 2 is delivered by ordinary mail to the supervisor. Maybe if the sites were located closer to each other or another way of transporting the information can be identified could result in a shorter lead time for the process.

3.4 The concept of learning organization

Continuous learning is firmly connected to learning. To get continuous improvement as a natural feature in organizations, it is vital to create a learning organization. One definition is: "A learning organization is an organization skilled at creating, acquiring, and transferring knowledge, and at modifying its behavior to reflect new knowledge and insights" (Bergman, Bo; Klefsjö, Bengt 2010)

Bergman and Klefsjö (2010) describe how Senge argues an organization shall be able to affect its surrounding in a beneficial manner, not only be affected by the surrounding. Senge describe five important elements which all need to be considered for a learning organization. These elements are; personal mastery, mental models, team learning, shared vision and system thinking.

- *Personal mastery.* Personal mastery is about personal development through learning and personal growth. It is the organization's responsibility to give the opportunity to its employees. The opportunity to fulfill oneself as a person. The organization is dependent on the individuals' willpower to learn but it is in the organizations interest to develop the individuals.
  Personal mastery is generally a matter of skills and knowledge, referring to the ability to widen ones intellectual horizon, gather energy, develop ones patience and adopt a matter-of-fact view of life.

- *Mental models.* Individuals interpret the surroundings in different ways. Based on our knowledge, suppositions and experiences we have different mental models. What is important is then to *understand* one's own mental model as well as each other's (and also the customer's). It can simplify the communication and reduce the mental gap between individuals.

- *Team learning.* Team learning is a skill and learning together is an ability which needs to be assimilated in good way. Sharing knowledge in the organization is important to make the information reach the operative efforts made for improving processes, products and in the end give the customers a better total experience. A high performing team can learn and develop together.

- *Shared visions.* A shared communicated vision shall create a feeling of belonging and desire to reach objectives. It is important the vision is not forced upon from above. A collective vision which the employees shall adapt to is not ideal. Instead can combining the individual

visions create stimuli to new thinking and acting. With a shared vision, there is an understanding and acceptance in the group of how to complement one other.

- *System thinking.* In a system can an event or decision in one part of the system have impact on another part of the system. There are many interactions in a system which needs to be perceived in advance. Otherwise can system parts be sub-optimized followed by overall losses.

People can get a very strong feeling of collective purpose when they are a part of a well-functioning group. The feeling of belonging to something greater than themselves gives incentives to create and perform. Bergman and Klefsjö describe how Garvin in his literature from 1993 discuss how to become a learning organization and emphasize success factors are being skilled in the following areas:

- o systematic problem solving
- o experimentation with new approaches
- o learning from their own experience and history
- o learning from experiences and best practices of others
- o transferring knowledge throughout the organization

(Bergman, Bo; Klefsjö, Bengt 2010)

3.5 Characteristics for Small and Medium sized-enterprises (SME)

It is argued (Boulter and Bendell 2002) that there has been an attempt to "push" ISO9000 standard down the supply chain as a reaction to larger organizations have obtained certification of the standard themselves. It may influence small firms to make the implementation of ISO 9000 for the wrong reasons. The general criticism is centered on the 'belief' that rather than ensuring quality to the customer, ISO9000 adds bureaucracy and costs to the small company. It is seen a bit problematic since the lack of literature applying quality management in SMEs makes it difficult to learn how to relate to the standard (Mulhaney, Sheehan and Hughes 2004) (Boulter and Bendell 2002). Nonetheless, people involved in business support and development have been aware of the positive aspects of application of ISO 9000 to SMEs. As small firms grow, the systemization of basic business activities may increase the capacity for growth. In the companies where implemented well, ISO 9001 has usually added structure, discipline control and traceability. A more structured organization may be necessary for a SME's potential for further growth (Alänge and Bengtsson 1992, Boulter and Bendell 2002).

In contrast to larger companies where resources are available, SME's have not the same opportunity due constrained resources (Boulter and Bendell 2002). There are not resources to allocate one person to work fulltime to deliver an implementation project since it is costly and require effort. Effort is required both during the implementation and after for maintenance. Allocating people already fully committed to their everyday work is problematic. However, participation of staff at all levels is important and can be achieved with effective planning and management of the overall project. Management should allow staff to set off time and be free from day-to-day tasks to be involved in the implementation process (Mulhaney, Sheehan and Hughes 2004).

Mulhaney *et al.*(2004) argue the responsibility should be clearly defined and need to be accepted at all levels. Empowerment is especially important at middle management and operational level where the long term effects are not always realized. Personnel should be involved in redefining their roles and the processes they are involved in. Beside defined responsibility is a time scale with explicitly defined measures of performance important. The measures, or goals, should be continually

monitored. According to Alänge *et al.* (1992) it is of vital importance the top manager is involved and sets attainable goals. The certification shall not be a goal but a means for developing a system. The standard can instead be used as a guideline. Besides setting goals should the top management show engagement and genuine interest in the development process. It is one of the manager's tasks to align personnel and distribute responsibility.

Managers of many SMEs are often aware of bringing in external consultants may not generate the wanted long-term effect. Management consultants tend to tell companies *what* they need to do whereas the companies struggle to appreciate *how* to do. Even though the implemented solutions meet the companies' requirements, it does not necessarily result in continual improvement into the culture. Continual improvement should be built into the processes (Mulhaney, Sheehan and Hughes 2004).

3.6 Quality management system standards, ISO 9000 Series

A quality management system is a system by which an organization aims to reduce and eliminate nonconformance to specifications, standards and customer expectations in the most cost effective and efficient manner- (Luthra 2011)

The purpose of a quality management system is to be a tool for controlling, managing and improving the quality of the organization's products and processes. The system shall be well documented and the documentation shall support the improvement work and generate a base for the audits of the organization's methodologies (Bergman, Bo; Klefsjö, Bengt 2010).

The ISO 9000 series is a set of standards developed by International Organization for Standardization. The series contain different standards which each of them focus on different parts of the quality system. The standards support the documentation of a management system which affects all functions in an organization. Independently of size or type of organization is the standard intentionally applicable to any organization (Bergman, Bo; Klefsjö, Bengt 2010).

The requirements for the quality system

There are requirements of what the quality management system shall consider in order to be certified according to the standard. Those requirements are specified in ISO 9001 and are the part of the series which cover processes but does not include any requirements on the products of the organization. It is the customers who have requirements on the product. Table 1 present the required areas and a short explanation of each. The four main areas are *management responsibility, resource management, product realization* and the fourth is *management, analysis and improvement.*

Table 1 Requirements of ISO9001:2008 standard (Swedish Standards Institute 2008)

Area of requirement	Explanation
Managements responsibility	
management commitment	Demands on commitment to the QMS's improvement and development. Also demands on communication to the organization
customer focus	Needs and expectations of the customers are identified and must be met for customer satisfaction
quality policy	Establish a quality policy and objectives
planning	Plan the resources needed to meet the established goals.
management review	The routine for the internal audit to make sure it is appropriate and meet its purpose

responsibility, authority and communication	Covers the requirements of administration of the quality management system
Resource management	
provision of resources	Declaration of mobilization and needed resources
human resources	The total needs of competence, i.e. education, training, skills and expertise. Ensure it is met
infrastructure	Management of infrastructure i.e. buildings, equipment and services needed for the business to be successful
work environment	Management of the mental and physical environment
Product realization	
planning of product realization	Documentation of product development
customer-related processes	Find and review customers' and organizations' product requirements. Get feedback from customer
design and development	Plan and control the product development. Establish procedures for review, validation and verification. Systematic processes of design and development.
purchasing	Control to ensure conformity of supplied products. Evaluation of suppliers ability to deliver expected quality
production and service provision	Controlled use of instructions, equipment and procedures. Establish controlled and documented traceability. Process control
control of monitoring and measuring equipment	Specify measurements, monitoring equipment needed to ensure product conformance. Includes measuring capability of instruments.
Measurement, analysis and improvement	
general	Specify, plan and implement the measuring and supervision activities required to ensure fulfillment of standard and improvements, and how to do it.
monitoring and measurement	Monitor measured customer satisfaction, processes and products.
control of non-conforming products	Documented procedure for identifying and screening non-conforming products before market.
analysis of data	Collect and analyze data to decide current state of customer satisfaction, process and product characteristics and suppliers.
improvement	Strategy for continuous improvement Eliminate causes of variation and deviation.

3.7 Conformity of Production (COP)

Conformity of Production is a means of evidencing the ability to produce a series of products that exactly match the specification, performance and marking requirements outlined in the type approval documentation. Whether you are a manufacturer, or the agent applying for approvals on behalf of a manufacturer, and whatever vehicle it is, suitable COP arrangements must be made (VCA, Vehicle type aproval and ISO certification through VCA worldwide 2011).

There are authorities (like VCA in GB or RDW in Netherlands) which certify companies to be approved as vehicle manufactures. These authorities make an audit at the manufacturers business site and
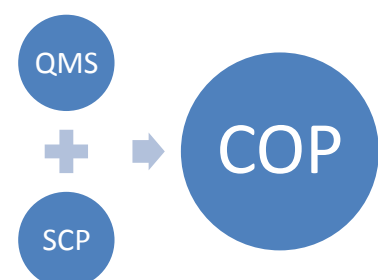
Figure 6 Illustration of required parts for COP

investigate whether the applying organization fulfill the requirements. There are two main routes for demonstrating COP compliance. The first method is through a recognized QMS such as the ISO 9001:2000 series or ISO/TS16949. Beside a recognized quality system, specific control plans (SCP) are also required. As the requirement for a recognized QMS is not mandatory, the second method for demonstrating COP compliance is for manufacturer's who do not have a recognized quality system. In these cases a quality manual and detailed control plans are required. See figure 6.

The quality manual and control plans should then be detailed enough to ensure a high degree of confidence that compliance with the relevant directive or regulations can be continually met. In conjunction with the quality manual and control plans a site visit may be required to ensure that the procedures supporting the application are in place and are sufficiently robust (VCA, Guide to Conformity of Production 2011).

For manufacturers who do not have a recognized quality system (ISO/TS) a copy of the quality manual or the documentation that the manufacturer uses to ensure product consistency should be submitted along with detailed control plans. Here follows a brief summary of what the authority expects from the quality system. The quality documentation should include but not be limited to following areas:

- List of approved suppliers
- Incoming goods
- Non-conforming goods
- Staff training
- Calibration of equipment
- Change control
- Final inspection
- Visit at site

For short description of each area see Appendix B.

The control plan is a list of process controls, actions and procedures, which make sure that the completed product will conform to the approved type. The control plan has to be more than a work instruction for assembly of the product; it should in detail describe how conformity to the approved type is ensured rather than simply describe the assembly procedure. The control plan should take into consideration at least the following areas; control description, test method (visual, electrical or mechanical), pass/fail criteria, frequency of test, responsible department, report method, responsibility for follow up (VCA, Guide to Conformity of Production 2011).

3.8 Quality manual

A quality manual contains the documents that control and specifies the processes in the organization. It shall describe how the company works with its quality management system. Once in a while, e.g. once a year the organization does an audit of the system. The purpose is to ensure the quality management system is effective for the organization and up to date. It shall help the organization meet its stakeholders' expectations and demands. The audits give opportunity to find areas for improvement. The quality manual is a "living document" which means it needs to be updated when for example a process is improved or a routine is phased out.

The documents in the quality manual have a certain format. Besides document name, area of content and reference number, revision number, author, validation date and approval date are included. This applies to all chapters in the quality manual.

It is vital the quality manual becomes a help which support the daily work. The manual shall only hold relevant information for the organization. The manual should be able to be used as an introduction guide for new employees. (Nilson 2011)

3.9 Documentation

This part of the theory deals with the difficulties with documentation. The studied material gives supporting advices when documenting procedures. The documents can easily become too informative and leave out the user friendliness that is necessary or otherwise will the documents not be used. The purpose is to have some supporting guidelines when documenting the processes in the organization. In a small company the verbal intercommunication is often quite good relative larger companies with more employees. Instructions can be communicated verbally to a large extent but sometimes when talking is not possible, procedure descriptions or guidelines can be helpful to perform a task. Here follows a list of aspects to consider when writing documents;

- Make sure the document or procedure is written adequately for the people who shall read it. Beware of the end user since people have varying degrees of expertise, background and learning styles.
- It shall be easy to read and understand. Keep down the number of words, use familiar words and short sentences. If the text is too wordy, too formal or too long, it can lead to misunderstanding or disregarding.
- Use somewhat informal or personal writing style if possible.
- Use gender-neutral words and cultural biases should be avoided
- Examples are often good for explanation
- Avoid cross-references. Do only use them to avoid large amounts of text.
- Avoid jargon and acronyms, can be misunderstood.
- Use bold or italic for highlighting. But use sparingly for best effect.
- Sequenced procedures should be numbered.
- Try to write in same terminology throughout the document to avoid confusing the reader.
- Procedures shall be properly organized with a logical sequence and starting with an overview, heading, purpose, stakeholders etc.
- A new user shall effectively perform the procedure. Make sure the writing is detailed enough.
- Manuals, paper-based or e-documents, should have a title page, table of contents, glossary and index

Summarizing what a good, well written document should be like;
- ✓ Be a series of logical steps, optimizing productivity and output quality.
- ✓ Defines who does what, when, where, how and why.
- ✓ Does not leave room for any sub-optimal interpretation.
- ✓ Minimizes the risk to the company by suitable controls (Berger 2008)

4. Empirical research

The content of this section is based on interviews with professionals within the area of quality management and change management. The interviewees have experience of management systems. The organizations they represent are Effort consulting, CANEA consulting group and Barium consulting. Interviews are also made with quality managers at three small companies. All companies are situated in the region of Gothenburg, Sweden. The transcribed interviews are attached in appendix A.

4.1   Management systems in consultants' perspective

Interviewed consultants have a similar view of the topic. It is quite straight forward what factors are important to take into consideration and as a whole the consultants have a similar focus. There are many significant matters to consider when working with business development since it is much about changing a behavior of the employees. In similarity to the cornerstones for the TQM philosophy are central areas process view, engagement of people and leadership commitment. To achieve a successful change process it is also important to build a management system that considers the company's real needs. It is the key according to the interviews.

Needs

The needs should be strongly connected to why (we have these needs), for whom (the stakeholders) and how the needs correspond to customer satisfaction. A mistake people often do is regarding the requirements for the standard too early. People tend to often miss goals at the start as well (Nyström 2011). People tend to seek inspiration from the requirements when they do not know what to do and are mostly interested in getting a certification. One risk is that the work is performed for someone else than the organization itself, which is dangerous since there will be a lack of commitment and the project will get the wrong focus. One should know why a management system is needed and it shall connect to the need one got. The system shall exist to keep up the quality, not be for the sake of audits (Franze 2011).

Motivation and responsibility

If the people who are affected by the new management system do not understand the purpose it will easily become seen as a controlling "must do" instead of a supportive help for the activities. The management should find and be able to show on win-win-situations and root the benefits to achieve acceptance for the changes. Then there is a better chance to succeed with the implementation. It is about creating an environment where the employees feel comfortable. A part of that is to assign process owners who are responsible for their processes. A process owner can be committed to an activity. If there is no process owner, there is a risk no one executes the task and the problem gets lower priority. Another partial key to unlock the potential defensiveness is to actively work with goals. Doing so can visualize the progress and achievements of projects and in that way give motivation to the involved people since they are shown positive progression (Franze 2011).

Why a management system?

In the startup of the work is it important to discuss and set up targets for the work. The involved group of people should together set the mutual targets and critical success factors. It is also important the target can be visualized and communicated to the concerned employees. The group should reflect on what effects are wanted in organization and what the outcome shall be. Long term goals are vital for sustainability in the development as well as short term goal for quick-wins which stimulate the motivation to continue the work. (Nyström 2011). Nyström says as an effect of visualized management system is increased clearness of the company's structure. The responsibility and work methods become clearer and better communication is one important effect. Sometimes is the case that the certification can be the target for the implementation in an organization and that

brings a huge risk. The mindset is then wrong and the chance to attain a supporting system is decreased. Then satisfaction is achieved when the organization is certified and changes for improvements are not considered, at the same time as the system becomes a bookshelf product. The results become a created system which does not become useful after the certification. It is therefore important to not have certification as a goal with the implementation (Nyström 2011).

With a clear structure in the company will you get an increased structure capital which is means the company becomes more faithful in the eyes of external stakeholders. If the company intend to do an exit it is definitely important to have a structured company. Buyer wants companies who know what they are doing (Book 2011).

Process view

Process view is a central concept in business development. Thinking and working with processes is about needs (the input). The consultants think process mapping contributes to increased understanding and is good for visualizing the activities in the company. It is not only about mapping, it also include risk management and problem solving (Book 2011). When the process mapping is performed in groups, visualization is good for the communication in the group. Discussing around a picture can help the discussion when there is a common reference. When talking about processes it is easy to fall into a definition discussion of what kind of process it is. E.g. "Is it a main process or a supporting process?". That is not the point so try to avoid that discussion. The point is to start thinking of what is really happening in the process, what is the process about. When having those discussions is it good to use the own internal language, otherwise it can be too complicated. There are some questions which can be answered to get a shared picture of what is happening. These are fundamental questions to be asked and answered:

- Who is the customer?
- Who is the supplier?
- What are the input and output?
- Who is performing the action?
- Who is process owner?
- What is the purpose of the process?
- What trigger the process?

When the quite straight forward questions got answers it is time to think more critically and be analytical. Questioning the routines is a good start. Ask more critical questions. Discussions are good and it is when it is discussed new ideas come up. Spreading the information in the group also increases the learning and awareness for the involved persons. Processes are custom made and the process description shall reflect the real present situation, not how it should be. Describing how it should be does not work. Instead document what is really done. The management system should mirror what the business really does, not before then can it become helpful (Franze 2011).Here follows examples of more advanced questions:

- How is it done?
- What are the risks?
- What results are expected?
- Which steps are taken?
- What results are of interest? (Book 2011)
- Can we do the same tasks with fewer resources?
- If we change, what happens in the system? (Syrén 2011)

When starting to map the processes it is good to start with a few ones that are well known for the organization. Start in small scale, learn from that and then extend. Begin with a main process for

example. They are known by many people and have often clear circumstances in terms of input, output, and stakeholders. Workshops are a common forum for this kind of exercises. In a workshop is it good if the group is composed of people with different competences. Many perspectives give the opportunity for people to learn from each other and the discussion does not become too focused on one particular area. At the same time the group can create a feeling of unity and give spirit and energy to the changes. Without going into group dynamics too much it just need to be said that the words "we" and "together" are central for a high performing group (Franze 2011).

Documentation

The produced documents, e.g. guidelines, templates and directions, should be a product that is appreciated and used by the employees. A crucial insight to grasp is that the documents should be supportive rather than being controlling or directive from the users point of view. The user friendliness is another part to consider. Keep down the information, make it concise and document only what is necessary and creates value. The advice is to use a familiar language and use words that are recognized in the organization. Short sentences are also good (Berger 2008). Think of what the needs are. As mentioned above shall the management system reflect what is really done, not any wishes of what to do. Guidelines and templates are good. They are not too restrictive and give at the same time directions of how to do. Checklists are another good way to describe different steps to perform in a process. Checklists are also good for the possibility to declare what is done and keep track of the work. The employees do not often know how to address the documentation. It can therefore be needed help or some education to establish some understanding. A common mistake is to look at what is required from external stakeholders. Wait with comparing the own business to any standard until later. Otherwise is it a risk to get the wrong focus (Nyström 2011).

Meeting a board member

A discussion was held with a board member at Nimbell who has been in similar work related situations before. The discussion was mainly focused on process mapping. The reason for that was to understand how to approach the process mapping part of the project. That person's recommendation was to start to look into the product development and market (sales) and after that procurement. Reasonable since those are all considered as parts of the main processes at Nimbell. Other advices of his were;
- keep every process description on one A4 page, and keep it simple
- build a clear structure in the company for structural capital
- make customer needs and requirements mirror into the business
- use balanced score cards for visualization (Nilsson 2011)

Sometimes can the reason for an organization to build up a management system be requirements from external stakeholder such as authorities or customers or both. Even the market can require it. The requirement is often that an organization shall have some kind of certificate e.g. certified according to the ISO9001-standard.

4.2 Quality Management System in medtech companies

Information was collected through interviews with employees in organizations that apply management system on daily basis. The interviewed persons are responsible in their own organization for the quality system. All the companies are in the medtech business and have therefore often requirements from authorities. The authorities require safe products since they are used with humans in different means.

ATLAB

One interviewed company, Arvidssons tandtekniska Lab AB (ATLAB) works with *learning alliances (which refer to a group of people* exchanging experiences), as their core activity to work with problem solving and spread knowledge. The PDCA-model is central for their learning alliances and

they hope the learning alliances shall stimulate a new behavior and be a part of the company's culture, i.e. a new way of approaching problems and share knowledge. To be competent and developing together is central in the business development. The company has very much intellectual capital which needs to be shared within the company in order to be superior in the industry (Lundahl 2011).

Lundahl points out it is relevant to consider using an own language and not a lot of fancy words. It is easier to communicate the meaning in that way. The terminology is therefore important to consider. Use words people are comfortable with.

At ATLAB the coordinator Gunilla Lundahl has just implemented a tool called the operational compass (verksamhetskompass). It is used for initiating projects and issues (an activity) which need to be improved or fixed. By using the operational compass Lundahl can keep track of the improvement work. The compass is like a log for improvements and quality errands. It is specified who is responsible for the activity, the status of the activity, actions taken, participants, plan, priority, due date etc. Co-workers can report quality issues e.g. non-conforming products into this log. Lundahl thinks she gets a good overview of what to prioritize with the log. She also mention the operational compass give also acknowledgment of the progress.

Promimic

Karin Breding is working as quality manager (and product developer) at Promimic with responsibility for the quality management system. She thinks implementing a quality management system is a step in the business development. The system shall be living and developed over time. It is important everyone is involved in the development work to catch the employees' engagement and interest - and get everybody to cooperate. It is not right to let the quality manager decide how the processes shall be operated. Since it is different persons in different processes it is reasonable the employees decide their own process. If any process does not work out well the team can look into that problem together, to find a solution. And you do not have to do everything at the same time, take part by part instead. It is about improving. It took Promimic about one year to get used to the quality system completely (Breding 2011).

Promimic has a computer program called CAPA which is anagram for Corrective and preventive actions. This program is a tool to gather, document and communicate problems and nonconformities in the business. Anyone can post a problem and then the quality manager look into it. Often is responsibility assigned to someone else than the quality manager.

The product developers do not like to be controlled since it inhibits them in their creative process. Instead documentation of the research is central. It gives traceability in the work. Breding says the documentation later becomes reports and they can go back and learn what not to do. When keeping a record of the work done, evidence is at the same time created for the work performed.

Breding's recommendations; Contact a supportive consultant who can help with the startup and find a good structure which is time consuming. That was what Promimic did.

Micropos Medical

At Micropos medical Hanna Syrén and her colleagues have tried to build up the system as simple as possible and regarded they are few people in the organization. Syrén says they have not any requirements they shall adjust to, just use common sense. The personnel at Micropos have declared areas in which they need documentation how work is done. A specification and a report can be enough for them. It is still quite unconfined and the routines they write are general and not too detailed. "We started slowly with some important routines. Instead of looking at a quality system, we

started with 'this is what we do' and then revised. We started with the processes we thought were more obvious for us" says Hanna Syrén.

Risk analysis and risk management are important for Micropos. Every time a change is made on their product they perform a risk analysis with focus on the end-user. The main question is "what can happen to the patient?", and if any aspect might be changed to the worse. Safety is everything for Micropos. The procedure of risk analysis is quite work intensive but give a good reflection of the reality. (Syrén 2011)

It is central to understand how the system supports the organization. It shall not been seen as a burden which it can feel like in the beginning. It can seem to be much work in the beginning but in the long run will it be helpful. Before start is it easy to think it is fine since you do not see everything.

Some comments in bullet form:
- o Micropos documents all data from customer. It creates a base for improvements.
- o All reclamations are documented if someone been in danger. There is a record for that.
- o It takes time to adapt to new routines and everything is still not perfect.

4.3 Summary of interviews

Table 2 summarizes the most important and common information from the interviews. These factors in the summary make the foundation of the development of the implementation. The important issues to consider, the general benefits and some of the possible pitfalls are gathered in the table to get an overview of the all aspects to take into consideration.

Table 2 Summary of important subjects to consider, general benefits and pitfalls

Important issues to consider:	Start small scale, Management's commitment, Process view, Identify needs, Set goals, Use own language, Get involvement, Customer focus
General benefits:	Clearness, Support in daily work, Structured company, Trust from external stakeholders, Achieve learning, Increased effectiveness, Improved commitment
Pitfalls:	No goals, Documenting too much, Unclear terminology, Too time consuming and too wide focus, Too low commitment, Disagreements render in split group

5. Action research at Nimbell

This chapter describes how the active research has been performed in the study a Nimbell. It includes a problem analysis, a plan of which steps to take, the workshops (including established routines) and proposal for a quality manual. The information from the empirical study is very much regarded in this chapter.

5.1 Problem analysis

Nimbell stands in front of a rather advanced project. As indicated in the interviews, adapting the company to a new approach can be problematic why consultants support can be very helpful. Highlighted in previous chapter there are many pitfalls which can obstruct the development of the project. Those pitfalls have been identified by considering the recommendations primary from the interviews, but also from the literature. Changing mind-set and adapting to new routines takes a lot of time since it is about learning new things and changing behavior. Time is required. The employees in the organizations have other obligation they prioritize. It is easy to adjust the prioritization to avoid failing external deadlines. Then the internal issues come secondary because it is not as important at the moment. Being aware of the fact the pitfalls (visualized in figure 7) exists increases the chance to succeed since one can recognize when heading towards them. Falling into the pitfalls will probably delay the project and affect the involvement negatively. There are many cause and effect relationships but the total problematic effect could be unsatisfying result of the implementation project i.e. the project have not given the expected output.
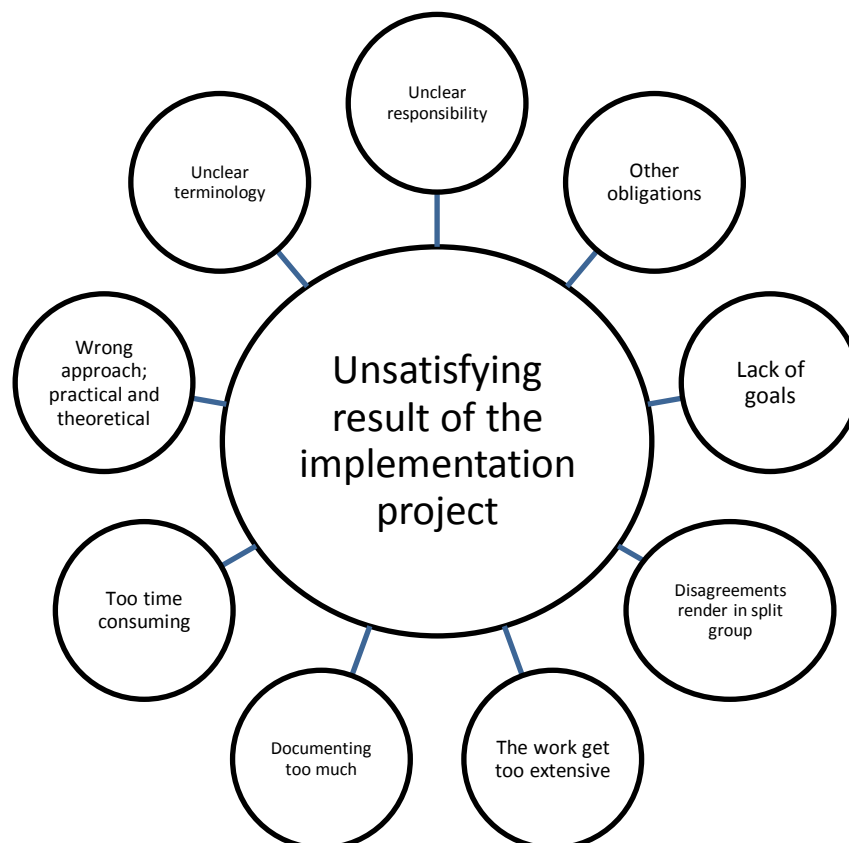
A very central part of a project is to involve the people in the organization. Making changes (or improvements) and make them sustain is becomes problematic if the changes are not established in the people they concern. Engaging people to wake interest is important to be able to get engagement. To be able to show positive outcomes it is important to create interest as well as a positive attitude for changes. Those factors are important to get engagement. These insights results in a need of finding out how to create engagement.

It is the people in the organization who shall use the system when it is established. It is difficult to adjust yourself if you do not really understand. An example is letting a process operator be involved in the development of the process to create ownership. The operator will increase the understanding and can accept the change more easily. Even better is if the operator thinks the improvement is his or her own idea. Maybe is the best scenario if the idea really is the operator's since it shows an understanding and will of changing. However, trying to establish changes which not have acceptance from the concerned people is often not successful. Commitment is needed. Commitment is achieved with responsibility, autonomy and interest. But who got the responsibility or interest of unknown processes? It is a question for later discussion.

Another problematic issue is that many processes are not really established in the company. Many of the activities at Nimbell are so called firefighting which means the focus is to solve most important issues first. There are no set routines and therefore is even the "as is" level very diffuse. As often in startup businesses the people have to find out how to solve tasks when they appear. Then there are no established routines. On the other hand there are ideas of how the organization should be. The problem is how to know which level to focus on and how to communicate that. Which approach should be used for process mapping? Recommendations promote a simple level on the approach meaning keeping it simple and understandable. There are some processes which have some kind of structure e.g. product development and operative procurement. The approach will be to look at those to practice the process mapping tool and start analyzing something not too abstract.

Since the start of the thesis project there has been a very strong focus on the requirements for certification. According to the consultants is that the wrong way to approach an implementation of this kind. One problematic aspect with only considering at the requirements is the negative approach it gets. Requirements are linked to obligations and control whereas expectations (or needs) can be linked to support and opportunities. The latter is more positive.

5.2 How Nimbell can move towards a quality management system

A general action plan (see figure 8) was established out from the empirical research and theory. The plan consists of two parts. The first is a startup phase which aim to establish understanding and insights in the company. This is done in workshops. The second part is where the development continues led by the company itself. That is after this master thesis ends. With support from the recommendations in this report and the draft of the proposed quality manual Nimbell can finish this journey on their own. The first part is described in the following section.
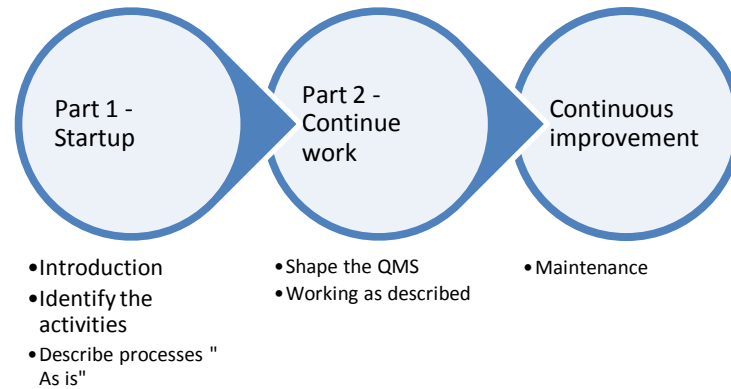

Part 1 - Startup
- Introduction
- Identify the activities
- Describe processes "As is"

Part 2 - Continue work
- Shape the QMS
- Working as described

Continuous improvement
- Maintenance

Figure 8 The steps towards a QMS

Part 1- Startup

As a startup of the implementation was an introduction session held. This is the introduction to the whole project for the employees. In this session was the focus on the task, the positive outcomes and how the work will develop. The intention was to have the discussion on a business strategic level, quite general and focused on the positive.

> **Step 1**
> - Short introduction to TQM and COP
> - Focus on potential benefits and pitfalls
> - Identifying the quality goals

The next step aimed to consider the current situation and analyze what activities there are in the company. In this session the process view was presented. The idea was to start thinking of what is done in the company and how are activities linked to create a common structure. It was a practical exercise with lots of discussion.

> **Step 2**
> - Follow up from last workshop
> - Identify activities
> - Identify areas for responsibility
> - Map the structure
> - A tactical perspective

> **Step 3**
> Consider following for each process:
> - Who is responsible?
> - Where takes the process place?
> - What triggers activity?
> - What happens, how is the activity performed?
> - What is input/output?

This is step 3, when some processes were described "as is". Considering a small scale company there are not many processes established yet. It was practiced on the ones that were relatively clear and running. The process mapping and documentation was performed after assembled recommendations and the focus was on an operative level.

Part 2 – Continue work

In the appendix G is a more extensive description of each step in part 2 to be found.

Gather the described processes and examine how they are documented. Make sure it fit together and correct inconsistency and gaps between the documented activities.

> **Step 4**
> - Quality manager and CEO review written documents
> - Does it fit together?
> - Deal with inconsistencies and gaps

Consider if it is in line with the quality policy and the company's objectives. Ask yourself if specifications are relevant for the business.

The next step is to make sure the company work according to what is decided. It can take time to get into "new" routines. Let the system reflect the existing reality and reflecting on the situation. The system shall be living so do update when necessary. Give education about how the system is structured and how it is updated. It is important to plan for audits to continuously develop, maintain a get support from everyone. Internal audits are good for engagement and opportunity for improvements.

> Step 5
>
> - Let the system reflect the reality
> - Do not overproduce documents
> - Give acces to the documents
> - Continue education of employees
> - Plan for internal audits

> Step 6
> - Maintenance - Keep the QMS simple, functional and relevant for the company's own operations

The last step is continuous, going on forever. It is maintenance. Make sure the purpose is fulfilled i.e. the system shall make sure process owners know and understand his/her role and responsibility as well as the activities shall be operated in a controlled manner. This step is further described in appendix G.

5.3 Workshops

Workshop 1 – An introduction

The journey started with an introduction workshop. The first workshop focused on identifying why Nimbell wants to start this project with focus on the positive aspects of having a quality management system. There was a discussion of what benefits the company can profit from a quality management system. Five open questions were presented with purpose to first start the brainstorming and then get the discussion going. The questions were the following: What shall we do? What is the task? Why do we want to do this? What is the expected result? What are our goals? As a result of the discussion the group listed strengths and possibilities. They are presented in table 3. Purpose and goal were two central areas

Figure 9 An illustration of the perspectives we discussion.

for the discussion on this strategic level. A short presentation was held about what it takes to receive a COP. Using the material from the theory chapter about Conformity of Production just to have some understanding of what it is about.

As important to promote the positive aspects it is also necessary to discuss possible pitfalls and how to avoid them. Important though not focus too much on the negative aspect, just be aware of them. We had a short dialogue about which potential pitfalls might create problems on the journey. A brainstorming session resulted in identified pitfalls, see table 3 for the result. By reducing uncertainties and explain the positive aspects and at the same time enlighten the group of difficulties creates improved understanding and hopefully a good feeling about the project. Uncertainty and fear is nothing that belongs in this setting.

Table 3 Strengths, possibilities, pitfalls and threats as a result of the discussion in workshop 1

Strengths and possibilities	Achieve customer satisfaction, improved efficiency, save time, better communication, learn about ourselves, improved external communication, external trust, learning journey, competitive advantage, investment, minimize risks, better structure on documentation, easier information exchange, start documenting, save consultant fee (by go on our own)
Pitfalls and threats	Too complicated, too controlling system, take too time consuming, we miss the point and don't improve

From the discussion core values were identified, which gave input to the quality policy, see appendix C for the quality policy.

Workshop 2 – Identify the activities

The second workshop started with a recapture of the introduction workshop, workshop 1, to recall what was discussed last time. Again, the focus was on the strengths and possibilities to get a positive feeling. After a short explanation of the tactical (activity focused) level we opened up the discussion about processes and how one interprets the definition of a process. The definition was brought from the Business dictionary which is stated in the theory chapter. It was also necessary to explain the different types of processes (main-, supportive- and management process) and its stakeholders (process owners, customers, suppliers etc.). With that perspective started the identification of the activities in the company. With post-it, brainstorming and a clean table started the arrangement and categorization of the activities. There

Figure 10 The second workshop

were many different activities which came up. They are listed in table 4. Based on the definitions of different processes we made a first drawing of our main process map. That one was documented. Appendix D contains the output from workshop 2.

Table 4 Identified activities in Nimbell

Business development	Intellectual Property Rights	Technical research	Service
Internal communication	Design	Production management	Spare parts
Human resources	Product development	Production optimization	Procurement
Project management	Production documentation	Market intelligence	Logistics
Documentation	Testing / verification	Market Communication	Operative procurement
Financing	Strategic procurement	Sales	Quality management
Development	Standard component research	Customer relations	Quality control
Research	Supplier relations	After sales	IT
Administration	Economy	Law	Outsourced: Production

At the end of the workshop 2 session we had a quick briefing. We summarized the session and the coming step was presented in a few PowerPoint slides. The areas for responsibility was not decided i.e. the process owners were not assigned as planned. Due to vague roles for everybody it was impossible to assign the process owners at the time. It was meant to decide the process owners before going into the next stage. Some processes have their natural process owners but others are more unclear.

Describe processes "As is"

This is the third step in the first part of the process. The idea was to map the different activities with process mapping and start thinking of how the activities are performed. The responsible employee, who is assigned process owner, shall together with the supervisor practice the process mapping tool. Being at least two persons makes it easier. Support can be needed and it starts a discussion. Together is the activity analyzed and a guideline is created for the process. The output shall aim for one A4-sheet with the important information about the activity or process. It can for example be written as a checklist or sequential work instruction.

The routines described in 5.4 are all examples of outcomes from this step. There was also other sessions focusing on the sales process, product development and one session looking at the operational procurement activity. It is only the session of product development which is included in the report. The others are not of different reasons; they are not totally finished and belongs to the quality manual.

Supported by the following questions can the visualization of other processes and routines be continued. When there is need for defining more or new processes can this description be helpful.

Each process description shall at last include the following:
- Process owner and controller.
- Where the process take place.
- What triggers the process to start, what the input is.
- What happens in the process, how is the process performed.
- What the output is.

There are some advices which should be considered at this stage which support the work.

o If the work is performed by trained personnel or a specialist it can be enough to refer to the relevant profession or specific qualifications instead of a detailed work instruction e.g. welder or product developer.
o Shall a task be performed by a new employed person might detailed instruction be necessary.
o From activities such as research and development shall notes and results be accessible for the whole organization.
o The activity sequence for a work might still be documented. The following questions are then helpful to reflect upon;
    - How is an initial enquiry received?
    - How is a file initiated?
    - How is the work initiated?
    - Who control/monitor the work?
    - What is documented/ recorded and who does it?
    - How does the work progress and is it inspected?
    - Is follow-up needed and who does it?
    - How is the result/output delivered?

- - Who/what decides when a job is finished?
  - o If there already are detailed instructions, do not write new once. Refer to the once which already are established.
  - o It is important to know the information flow. If there is a risk of forgetting, misunderstanding or accidentally changing the information, find a way to minimize that risk. Written or electronic methods are often preferable.
  - o Most important – *keep written documents simple and user friendly.*

After documenting the activity shall the instruction or checklist be included in the quality manual. It becomes a one of the company's routines.

5.4 Implementations, set routines in the product development

As a result of the third step have some routines been established.

Product development log

The scientists in the medtech companies have a log in which they document their experiments. Keeping a record of the work is good since one can backtrack what has been done, why certain choices and decisions are taken. One can follow the research, there is traceability. Documenting decisions and choices with a motivation is helpful for both yourself and colleagues. With inspiration from the medtech companies an idea came up of implementing a product development log. It shall be used as a work log for the daily activities. It is not only good for the possibility to backtrack the work but also for the reflecting process. It is often easier to remember what have been done if notes are taken.

To start the thinking process there are some questions which one can ask oneself when reflecting over the day's work. One can reflect upon: What was good today? What have I accomplished? What progress have I made today? Could I do something different? How shall I continue? What decisions did I make, and based on what information? The reflection should stimulate the employee to get new perspectives and find opportunities for improvements. There is no template to fill out which might be needed to stimulate the writing. The users have established an e-document which is the log where they document the work.

The routine was established together with the product development team and is now in a test period. An informal follow up revealed they take notes on important decisions and production information when doing research.

Product development checklist

This routine was established to support the design process in the daily work. A checklist has been developed in cooperation with the product development team. The product development checklist is a supportive tool with purpose to ensure the product developer considers all known aspects when developing (or designing depending of definition) a component. There are three core aspects which are expressed as (at the moment) more important for the company than any others. Those are; cost, weight and customer requirements (the specification).

A copy of the checklist is placed at the desk directly in front of the product developer. Since the checklist is used in the everyday work it is important there is instant access to the tool, otherwise will the checklist not be used. The tool shall be seen as an instrument to support as well for control. The checklist is attached in appendix D.

Drawings

The product development team requested a better way to structure and archiving the drawings. During one session was the focus on how the drawings can be organized in an improved file structure. The problematic part was to find a smooth naming procedure for drawings. The possibility to understand the content from the filename is really important. As complement for the enumerated drawing numbers are characters for different types of components (S = sheet metal, T = tube, M = machined part, R = raw material or SS = assembly). There is as well as drawing status (A, B, C or P) for each drawing. Status "P" is for production and "A" is at concept level and may never reach production. The whole routine is attached in the appendix D.

Connected to the drawing routine are the article number list and the drawing file structure. The article number list is a register which holds all drawings. The article number list creates an accumulated drawing number to each new drawing which ensures any drawings have the same drawing number. The new structure is reflecting the product's different areas. These are not official documents.

5.5 Quality manual

The thesis has resulted in a draft for a quality manual at Nimbell. The development of the draft has been a job parallel to the workshop activities. The draft contains 9 chapters plus an archive for old documents which are more or less completed. The chapters 1 to 9 contain general descriptions of the system, more specific guides and checklists for some important activities. The quality manual concludes the most important and implemented activities in Nimbell's business. It is always Nimbell's aim to find out the best way to perform the operations and update the guidelines for their business. In order to satisfy the needs of their customers and other stakeholders it involves every employee in the continuous improvement work.

The quality manual should be used as a guiding and supportive tool in the daily work. It is important that the quality manual is always up to date and available for the employees. A copy of the quality manual is located at Nimbell's web server where everyone in the staff can read it and take part of the content. The CEO is the only one who is permitted to approve changes in the quality manual though. Attached to most chapters are some forms which are used for that specific area. Those forms are mostly in Swedish due to user friendliness.

The draft for the quality manual use the ISO9001:2008 standard as a reference and starting point. A part of this standard's requirements together with the requirements for achieving Conformity of production (COP) are the foundation for the quality system. Independently of business area, the ISO9001:2008 standard will be adapted to the specific business and so is also the case for Nimbell. Since it is a small business the system has been adapted to the company's own capabilities and needs. If the company works according to the ISO 9001 standard is conformity of production (COP) not far away. It is not an obligation to be certified according to any ISO standard but it makes the approval for COP easier since there is already a developed and recognized system in the company.

There are different motives for working according to a quality management system. As expressed in the quality manual are they the following;

- secure the quality of the operations,
- find more effective and more structured ways to operate,
- get support in the daily work,
- be a more attractive company on the market, both for customers and suppliers,
- achieve a more sustainable business,
- get greater credibility towards customers, suppliers and authorities.

Each document in the quality manual has its name and a number based on which chapter it belongs to e.g. N1.2 Quality policy, which is found in appendix C

An important part of the system is the suggestion log, an electronic noticeboard. It is a log for ideas which anyone in the company has access and can document good ideas. For example: problematic activities which need improvements or ideas to opportunities for improvement of a process. The log shall be checked by the person responsible for the quality management system once in a while. The responsible person shall ensure the ideas (or problems) in the log are raised. This element was developed by inspiration from the operational compass at ATLAB.

There are activities to establish and maintain the efficiency of the quality management system. Those are documented in the quality manual or are referenced to from the quality manual. Such activities are e.g. improvement work and audits. The quality manual's table of content is attached in appendix F for an overview of the content.

6. <u>Discussion</u>

This chapter describes the situation at Nimbell and what actions need to take place in order to move towards a quality management system. Generally focus in the project has been on adopting the process view, learning and documentation, which all are connected.

6.1 The mindset and focus on the project

The focus at the company is today on the product and the market. The time to market is vital for Nimbell and that influences the focus of this project. Since the company wants conformity of production certificate (COP) for the product, the focus is very much on the requirements for that certification. It was expressed that "we do what is required" to be approved manufactures of our developed vehicle. Any standard could provide a platform for the development of a quality management system but it is very easy to get on wrong track when focusing on the requirements instead of the needs for the company. That is what has happened, even before the project started. As was emphasized by interviewees, it is important to get the right mind-set of quality management when starting the project. It is important to understand why a structure is important for the organization and what they really need to focus on (Franze 2011). Otherwise the implementation will probably not be established properly in the organization. It takes more than a standard to create a culture of continuous improvement and commitment. It takes a renewed mindset. It has shown from the workshops that there is a focus on fulfilling the requirements for certification for COP. It is more important than getting a proper implementation with focus on the needs. The "should be" (Alänge, Sverker WP 1996:01) state is considered at once. This has been a barrier in the work to overcome this mindset. The quality system should be adapted to the business, not the other way around. There is a correlation between doing a good adoption of the system to the business and understanding the "why" and "what" the management system will be used for (Franze 2011). The start should be critically reflecting on what the business is doing right now and define the "as is" level of performance. From that point can a "should be" level be defined (Alänge, Sverker WP 1996:01).

It is hard to get routines sustainable if they are not established within the people. The routines get established by engagement and understanding. Based on the literature and *let everybody be committed*, responsibility should be delegated to the people who are involved with the processes to get engagement. The responsibility implies deciding how the process is operated, make sure the operation is performed as decided and try to find improvements. It is not right to let a researcher for the company decide how the operations are performed. The researcher should instead be a support in the development of operations (Mulhaney, Sheehan and Hughes 2004).

6.2 Timing, resources and commitment

The timing of a project is very important. When deciding to go through with an implementation project which will involve and affect the whole company it is important to set off time and resources for the project. It is about prioritization of the resources in the company and allocate time (Mulhaney, Sheehan and Hughes 2004). It is the people in the company who should be part of the establishment of the new processes. To get engagement from the employees, the top management has to support and sometimes order the staff to set off part of their time for improvement work activities (Bergman, Bo; Klefsjö, Bengt 2010). Balancing resources are difficult calls when there is lack of time due to deadlines. Taking resources for other projects increases the work load on the employees. This kind of project which involves many employees (also seen as much resources) demands setting off time. Planning the resources has shown to be important.

Vacation is also a factor that disrupts the flow of an ongoing project. The weeks before vacation are often very busy for the people who are not absent and can therefore not participate. Therefor it is

advisable to focus on one big project at a time and plan it well when time is available and people are less occupied.

6.3 Understanding the process view

Understanding the process view requires knowledge about process management, the methodology and the theory behind it. Most important is probably to understand why it is emphasized. Connected to the process view is the process mapping tool. It is a tool among others but with the valuable feature that process mapping *visualize* complex interactions between linked activities i.e. processes. It is the work with process mapping which is important, since the work of producing a shared picture which visualizes a situation and triggers a discussion (Franze 2011). Discussing processes will lead you to insights of what is happening in the business and identifying losses in efficiency, quality and adaptability (Bergman, Bo; Klefsjö, Bengt 2010). It's from those insights one can find opportunities for improvements.

With the process mapping tool the discussions can start. Since Nimbell doesn't hold many employees at each function, each one involve one person, it is good if more people than the processes owner can attend during the process mapping sessions. Even though the observed process itself not involves all employees in the value adding procedures, there are many positive aspects of engaging more than just the process owner and process manager (who are the same person many times). There will not be any discussion with only one person involved, so a group is to prefer. When more people are involved is it easier to get a holistic view since the output from ones process is the input for one other's. It also helps minimizing the risk for sub-optimizing the process. That risk decreases if more aspects (a broader view) can be regarded. There is *system thinking* (Bergman, Bo; Klefsjö, Bengt 2010). One must be aware of that changes in one part of the system can affect another part. Being able to understand the process view concept enables a way to look at the system. It is also easier to generate new ideas are much easier together, if the environment allows. Along with discussion comes also learning of the process and deeper understanding. I think one can gain insights of coworkers' needs and work as well as your own. Sharing *mental models* helps understanding and improving communication in the team. *Team learning* skill is therefore an important part of the learning process to share knowledge in the organization (Garvin 1993: 78-91).

The negative aspect is that what takes very much of the organizations resources (Boulter and Bendell 2002). The more people in the discussion, the more tend the meeting to spin out and might lose focus since other interesting topics arise. Having a proper plan for the meeting can prevent it from going out of hands and occupy too much time. It is sometimes problematic to plan when all employees are occupied with other tasks and time is a scarce commodity.

Guidelines for process mapping have been developed for the workshops. From the guidelines have some processes been mapped as a step towards further development of the processes. The guidelines are general for any process and could be used in the future work.

6.4 Documentation

The company did not have any documentation of their processes before this master thesis project started. Since the recommendations from the empirical research are all pointing in the same directions about documentation, a guideline for how to approach the document writing has been composed. The recommendation to Nimbell is an assembled and adapted guideline with influences from Berger(2008) and the interviews. It can be problematic with increased documentation (Alänge and Bengtson (1992) WP 1993:09) but keep it simple is the overall recommendation. The purpose is to avoid unnecessary paper work, keep it manageable and useful. It is a balance between too much information and too incomplete. As appointed by Berger (Berger 2008), think of its user friendliness and purpose. Specifications for example shall not leave any room for miss-interpretation.

When documenting, the reflecting process starts. Taking notes for example is often for oneself to help the memory but it is also good since one starts thinking. Research in the medtech business requires a research-log is established. The daily activities are briefly summarized which give traceability in the work at the same time as it gives time for reflection in the daily work. In this matter it does improve the *personal mastery* (Bergman, Bo; Klefsjö, Bengt 2010). Having a development-log for each employee working with product development was discussed in a workshop and it is now established as a new routine in the design and development work. Having a record of what work has been made is a receipt of progress in work and at the same time be used as evidence of what work has been made.

6.5 Learning circles

The circumstances for creating an efficient learning environment are very good. The environment is friendly and open-minded and the flat organization encourages discussion. The employees at Nimbell are newly graduated from university, are skilled and have high learning potential. It is a chosen strategy to cooperate closely with suppliers to learn from them and have frequent contact with the potential customers. Updating customers, keeping their interest up and to understand their needs and expectations are central for Nimbell. The people in Nimbell are well aware of the importance of knowledge and sharing it among each other. Increased knowledge and simplified information exchange were two of the expectations with implementing a quality management system.

With inspiration from ATLAB (*learning alliances*) and the Japanese kaizen, a concept has been developed called *learning circles*. The purpose of the learning circles is *setting off time* (Mulhaney, Sheehan and Hughes 2004) for improvement work, get increased understanding of each other's work and take discussions to a higher level of reflection. For me is teaching others one of the best ways of learning myself. From that point of view is learning circles developed which includes the improvement aspect. The concept is about educating each other in recently discovered areas. The participants improve their own knowledge by reflecting on their work before and during the session when educating the colleagues. At the same time, knowledge is shared within the group. The colleagues can learn about areas they normally not are involved in. During each session every participant makes a short presentation of any recently learned work related topic. The presentation which is prepared with very few slides does not take more than a couple of minutes. Afterwards time is allocated for reflection. That gives opportunity for the audience to give feedback, ask questions, come up with improvement suggestions and reflect on how the new learning affects them. Once again, time management and routines is important. Dedicating resources for improvement is important (Mulhaney, Sheehan and Hughes 2004) and one opportunity is to have scheduled forums for certain activities. The *learning circle* is a forum which is one way of setting off time for improvements and is intended to be a repeated routine.

A moderator should be assigned for the learning circles. The ideal moderator is not biased any point of view which probably is not the case in the small company. An ideal moderator holds tutoring expertise which the personnel in Nimbell could lack. If there is no dedicated person for the role as moderator, one idea is rotate the role as moderator between every topic to share the opportunity to learn from that role.

A short guide has been written where this concept is explained. In my opinion can it be really interesting to try this concept. The guide is attached in the appendix E.

6.6 Education

The employees of Nimbell have according to themselves not had any deeper knowledge in quality management when the project started. Some of them have had a course in total quality

management at university. To get involvement and engagement it is important to understand why the quality management is important. Education is often the way to grasp the topic and achieve understanding which is linked to involvement. All employees need training in the principles of TQM. Topics such as the basic concepts and tools of quality management should be included (Haksever 1996).

Analyzing the knowledge level could identify gaps to fill. Education is though time consuming (it would take relatively much time from the company's total human resources) and was therefore lower prioritized for the thesis. To save time the plan was to include the education in the workshops and present theories and methods as the project proceeds. Looking back today it is questioned by the thesis project leader weather that is a good strategy. Instead of building the path as the journey proceeds, it would perhaps be more successful to build a steady foundation of knowledge before hitting the road of the journey. It is probably on the researcher's responsibility to educate in some extent. A nice start would have been more of the basis of quality management. With more education could the upcoming implementation become easier and the education be supportive for further implementation. Insight could increase the interest and also be a catalyst for further work.

6.7 Workshops

The workshops have been interesting from my point of view. As moderator and leader of the workshops I have got new experiences: the leadership experience from the workshop aspect and practices of preparing and leading education. In my own point of view am I not an expert yet (as professionals are) but might be seen as one by the participants. A part of the role is coaching the employees to get insight of their need for improvement.

In the active research and organizational learning perspective workshops are an appropriate path to take when interaction and engagement is required for this kind of project. The workshop is a forum where thoughts are shared through discussion which increases the understanding of the coworkers and the area of discussion. At one workshop it was revealed that the group had different views on how the product development process relate to the other main processes in the organization. The outcome of the discussion was a shared view of the main process map and how it is linked to the different activities.

Thinking of the question "How to implement a quality system in a start-up company?", it has shown commitment is one important factor for successful implementation. The commitment is captured through participation and interest which is argued workshops can create. The workshops made its purpose by starting the discussion and awake the awareness. It is good if the participants understood the process view and gave them insights of why they should use process mapping to visualize the activities. An answer to the question would be get commitment to the project from the responsible individuals by participation in workshops.

6.8 The interaction between the Nimbell and researcher

This section discusses some thoughts about the role as researcher in Nimbell. It is from my own point of view and is perhaps only my truth, and shall therefore not be seen as objective since I am aware of my biases.

In one perspective I have regarded myself as a support function to the main activities at Nimbell (Mulhaney, Sheehan and Hughes 2004). That is the role as quality manager or change manager in the company. In my eyes the primary task would then have been to support the other processes and help them perform a better result. Rephrasing it as help the process owners find ways to improve their job. Anyhow, I see them as internal customers for my services. That means I have to create results they need and expect.

So what were the expectations on the project? It has been in both parts interest to get a good result of the project. I have however interpreted the expectation from Nimbell as I should create a quality management system they can adapt to and work according to. There is a risk there will not remain any ownership with that approach to the work after the implementation. The risk is the quality management system will not be used if one external person is responsible for determining all activities it includes. Adapting to someone else processes will be problematic as well as for me to create all processes I do not even work with. It is actually a problem, doing as someone else is telling you without having insight of why it is important (Franze 2011). Instead my policy has been that the process operator is also the process owner. First establish and confirm responsibility of the processes and then get support to develop from the quality manager who is a supportive guidance (Mulhaney, Sheehan and Hughes 2004). The quality manager would be like a coach. The support can be in form of discussion partner for improvement or reflection. This opinion of mine was declared during the early workshops when I got the insight of how it should work.

Deciding areas of responsibility have been more difficult than expected though. The people at Nimbell have somewhat identified roles but the responsibility for many operations is still not decided. Some of those operations are closely linked to the manufacturing process which is a central activity for Nimbell. It is the manufacturing process which shall be evaluated for the COP. The production partner is not definite yet which means the processes are vague. It is preferable Nimbell could get support from its production partner with the production planning. The manufacturing processes will be determined after the production partner's capabilities and resources. When there are no set processes to study it is difficult and double work to try find any "as is" or "should be" level of performance (Alänge, Sverker WP 1996:01). One can just say what the expected output shall be.

6.9 Responsibility

An interesting question to formulate concerns who have had the responsibility for the project. Who is responsible for the implementation? Should the consultant, the supplier of knowledge and methods, be responsible for engaging the customers? One can think it is in the customer's interest the product is delivered properly and therefore follow up the order. On the other hand has the supplier responsibility towards the customer to deliver the specified product. But if they are developing the product together, who has the responsibility then? Both are dependent on each other. The customer needs the supplier and vice versa. I think I could have been pushier on the people to have the sessions. At the same time as it would be good with initiative from the company's side to speed up the development. Both parts would then have been more interacting and more routines could be analyzed.

6.10 Goals

There should have been set up some short term goals and deadlines along the way for the people at the company. The interviews and literature indicate the importance of set goals and show on win-wins (Alänge and Bengtson (1992) WP 1993:09) but I disregarded that because I thought everybody were focused and enthusiastic like me. It would maybe motivate us all to work more focused and motivate the employees set of time for evaluating more processes. It would also be a good exercise since it is overall lack of spoken goals in the business. For the project could one goal be: everyone documents one process (or routine) every week with support from the researcher/ quality manager. There was one attempt to speed up the process documentation but it failed due to a deadline for the product development.

7. Conclusion

This chapter shall summarize the findings and experiences (learning) from of the project. This section concludes the primary aspects to take into consideration when implementing and managing a quality system. It also answers the questions defined in the problem definition.

7.1 The primary aspects and requirements

To successfully succeed projects which involves people other than you is it helpful if the group of people cooperates and works in the same direction. A shared vision and agenda is necessary. If the team is functional it will probably perform better as a group than each individual do on their own. Teamwork is therefore a common working structure. It is though important to have engagement from all contributing people. It takes engagement to complete tasks with a good result and that also apply to group tasks. It is necessary everybody is interested in contributing to making a difference. It is therefore the primary task to engage people, get them interested and be motivated to contribute their best to the effort. Get the people in the team in the same direction towards a shared vision. The manager's task is to give people energy, guidance and support, but also put pressure on them to perform their best. The support can be education and mental pep talk which give energy to most people. Others need to be pushed and have demands from their chief to be motivated to perform, and then goals or deadlines are better. Established personal responsibility is another factor that creates commitment.

Considering the discussion and conclusion, it is vital to make the quality management system specific to the company's needs and resources. Not adjust the company to any standard. From this research it cannot be said whether there is any quality system approach more suitable for a startup company, it depends on the business' needs. The three principles; process view, continuous improvement and commitment from everybody have all been considered during the studies at Nimbell. From these three principles point of view could we discuss the company's present state, *as is.* A general approach based on the interviews made is to keep the system simple, easy to understand and after the company's own needs. With a well-known and structured foundation of the system is it easier to continue the development. The implementation method has been developed with those approaches in mind.

The implementation method developed and used for this project have overall been applicable for this project. Even though trying to avoid pitfalls one can fall into them anyway. It can be useful to do some time because it leads to progression in the long run. Insights are earned which give knowledge of how to perform better the next time (trial and error).

It was found that workshops is good a tool for creating involvements in a development process. When it is used correctly it triggers discussions which stimulate learning. Just focusing on discussions leaving out practice is not optimal for learning. Without practice it is not much of a workshop. The practice should be included in the workshops and in order to put some pressure on the participants to deliver results. Short term goals should be set to work towards. Having clearer goals would probably make the group more involved in the project and put more resources into it. Clearer goals could therefore have generated more engagement and a faster startup of the project. When processing a project which is separate from core activities, the timing and planning is crucial. The resources are few and the employees have often very much to do due to different deadlines from

other projects in a startup company. The time around vacation is for example not a good time to try to involve people in other projects than their own. Therefore is timing one factor which is vital for the projects existence and success.

The discussion about education in last chapter ended up in the conclusion that it is the project owner's responsibility to educate in the topic. The education shall give a base to develop discussions from. It would also establish a better understanding for business development. If there is an unidentified gap between the people in the Nimbell and the theory, try to identify the gap then educate to fill the gap. To be able to fill the gap perfectly in this project, it would be needed to have a teacher with better skills and knowledge of the topic.

A specific insight connected to the subject is that I believe I have realized the purpose of *process view.* Before was my mind set that process view and process mapping are just for showing how the processes are operated. But I have changed my mind and now understand that the process view allows visualization to simplify the communication and start a discussion which leads to improvements and learning.

8. Recommendations

I recommend Nimbell decides the areas of responsibility and make those clear and satisfying for everybody.

Consider the quality manual as a draft, preparation and proposal for the quality management system. The quality management system contains four main chapters which are Managements responsibility, Resource management, Product realization and Management analysis and Improvements. The quality manual's table of content is attached in appendix F for an overview of the content.

Put up individual short term goals and gates, work towards the goals and follow up. There are examples in the report.

Set off time for further development of the quality management system. Everybody should be involved, not only the overall responsible quality manager. I recommend at least one hour per week for group work e.g. workshops.

Continue the implementation of the quality management system. There is an instruction in the appendix G for part 2.

Try out the concept of learning circles. Make it a weekly routine and make it an opportunity to reflect on the business and its environment. There is a guide to the approach in appendix E.

Use the general writing guidelines when documenting for the quality manual. They are quite straight forward and can be helpful when working with the documentation.

Decide production partner and in collaboration with them discuss and decide how to reach conformity of production.

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10. Appendix

10.1 Appendix A

Interviews (in Swedish)

The questions

- Berätta gärna lite om din bakgrund och vad du har arbetet med inom området.

- Är vettigt att lägga tid på det ledningssytemet redan i ett tidigt stadie av företagets utveckling eller senare bör man vänta?
    - o Vilka är fördelarna?
    - o Finns det något som indikerar när man bör ta tag i den här biten på allvar?

- Var börjar ni konsulter när ni kommer in i företaget?
    - o Hur brukar ni börja nysta och vad skiljer stora och små företag?
    - o Berätta vilka verktyg använder ni er av?

- Vad tycker du/ni är viktigast med ledningssystem?
    - o Vad tror du är kritiskt för nystartsföretag?

- Vad finns det för risker med att med den här typen av implementering?

- I vilket stadie brukar företag kontakta konsulter för att införa system?
    - o Ca. antal anställda eller omsättning?

- Hur utvärderar företagen (era kunder) generellt hurvida en implementering är lyckad?
    - o Går det?
    - o Tittar ni bara på nyckeltal?

- Vad gör ni för att komma igenom den defensiva attityd som kan uppkomma vid förändringar (för att få fokus på kundernas behov och egna strategier)? (tips och trix eftersöks)

- Låter du personal dokumentera sina egna områden/processer? Och varför?

- Vad anser du om ISO 900X , och ISO 14001? Är det något att bli inspirerad av i detta fallet? Hur är anseendet för dessa i industrin idag?

- Bör man sikta på certifiering? Är det ett bra mål?

The answers from the interviewee

Stefan Book, Effort consulting, 20110328

Är det okej att jag spelar in samtalet? - Ja
1. Berätta lite om din bakgrund och vad du har arbetet med inom området.
   - Jobbade på Saab och Volvo innan Chalmers inom produktionen. Började med processrelaterade frågor till -95 i samband med exjobb mot ledningssystem för att hitta drivkrafter och resultatdrifter. Delresultat ger ett slutresultat. Alla delresultet måste levereras.

2. På frågan om det är vettigt att lägga tid på ledningssystem tidigt eller senare svarar jag på en skala 1 till 5 – FEM! Det är ablsolut vettigt att göra det tidigt. Det är abslout nödvändigt för man kommer behöva göra det någon gång ändå. Och ska du göra en "exit" är det definitivt viktigt att ha ett strukturerat bolag. Googla på "strukturkapital" så

får du se, det är i princip definitionen på ett väl utvecklat ledningssystem. Och du blir mycket mer trovärdig om du har det. Folk vill ha ett bolag med fokus som vet vad dom sysslar med.

3. Var börjar ni konsulter när ni kommer in i företaget? Hur brukar nu börja nysta? An vänder ni er av några verktyg?
   - Få rätt mindset i företaget.
   - Jobbar du med ett ledningssystem så bör du jobba processorienterat! Om man förstår hur man skall gå tillväga har man en väldigt bra plattform när man skall implementera. Man behöver forma sin logik när det gäller att nå sina resultat och där kommer de olika processerna in som har en viss följd/logik. (Stefan börjar desgina en processstruktur, vilket han tycker är helt meningslöst för det blir bara en diskussion). Ha fokus på behoven och tänk på olika intressenter som behöver få ett värde till sig. Det är lätt att man hamnar i att bara snacka huvudprocesser och stödprocesser..Sätt kundens behov i fokus. Språkbruket blir ofta komplext och man förstår inte alltid vad man gör..man förenklar och missar kanske vissa saker.
   - Ska du hitta hela komplexiteten så behöver man gå in på detaljnivå – så småning om! Men det behöver inte ni göra nu, utan börja med att hitta en grundstruktur ganska snabbt. Grundstrukturen för att ha en plattform, den hittar man på en dag(?!). Sen är man öppen för förändring och utveckling av den. Man ska hitta en struktur egentligen där du förstår grovt processerna, hur man jobbar med målsättningar och visualiserar målbilden. Mycket handlar om att man kommunicerar sin grej och ställer kritiska frågor för då kommer man på saker, så du får ett ökat lärande internt i organisationen. Det är NÄR man dokumenterar och kartlägger som man hittar grejerna. Så gör man det med avseende på att hitta bästa möjliga arbetssättet från där man är idag och har fokus på behov och genomför förbättringar där det behövs. Då får du ett förbättringsarbete och drivet som också genererar ditt ledningssystem.

4. Vad tycker du/ni är viktigast med kvalitetssystem?
   - Lära sig tänka i processer. Inte bara att rita upp processer utan man jobbar med målbilder, risker, problemlösning.
   - Tänka på att bygga på den kompetens som finns i bolaget och det naturliga språk som finns internt.
   - Processer handlar om att jobba mot behov. Då kommer andra typer av frågor in, som arbetsmiljö, miljöfrågor som är viktiga frågor att beakta. Vad tar vi ansvar för? Hänger ihop med hållbar utveckling. Vad är det för resultat man vill åstadkomma och så söker man sig fram och prioriterar de processer som är vettigast att börja med. Men för att kunna prioritera så måste man först hitta dem. Och det finns tusen sätt att se en verksamhets processer utan de skall designas så att kunden är bekväm med dem. Då du pratar om ISO är då risken att du snöar in på kravbilden. Vissa stirrar på kraven och andra på behoven, vilket blir en vattendelare. Istället skall alla jobba utifrån behoven och inte kraven så kan du börja nyttja kravbilden, och tänka vad innebär det för oss?..Sen finns det ju såklart metoder som vi jobbar med för att bena ut behoven, målbilder (anm. Genom att ifrågasätta och ställa frågor). Börja alltid med behoven, när du väl har förstått essensen att jobba i processer. Få rätt mind-set!

5. I vilket stadie brukar företag kontakta konsulter för att införa system?
   - Ca. antal anställda eller omsättning?

   - Ett kvalitetssystem har du ju alltid, antingen du vill eller inte så att säga. Det är det som producerar den kvalitet du producerar. SEN är frågan, vill du göra det mer eller mindre MEDVETET. Rimligtvis är det bra att vara medveten om vad man gör. De har ju tänkt på det när de startade på något sätt så har de ju tänkt på det. Men man behöver ju inte certifiera sig bara för att man jobbar med ett ledningssystem. Är det då värt att då i ett tidigt skede tänka efter du det jobbet ska gå till. – Då blir det intressant för idag är världen präglat av ett feltänk. Man tänker att ISO 9000 är ett ledningssystem men det är bara en standard.
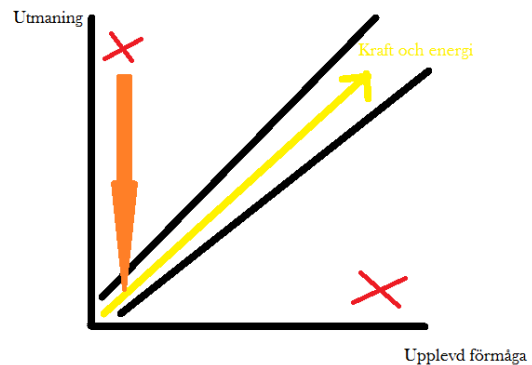
- I princip, och såhär förklarar man vår affär idag. Kunderna står inför en utmaning och har en viss upplever själva att de har en viss förmåga. Det skall finnas en balans som ger kraft och energi, riktning. Det är när utmaningen upplevs mycket större än förmågan som som ett behov för hjälp kan uppkomma. Då hjälper vi dem att droppa ned i fållan igen. Så man själva kan förstå i vilken riktning nå dit och driva framåt.

- Kraftsamling tillsammans. Du vill nå resultat men du måste ha en kraftsamling för att tillsammans tro och vara engagerade.

6. Hur utvärderar ni generellt hurvida en implementering är lyckad? Går det? Tittar ni bara på nyckeltal?
   - Vi implementerar inte. Vi vidareutvecklar vad de redan är bra på. Mäter kundernas reaktion. Stefan samlar på citat från sina nöjda kunder. Inga enkäter, det är man "fed up på". När det gäller kunderna så gäller att jobba med avseende på de resultat kunden vill uppnå och att hitta relevanta mått i deras processer och relevanta målbilder för dem. Så vi hjälper dem hitta mått men oftast är det inte där drivkraften hamnar utan i att tänka i processer. Att tänka i processer och hitta sätt att söka sig fram. Den bästa vägen måste man söka efter. Det som är våra mål och mått är deras mål och mått. Lyckas vi väl så ska kunden uppleva att de har bättre förutsättningar att jobba i sin verksamhet. Det är väldigt svårt att mäta kundens nöjdhet. Kommer de tillbaka är det ofta nödja och då har vi förmodligen hjälpt dem att finna kraft och energi tillsammans. Jag tar gärna in feedback från kund.

7. Vad gör ni för att komma igenom den defensiva attityd som kan uppkomma vid förändringar för att få fokus på kundernas behov och egna strategier? (tips och trix)

- Det handlar lite om vad det finns för mönster i organisationen. Om det är en specialisttung verksamhet så vill man inte börja snacka om processorgientering utan knyta an och få kontakt mot specialitkunskaper. Du sätter fokus mot specialistens intressen och frågar om olika behov som finns relativt den(specialisten, den positionen). Vad finns det för risker? Hur går det till? Nyfiket hitta fram till en väldigt bra bild med fokus på just det som är specialiten. Och därifrån kan man sen börja växla över och göra det man gör – man jobbar med processer. Man kan ju jobba med processer utan att ens säga att du gör det. "Vad är det för resultat du vill åstadkomma här borta?", "Vad är viktigt att tänka på då?", "Vilka steg tar du?", du kan alltså få fantastiska förbättringsmöjligheter och jobba med processer utan att nån vet om det. För att förstå vilken kompetens som behövs kan vi analysera de flödena bakom det resultat som presteras. Och vad som också genererar resultat är output till kunden, men inte bara, i vissa typer av processer är det medarbetaren(intern output, tex utvecklingssamtal) och då vill du ha målbilder för medarbetaren, ledaren och företaget i stort. Tänka Intressenter. Vilka resultat är intressanta? Hur får vi resultat som är intressanta? Förstår du inte kundens behov kommer du inte kunna leverera rätt resultat. Grejen med processynen är att du får en väldigt bra överblick över olika delar som samverkar. Med hjälp av en processyn benar du upp specialistens behov, mål och resultat.

- Felet är när man kommer uppifrån och försöker lägga på en modell. Kom istället in underifrån med en helhetssyn. Får du med dem som är mest kompetenta på sin grej att förstå olika behov. Men trycker du på massa saker är sannorlikheten stor att du skapar spänningar mellan det här två(krav-folk vs. behovfolk).

8. Vad menar du med offensiv utveckling?
   - Det kan handla om att en organisation har en historik som försvårar utvecklingen eller att ett visst synsätt blockerar en offensiv utveckling. Det kan också handla om en situation där vissa krav är svåra att hantera - vara operativ, faktiskt göra de här sakerna för att utvecklas.

9. Måste man sikta på certifiering?
   - Nä alla gör inte alls det, det är väldigt olika. Nä, det är också ofta att visa hur man får en gemensam syn på ledningssystemet och hur man ska jobba. Certifikat behövs sällan tidigt, men kan behövas för att komma in på marknaden. Jag tycker det bäst att jobba så att när man vill kan man certifiera sig när man vill. Men det som är bra med ISO är att det är relevanta frågeställningar för ett bolag. Men det kluriga är "hur jobbar vi med kravbilden" vilket är gemensamt för lean och six sigma med mera.

10. Vad anser du om TS 16949 och ISO 14001? Är det något att bli inspirerad av i detta fallet? Hur är anseendet för dessa i industrin?
    - Det är värt men, men om man jobbar med processstrukturen och hittar sin logik så kommer man ha 90% av logiken i 14000 klart. Det är ju ett litet bolag så det är ju oerhört lite jobb för er. Kommer

du in och läser det blir det komplext men säg två dagars jobb så har man en grundstruktur som tillfredställer alla krav. Har du väl fått en processtruktur kan vi titta på påverkan. Vad ska vi ta ansvar för relativt kund? På samma sätt som i 9000 med fokus på kunder så är detta med fokus på miljön, vad ska vi ta ansvar för..samma logik men med miljön som intressent. Visst finns det regler för kemikalier och man ska ha koll på kemikalier, transporter diverse miljöaspekter. Skit i att snacka om miljöaspekter (det blir tråkigt) utan prata om vad vi behöver beakta relativt miljön. Vilka huvudsakliga intressenter har du som är intresserade av att man jobbar med kravbilden. Man bör ta hjälp av någon (ett proffs) initsialt för att få koll på grundstrukturen.

- Men i ett litet bolag kan man inte ha någon som jobbar med verksamhetssystemet som sådant i fokus. Man behöver en del stöd när man gör det. Det krävs att man jobbat med det en del, som med en snickare. Att fråga honom hur han bygger ett bra hus är ju svårt. Det gäller att kunna se mellan raderna så att säga. Tyst kusnkap skall fram. Det gäller också att skapa legitimitet för det man gör också.

- Du lär dig hantera krav så då blir det inget problem när du hittat din struktur att beakta fordonsindustrins krav. Men TS hjälper dig inte hitta någon bra struktur. Det gäller ju att hitta den här strukturen som är det resultatdrivna och sedan också förstå hur man kan jobba med kravhantering. Och har du väl sett den logiken kan du bara ta in kraven. Men du jobbar varken med TS eller ISO kraven i början utan du vill hitta din struktur i de här processerna som man känner sig bekväm med. Och det är ju ett benande där man ställer frågor...Utifrån det handlar det också om att matcha roller mot de processer man ska ha.

11. Risker? Det är nyckeln att matcha organisationen till den här projektsynen och risken är att du får en matrisorganisation i ett väldigt tidigt skeda där du tänker nästan avdelningsmässigt och i andra hand processmässigt.

12. Låter du personal dokumentera sina egna områden/ arbetsbeskrivningar?
    -Nej nej, det går inte. Det förstår inte vad de ska göra, vad de ska uppnå. Man får sitta med dem och gärna kring problemområden, resultat, kanske en parkeringsplats för idéer. Då får man något som känns kul och skapar ett driv framåt. Hitta ett sätt att jobba med olika frågor systematiskt. Då får man en inteligent process-struktur. Och den är inte det med bara för att du har 15-16 processer utan logik. Utan det är när du själv hittat en struktur som du kan bena upp i olika typer av resultat du vill prestera. Sen kan du börja sätta målsättningar, och mot den kan du härleda krav. Så om du börjar få krav från kunder kan du härleda dem rätt in till rätt ställe i strukturen. Det som krävs är att ganska noga definera upp vad som är innebörden..
    Sen kommer Stefan till att skapa en identitet: Vad är det för identitet du vill ha kring ditt bolag, internt och externt. Samma med visioner! En vision skall väcka känslor och ett go, en vilja. Våran vision är att vi skall uppfattas som världsledande av våra kunder och medarbetare. Kan vi mäta det? Det skiter jag i, jag vill ha känslan!

Leif Nyström, CANEA consulting, 20110412

1. Berätta gärna lite om din bakgrund och vad du har arbetet med inom området.
   Började på canea -98. Då med kvalitet och kvalitetsledning. Integrera system. Eftersom vi jobbar processbaserat inom många områden så blev det att jag jobbar mer och mer mer processer – processorientering. De senatse åren har det blivit att jag jobbar med processer utifrån ett effektiviseringsperspektiv. Jag har ju arbetat en del med fordonsindusrti och flygindustri och finns det ju standarder som är specifika för de olika brancherna. Alla ISO bygger på ISO 9001.

2. Är vettigt att lägga tid på det ledningssytemet redan i ett tidigt stadie av företagsutvecklingen eller senare bör man vänta?
   - Vilka är fördelarna?
   Ja, att man lägger tid på det men bygg inte upp något stort system utan gå efter vilka behov som finns. Men, att man faktiskt tar sig tid och funderar över vilka behoven är. Det blir väldigt lätt så, "nämen vi är så få, vi behöver inte det". Vissa behov finns faktiskt, saker som man behöver ha tydligtgjort och då är regler bra. (Ex med bostadsrätter, när ska vi ta in offerter..)
   Gör det inte för stort! Man behöver inte dokumentera allting utan fokusera på det som tillför värde. Så svaret blir ja.

Vi har ju i tidigare exjobb som går lite mer på djupet vilka effekter man ser, det finns ju mer specat men om man sammanfattar så ger det en ökad tydlighet i företaget. Det gäller ansvar, i arbetssätt man har samsyn. Bättre kommunikation är e följdeffekt av det här.

- Finns det något om indikerar när man bör ta tag i den här biten på allvar?

Det är ganska vanligt att det finns kundkrav, självklart. Det är nog inte det vanligaste i vårt fall då vi jobbar oftast med firmor som redan har befintliga system. Det finns ju mycket billigare sätt att skaffa sig ett system, det finns ju att köpa på nätet..Köpa ett antal skriftliga rutiner så har du ett system. Det vanligaste anledningen till att de kommer till oss är Känner att det är saker som faller mellan stolarna och det finns saker som inte riktigt funkar. Det vanligaste är att de inte får ut den potential/nyttan ett ledningssystem borde ge internt. Det är olika när man bör ta tag i det från ett renodlat företagsperspektiv, men gör det gradvis (börja smått).

3. Var börjar ni konsulter när ni kommer in i företaget?
   - Hur brukar ni börja nysta?

Ett feltänk i grunden är vanligt med hela systemet. Man tar inte det befintliga systemet utan man får bygga om det i grunden och använda delar utav det befintliga gamla. Det är ofta så att det mest konkreta, checklista för en maskin, är det inget fel på mer än att de kan vara svåranvänd. Felaktigheterna hittar man oftast i utgångspunkerna för ledningssystemet. Däremot tycker jag att standardkraven som finns utifrån 14001 styr bättre i det övergripande tänket än vad än vad 9001 gör på kvalitetsidan, därför att 14001 styr mer på att du ska ta reda på vad du har för miljöpåverkan, du ska ta fram vilka är dina miljöaspekter, vad är betydande. Hur gör vi det då? Jo. Det finns lite olika mallar. Det där grundtänket med att vilket fokus ska vi ha i vårt system, det finns då inte den kravställande delen i 9001 vilket många det är som tittar på standarden och bygger system för att uppfylla den (typ 9001). Det gör att de ofta hamnar fel. Om man inte vet, var ska vi börja någon stans? Ja, då gör man ju så gott man kan men har du inte den här, klart och tydligt, "vad är det som är mest kritiskt och viktigast i verksamheten" dvs. Vad är det systemet skall fokusera på att stödja och styra? Då är det väldigt svårt att uppnå ett fokus i själva systemet sen om man inte vet vilket fokus man ska ha från början.

   - Om det då är feltänk, hur får ni dem på rätt väg?

Vi använder ett koncept som vi kallar "ledningsworkshop". Det går ut på att vi börjar med strategin. Vi har alltid utgångspunkt i organisationens strategi, ibland saknas det saker där som vi stannar upp och kompleterar. Det startar där; med den här strategin, de här långsiktiga målen finns, den strategiska inriktningen, vad är det då som är viktigt i den här verksamheten. Då har vi intervjer med nyckelpersoner (ledningsgruppen), skaffar en bild av helhetsflöderna, så sammanställer intervjerna, vi samlar nyckelpersonerna (ledningsgrupp plus ev några till) för workshop på en eller två dagar beroende av storlek på företaget och omfattning som man skall täcka. Då går man igenom resultaten från intervjerna sammanställt. Vad det är som är viktigt, frågat på väldigt olika sätt då. Det ger en bruttolista med framgångsfaktorer med saker som man måste vara bra på som folk tycker är viktigt. Men den här listan är ofta väldigt lång för att folk tycker lite olika. Vi ägnar mycket tid åt att få den här gruppen med nyckelpersoner att koka ner det här till en lista på 4 till max 8 punkter. Vi är som facilatorer under en sådan workshop. Och ställer också lite krav på hur de skall gå tillväga. Och ofta vill de göra det lätt för sig och använder uttryck som "rätt kvalitet", "rätt tid", "till rätt pris". Me då säger jag ni får inte använda ordet "rätt". Det är för ospecefikt, inte tillräckligt konkret. Jaha, då måste man ställa sig frågan "vad är kvalitet för oss". Och få dem tänka i rätt banor. Sen är det det med att man ska från en lista med kanske 40 punkter ska man komma ned till 4-8 punkter, vissa saker går att slå ihop och men det är ganska mycket som inte platsar, om man då prioriterar så innebär det att man måste välja bort och det är dom diskutionerna som leder fram till den här slutliga listan, den är väldigt väldigt viktig, för då har dom själva arbetat fram själva att "det här är det som är kärnan, våra kritiska framgångsfaktorer". Sen är det ju så att man under intervjuerna att man får reda på en hel del. Vi ställer ju frågor kring processdelen för vi är ju väldigt processinriktade i vårt arbetssätt. Dessutom så arbetar vi en del med hypoteser, lite grovt, så här ser, verkar era processer se ut. Output från en workshop är en huvudprocesskarta som ledningsgruppen har arbetat fram. Det är inget vi gör åt dem. Vi hjälper till med en hypotes som är felaktig, den måste ändras för att det finns olika svar på saker och ting. Tex. här kan vi inte få en gemensam bild, hur ser verkligheten ut egentligen. Viktig output från ledningsworkshop är fokus för ledningssystemet (utgångspungter) och en huvudprocesskarta som ganska ofta är strukturen för det vidare arbetet. Så att det ger väldigt bra förutsättningar för att arbeta vidare. Om

man har mer tid kan man titta på processägare för respektive process och vilka är de övergripande målen och vilka är de eventuella processmålen. Då snackar vi två dagar.

- Är kundbehov/krav inbakat i strategi?

Visst är det så. Och det är väldigt branchspecifikt. Ta fordonsindustrin, där är det svårt att komma ifrån att man måste leverera på utsatt tid, inte för sent, inte för tidigt. Leveransprecition. Varför är den så viktig och kritisk? Jo, för att kunderna kräver det. Eller i privat sjukvård, där kan det vara tillgänglighet. Är det inte det kan man ju gå till den vanliga sjukvården som man inte behöver betala så mycket för. Så det är ju lite olika.

4. Vad tycker du/ni är viktigast med ledningssystem?
   - Vad tror du är kritiskt för nystartsföretag?

   Att fastställa de kritiska framgångsfaktorerna, för de behöver speglas i den huvudprocesskarta som man fastställer. Det måste finnas en koppling mellan de kritiska framgångsfaktorerna och hur du definerar din huvudprocesskarta.
   Gör det inte för svårt!
   - Allmänt?

   Olika. En sak som är vanlig är att man gör det <u>avdelningsvis</u>. Det är ett problem. Det går tillbaks till om vi ska få ut nyttan av ett ledningssystem. Om vi tar det från kvalitetsperspektivet först är det ju att kvalitetsbrister, var uppstår dem? Jo, ofta i överlämningar! Mellan enheter i dellinjen. Om jag bara tittar på min egen del där en avdelningschef bara har syftat till att optimera sin egen del - problemet blir då att inte så många tänker på att optimera helhetsflödet. Och det är där processerna kommer in och är en viktig del när man pratar ledningssystem. Bredare, om vi tar miljö tex. du ska ju identifiera vilken miljöpåverkan du har. Där är de nedbrutna processerna ett väldigt bra stöd för du kan ju ta en nedbruten process. Så då ser du att du har en resursanvändning, resultatet har kanske någon miljöpåverkan och sen vad är det för utsläpp som just avgränsade processer ger. Så samma struktur för kvalitetsdelen som för miljödelen som du kan använda dig av. Jag ser ju då processerna som ett verktyg som man använder sig av. Svårare för arbetsmiljö då..

5. Vad finns det för risker med att med den här typen av implementering?
   - Att man dokumenterar för mycket.
   - En risk är att man utgår från standarden
   - Man dokumenterar vad man gör utan att ta reda på behov och vad som är viktigt att styra och stödja.
   - Man inte tänker användarperspektiv. Kundfokus finns någorlunda.
   - Certifikat viktigare än systemet
   - Systemet ej beskriver verkliga arbetssättet
   - Undermålig implementering
   - Om det är ett fåtal personer som sitter och skapar ledningssystemet blir det mycket beskrivningar hur det borde men inte funkar i verkligheten. Då bygger man in impedans mellan dem två. Då får man jobba så som är skrivet men vår erfarenhet är att det är bättre att dokumentera som det görs för då blir dokumentationen som en gemensam utgångspunkt för förbättringar. Då missar man om man går direkt på ett önskeläge som fåtal känner till
   - Upplevs inte som en hjälp.
   - För mycket fokus på styrning för lite fokus på stöd.

6. I vilket stadie brukar företag kontakta konsulter för att införa system?
   - Ca. antal anställda eller omsättning?
     Väldigt olika

7. Hur utvärderar företagen generellt hurvida en implementering är lyckad? Går det?
   - Tittar ni bara på nyckeltal?
   Problemet är att många företag inte har en tanke på att sätta upp några mål när man startar. Vad vill man få ut? Vilka effekter i verksamheten vill man ha? Då får man börja där. Vissa vill inte ha målen, utan jobba mot ett certifikat vilket inte blir så bra i längden. Har man satt upp mål är det mycket enklare.
   En sätt att följa upp är att mäta interna kundnöjdheten med en enkät bland personalen med ett antal frågor relaterat till ledningssystemet. Sen gör man samma enkät igen och jämför.
   Revitioner

Ingen historik alls så är det svårt.

Du kan mäta direkt, du kan fråga kunderna, du kan fråga dem som använder i systemet dvs jobbar i verksamheten. Man kan fråga, har verksamheten blivit mer eller mindre svår att jobba i, gör vi mer eller mindre fel etc.

8. Vad gör ni för att komma igenom den defensiva attityd som kan uppkomma vid förändringar (för att få fokus på kundernas behov och egna strategier)? (tips och trix)

Vi har ett helt kapitel om det (Leif slår upp ett kompendium med exempel på utbildning).Nä...Vi använder väldigt många olika verktyg. Det här är ju ett stort område för oss. Vi jobbar ju med förändringsledning. Man kan inte bara ta en sak rakt av. Ska man plocka ut det viktiga då..Så tror jag att man går igenom vilka intressenter har vi, inte över en kam, utan vi bryter ned det lite. Sen ser man för varje, vad kan man se för fördelar och nackdelar. Fördelarna, hur kan man realisera eller förstärker kommunikationen av dem och nackdelarna – vad behöver man göra för att undvika dem. En förändringsanalys i tidigt skede. Detta är för alla intressenter. Det finns ju hur mycket som helst att prata om det här..Man pratar ju om involvering, skapa tydliga mål, mäta och följa upp, kommunicera genom hela genomförandet, skapa engagemang, att ha tydlig metodik, att arbeta med riskhantering kontinuerligt. Men viktigast är <u>förändringsanalysen</u>. Vad är positivt, negativt och vilka åtgärder tar vi till. Så här ser den ut..Leif ritar

Intresenter	Positivt	Negativt	Åtgärd

Bryt ned det tillräckligt så det inte blir för grovt..Och sedan. Vad gör vi då. Hur kan vi förstärka så de ser fördelarna och tror på dem. Då kan vi bemöta om det kanske är fel uppfattning. Eller om det är ngt vi själva måste tänka på vid genomförande. Då har vi ett antal ÅTGÄRDER som måste genomföras. Det är de som man sätter i verket. Det är då de <u>specifika åtgärderna</u>. Sen även de generella som nämns ovan, med målbild etc. Ofta hamnar det ganska känsliga saker i den här åtgärdskollumnen. Det är ingenting man vill visa upp. Om alla såg det som jättepositivt så vore det inget svårt att förändra. Ofta kommer det ganska negativa saker där. Det är inget man vill sprida till alla i företaget. Det skulle vara förödande. Det är ofta konkreta saker.

9. Låter du personal dokumentera sina egna områden/ arbetsbeskrivningar?

Ja, annars blir det väldigt dyrt för dem..Vi hjälper dem att definera hur flödet ser ut. Det gör vi ofta med några intervjuer sen samlar man de berörda för en workshop. Sen, så hjälper vi dem komma fram till vad är det för behov, stöd och styrning som finns..som dom behöver. Jag är noga med att inte bara pratar om styrning. Stöd är bättre att prata om. Arbetsbeskrivingar arbetar vi inte så mycket med. Föredrar mallar. De styr och stödjer bra. Man behöver inte dokumentera allting utan bara det som det finns behov för. Tittar man då på en process så tar man fram vad är de kritiska framgångsfaktorer, vad får inte gå fel. Bara skriva ned vad man gör är ofta det sämsta man kan göra. Däremot vad som är viktigt är IT-systemen. De som jobbar med ledningssystemen är generellt sett alldeles för fokuserade på dokumentation. Men det handlar om hur uppnår man en effektiv styrning av sin verksamhet. Det kan mycket väl vara så att man har ett IT-stöd. Kan man använda affärssystemet här? Har vi någon ärendehanteringsmodul som är applicerbar? Och sen är det ju så, allt behöver inte vara dokumenterat. Vi hjälper till att definera flödena. Och sen hjälper vi till så att de själva kan definera vad behöver vi för stöd och styrning. Sen får de själva ta fram stöd och styrning.

Hur man dokumenterar behöver man ofta hjälp med. Och sedan någon som finslipar i slutet för annars ser det väldigt olika ut..Men det behöver göras av de som jobbar. Annars blir det bara att en konsult var inne och gjorde såhär. Vad vi kan göra är att skriva rutiner för specifika rutiner som inte redan finns. Det är en viktig del i implementeringen att låta dem ta fram stödet och styrningen själva. Det skall inte vara påtvingat. Sen när man gått igenom alla processerna tar man fram standarden. Man ska alltid ta fram den sent i ett sånt här projekt. Då kan man göra en GAP-analys. Vad finns, vad kräver standarden. Då kan man komplettera om det finns ett gap. Men den skall alltid komma in sent för att säkerställa att man tar fram systemet utifrån vilka behov som finns.

10. Vad anser du om ISO 9000 , och ISO 14001? Är det något att bli inspirerad av i detta fallet? Hur är anseendet för dessa i industrin idag?

Siffermässigt är intresset hela tiden mycket ökande, antalet certifikat ökar hela tiden. Vad man säger om systemen är en annan sak...Det ju system för egna verksamheten. Det är ju så att väldigt många har system som är framtaget inte för egen skull. De är inte så att man vill ha bra stöd och styrning av verksamheten utan någon kom och krävde det här. Eller vi själva kom på att det är bra mot marknaden att vi har ett certifikat.

11. Bör man sikta på certifiering? Ett bra mål? (del 4)

Man skall inte ha det som ett mål när man sätter igång med arbetet. Då bör man istället tänka "vilka effektmål kan man få ut av det här?". Kan vi kapa några ledtider, kan vi minska några onödiga kostnader (kvalitetsbristkostnader), kan vi minska resursanvändning mm. Det är saker man bör fundera på om man kan sätta upp några mål där. Men vi mäter ju inte i dagsläget... Hepp. Men då är det något som man kan komma igång med så fort som möjligt då och samtidigt börja rulla igång ledningssystemet. Då ser man ju vilka effekter man får internt och sen kan man gå ut med att vi skaffat ett system för oss själva, det kan vi ju använda och certifiera. Då blir det som ett nästa steg.

Vi hjälper dem att arbeta fram vad och hur de ska mäta.

Jonathan Franze, Barium consulting, 20110419

1 Berätta gärna lite om din bakgrund och vad du har arbetet med inom området.

Driver projekt från att det sålts in till att det används på riktigt. Man kan visualisera hur man jobbar. Man lägger in information som visar olika steg, rutiner osv.

2 Är vettigt att lägga tid på det ledningssytemet redan i ett tidigt stadie av företagets utveckling eller senare bör man vänta?
   - Vilka är fördelarna?
   - Vilka nackdelar?

Det beror på. I vissa fall finns det legala krav som att man måste uppfylla en viss säkerhetscertifiering, och då finns det ju ISO-standarder. Då gör man det bäst genom visualisera i form av processer. Ett processorienterat ledningssystem. Det finns inget självändamål i att skapa ett ledningssystem. Det är bättre att sikta på ett effektivare arbetssätt. Det gör man bäst genom processer. Skapa 1,2 eller 3 processer som är verkligen fokuserade på att så här ska vi hantera produktionen eller en leverans så blir det en del av ett ledningssystem automatiskt för att man kan betrakta dem utifrån ett ledningsperspektiv.

Det är absolut bra att fousera på en process och gör det bra. Ta lärdom av det som man lyckats med så kan man växla upp och köra på fler ställen. Det svåraste är ju att få folk att efterleva det, uppskatta det och att det blir en verklig hjälp och inte ett måste. Det fås enbart om man börjar itterativt, smått, testar och anpassas till en själv. Då kan man inte ta det storskaligt från början.

Det handlar även om förändringsbenägenhet, hur inställd är man. Företagsklimatet, hur är det?

Nackdel i ett mindre företag är att man saknar någon som specifikt tänker på de här sakerna. Och i ett mindre företag ska alla göra det själva på något sätt och då hittar man egna vägar o så tänker man " jag borde följa den här processen men jag gör det på mitt sätt för att det är lättare". I ett större företag blir det förväntat att man gör som man är styrd (en låsning). I ett mindre företag går det ju väldigt mycket snabbare att förändra, färre personer att involvera. I större företag måste man göra det gruppvis, avdelningsvis och tar längre tid bara det..Man måste kanske utbilda någon för att rulla ut en förändring. Man måste fånga engagemanget!

Det är viktigt att få med rätt folk på rätt plats. Och det kan vara omöjligt om det inte kommer från ledningen där det finns mandat. Men så är det ofta i de små med. Där är det initsierat av VD, eller chef. Har du inte rätt grupp är det väldigt svårt. När vi jobbar så tänker vi oftast på gruppen, så att champions som är drivna. Och med en bredd så man har personer som inte bara är fokuserade på sin del och så att man inte glömmer bort resten. Det handlar ju om människor, oavsätt om det är stort eller litet företag som ska jobba i processer. Och då måste det skräddarsys. Då finns det ju självklart hjälpmedel som diversefiering av grupper, validera mm.

Ett verktyg är ju bara ett verktyg, sen är det kontexten som är det viktiga.

Om man går in och har ett upplägg om hur man borde jobba, nu ska vi bestämma hur arbetet ska ske. Istället kan man bygga upp det i takt efter man upptäcker hur man faktiskt jobbar. Ledningssytemet bör spegla vad man jobbar med. Ledningssystem skall vara ett aktivt hjälpmedel för sitt företag. Om det är så man är beroende av att redovisa exakt hur vi jobbar, då är det jätteviktigt att man har ett ledningssystem.

Är det inte så att man alltid har ett ledningssystem? Bara det att det inte är visuellt utan underförstått. Ofta kräver myndigheter att det ska vara explicit. Du ska ha det som styrande. Men egentligen är det viktiga att du har ett kvitto, den redovisande biten. Du får redovisa hur du använt dig av de styrande dokumenten.

Kommer man över ett visst antal anställda så behöver man ha någon form av central kommunikationsplattform. Då är ett ledningssystem ett bra sätt att göra det på. I vissa fall används ett ledningssystem bara för kontroll för att någon vill sen det.

3 Var börjar ni konsulter när ni kommer in i företaget?

- Hur brukar ni börja nysta och vad skiljer stora och små företag?
- Vilka verktyg använder ni er av?

4 Vad tycker du/ni är viktigast med ledningssystem?
- Vad tror du är kritiskt för nystartsföretag?

Matcha behoven som man har! Man ska veta varför man vill ha ett ledningssystem. Tex legala krav, komplex process med mycket att tänka på, hålla uppe en hög kvalitet på en nichad produkt. Det ska vara starkt knutet till varför, åt vem och hur matchar det kundnöjdhet (både internt och externt).

5 Vad finns det för risker med att med den här typen av implementering?

Det finns ju en risk att man vill göra det för någon annan. Vi frågar vilka intressenter finns det. Vem är kunden till systemet? Då ingår ofta lagkrav, kunder, revitionspersoner. Det finns inget självändamål att göra ledningssystem för kontroll. Utan det måste byggas in i alla arbetssätt. Det ska finnas till hands för att se till att kvaliteten hålls uppe.

6 I vilket stadie brukar företag kontakta konsulter för att införa system?
- Ca. antal anställda eller omsättning? Alla möjliga

7 Hur utvärderar företagen generellt hurvida en implementering är lyckad? Går det?
- Tittar ni bara på nyckeltal?

Vad får de för priset de betalat. Mycket handlar om engagemang. Då kan vi spåra hur många som använder systemet (läser dokument mm). Sen finns också den allmänna uppfattningen med mjuka delar om det har förbättrat verksamheten. Tydligheten kan bli bättre. Vi frågar "när är kunden nöjd" när vi startar. Lika mycket som man undersöker vem som är kund och intresent så vad är kundnöjdhet? –snabbare att arbeta, enlare att hitta, färre frågor mm.

Först kartlägga inom sin egen bransch och hitta nyckeltal att jämföra sig med. Som vilken benchmarking som helst.

8 Vad gör ni för att komma igenom den defensiva attityd som kan uppkomma vid förändringar (för att få fokus på kundernas behov och egna strategier)? (tips och trix)

Från kund till kund gäller det att känna av vem i en grupp som är defensiv. Då gäller det att skapa en miljö som är trygg. Förändring är svårt för alla att ta till sig. Att förankra nyttan är ju vårat uppdrag i första hand. Att få slutanvändaren att förstå nyttan i sin egen process. Ofta är det också ett internt arbete. Men visa på quick-wins och win-win situationer är bra om man kan visa på. Konkret i vår metodik tar vi reda på tre saker; hur ledningens engagemang ser ut, hur kan man få andra att acceptera den här förändringen (bred projektgrupp, pratar om det, informationskanal, klar och tydlig plan över ägarskap så att det finns någon som driver dess vidareutveckling)

9 Låter du personal dokumentera sina egna områden/processer?

Det gör vi! Vi brukar ha processkartläggningsworkshoppar dit vi bjuder in de personerna som är involverade i en process. Så går vi igenom; Vad är det här för process, vad heter den, dess syfte, vilka är kunder till processen. Låt oss kartlägga, hur börjar den. Någon är utsedd att rita upp processen. Blir utbildning i kartläggning och processtänk.

Väldigt mycket handlar om kritiskt ställa frågor om processen. "Är det verkligen så". De klassiska "5 varför" Man låser sig själv, ser inte potential till förbättringar. Har man rätt grupp så finns det många perspektiv att få in. Skapa en stämning av att man gör det tillsammans. Man förankrar samtidigt processen så att det tas ansvar för den, följer den och förbättrar den.

10 Vad anser du om ISO 900X , och ISO 14001? Är det något att bli inspirerad av i detta fallet? Hur är anseendet för dessa i industrin idag?

Otroligt många kunder är certifierade men det är bara ett diplom på väggen och några pärmar. Då är det ofta tänket som saknas.

Kan ofta vara infört på bred front men inget förankrat.

Det bästa är väl att ha någon form utav lean-tänk och så har man kvalitet inbäddat i det. Mycket är samma skolor alltihopa så det spelar inte så stor roll. Bara det är agilt (rörligt). Men allt ramlar ner till processer. Synligör processen för att kunna förbättra den.

11 Bör man sikta på certifiering? Ett bra mål?
Kunderna skiter ju egentliden i om man har lite papper på en certifiering utan bryr sig bara av kvaliteten som man förväntar sig.
Man ska fundera över varför man ska certifiera sig och att inse att det är en modell och som måste anpassas för sin egen verksamhet. Det skall inte vara ett mål men det kan vara ett krav. Målet får inte vara att vi gör det här för att bli certifierade.

Vem bör man ha som processägare?
Den som äger pengarna äger processen. Finns det ett ekonomiskt ansvar för en del/område av processen. Kvalitetspersoner däremot skall vara involverade i alla processer som ett stöd framförallt. Kvalitetsansvarig ska ju ha reda på vad det är för kvalitetskrav och i såfall informera vidare om det. Det kan den personen behöva hjäpa processägaren att ta hänsyn till. Ofta gör man fel och ser kvalitetsansvarig som styrande och inte som stödjande. De ska ju hjälpa till att hålla en hög kvalitet inte säkerställa hög kvalitet.

För övrigt:
Customer expectation/experience management (CEM) som är i ropet nu. Allt man gör måste vara i linje med kunden förväntningar. Allt från produkten till all interaktion med kunden. "Vad är bäst för kunden". Förväntningar på något sätt. Allas roller ska generera bättre kundupplevelser. Kundens upplevelse är allt från "jag vill ha detta" till lätt att hitta, bra info, lägga beställningen. Hela kedjan skall vara kunden till lags. Det är processen som gås igenom som ska spegla värde för kunden, vad kunden förväntar sig. Allt man gör, gör man för eller åt någon, även internt.
Gör bara det som behövs, gör inget mer och gör det rktigt bra, och det är lite lean. Och uppnår man det så har man effektiviserat.
Processorientera handlar om att man följa sin process och effektivisera den.

Karin Breding, Quality manager Promimic, 20110524
- Hur har ni gått till väga när ni började med ledningssystemet?
-Vad började ni med?
-Vad är viktigt att tänka på?
-Vad är mindre viktigt (överreklamerat)?
-Hur ska man lära sig tänka i processer? Hur tänkte ni innan? Hur ser du på processer och hur ska man kommunicera det till medarbetare?
-Måste man ta hjälp av erfaren konsult? På vilket sätt har det hjälp er? Alt. Hur skulle det kunna ha hjälpt er?
-Har ni några bra verktyg som du kan tipsa om? Jobbar ni tex med kvalitetscirklar som PDCA? Balanced scorecard?
-Berätta hur ett kvalitetsärende kan se ut. Vad gör ni? Arbetsgång.
-Jag tänkte börja med en intern enkät, en första workshop (berätta vad vi ska göra, hur generella planen ser ut, var vi börjar, vad som förväntas osv.)
-Har det varit svårt att förankra det nya förhållningssättet som ISO-certifieringen kan ha inneburit?
-Är spårbarheten lika central i ISO 13485:2003 som i ISO9001? Hur fungerar det hos er? Tips?
-Har det varit svårt att få ha koll på alla krav och lagar? Berätta mer.
- Att implementera kvalitetssystem är ett steg i ledet av företagets utveckling. Det skall utvecklas med tidens gång och vi får lära oss att leva med det så att det blir en del av oss. Det är viktigt att alla i företaget är involverade i utvecklingsarbetet för att få intresset och engagemang hos medarbetarna – och att sammarbeta. Det är inte meningen att kvalitetsasnvarig ska bestämma hur alla processerna ska fungera. Det är ju olika personer som arbetar med olika processer och då är det vettigt att de utformar sin egen process. Sen kan man gemensamt slå sina huvuden ihop för att hitta förändringar om det inte fungerar bra. Samtidigt behöver man inte göra allt på en gång utan man kan ta det bit för bit och hela tiden utvecklar sig. För det handlar mycket om att man ska förbättra sig.
Det tog ca ett år innan vi blev helt vana med kvalitetssystemet, men nu är det ett hjälpmedel i det vardagliga arbetet. Nu har vi haft det och varit certifierade i några år.
- Det är jättebra med konsulter för de kan hjälpa till med att tänka rätt och hitta spåret. De har ofta en bra grundstruktur som man kan utforma utefter sina egna behov. Karin rekommenderar att ta hjälp av en konsult därför att att hitta strukturen är tidskrävande och skulle kosta mycket i timmar. De är även bra för mig som inte

X

har någon utbildning i ämnet då jag kan kontakta dem för konsultation är jag känner mig osäker eller behöver hjälp.

- Vi använder os av en programvara som heter CAPA. CAPA är ett anagram för corrective and preventive actions. Det är ett hjälpmedel för att sammanställa, samla, dokumentera, kommunicera problem och avvikelser I verksamheten. Här lägger någon in ärenden som behöver åtgärdas, så tittar jag på dem och fördelar ut ansvar för uppgiften. Vi jobbar inte så mycket med strukturerade kvalitetscirklar för det tar för mycket tid, utan många ärenden diskuteras ganska informellt. Vi behöver inte ha en stående tid för kvalitetsmöten utan kan ta det ganska spontant inom några timmar. Det är inte så att vi behöver hitta en tid om tre veckor för att alla är så fruktansvärt upptagana.

- Produktutveckling är en stor del av vår verksamhet och den är svår att styra med givna processer. Produktutvecklarna är inte så förtjusta i att jobba efter regler för det blir betyngande. Vad man kan göra däremot är att dukumentera bättre vad man gör genom labböcker. Det ger en spårbarhet. Vi har även blivit bättre på att få ut rapporter av projekten. Då kan man fastställa slutsatser och lära, gå tillbaka för att se vad man andra har gjort. Samtidigt är det bevis på att man har gjort något, även om det inte blirnågot man jobbar vidare med. Istället kan man visa på vad man lärt sig och visa på vad man inte skall göra.
I övrigt kan man börja med att skapa batchnummer för att få spårbarhet i utvecklingsprocessen. Det är saker kring processerna för det är stödjande som är centrala här.

- Andra områden som kan vara intressanta för företaget är personalfrågor, arbetsmiljö, miljöprofilering, vad gör vi vid skador/olyckor.

- Det är viktigt att kvalitets och processutvecklingssamornaren är nära processerna, visar intresse och engagemang för att processarna ska förstå vitsen..

Gunilla Lundhal, Arvidssons tandtekniksa Lab AB, 20110516

Berätta lite om vardagen och hur kvalitetssystemet stödjer er i ert arbete.
-Hur har ni gått till väga när ni började med ledningssystemet?
-Vad började ni med? Vad är viktigt att tänka på?
 -Vad är mindre viktigt?
-Hur ska man lära sig tänka i processer?
-Hur tänkte ni innan?
-Hur ser du på processer och hur ska man kommunicera det till medarbetare? (Book; målbilder, risker, problemlösning)
-Hur ska vi få rätt mind-set?
-Måste man ta hjälp av erfaren konsult? På vilket sätt har Effort hjälp er?
-Har ni några bra verktyg som man kan använda? Jobbar ni tex med kvalitetscirklar som PDCA? Balanced scorecard?
-Berätta hur ett kvalitetsärende kan se ut. Vad gör ni? Arbetsgång.
-Varför siktar ni mot FR2000? Har det varit svårt att få ha koll på alla krav och lagar? Berätta mer.

- Lärande allianser. De skalla vara kärnan i spridningen av kunskap och problemlösning. Tillsammans skall en grupp personer sitta ned och spåna på hur ett problem kan lösas. Arvidssons har inte startat upp lärande allianserna ännu men de är tänkt att allianserna ska jobba efter PDCA-modellen med planera, utföra, studera, agera. Till sin hjälp har de sju stycken verktyg som Stefan har gett dem att arbeta med. De verkar inte alls förankrade hos GL eller FA. Det är modeller som Ishikawa, Orsak-verkan diagram, Matrisdiagram (Krav vs Process) , Mötesstruktur mm, Prioriteringsmatris. (Fick en kopia på dessa verktyg)
GLs förhoppning är att lärande allianserna ska ge liv åt ett nytt beteende och kan bli en del av företagskulturen. Att just vara kompetenta och utvecklas genom varandra är en central del av företagsutvecklingen för att kunna vara ledande inom området. Att bevaka omvärden (iakta marknade, se till kundernas behov, hänga med på nya tekniker, ta in tandläkares åsikter mm) är mycket viktigt för att hänga med i utvecklingen och inte bli omsprungna av konkurrenterna. Företaget är mycket värde i form av kunskap, vilken skall förmedlas internt för att bevaras.

- Verksamhetskompass. Är lite av hjärtat av systemet som fungerar som en förbättringslogg. Där initierar man ärenden som skall behöver åtgärdas; ansvar, status, åtgärder, meedverkande, plan, allians, prioritet, datum osv. Hit rapporteras också avvikelser som kan vara kvalitetsärenden. Det är även till för att vägleda i det dagliga arbetet och ger en god överblick över vad som behöver göras.
Verksamhetskompassen är även en logg över vad man gör och att man gör något. Det kan kännas som inget händer med GL uttrycker att då får man ett kvitto på att man faktiskt gör något.

- S. Book har varit till stor hjälp. Innan så hade Arvidsson siktat mot en FR2000-certifiering(branchspecifik certifiering som tar in krav från bla ISO 9001 och ISO 14001). Fredrik och Stefan "fann" varandra under 2009 och då började arbetet med att bena ut och mappa verksamheten. Se figur 1 "Hur hänger det ihop". Det gjorde att de fick tänka till kring hur de jobbar idag och vad de vill göra, vilka värderingar de har. Book gjorde en analys av Arvidssons genom att intervjua FA, en bra analys som lyfter vad som varit problemen i företaget och vad som hindrat dem i sin utveckling. En förbättringsplan etablerades. Det har varit central att det ska få ta sin tid, deadlines har inte varit speciellt förekommande. FA och GL har givits tid att mogna in i rollen som förändringsledare. FA säger flera gånger att han funderar ibland på om han gör rätt saker (med tanke på att det känns som om det inte händer något, man gör bara samma saker hela tiden).
  Faktorer som Book hjälpte Arvidsson att få insikt kring; de har fått en struktur på verksamheten, det har blivit lättare att hitta anvar för områden (processer). De upprättade processbeskrivningar och fick ordning på sin infrastruktur på ett överskådligt sätt.
- Egna(VL) ord. Det har varit viktigt och noga att skapa egna definitioner av begrepp för att de ska känna sig fria. Tex. använder de inte ordet processer utan vill prata om områden. Det skall inte vara massa fina ord som bara slängs med för att de är buzz-words, då är det svårare att ta till sig den verkliga innebörden och det blir ett motstånd. Ett naturligt språk är viktigt för att nå ut till medarbetarna med budskapen.
- Den egna strukturen av systemet är också viktig. Istället för ISO:s kapitelindelning har Arvidsson gjort en områdesindelning som är relevent för dem. Det kan dock innebära mer jobb för revisionen men spårbarheten mot kraven finns där!
- FA tycker att riskhanteringen var tråkig men att den är säkert viktig den med.
- Book och FA hade en idé om att outa en fejkad revision och samtidigt säga att de inte behöver göra något innan revisionen för de söter sig bra som det är.

Centralt från intervjuen:
Verksamhetskompass
Egna ord, naturligt språk.
Fokus på lärande och utveckling
Kulturen skall speglas i verksamheten

Hanna Syrén, Micropos, 20110603
Berätta lite om vardagen och hur kvalitetssystemet stödjer er i ert arbete.
Hur har ni gått till väga när ni började med ledningssystemet?
-Vad började ni med?
-Vad är viktigt att tänka på?
-Vad är mindre viktigt (överreklamerat)?
Hur ska man lära sig tänka i processer? Hur tänkte ni innan? Hur ser du på processer och hur ska man kommunicera det till medarbetare? Hur ska vi få rätt mind-set?
Måste man ta hjälp av erfaren konsult? På vilket sätt har det hjälp er? Alt. Hur skulle det kunna ha hjälpt er?
Har ni några bra verktyg som du kan tipsa om? Jobbar ni tex med kvalitetscirklar som PDCA? Balanced scorecard?
Berätta hur ett kvalitetsärende kan se ut. Vad gör ni? Arbetsgång.
Hur håller ni koll på spårbarheten?
Vad mäter ni för att påvisa framsteg?
- Vi har försökt bygga upp det så enkelt som möjligt, och anpassat efter att vi är få personer så att de personer som sitter bakom har grundkompetens. Vi har satt upp rutiner kring alla möjliga områden som dokumentation, hur vi registrerar dokument och vilken typ som skall registreras. Då har vi inga direkta krav på vad de skall innehålla, utan vi har använt mycket sunt förnuft så vi kan hitta vad vi gjort och varför. Finns det då i en spec och en rapport så är det okej. Det behöver inte styras så mycket när det inte är så stort ännu, det är rätt fritt. Vi skriver många rutiner generella och inte grotta ned oss i detaljer
- Vi började sakta men säkert på några rutiner som är viktiga. Istället för se hur ett kvalitetssystem ser ut så började vi med "såhär jobbar vi", och sedan reviderar vi. Vi började med de processer vi tycker var tydliga att vi jobbar med. I en utvecklingsmiljö började vi med design control, ställde oss frågan " hur jobbar vi när vi utveckalar en produkt, när vi samlar in information osv."
- Revisioner internt och på leverantörer. Internt 1ggr/år
- Riskanalys är stor del för oss. Det är våran stomme. Det blir brister ibland när det inte finns nedtäcknat ordentligt. Vad kan hända patienten? Allt är säkerhet! När vi gör ändringar så måste vi gå igenom riskanalysen och fråga oss själva om vi påverkar något till det sämre när en ändring görs. Tungrodd men bra, väl beskrivande och spegalar tydligt verkligheten.

- Jag, VD, tekniska chefen och en konsult gjorde detta från början. Hanna gick en kurs och pluggade på direktiven. Hanna tycker att konsulten hade bra koll på detaljerna och kan förklara vad standarderna betyder. Det blev mer effektivt, helt klart!
- Viktigt att förstå hur det kan hjälpa oss! Man får inte se det som en börda vilket det kan kännas som i början. Därför anpassade vi det efter hur vi jobbar, då blev det en hjälp. Man märker ju först när man ser långsiktigt att det är hjälper till men mycket i början. Innan tycker man det funkar bra o ser inte allt.
- Krav på CE-märkning. Vi följer en standard men är ej ISO certifierade.
- Det tog lite tid att komma in i rutinerna, och alla är inte helt hundra ännu. Men det måste ju få leva iom. att man växer.
- Ledningensgenomgång
- Dokumeterar allt vi samlar in från kunderna. Man vet att man måste göra det. Sen följer vi upp, och ser nog att vi har förbättrats.
- Vi måste ju ha strukturer för förbättringsarbetet.
- Reklamationer måste dokumenteras om det har varit med risk för någon person. Det görs med ett reklamationsregister
- Provade gemensamt dokument där man lyfter problem eller förbättringsåtgärder. Men det blev inte att alla använde det.
- Spårbarheten är jätteviktig. Då har vi formulär som vi fyller i så vi vet var varje produkt finns. Alla delkomponenter är då spårbara för de finns registrerad på varje produkt.

10.2 Appendix B

Explanation from the certifying organization VCA

Approved suppliers	how the company selects suppliers to provide quality goods or services and how they ensure they use only those suppliers
Incoming goods	how the company ensures that the goods it receives conform to the required specifications/order
Non-conforming goods	how does the company ensure that any incoming goods or manufactured goods that do not conform to specification are not used in production or distributed to the end user
Staff training	how does the company ensure that its staff are properly trained and how it records that training
Calibration of equipment	how the company ensures that any equipment used for manufacture or for test are maintained in calibration
Change control	how the company ensures that any changes in design or assembly processes which may affect the validity of the approval is notified to the relevant departments and or the relevant approval authority
Final inspection	how the company ensures that the final product conforms to its specifications has appropriate labeling and instructions for use.

10.3 Appendix C

Quality policy

Nimbell's goal is to deliver the right product, at the right time and to the right price to our customers. Nimbell shall develop and deliver products which every single time meet, and preferably exceed, our customers' requirements and expectations.

To achieve this shall we:

Build a clear structure in the company
Focus on and be service minded to our customers
Have an environment which stimulate the employees to be involved and motivated
Follow and improve our processes

Nimbell wants to always move forward and improve the business. This can be achieved by:

Be open-minded to changes
Deploy time for improvement work
Foster new ideas from all stakeholders
Promote knowledge, motivation and good ideas
Follow up customer orders
Reflect upon our actions

10.4 Appendix D

Output from workshop 2

Figure 3 Identified activities
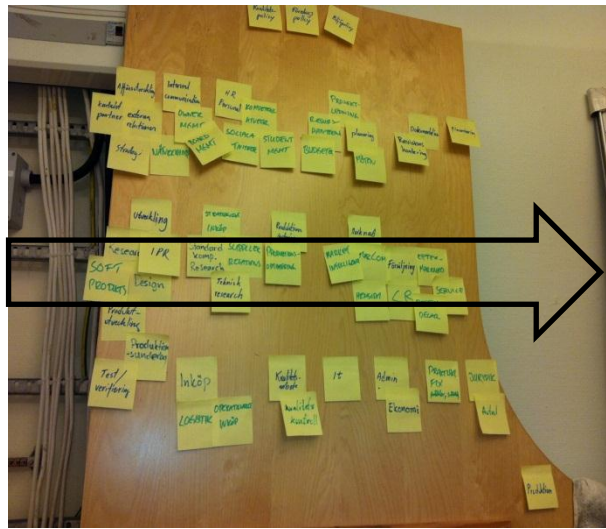
Figure 3 Arranged activities
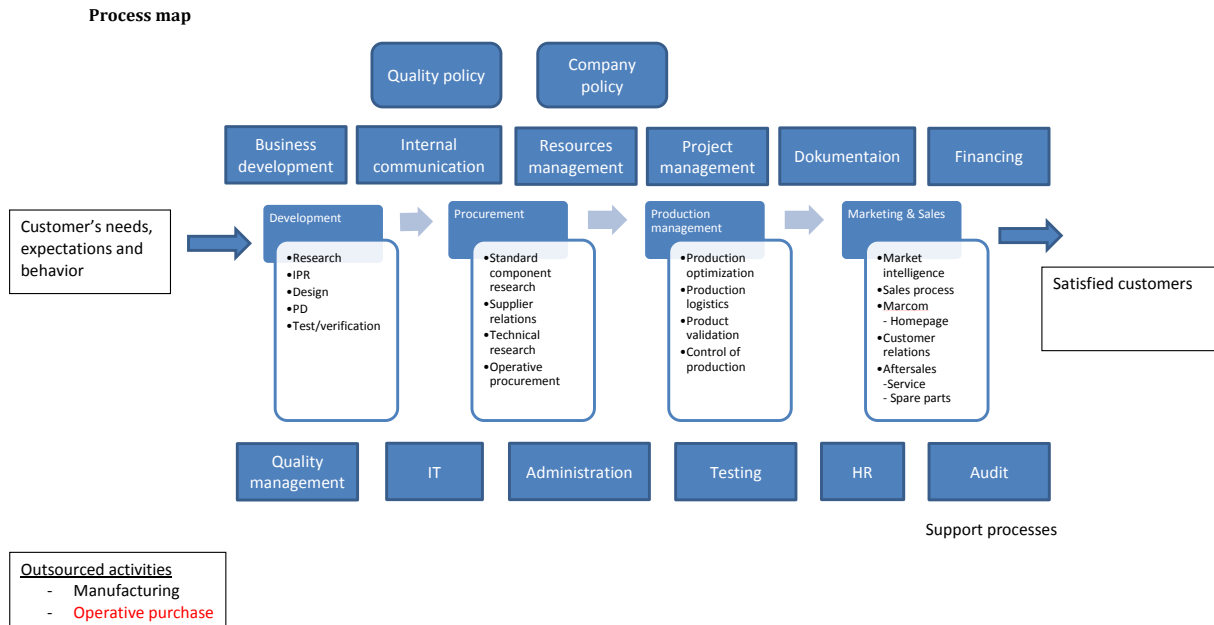
Process map

Figure 3 Main process map

Product development checklist

The checklist states which aspects to consider when developing /designing details and components. These are the three most important aspects which are considered first and at all times.

Cost
Weight
Customer requirements

Also very important but secondary are the following aspects. Process each of the aspects and reflect on weather each one is regarded. If yes, it is probably OK. If anything is not satisfying the responsible developer shall;

1. Execute an analysis, find a solution
2. Make a risk analysis
3. Make a note to communicate eventual shortage or possible risk

Also regard the following areas

Aftermarket and service
Choice of material
Design for assembly
Environmental aspects
Fatigue
Fulfilled design parameters and customer requirements
Lead time
Legal requirements
Manufacturing technique
Module based / general solution
Number of dependences
Possible risks (long and short term)
Proper strenght (over-/underdimentionsed)
Surface treatment
Tolerances

When every aspect is regarded is the detail ready for the next stage.

Drawings – the routine

Production

After the development and design processes, the product drawings are produced and handled. The drawings are produced by the R&D engineers. They are responsible for the drawings linked to the detail they are responsible for. A drawing is signed by its creator, and is saved with date of revision, version and drawing number. The drawing is saved in Sugar sync in proper folder (Eg T10 Lastsystem).

Eg.1 TAA-5XXXY_A/B/C/Pzz
Eg.2 T01-5024SS_7076M_A01
Eg.3 T10-3012_P01

TAA; T is for Trigo, AA is for area. There are 12 areas. (TAA = T01-T12)

Suffix Y=
S for Sheet metal
T for Tube
M for Machined
R for Raw material
SS for Welded assembly

-3000 is an assembly
-5000 is a detail part
_7000 indicate material part, and is a part of a -5000 detail
XXX is an increasing number, specific for every drawing

Drawing status:
A Concept
B Prototype
C Buy tools
P Production
A or B may never be used for any production. C may be used for tools. P is only for completed details, ready for production.

_rev indicate which revision the drawing is. It is indicated with capital letters starting on "01" (Eg. P01, A/B/C/Pzz)

All material part starts with _7XXX, were XXX is an increasing number starting on 001.

When drawings are given to external producers, manufacturer or assembly plant, agreements are made between external stakeholder and Nimbell for handling and control of the documents.

Archiving
Nimbell has a product register for each project. An article number list is linked to this product register. The article number list state which article numbers are used and give a short description about each detail. The drawings are mostly electronic and are therefore stored in the Sugar sync cloud and on the creator's hard drive, within the given project directory.

When archiving finished drawings, the article number list is updated and the following shall be specified; type of drawing (P/T/M/R/SS), drawing number, area and short description. Every new detail gets a new accumulated drawing number (3/5/7 XXX). Revised parts only change revision number.

Distribution
Nimbell distribute drawings restrictively. It is mainly spread to the manufacturer of the components, which is often in the procurement process and the management of production process. The suppliers are often the ones receiving the drawings. When a drawing is distributed to external party, the sent drawings are archived in an outbound folder (utskick 2011) stating date of archiving.

10.5 Appendix E

Learning circles describes in Swedish. The pictures should be read as rows, not columns.

Lärandecirklar **- ett steg i kompetensutvecklingen**	**Vad kan vi göra?** Vi håller lärande cirklarna några gånger i månaden, förslagsvis en gång i veckan, under 1 timma. Då sitter vi ned tillsammans och varje deltagare får en kort stund till att hålla en kort presentation för att utbilda resten av teamet i något han/hon har lärt sig den senaste tiden. Helst ska det vara arbetsrelaterat men spelar inte så stor roll vad det är. Det kan behöva göras förberdelser, tex powepoint slides eller annat material. Efter presentationen är finns det tid för frågor, feedback och reflektioner. Det är diskussionen som är viktig.
Varför? Den här övningen är en del i vår interna utbildning och skall ge oss avkastning map. flera områden. De är bland annat; - Breddad kompetens, möjlighet till uppbackning - Tid för egen reflektion - Finna förbättringsmöjligheter - Väcka idéer - Förbättrad presentationsförmåga - Öva pedagogik - Utveckla procedurer - Förståelse för varandras arbete - Utrymme för feedback, öva ge feedback - Förbättrad gruppdynamik	**Hur?** • Varje deltagare förbereder en kort presentation, 4-6 min, om något man lärt sig den senaste tiden och som kan vara värdefullt eller intressant för de andra deltagarna att ta del av. • Det kan också vara ett ämne för diskussion där man vill få in åsikter om sitt arbete tex.om man kört fast. Då kan man förklara sin situation/ case och så blir det en diskussion kring det. • En deltagare agerar Reflektionsledare (moderator). Kan vara en roterande uppgift.
Reflektionsprocessen Reflektioner kan vara enkla eller komplexa. Enkla – behandlar ofta de sakliga ämnet Komplexa - mer subtila och innefattar underliggande känslor och meningar.	**Fördelar** • Organisatoriskt lärande • Praktisk, relevant och användbar kunskap • Man lär av varandra – gränser tänjs • Känsla av delaktighet • Meningsfullt • Det egna arbetssättet utvecklas

Vad är syftet med reflektion?

Reflektion syftar till att ge deltagarna möjligheter att utföra sina arbetsuppgifter än mer kvalificerat

(... med större glädje och tryggare yrkesidentitet och med mindre risk för utbrändhet)

Vad är då reflektionshandledning?

Teamet får genom handledning möjlighet att utnyttja sin samlade kompetens...

... genom gemensam reflektion

... genom att i handledningssituationen skapa distans till arbetsuppgifterna

... vinna förståelse för svåra relationer och processer i arbetet

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Förutsättningar

- Tid erfodras
- Planering
- Förhållningssätt (diskussion/dialog)
- Resurser
- Ledningens stöd

Gibbs reflektionsmodell

Reflektionsledaren (moderator)

- Är inte ”expert” i ämnet
- Är lyhörd
- Får laget/gruppen att fungera som ett lag, men låter laget diskutera och planera sitt eget arbete samt aktivt stödja och utmana varandras förståelse
- Stimulerar diskussion av den egna verksamheten och därmed nytänkande

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Referenser

- http://www.lj.se/info_files/infosida33112/bildspel_reflektion_060829.pdf

10.6 Appendix F

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10.7 Appendix G

Instructions for part 2

Step 4 – Gather the documented material and examine to:
- Examine what has been written
- Secure everything fits together
- Identify gaps and inconsistencies

Make sure it fit together, make corrections when you spot inconsistencies and gaps between the documented activities. Consider if it is in line with the quality policy and the company's objectives. This will be the foundation of the documented activities in the company. Make sure it is consistency in the format. It is easier to recognize and feel comfortable with. It enables the possibility for people to revise the documents themselves.

Step 5 – Work after the principles

The next step is to make sure the company work according to what is decided. Involve people to the system to make it living, so do update when necessary.

a. Do not create unnecessary documents. Do only document what is actually done today and define the processes show how the job is performed. Leave out how it would or should be. Do only create templates or checklists if it will help someone. A signature or clarification can be enough.

b. Remember, document when;
   i. Problems arise, use suggestion log
   ii. When a good suggestion comes up, use suggestion log
   iii. Customer or employee expresses a need

c. Everyone shall have access to the documents which concerns them i.e. activities they are involved in. Education of the system is probably needed, how it is structured and why. Document control ensures the latest copy is used.

d. Everybody needs training to understand how to keep the system up to date if changes need to be done in any specific area of responsibility. Everyone shall have the knowledge how to do changes in the system and how one document problems and rise suggestions for improvements. Changes shall be approved before they are incorporated (put in place).

It is important to plan and execute internal audits to regularly maintain, develop and get support in the company. Doing internal audits is good to engage and identify new improvement possibilities.

Step 6 - Maintenance

Keep the QMS simple, functional and relevant for the company's own operations.

- The purpose is to secure the operations are made under controlled circumstances and make sure process owners know and understand his/her role and responsibility
- With the quality management system shall it be possible to identify; how, when, why, where and why a job is done, control an operation. The language shall be easy to understand, as it is at the company site.
- If the details have to be extensive and complex checklists are often an appropriate alternative to secure everything is made right and in the right sequence.
- If anything goes wrong or is unclear shall information be available close to the operation/ activity. E.g. A car owner keep the car manual in the glove box.
- Documents shall be in a format which fits the business. Since there are computers, it is preferred to have a computerized system before paper copies.
- The documentation shall reflect what happens in the Nimbellt the moment. During audits shall it be questioned and searched for evidence that the personnel understands and can handle the quality management system. Evidence is searched for in protocols, records, registers and reports.