A Framework for Designing a Lean Production System for SMEs, which eases the certification of ISO 9001 & 14001

A Case Study: CombiQ AB

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This thesis work has been carried out at the School of Engineering in Jönköping University in the subject area of Production Systems. The work is a part of the two-year university diploma of the Master of Science program within the field of engineering.

The authors take full responsibility for opinions, conclusions and findings presented.

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“As for me, all I know is that I know nothing.”

- Socrates
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Despite our friendship, we would like to thank each other as colleagues due to the “once in a life-time” experiences during this project.

Our final words:

Dedicated to my dearest family and beloved Elena…
   I love you all!
   Talat

I am passionately grateful for the support of my parents Anita and Raul, and the great sweetness of my sister Ane,
   Raul
Summary

In order to survive in highly competitive local and global markets, it is vital to satisfy the changing demand of the customers. Thus, the importance of competitive factors arises. The companies should provide sufficient amount of products or services on time with the most advantageous prices and best possible quality. Additionally, flexibility is crucial to deal with the change in demand. Therefore, a flexible production system for manufacturers is vastly required.

The aim of this Master Thesis is to provide a framework for Small and Medium-sized Enterprises (SMEs) that seek ISO 9001 and 14001 Certifications by proposing a Lean Production System. As a case study, the Swedish company CombiQ AB is investigated regarding its current situation with short and long term goals. Thereby, this framework includes the design of a suitable production system that meets CombiQ’s needs and additionally to that, instructs the company how to build up a Lean Production System.

In parallel with ISO Certification requirements, two main Lean Techniques (5S and Kaizen) are explained and exemplified throughout the project. These techniques are straightly linked with the requirements of Quality Management Systems (ISO 9001) and Environmental Management Systems (ISO 14001).

As for empirical data, this project is constructed by six interviews within the company and one additional interview with an ISO auditor. As a complement, operational and managerial processes are observed. Additionally, relevant literature is examined, presented and aligned with empirical findings in order to cover the essential concepts of this thesis.

The final proposal is the usage of lean thinking as a core philosophy guided by the lean principles and techniques with the ISO requirements in parallel, which are the selected concepts to design a desired production system. Once the design is proposed; as further steps, the company would be able to continue the development process by implementing and starting-up the production. Last but not least; as the major outcome of this Lean Production System framework, the ISO certifications would be accomplished with a higher customer satisfaction and competitiveness.
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1 Introduction

This chapter contains the background of the research, the objective and research questions, including the limitations of the study and finally the outline, which presents the whole report in a structured way.

1.1 Background

As industrial competition increases, it becomes more apparent that improved levels of output, efficiency and quality can be only achieved by designing better production systems rather than by merely exercising greater control over existing ones. (Bennett, 1986)

If the past 120 years are observed, one of the most common characteristics of small businesses is to evade competing directly with larger enterprises, which are in the same market. That is why, there is a tendency for small businesses to satisfy specific needs of small market segments by having a specialized short-run production. (Lamprecht, 1996)

According to Bellgran and Säfsten (2010), the most important competitive factors of the enterprises are cost, quality, flexibility and deliverability. In other words, the customers seek products or services with an optimum price and best quality, on time and in adequate amounts. The more competitive factors are developed, the more improved competitiveness is obtained by the enterprises. Thus, having a proper production system is vital for the companies in order to achieve long-term success.

Since, to create value for the customer and the elimination of waste in the organization are the milestones for the success of the enterprises, Lean philosophy and techniques are the most powerful tools for this objective. Lean manufacturing is a five-step process: defining customer value, defining the value stream, making it “flow”, “pulling” from the customer back, and striving for excellence. (Womack and Jones, 2003)

During the last 10 years, companies have focused too heavily on techniques such as 5S and Just-In-Time, without understanding the “Lean Manufacturing” as an entire system that must permeate an organization’s culture. Another misperception about lean thinking is that, in most companies where lean is implemented, senior management is not involved in the day-to-day operations and continuous improvement that are part of lean. (Liker, 2004)

CombiQ AB is a Swedish company located in Jönköping Science Park, which develops products, systems and solutions by using radio-frequency identification (RFID) technology. Their customers and partners are part of the following fields: after sales and service, healthcare, logistics and security. The company requires aims to get certified by ISO qualifications, 9001 and 14001, as one of its goals for the present year.
It is believed that, a production system with standardized processes supported by lean philosophy and quality management system will lead the company to achieve the desired goals with a total involvement from both board of management and workers. The production concepts must be in parallel with the company’s philosophy during the whole process. (Liker, 2004)

1.2 Objective and research questions

For small and medium enterprises (SMEs), it is essential to have an efficient production system according to the knowledge of the authors of this paper, which was gathered in Jönköping School of Engineering and previous studies. When the idea was mentioned to the professors in JTH and board of management of CombiQ, a significant support and encouragement was received.

Once the industrial market and the companies are observed, it is difficult to see small and medium sized enterprises (SMEs) being as competitive as relatively big manufacturers. One of the main reasons for that is, not having a production system, which organizes and optimizes the input and processes in order to have maximized outputs in quality and quantity perspective. Therefore, the objective of this project is to focus on the design of a lean production system for CombiQ in Science Park, in order to assist the company to achieve long-term success and required ISO certifications.

Moreover; as a future step, the designed theoretical framework will lead the company to develop and implement an adequate production system that will be enhanced by the proposed techniques and tools.

The research and investigation are based on the following research questions:

Research Question 1: How can a conceptual framework of a lean production system for a small company that innovates electronic products be designed?

Research Question 2: Which are the most appropriate lean production system techniques that ease the process of achieving ISO 9001 and ISO 14001 certifications?

1.3 Delimitations

Considering the facts that developing a production system is a very wide subject and the limited time frame, the thesis’ aim has been narrowed to focus on the design of the mentioned system.

Starting from the point where developing a production system involves different phases, such as planning, design and implementation (Bellgran and Säfsten, 2010); the present project is focused on the preparatory design and design specification, in which a pre-study, a design and evaluation of conceptual production system and finally a detailed design of the chosen production system are carried out.
The present project is not taking into consideration the whole lean concept and techniques due to the time frame and the company’s goals and needs. By considering this fact, the research consists of two of them, 5S and Kaizen, which are explained throughout the paper.

Another delimit is financial feasibility. All changes and improvement decisions are made by the company. The tools or techniques will be applied if they are economically affordable for the company. The financial concerns in the tool or technique selection phase can affect the outcomes.

The actual situation of the company within the production development process is positioned at the product design, development and prototyping phase. Therefore, it was difficult to analyze the proposed production system with their current production, due to the fact that they do not have constant and planned production.

1.4 Outline

Chapter 2. Method
In this chapter, the reader can find a definition of research, the type of the chosen case study, and research approach. Also, the data collection techniques are described and information about data analysis can be found with the research process. Finally, reliability and validity concepts are described.

Chapter 3. Theoretical Background
As a secondary data collection, the relevant literature is observed. The reader can observe the reviewed literature as the following topics: Production System Design (PDS), ISO Certification, Lean thinking, Production Planning and Total Quality Management (TQM).

Chapter 4. Empirical Findings
As a primary data collection, the findings of the chosen methods (observation and interviews) are presented. The observations and part of the interviews were conducted within the company with employees and top managers. Additionally, another interview, which was carried out with an ISO auditor can be observed.

Chapter 5. Analysis
In this chapter, the reader can find the analysis that is carried out by combining literature review, observations and interviews. The analysis denotes the current situation of CombiQ and its relation with the mentioned topics in the Theoretical Background chapter. This analysis was mainly focused on the selected case study; although, it can be applied to SMEs that share most of the same characteristics and conditions as CombiQ.
Chapter 6. Discussions and Conclusions

This chapter contains the respective discussions regarding the method and findings of the thesis. The way the researchers carried out the project through research questions, tool and technique selection, and finally the conclusions with the main drawbacks and future steps are mentioned.

Chapter 7. References

The list of reviewed literature can be examined in this chapter.

Chapter 8. Search Terms

The list of the most relevant terms can be viewed in this chapter.

Chapter 9. Appendices

Conducted interviews, informative tables with comparisons, and detailed information about ISO standards are enclosed.
2 Method

In this chapter; the chosen research approaches, methodologies and techniques are explained. The reader can find the reasons of why the chosen methods are appropriate for this research. The chapter will continue by denoting the used data collection methods that are suitable for the research process. At the end of the chapter, the validity and reliability concepts can be observed.

2.1 What is Research?

Before explaining the research process and methodology, it is important to clarify the understanding of research concept at the beginning of the chapter in order to increase the perception of the methodology. When the literature is observed, many definitions of research can be found, changing in emphasis on different scopes.

The Oxford Dictionaries (2011) define research as “the systematic investigation into the study of materials, sources etc. in order to establish facts and new conclusions”. Furthermore, a more technical definition of research is “the inquiry of hypothetical propositions about presumed relations among natural phenomena in a systematic, controlled, empirical and critical way.” (Walliman, 2001)

2.2 Single-Case Study

In this research, Single-Case study strategy was chosen because of several reasons explained below. Since the data collection and data analysis were only performed in CombiQ, all the attention was given and focused on only one case or company (not multiple-case). This brought a thorough understanding of the research area, which led the researchers to obtain comprehensive and remarkable outcomes (DePoy and Gitlin, 2005). Another reason of the current selection is exploratory single-case study is the most feasible research procedure for this situation (Yin, 1994), because it provides a flexible way to conduct investigations and a better insight about CombiQ’s system.

The research strategy was selected according to the reasons that Yin (1994) suggested:

- Structure of the research questions
- Researchers’ control over behavior of events and actions
- Focus on contemporary events

DePoy and Gitlin (2005) claims that case study is useful when:

- There is a small amount of knowledge of a phenomenon when collected and grouped responses do not provide enough insight into the interested phenomenon
- Studying on a particular group with similar characteristics is not possible or desirable
There is a desire to determine and observe the consequences of interventions
There is a desire to gain pilot knowledge in a cost-efficient way

Yin (1994) says that, case study is a helpful method when the purpose of the study requires deep analysis and draw comprehensive conclusions. According to DePoy and Gitlin (2005), the main advantageous characteristics of case study are being flexible, ability to contain multiple purposes and ability to use multiple data collection methods. Thus, the main characteristics of case study are the most appropriate for the chosen research area.

2.3 Qualitative Approach

The choice of the method depends on the purpose of the research (Walliman, 2001). Since the research focuses on designing a lean production system, and not implementing or evaluating the system; there is no need to obtain quantitative data for its further analysis. Therefore, qualitative approach is more suitable and can be supported with the following chart.

<table>
<thead>
<tr>
<th>Quantitative Methods</th>
<th>Qualitative Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dealing with numbers</td>
<td>Dealing with descriptions</td>
</tr>
<tr>
<td>Data is measured</td>
<td>Data is observed</td>
</tr>
<tr>
<td>Objective</td>
<td>Subjective</td>
</tr>
<tr>
<td>Particular point of view</td>
<td>Systematic point of view</td>
</tr>
<tr>
<td>Focus on results</td>
<td>Focus on processes</td>
</tr>
<tr>
<td>Statistical analysis</td>
<td>Text and image analysis</td>
</tr>
<tr>
<td>Instrument questions</td>
<td>Open ended questions</td>
</tr>
<tr>
<td>Generalization is reliable</td>
<td>Generalization is not reliable</td>
</tr>
</tbody>
</table>

Creswell (2003) states that qualitative methods create conclusions via data, which is not supposed to be numerical. Also, the researcher uses interpretivist approaches with inductive reasoning which are explained in the following statements:

- Interpretivism seeks for significant relationships and discovers the consequences and outcomes; we have chosen this philosophy to guide our research (Walliman, 2001)
Inductive reasoning leads the researcher from specific cases to understand general principles. In other words, the specific cases become the basis and generalization is made via them and general statements are made (Williamson, 2002). Inductive reasoning is case oriented (Granzino and Raulin, 2004).\(^1\)

Because of the exploratory purposes about a phenomenon, the study is conducted with qualitative method. Qualitative method is chosen because it acts in parallel with the research objectives that enables to understand the real meaning of the events, actions, particular contexts in which the participants act.

\(^{1}\) For further analysis of inductive and deductive reasoning, an explanatory table is attached in the appendix.
2.4 Research Process

In this part, the research approach and methodology is explained with the reasons why they were chosen.

First of all, the research study was conducted by structured phases, because they help to reduce the complexity of the work, as Walliman (2001) stated. Therefore, the process follows the next phases:

1. Idea generating phase
2. Problem definition phase
3. Procedure design phase
4. Observation phase
5. Data analysis phase
6. Interpretation phase
7. Communication phase

With a brief explanation, in the Idea generating phase, identification of the interested study was made. In Problem definition phase, the ideas from Idea generating phase are filtered and specified into two research questions, which were denoted under the “Purpose and research questions” title in the “Introduction” chapter. In the Procedures design phase, the specific procedures, which were used to gather and analyze the collected data, were decided. In the Observation phase, the procedures denoted above were taken into action and used in the company. In Data analysis phase, collected data was analyzed with several scientific methods. In the Interpretation phase, the obtained results and outcomes were compared with the expected results and outcomes. Also the verification of results and outcomes were made if they were supported by the theory or not. In the Communication phase, the written and oral report was structured and prepared for the presentations.

2.5 Data Collection

As Denscombe (1998) explains in his book, the different research methods (such as questionnaires, interviews, observation and documents) can come to complement each other. They can be combined in such way to produce differing but mutually supporting ways of data collection. Therefore, different methods were conducted according to the project aims for each type of data in order to improve the quality of the research.

Once the previous concept is understood, the analogy of Triangulation arises as the use of two or more methods or techniques to investigate the same research question. Where seeing things from different perspectives and the opportunity to corroborate findings, enhances the validity of the data by giving more consistency across the methods and support to the analysis. (Denscombe, 1998; Williamson, 2002)
Therefore, interviews and observation were conducted as a part of primary data and finally but not least, the secondary data consists of the literature review. Noticing that the data obtained from the one-to-one interviews and observations regard the qualitative research.

2.5.1 Primary data collection

2.5.1.1 Interviews

Interviews are one of the main techniques of this research due to their particular linkage with qualitative approach and also because of their frequent usage in case studies. Hence, they are completely relevant to the project; besides to the fact that their response rate is so much higher than questionnaires. (Williamson, 2002)

One of the main reasons this type of data collection was chosen is because of its adaptability; where a skillful interviewer can follow up ideas, probe responses and investigate motives and feelings, which the questionnaires can never do. The way in which a response is made via the tone of voice, facial expression, hesitation, etc. can provide information that written response would conceal. (Bell, 1999)

There are three types of interviews: Fully-Structured, Unstructured and Semi-Structured as Williamson (2002) defined. However, for the purpose of this project, semi-structured interviews are the most suitable ones because of the mixture of the first two types. So, the chosen type has a standard list of questions (as a structured type), but also allows the interviewer to follow up on leads provided by participants for each of the questions involved, as unstructured interviews propose.

Regarding the research approach, exploratory and other in-depth interviews are very appropriate in interpretivist methods. Besides, exploratory interviews can be very useful in the early stages of most research projects. (Williamson, 2002)

Before conducting the interviews, an appointment with every single worker of the company was fixed, in order to book an interview-room and a proper time for them, where the interviewees were not interfered or disturbed with their daily activities. Full information regarding the purpose of the research was given, like how long the interview was likely to last and they were asked for permission if the interview could be tape-recorded. An important thing concerning the tape-recording is that research reports are enhanced by the opportunity to quote the actual words of respondents. The interviews were performed in a limited time, considering the high workload of the interviewees and a reasonable working time.

Additionally to the interviews within the company, an interview with an ISO auditor was conducted in order to have an outer perception of this case.

Regarding the variation in interviewer’s techniques and factors that may bias an interview, no such problems occurred since both of the interviewers conducted the interviews and led specific parts of the interview towards all respondents. In addition to that, the interviews differed in some questions for each interviewee according to their job position and tasks inside the company.
2.5.1.2 Observation

As a complement of interviews, observations were made due to their numerous advantages. For instance, they offer the researcher a distinct way of collecting data, where it does not rely on what people say or think. This method is much more direct than that; because it draws on the direct evidence of the eye to witness events first hand. It is based on the premise that, for certain purposes, it is best to observe what actually happens. (Denscombe, 1998)

Instead of a systematic observation, participant observation was chosen for this project. Because is oriented for qualitative data collection due to its aim of infiltrating into situations, sometimes as an undercover operation, to understand the culture and processes of the groups being investigated. (Denscombe, 1998)

Due to the opportunity of one of the researchers, who works in the company every day, this method could be carried out with the same frequency. Taking special notes to the moves around the workshops and common working areas in order to identify main problems and unusual behaviors occurred by external factors.

2.5.2 Secondary data collection

2.5.2.1 Literature review

Defining secondary data as the material that already exists, literature references are useful for constructing the theoretical background, which is important for any kind of research in order to understand the results through it (Williamson, 2002; Robson, 2007). As Bell (1999) denoted, the aim of any search is to retrieve information of direct relevance to the research and to avoid being overloaded with material of only peripheral interest.

The used literature is based on what the researchers learned during their years at the University of Jönköping, from the program books and other books related to the topic of this project, such as Lean Thinking, Production Systems Design and ISO Certifications; including relevant articles found via the library search engine.

The theoretical framework was performed to be the basis for the analysis and interpretation of data, consequently a coherent pattern is used to organize and classify it, as Bell (1999) suggested. In other words, the information was summarized; the facts and the relationships between them were explained for a better understanding.

2.6 Data Analysis

Many researchers leave the analysis once all the data collection is done, however it might bring some drawbacks to the project analysis due to time and in some cases regarding cost issues. Therefore, many forms of qualitative research encourage researchers to analyze data as the collect it. This helps researchers to stay on top of the large amount of data that they are likely to collect, and to stop collecting it when they have enough data to answer their research questions or they begin to have more data than they can analyze. (Williamson, 2002)
The interviews were tape-recorded and written down into a word processor in order to make the information much more accessible and easier to analyze. Also, some comments or memos about the overall impressions were added during the interviews so it would be easier to relate every moment while reading through each transcript; such as Williamson (2002) recommends.

The most relevant information from each interview was taken and considered as powerful input to the new production system. Opportunity areas were deducted from the interviewees’ opinions about the current situation of the company and immediately enough requirements, that could help to develop the basis of our project, were gathered.

Combining the interviews with the observations, several similarities were denoted between them. The waste of time while looking for the proper tools in the workshop can be an example as many others. The observations helped to give a personal thought about how things work inside the company and how the workers perform their normal activities. None a specific day was chosen for conducting the observations; in fact the natural behavior of the employees was observed through several days in order to obtain more data from different working conditions.

### 2.7 Validity and Reliability

In the beginning of this part, it is useful to increase the understanding of validity and reliability.

Williamson (2002) clears the concept of validity and reliability like the following:

- **Validity** is the capacity of a measuring instrument to measure what it purports to measure, or to predict what it was designed to predict, or, the accuracy of observations
  - Internal validity is related to the conclusiveness of the results obtained which are attributable to the impact of the independent variable, and not caused by other unknown factors
  - External validity is the generalizability of the findings, which can be generalized to other populations
- **Reliability** is the consistency of results produced by a measuring instrument when it is applied more than once in a similar situation

As it is mentioned before, the exploratory single case study is carried out for this project. The concern of validity regarding the chosen method is that the reality cannot be found in advance. The reality is being approached throughout the research process (Creswell, 2003). Another fact about case study method is, reliability increases if the studies are applied more than once in a similar situation (Yin, 1994). Multiple case studies could produce more reliable results if it were possible to have not limited time and more than one company. Thus, the authors structured the methodology part according to the several limitations.
On the other hand, single case study increases the understanding of a specific phenomenon and obtains detailed insights (DePoy and Gitlin, 2005). Since, the system of CombiQ is well known by the researchers and interviewees, all the causes and effects could be observed and no unknown factors were detected. If the external validity is considered, it is one of the disadvantages of qualitative methods (Creswell, 2003). As it is mentioned before, generalization is not reliable in qualitative studies.

Concerning about the data collection methods, the interviews present different advantages and disadvantages towards validity and reliability. While conducting the interviews, the validity increases due to the fact that data can be checked for accuracy and relevance, as they are collected. But on the other hand, the impact of the interviewer and of the context means that consistency and objectivity are hard to achieve; therefore, reliability decreases. (Denscombe, 1998)

In order to reduce the drawbacks of reliability, such as affecting the interviewee response, the interviewers kept the same conditions for every interview, dressing properly, showing good manners, behaving neutrally, etc., so the consistency and objectivity of the data collection are coped in an unbiased way.

All the interviews were conducted in the conference room of the company, which was booked in advance, enhancing the working environment and making it suitable for the interviews. Additionally, all the interviews were conducted in English in order to have a common language in all the sessions, even though for some interviewees took more time looking for the proper way of expressing themselves.

As it was explained before, one of the researchers works in CombiQ, which enhances the validity of the project by considering that the dynamics of the system are well known. On the other hand, the other author compensates the bias caused by the previously mentioned researcher, because of being outside of the company. In other terms, the observations are perceived from different perspectives providing different insights about the system.
3 Theoretical background

In this chapter of the thesis, a comprehensive literature review regarding the research area is made. The relevant literature is studied under five main topics: Production System Design, ISO Certifications, Lean Thinking, Production Planning and Total Quality Management. These five main sections are classified into subdivisions in order to increase the understanding of the concepts.

3.1 Production System Design (PSD)

3.1.1 What is a Production System?

Due to the aim of the present thesis, it is really important to give a careful explanation about the production system. But before describing what a production system is, it is essential to understand the concept of system. Therefore, according to Bellgran and Säfsten (2010), a system can be defined as “a collection of different components, such as people and machines, which are interrelated in an organized way and work together towards a purposeful goal”.

From a simple point of view, a production system is any type of activity that produces something. However, it can be formally defined as a system that receives an input and transforms it into an output or product with an inherent value, as the black-box principle states. Thereby, production is considered as a transformation system, where goods and/or services are created through a combination of material, work, and capital. (Bellgran and Säfsten, 2010)

A clear example of a production system can be a pencil factory; where the input is the raw material like wood, graphite and painting. The transformation consists in all the processes like cutting the wood and adding the graphite. Finally, the output will be the finished product, a pencil. (Sipper and Bulfin, 1998)

While thinking of production systems, big manufacturing processes can be thought, but there are some other different systems, such as universities. Where the students are the input, knowledge acquisition is the transformation and the output is a person with education. Therefore, production systems can be divided into: manufacturing and service oriented. Mostly the inputs and outputs in manufacturing systems are tangible; while in service-oriented systems are intangible, like information (Sipper and Bulfin, 1998).

Considering the previous examples, it is relevant to clarify the terms of manufacturing system and production system, where the first one “consists of the arrangement and operation of machines, tools, material, people and information to produce a value-added physical, informational or service product whose success and cost is characterized by measurable parameters”. And the Production System consists of all of the elements and functions that support the manufacturing system. (Cochran, 1999)
It is important to understand the components of a production system and how these components interact with each other in order to develop and operate production systems successfully. (Bellgran and Säfsten, 2010)

3.1.2 Why a new Production System?

If the manufacturers are observed, there are several main reasons and their subreasons for the companies who are driven to change their systems. Many studies show that the companies are triggered to change because of the introduction of new products or product families, which cannot be produced with the existing systems. Another reason for change is the opportunity of improvements in the working environment, techniques and capacity. (Bellgran and Säfsten, 2010)

According to Bellgran and Johansson (1995), another aspect of having a new system is profitability. In other words, the rapidity of the changed system shortens the time to market while reducing the lead times and it increases the possibility to raise the revenue.

Another aspect of the change is increasing the overall quality of the system. If the system covers all the previously set requirements, the change phase would be shortened and the future adjustments would be minimized. On the other hand, the requirements and expectations of the system can be discussed. It is common that, the requirements can contradict and it is difficult to obtain the satisfaction and motivation of the employees. In this case the flexibility of the system plays a vital role. (Bellgran and Johansson, 1995)

In addition to the knowledge mentioned above, in change process, there are two distinct variables that are “degree of change” and “reason for change”. In parallel with the mentioned reasons above, degree of change can be a minor change or a major change. In a simple explanation and examples, a minor change can be improvement of an existing production system and a major change can be development of an entire new system. But, as a major change, a new production system does not necessitate extensive changes. Thus, it might be similar to the existing production system. If the minor changes are considered, there is no shift from basic fundamentals and paradigms of the existing system and cause and effects affecting the system performance. If major changes are considered, they are more radical, multi-level and there can be a shift from basic principles of the existing production system compared to minor changes. Generally, major changes are project based where minor changes are carried out as a part of everyday work. (Bellgran and Säfsten, 2010)
Based on the reasons for change, the change process can be structured as planned and un-planned. Planned changes are structured within the organization in order to make improvements. Un-planned changes are structured by outside of the organization in order to make adjustments according to requirements. Planned and un-planned changes can be supported by the organization theory. Planned changes can be considered as Internally initiated where the un-planned changes can be considered as Externally initiated. Additionally, external reasons are more driving or dominating, and they might be combined with internal ones. (Bellgran and Säfsten, 2010)

<table>
<thead>
<tr>
<th>Reason to change</th>
<th>Internally initiated</th>
<th>Externally Initiated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor Improvement</td>
<td>Development</td>
<td></td>
</tr>
<tr>
<td>Major Transformation</td>
<td>Revolution</td>
<td></td>
</tr>
</tbody>
</table>

Figure 2. Change Situation. (Bellgran and Säfsten, 2010)

3.1.3 Factors structuring the Production System

Since the main reasons for change and degrees of change are explained, it is good to mention about the main factors that structure production systems.

3.1.3.1 Competitive factors

Nowadays, customers’ demand concerns more than low costs. Additionally to low cost (best price); the customer demands good quality, adequate amounts and on-time delivery. In order to survive in the competitive environment, companies should handle increasing demand effectively and efficiently. According to the changes in the competition or the position of the company in the market, the competitive factors can be changed and developed over time. Also, the importance of each factor can be different in terms of the demand of the customer and competitors. (Ulrich and Eppinger, 2008)

According to Ulrich and Eppinger (2008), the most important competitive factors are explained below:

**Cost:** Requires the capability of producing and delivering with low costs.

**Quality:** Requires the capability of meeting demand and expectation of the customer. The product should be in the specifications, which match with what customers want from the product.

**Flexibility:** Requires the capability of adjusting the production according to necessary changes in a quick and efficient way. There are different kinds of flexibilities such as volume flexibility, product mix flexibility, etc.
Deliverability: Requires the capability of delivering in a fast and reliable way. Fast and reliable delivery can be explained by delivering according to the plan and in the right time interval. Apart from a proper production system, Customer order decoupling point plays a vital role in shortening the delivery lead times. Customer order decoupling point can be observed in Production Planning section.

3.1.3.2 Manufacturing strategy and its relation with Marketing and Corporate strategy

Continuously and rapidly changing business situations, market conditions and other dynamics and functions lead the companies to have different kinds of strategies in order to organize their activities in a structural level. (Hill, 2000)

Swamidass (2000) suggests that, the strategies in different levels might seem different and not related but they are integrated and contributes each other. In the table below, the strategies and key questions that define them can be observed.

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Key Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corporate Strategy</td>
<td>What set of business should the company be in?</td>
</tr>
<tr>
<td>Business/Market Strategy</td>
<td>How should the company compete in given business/market?</td>
</tr>
<tr>
<td>Manufacturing Strategy</td>
<td>How can the manufacturing function contribute to the competitive advantage of the business?</td>
</tr>
</tbody>
</table>

It is not enough for the companies to have sole strategies to reach the success. For the success companies should and must link the strategies each other and create interfaces between them. This requires a comprehensive study about the corporation, market and the manufacturing. For this to take place, there should be reliable and relevant information about the manufacturing capability according to the needs of the corporation supported by the traditional marketing information about the customers and opportunities. The list below explains the steps of how to link manufacturing to marketing with corporate strategy. (Hill, 2000)

1. Define corporate objectives
2. Define marketing strategies to meet these objectives
3. Assess how different products qualify in their respective markets and win orders against the competitors
4. Establish the appropriate process to manufacture these products (process choice)
5. Provide the manufacturing infrastructure to support production
Swamidass (2000) says that, manufacturing strategy focuses on how manufacturing strategy decisions are made and put into practice. It is defined by the competitive factors. Additionally, Hill (2000) indicates that the manufacturing strategy is structured by clarifying the priority between competitive factors as “order qualifying” and “order winning”. Order qualifiers satisfy the attributes of a product that are required in order to enter a market. Order winners distinguish and coming up with a product in specific areas or providing elements that are not available in the competition.

Manufacturing strategy defines the manufacturing priorities of the company concerns about the impact on the decisions of hard (structural) and soft (infrastructural) manufacturing issues. These issues are shown in the table below. (Swamidass, 2000)

**Table 3. Structural and infrastructural issues in manufacturing strategy (Swamidass, 2000)**

<table>
<thead>
<tr>
<th>Structural issues</th>
<th>Infrastructural issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capacity (amount, timing, subcontracting, etc.)</td>
<td>Organization (management structure, etc.)</td>
</tr>
<tr>
<td>Facilities (size, location, focus, etc.)</td>
<td>Quality policy (monitoring, intervention, assurance, etc.)</td>
</tr>
<tr>
<td>Process technology (equipment, automation, configuration, etc.)</td>
<td>Production control (decision rules, material control, etc.)</td>
</tr>
<tr>
<td>Vertical integration (make-or-buy, supplier policies, etc.)</td>
<td>Human resources (skills, wage, management style, etc.)</td>
</tr>
<tr>
<td>Vertical integration (make-or-buy, supplier policies, etc.)</td>
<td>New products (design for manufacture flexibility, etc.)</td>
</tr>
<tr>
<td>Performance management and reward (financial, nonfinancial systems, etc.)</td>
<td></td>
</tr>
</tbody>
</table>

3.1.3.3 Production system and its relations with competitive factors and manufacturing strategy

If the production system is wanted to contribute and satisfy the competitive priorities of the company, the system should answer the market necessities and expectations. (Hill, 2000)

For each specific manufacturing strategy, there should be a proper production system. It is also denoted that, if different manufacturing companies use different production systems, they could still fulfill similar market needs. In contrast, the same chosen production system can satisfy different kinds of market demands. Thus, it is not possible to organize the exact production system only according to the market demand. (Bellgran and Säfsten, 2010)
Swamidass (2000) states that; the manufacturing strategy is developed from corporate strategy and business strategy, which have a direct linkage to competitive factors. For a company, in order to survive in the market and obtain a satisfactory share, the production system should be arranged to guess and support the needed products with a good quality, low cost, on time delivery. As a strategic decision, developments and investments should be made to make the system undertake in the opportunity areas, which are defined and supported by the strategies.

### 3.1.4 Framework for Production System Design (PSD)

A proper research provides a solid structure in design, which later can be converted into models and methods to support design projects. Consequently, the development of these models and methods will guide the researchers to convert theory and knowledge into usable tools, in this particular case for small and medium enterprise applications. In other words, a design methodology provides a thorough understanding about the design process, which turns out to be extremely useful for the designers, and such steps are: (Bellgran and Säfsten, 2010)

1. Models of design and development processes
2. Methods and techniques to be used within these processes
3. A system of concept and corresponding terminology

There is a need for constructing a theoretical background of various characters that will make easier the communication referring different phases within a production system development. Considering that the development process requires a description of the different phases, the following topics of this project explain the phases and their respective terminology within the process chain facilitating the practitioner to get a better understanding.

Moreover, the methodology of the Production System Design (PSD) helps to translate strategic manufacturing objectives into design and implementation actions. Thus, a theoretical framework enables the decomposition of a production system design from a strategic level to the implementation level. Also, it is being used to design, deploy and communicate the objectives of “lean” production systems, which will be explained in Lean Thinking section. (Cochran, 1999)

In some occasions, the terms of design and development are treated as different phases within the production system process, thereby the importance to clarify this misconception. According to several authors, design is the initial phase of the development of a production system. Both terms are described below (Bellgran and Säfsten, 2010):

- **Design.** “The design of production systems involves problem definition, identification of the goals, and to put forward different alternative solutions (problem solving). After that the different suggested solutions should be evaluated, a solution should be selected and developed further to a detailed level (decision-making). The result is a description of the production system to (system solution).”
Development. “The development of a production system includes besides the design stage, the implementation of the solution, which involves building and industrialization of the production system. Thereby the concept development involves a large part of the life cycle of a production system than the conceptual design.”

As it is mentioned in the description of the design, a problem solving and decision making process are taken into action; where the design process is a form of solving the problems observed in the current situation of the company. In other words, design is a continuous process normally resulting in a decision concerning a PSD that follows specific requirements. (Bellgran and Säfsten, 2010)

It is clearly seen through the development of a production system that a lot of decisions are made, which is why this process might be considered as a complex form, especially while designing it. Thereby, it is important to choose the right decisions, which will provide high value to the customer and also to meet the company’s goal. Undoubtedly, there can be some conflicts between the values of the customer and producers, between several customers, or even between various producers while decisions are taken in production system design. Thus, lining up the interests is such a critical element in production system design and it is quite certain that tradeoffs will show up and will have to be coped. (Ballard et al., 2001)

The TFV (Task/Flow/Value) concept of production, adds to the general model of production the idea of flows of materials and information through networks of specialists, and the conception of production in terms of the generation of customer value. Where the desired goal within a production system is to maximize the value and minimize the waste. This goal is part of every company’s business strategy and once it is established, the decision of choosing the right products and customers is vital. Therefore, the producer must design, control and improve the production system in order to deliver such products to the customer with an added value. (Ballard et al., 2001)

3.1.5 Working with a structured process

The opportunity of working with a structured methodology eases the development of a production system; moreover, it guarantees an outcome with good quality and facilitates the coordination and management of the project. According Bellgran and Säfsten (2010), Figure 3 gives a solid structure in order to achieve a successful development of a production system. This process can be classified in three general stages: Plan, Design and Evaluate, and Implement.

As it is stated in the delimitations of this thesis, the focus is within the Design and Evaluate stage. However, a brief overview is provided for the Plan and Implement stages in order to increase the understanding of the Production System Development Process. All these stages are explained by Bellgran and Säfsten (2010) in the following order:
Plan

This stage regards to the Management and Control of the Structured Methodology, where the first decisions are made while preparing the investment request for the project and structures the planning of system development. Some of these decisions are taken when the company has to choose between a daily operation and a long-term development process, also between a product development and a production development; which is linked to the product life cycle or production system. Furthermore, a team has to be gathered with internal and external personnel, assign a project manager and discuss about how the information will flow within the departments. In addition, this team should have creativity and analytic abilities in order to prepare the request for investment and plan the realization of the project.

Design and Evaluate

This stage consists of two main concepts of design:

- **Preparatory Design**: a proper research must be done in order to achieve a good production system. This research provides valuable knowledge that can contribute to improvements of existing production systems or other side processes inside the company. The prerequisites should be thoroughly analyzed, so rapid conclusions and decisions can be avoided; hence, background analysis aims to look backwards and inwards in order to bring obtained experiences into the coming production system. On the other hand, as a complement to the background study, the pre-study aims to look ahead and outwards so the goals and strategies of the company can be fulfilled. By analyzing external developments and market potential, the company is able to identify interested parties’ demands and management’s targets. Thereafter, the pre-study clarifies the system factors and how to carry them out through decisions within the internal/external production processes.

- **Design Specification**: The design of conceptual production systems concerns the selection of methods, tools and strategies in order to establish processes, operations, layout, technological level, material supply, work organization and work environment. All these factors reduce the complexity by providing more solutions and increasing the communication and support. After that design, different alternatives are evaluated in order to determine which ones best fulfill the demand requirements. Finally, the team members proceed with the chosen solution and formulate a detailed design, that offers a designed work place and work tasks according to the chosen system solution.
Figure 3. Production System Development Process. (Bellgran and Säfsten, 2002)
Implement

After the system solution is achieved, the next steps are to decide what to manufacture or buy, evaluate suppliers, purchase equipment, install and verify it. This is part of the Realization and Planning of the production system, just before starting up the physical production system. Beforehand, a model should be selected which aims to prepare the organization and plan the training of the personnel. Once the physical production system is delivered, the company should be able to carry out the start-up and evaluate the results of the production system and development process. Finally, a constructive feedback can be given to the process owner after reviewing the operation of the system.

In the beginning of this chapter, the difference of production system and manufacturing are explained, consequently an obvious connection between production system design and manufacturing system design (MSD) is noted, where the first one includes the design of the performance measurement system and supporting elements of the manufacturing system. The production system defines the measurable parameters that the manufacturing system must achieve. Production system design, therefore, must consider the methodologies that are needed to cost-justify new equipment. Concluding that, the PSD encompasses and includes the MSD and predicates overall design effectiveness. (Cochran, 1999)

3.2 ISO Certification

3.2.1 Characteristics of SMEs

It is important to indicate the characteristics of SMEs in order to make an analysis about the relationship between the ISO requirements and application conditions with an SME perspective.

In brief the main characteristics of SMEs are shown below. (Lamprecht, 1996)

- Management accumulates roles in the development processes and inevitably have to assume administrative roles
- Limited and few financial resources
- High turnover of collaborators
- Accumulation of responsibilities and roles
- Sources of experts and capability
- Increasing customer requirements for quality products that are delivered on time and within the specified budget
- The existence of products developed internally with commercial potential

More detailed information about the characteristics of SMEs and the comparison with the large organizations can be observed in the following table.
Table 4. Comparison between characteristics of large organizations and SMEs (Ghobadian and Gallear, 1996)

<table>
<thead>
<tr>
<th>Category</th>
<th>Large organizations</th>
<th>SMEs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management</td>
<td>Hierarchical with several layers of management</td>
<td>Flat with very few layers of management</td>
</tr>
<tr>
<td></td>
<td>Mostly bureaucratic</td>
<td>Mostly organic</td>
</tr>
<tr>
<td></td>
<td>Extended decision-making chain</td>
<td>Short decision-making chain</td>
</tr>
<tr>
<td></td>
<td>Top management a long distance away from the point of delivery</td>
<td>Top management close to the point of delivery</td>
</tr>
<tr>
<td></td>
<td>Top management’s visibility limited</td>
<td>Top management highly visible</td>
</tr>
<tr>
<td></td>
<td>Dominated by professionals and technocrats</td>
<td>Dominated by pioneers and entrepreneurs</td>
</tr>
<tr>
<td></td>
<td>Range of management styles: directive; participative; paternal; etc.</td>
<td>Range of management styles: directive; paternal; etc.</td>
</tr>
<tr>
<td>Operational</td>
<td>Individuals normally cannot see the results of their endeavors</td>
<td>Individuals normally can see the results of their endeavors</td>
</tr>
<tr>
<td></td>
<td>Low incidence of innovativeness</td>
<td>High incidence of innovativeness</td>
</tr>
<tr>
<td></td>
<td>Clear and extensive functional division of activities. High degree of specialization</td>
<td>Division of activities limited and unclear. Low degree of specialization</td>
</tr>
<tr>
<td></td>
<td>Activities and operations governed by formal rules and procedures.</td>
<td>Activities and operations not governed by formal rules and procedures</td>
</tr>
<tr>
<td></td>
<td>High degree of standardization and formalization</td>
<td>Low degree of standardization and formalization</td>
</tr>
<tr>
<td></td>
<td>Wide span of activities</td>
<td>Narrow span of activities</td>
</tr>
<tr>
<td></td>
<td>Formal evaluation, control and reporting procedures</td>
<td>Informal evaluation, control and reporting procedures</td>
</tr>
<tr>
<td></td>
<td>Control oriented</td>
<td>Result oriented</td>
</tr>
<tr>
<td></td>
<td>Slow response to environmental changes</td>
<td>Rapid response to environmental changes</td>
</tr>
<tr>
<td></td>
<td>High degree of resistance to change</td>
<td>Negligible resistance to change</td>
</tr>
<tr>
<td></td>
<td>Training and staff development is more likely to be planned and large scale</td>
<td>Training and staff development is more likely to be ad hoc and small scale</td>
</tr>
<tr>
<td>Organizational</td>
<td>High incidence of unionization</td>
<td>Low incidence of unionization</td>
</tr>
<tr>
<td></td>
<td>Potentially many internal change catalysts</td>
<td>Very few internal change catalysts</td>
</tr>
<tr>
<td></td>
<td>Multi-sited and possibly multinational</td>
<td>Single-sited</td>
</tr>
<tr>
<td></td>
<td>Cultural diversity</td>
<td>Unified culture</td>
</tr>
<tr>
<td></td>
<td>System dominated</td>
<td>People dominated</td>
</tr>
<tr>
<td></td>
<td>Rigid organization and flows</td>
<td>Flexible organization and flows</td>
</tr>
<tr>
<td></td>
<td>Many departments</td>
<td>Few departments</td>
</tr>
</tbody>
</table>

Talat Pekmezci 23  Raul Padilla
3.2.2 What are ISO 9000 Standards?

The ISO 9000 series is recognized and accepted all over the world. It is a set of standards, which clarifies the requirements for quality systems or in other words Quality Management Systems (QMS) (ISO 9001, ISO 9002, ISO 9003). There are also other types of standards that provide directions to accomplish the interpretation and implementation of the quality system (ISO 9000-2, ISO 9004-1). (International Organization for Standardization, 1996)

According to International Organization for Standardization (1996), the definitions of ISO 9001, ISO 2002 and ISO 9003 can be observed below.

- ISO 9001 contains requirements to be satisfied where a business is operating in design and development, production, installation and servicing.
- ISO 9002 contains the equivalent requirements with ISO 9001 where a business does not carry out design and development.
- ISO 9003 is another equivalent model with ISO 9001 where process control, design control, purchasing or servicing are not required. In ISO 9003 final products and services are checked if they meet the specified requirements by inspection and testing.

The differences between the standards do not make one standard higher or superior than the other one. The set of standards should be examined through the company according to their operations and the best option should be chosen. (Lamprecht, 1996)

3.2.3 ISO 9001 Certification

International Organization for Standardization (1996) explains ISO 9001 as “Model for quality assurance in Design/Development, Production, Installation and Servicing” as it is mentioned above.

ISO 9001 certification provides the companies, which are certificated, the information needed to prove to the customer that the quality system is satisfactory, sufficient and appropriate while indicating that the products meet all the design parameters. (Ferguson, 1996)

All over the world, ISO 9001 is recognized and it is a certainty that the buyers use it as a device for monitoring the potential suppliers. The reason for that can be understood if the Quality Assurance Requirements for certification is observed. Quality Assurance Requirements for ISO 9001 include nearly 150 specific requirements in 20 different categories. Those categories are presented in the table below. (Lamprecht, 1996)
In the Appendix 9.2, categories and requirements of ISO 9001 are shown in a more detailed way.

**Table 5. Quality system elements and requirements of ISO 9001 (Lamprecht, 1996)**

<table>
<thead>
<tr>
<th>Category title</th>
<th>Corresponding paragraph in ISO 9001:1994</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management responsibility</td>
<td>4.1</td>
</tr>
<tr>
<td>Quality system</td>
<td>4.2</td>
</tr>
<tr>
<td>Contract review</td>
<td>4.3</td>
</tr>
<tr>
<td>Design Control</td>
<td>4.4</td>
</tr>
<tr>
<td>Document and data control</td>
<td>4.5</td>
</tr>
<tr>
<td>Purchasing</td>
<td>4.6</td>
</tr>
<tr>
<td>Control of customer –supplied product</td>
<td>4.7</td>
</tr>
<tr>
<td>Product identification and traceability</td>
<td>4.8</td>
</tr>
<tr>
<td>Process control</td>
<td>4.9</td>
</tr>
<tr>
<td>Inspection and testing</td>
<td>4.10</td>
</tr>
<tr>
<td>Inspection, measuring and test equipment</td>
<td>4.11</td>
</tr>
<tr>
<td>Inspection and test status</td>
<td>4.12</td>
</tr>
<tr>
<td>Control of nonconforming product</td>
<td>4.13</td>
</tr>
<tr>
<td>Corrective action and preventive action</td>
<td>4.14</td>
</tr>
<tr>
<td>Handling, storage, packaging and delivery</td>
<td>4.15</td>
</tr>
<tr>
<td>Control of quality records</td>
<td>4.16</td>
</tr>
<tr>
<td>Internal audits</td>
<td>4.17</td>
</tr>
<tr>
<td>Training</td>
<td>4.18</td>
</tr>
<tr>
<td>Servicing</td>
<td>4.19</td>
</tr>
<tr>
<td>Statistical techniques</td>
<td>4.20</td>
</tr>
</tbody>
</table>

ISO 9001 has different versions. Each version helps the companies that design their own products and services to achieve desired quality. By time, the versions are upgraded according to the changes in the market and management techniques. The Quality Management is one of the core focuses of ISO 9000 standards. In ISO 9001:2000, 20 category title of ISO 9001:1994 are transformed into 8 main quality management principles and 5 main management requirements which can be observed in the following table. (Zeng *et al.*, 2005)


<table>
<thead>
<tr>
<th>Quality management principles</th>
<th>Management requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customer focus</td>
<td>Quality management system (QMS)</td>
</tr>
<tr>
<td>Leadership</td>
<td>Management responsibility</td>
</tr>
<tr>
<td>Involvement of people</td>
<td>Resources management</td>
</tr>
</tbody>
</table>
The benefits of implementing ISO 9001 can be observed in many categories. These categories can be the type of ISO 9001 such as ISO 9001:1994 or ISO 9001:2000. Another category can be internal benefits and external benefits of the implementation of ISO 9001 standards. These internal and external benefits can be sub-classified in different categories in which the results are required to be observed. (Sampaio et al., 2009)

According to Psomas and Fotopoulos (2009), ISO 9001 improves the performance of SMEs. There are many benefits for SMEs in different categories. However, cost reduction aspect of ISO 9001 implementation is not included in many researches. It is also indicated that the benefits are more internally than externally.

Sampaio et al. (2009) identifies the benefits of ISO 9001 standards as in the table below.

<table>
<thead>
<tr>
<th>External benefits</th>
<th>Internal benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access to new markets</td>
<td>Productivity improvements</td>
</tr>
<tr>
<td>Corporate image improvement</td>
<td>Product defect rate decreases</td>
</tr>
<tr>
<td>Market share improvement</td>
<td>Quality awareness improvements</td>
</tr>
<tr>
<td>ISO 9001 certification as a marketing tool</td>
<td>Definitions of personnel responsibilities and obligations</td>
</tr>
<tr>
<td>Customer relationship improvements</td>
<td>Delivery times improvements</td>
</tr>
<tr>
<td>Customer satisfaction</td>
<td>Internal organization improvements</td>
</tr>
<tr>
<td>Customer communication improvements</td>
<td>Nonconformities decreases</td>
</tr>
<tr>
<td></td>
<td>Customers’ complaints decreases</td>
</tr>
<tr>
<td></td>
<td>Internal communication improvements</td>
</tr>
<tr>
<td></td>
<td>Product quality improvement</td>
</tr>
<tr>
<td></td>
<td>Competitive advantage improvement</td>
</tr>
<tr>
<td></td>
<td>Personnel motivation</td>
</tr>
</tbody>
</table>

Casadesus and Karapetrovic (2005), categorize the benefits of ISO 9001 implementation in a more detailed way, which are demonstrated in the table below.
Table 8. Different kinds of benefits of ISO 9001 implementation (Casadesus and Karapetrovic, 2005)

<table>
<thead>
<tr>
<th>Operational benefits</th>
<th>Financial benefits</th>
<th>Customer benefits</th>
<th>Worker benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improving supplier relationships</td>
<td>Increasing sales</td>
<td>Customer loyalty/Repeated purchases</td>
<td>Health and security at work</td>
</tr>
<tr>
<td>Decreasing logistics costs</td>
<td>Return of investment</td>
<td>Customer satisfaction</td>
<td>Team participation</td>
</tr>
<tr>
<td>Increasing inventory turnover</td>
<td>Market share</td>
<td>Decrease in the customer complaints</td>
<td>Work satisfaction</td>
</tr>
<tr>
<td>Decreasing nonconformities</td>
<td>Sales per employee</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meeting delivery date</td>
<td>decreasing lead time</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3.2.4 Quality Management Systems (QMS)

A Quality Management System is a group of documents that identify the organizational processes and clearly define the areas of responsibility. In a holistic point of view, it generates a common language and a common picture for the whole organization. Basically, QMS has two main purposes. Firstly, if someone in the organization is required to undertake a task that is not a day-to-day or a regular task, the documents provide a support and a guideline in order to perform the task. Secondly, the documents are used when there is a want or need to review specific processes and procedures due to the problems or improvement of the work. (Pokinska et al., 2006)

The basic requirements of QMS are defined by ISO 9001. As it is mentioned before the main purposes of the standard are making the company to be able to meet the customer requirements and regulatory requirements and also improve customer satisfaction.

The standard has key requirements on QMS, management responsibility, resource management, product realization, measurement analysis and improvement. As it can be seen from the requirements, QMS is one of the core factors in ISO 9001 certification. (Sousa-Poza et al., 2009)

QMS contains wide spectrum of concepts and methods. In order to provide support to the necessities of ISO 9001 standard, QMS identifies some principles for quality management. (Lee, 1998). According to Lee (1998), these principles are:

- Customer focus
- Leadership
- People involvement
- Process approach
- Systematic management approach
- Continuous improvement
- Information-based decisions
- Mutual benefits in the relationships with suppliers
There are several challenges for SMEs in terms of QMS. SMEs might encounter some problems because of lack of financial and human resources, inadequate technical knowledge of quality management, a lack of knowledge in formalized systems, not having enough experience and knowledge in internal auditing. Another main problem that SMEs may face is a focus on core business activities such as production, sales, customer service by managers and employees. However, besides that focus, there must be enough knowledge about quality system management requirements and on how to improve processes. (Sousa-Poza et al., 2009)

In order to develop and implement an effective QMS while considering the challenges, the main principles of quality management should be integrated and this process has several stages as it is stated by Lee (1998). These stages can be listed as the following.

- Determination of necessities and expectations of the customers and all stakeholders
- Definition and establishment of quality policies and objectives of the organization
- Determination of the processes and responsibilities necessary to achieve the quality aims
- Determination of the supply of resources necessary to achieve the quality aims
- Definition and establishment of methods to verify the efficiency and effectiveness of each process
- Application of those methods to verify the efficiency and effectiveness of each process
- Determination of the methods to prevent non-conformities and eliminating their reasons
- Establishment and application of improvement processes for the QMS

In order to accomplish the certification of the QMS based on the ISO 9001 model, the organizations should consider the following steps according to the stages listed above. (Lee, 1998)

- To know and display the system capacity focused on the customer requirements
- To plan and document all the activities which affect the overall quality
- To identify and assign staff with competencies to relevant tasks with their competencies
- To choose and make available the human and material resources necessary to sustain the QMS
- To prevent non-conformities and handle them when they occur
- To determine the critical processes in order to attain customer satisfaction
- To maintain a continuous program of evaluation of the performance of the system
According to Psomas and Fotopoulos (2009), QMS required for the ISO certification is in parallel with Total Quality Management (TQM). It is also stated that ISO 9001 structures a basis for total quality management or it is complementary for total quality management depending on the situation. Their study shows that, companies that want to be certified for ISO 9001 or maintain their certification can stay at the basic levels of total quality management. On the other hand, if a company aims to go beyond ISO 9001 should reach a comprehensive total quality management level and increase all TQM aspects in order to be more and more competitive.

Detailed information about total quality management and its relation with ISO 9001 set of standards can be observed in one of the following titles which is named as Total Quality Management (TQM).

### 3.2.5 ISO 14001 Certification

ISO 14001 stands for Environmental Management System (EMS), which is also developed by International Organization for Standardization, like ISO 9001 set of standards. Basically, ISO 14001 standards require an enterprise to identify general environmental objectives and targets and develop an environmental policy. (Jiang and Bansal, 2003)

Rondinelli and Vastag (2000) explain that ISO 14001 provides a very comprehensive format in order to develop an environmental policy, determine environmental aspects, define environmental targets, implement a program to achieve company’s goals, monitor and measure effectiveness, correct non-conformities and problem and review management systems in order to support continuous improvements.

**Table 9. Environmental system elements and requirements of ISO 14001 (Wilkinson and Dale, 2002)**

<table>
<thead>
<tr>
<th>Category title</th>
<th>Corresponding paragraph in ISO 14001: 1996</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Requirements</td>
<td>4.1</td>
</tr>
<tr>
<td>Environmental Policy</td>
<td>4.2</td>
</tr>
<tr>
<td>Planning</td>
<td>4.3</td>
</tr>
<tr>
<td>Implementation and Operation</td>
<td>4.4</td>
</tr>
<tr>
<td>Checking and corrective action</td>
<td>4.5</td>
</tr>
<tr>
<td>Management review</td>
<td>4.6</td>
</tr>
</tbody>
</table>

In the Appendix 9.3, a more detailed information about ISO 14001 requirements can be observed.

In parallel with the content of the table above, the main requirements of ISO 14001 and environmental management system can be listed as the following: (Wilkinson and Dale, 2002)

- With the commitment of the senior management, development and adaptation of an environmental policy
- A process of planning activities which identify and classify all the environmental aspects of the facility’s operations, legal and any kind of require-
ments, objectives and targets for environmental improvements, set of environmental management programs

- An implementation and operations system which contains a clearly defined structure for responsibility of environmental management, programs of training, employee empowerment in the whole facility, internal and external communication of the EMS, environmental management documentation system, documentation control systems, methods for operational control of environmental effects and urgent situation attentiveness and quick response

- Creating a control and corrective action system which ensures and consists of measurement and monitoring, non-conformities reporting, behaving corrective and preventing

- Management review which evaluates the properness and effectiveness of the environmental management system which assists continuous improvements

According to Rondinelli and Vastag (2000), if an enterprise elicits the requirements that are mentioned above, there are several advantages and benefits. These benefits are:

- ISO 14001 assists the corporations to harmonize and ease their environmental management with a robust framework in terms of local, national and international regulations

- Being certified by ISO 14001 helps the companies to prove the quality of their environmental management system to all stakeholders in the system, shareholders, governmental and civil regulatory agencies, insurance companies and financial institutions which may question the company’s commitment to the environmental performance and reducing risks

- ISO 14001 certification facilitates the enterprises to reduce their danger level for the environment, increase the efficiency by reducing the waste from all the operations while creating an environmental awareness among the employees and establishing strong image of social responsibility

- ISO 14001 ensures the national and international competitiveness by increasing the investor confidence in the company

- The enterprise maintains cost reduction in energy, materials, fines and penalties

- The organization affects the competitors, suppliers, customers, and vendors with environmental responsibility. Their attention can be attracted on the negative environmental impacts

3.2.6 Implementation of ISO 9001 or ISO 14001 Certification (General framework for any kind of ISO standards)

The given implementation framework can fit almost all different kinds of ISO certifications. The general steps guide the companies and help them to behave and act in a structured way. In this phase being determined, organized and patient is
essential because of dealing with 150 different kinds of requirements in 20 different categories. (International Organization for Standardization, 1996)

Ferguson (1996), examines the ISO standards implementation framework as the following:

Table 10. ISO certification implementation framework (Ferguson, 1996)

<table>
<thead>
<tr>
<th>Step 1. Decide to proceed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 2. Assess current position</td>
</tr>
<tr>
<td>Step 3. Determine shortfalls</td>
</tr>
<tr>
<td>Step 4. Develop an implementation plan</td>
</tr>
<tr>
<td>Step 5. Perform the documentation process</td>
</tr>
<tr>
<td>Step 6. Manage transitional activities</td>
</tr>
<tr>
<td>Step 7. Validate the compliance to ISO</td>
</tr>
<tr>
<td>Step 8. Pass the registration audit</td>
</tr>
</tbody>
</table>

*Step 1. Decide to proceed*

In this step, the company should determine whether or not they are ready to progress on the process of ISO implementation. The implementation action should be considered and planned in a holistic point of view before deciding on to use the ISO 9000 quality system standards. In other words, the company should calculate if the implementation is important enough to spare necessary time, money and effort.

*Step 2. Assess current position*

In this step, the company should decide which ISO directive set of standards is the most appropriate for the objectives and processes of the company. Then, the chosen standard should be examined in a detailed way and the operations and functional areas should be adjusted in parallel to the requirements of the chosen standard. The analysis of the current situation and current quality system should be made in order to prepare shortfall or gap analysis for the next step.

*Step 3. Determine shortfalls*

In this step, the company should keep on analyzing the current quality system and situation. The determination of the gaps or shortfalls between what is indicated in the ISO certification requirements and the company performance should be made. This comparison is called shortfall analysis or gap analysis. The results should be accurate because discovered shortfalls would be the basis of the detailed implementation plan.
After choosing which set of standards fits the company’s business, processes and objectives, the next step is to examination of the desired standards. All the requirements of the standards should be observed under the current circumstances and the company should not ignore or exclude any applicable requirements. The companies cannot reject a requirement of any standard as irrelevant just because they do not want to do it. Previous experiences with the requirement are not important in this case. Just because the company has not worked with the requirement or has failed while implementing it, does not mean that it is not applicable in the served business. Thus, questioning a requirement and trying to understand it plays a vital role at the implementation phase. The following list indicates the basic questions to increase the perception and understanding of a requirement: (International Organization for Standardization, 1996)

- What is the idea or principle behind this requirement?
- What kind of problem could be prevented by meeting this requirement?
- Why would meeting the requirement give confidence to the customer?

**Step 4. Develop an implementation plan**

In this step, a plan for implementation of chosen set of standard should be built and scheduled. This implementation plan is grounding for maintaining and assuring a successful and productive ISO 9000 based quality system.

**Step 5. Perform the documentation process**

In this step, the company should develop all required documents to fulfill the chosen standard.

In order to do this action, help from International Organization for Standardization is provided. This help includes numbering and linking the documents, developing the own quality manual of the company, and all aspects of writing and controlling documentation. ISO standards require documentation in a simply stated in a ambiguous and understandable way. The documents should guarantee common understanding. (International Organization for Standardization, 1996)

**Step 6. Manage transitional activities**

It is a common belief that the biggest shortfall about ISO certification is in the area of documentation. But, there is usually equal or more effort is required in other ISO supportive areas. Transformation of the management style of the company to the new ISO environment, explicit training and practice on applying the new compliance and documentation methods, creation of the users’ responsibilities understanding in the new ISO environment and how to manage the transition from current system to the implementation of ISO system are included in these areas.

**Step 7. Validate the compliance to ISO**

In this step, the company should prepare an internal quality audit in order to understand if the company is ready for an inspection.
Additionally, this helps the company to fulfill the internal audit requirement of ISO certification, which is numbered as 4.17 in ISO 9001 requirements. The findings of the audit should be examined according to ISO requirements to find out the overall effectiveness of the implementation process.

**Step 8. Pass the registration audit**

In this step, the company experiences the registration audit. Choosing a registrar, the preparation for the auditors, perform corrective actions and stabilize the changed system after passing the audit are included should be done.

### 3.2.7 Integration of ISO 9001 (QMS) and ISO 14001 (EMS)

When the business environment is observed, there is a trend towards combined, complex and complete management systems, which leads the competitiveness in both local and global economy. It is required that related systems should be connected and integrated together in order to reach different objectives with relatively reduced costs. If a company wills to improve both quality and environmental performance, integration of ISO 9001 and ISO 14001 (Integrated Management Systems) is a good idea. (Karapetrovic and Willborn, 1998)

Wilkinson and Dale (2002) suggest that ISO 9001 and ISO 14001 have similar requirements that they can be integrated in order to improve the performance. The three common components (Management responsibility, Process management, Support systems) of both of the certifications can be handled together to reduce the workload and duplication of the tasks that ease the integration process. These similarities can be used for merging the documentation and implementation process should be undertaken with Total Quality Management approach approaches such as total involvement, teamwork, education and training, commitment and leadership.

The following table contains a general information and comparison between ISO 9001 and 14001. (Karapetrovic and Willborn, 1998)

<table>
<thead>
<tr>
<th></th>
<th>ISO 9001</th>
<th>ISO 14001</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>Effective documentation of the quality system elements.</td>
<td>Assist organizations to achieve environmental performance by managing and evaluating environmental aspects of operations</td>
</tr>
<tr>
<td><strong>Emphasis</strong></td>
<td>Validate supplier ability and capability to perform according to QMS requirements</td>
<td>Establish EMS to establish environmental protection and sustainable development</td>
</tr>
<tr>
<td><strong>Applicability</strong></td>
<td>Applicable to all kinds of organizations</td>
<td></td>
</tr>
<tr>
<td><strong>Participants</strong></td>
<td>Organizations that wish to develop their quality systems</td>
<td></td>
</tr>
<tr>
<td><strong>Evaluation</strong></td>
<td>Specification for design, development, production, installation and servicing by 20 principle clauses (See Table 5)</td>
<td>Does not state specific environmental performance criteria, but 5 basic elements are required (See Table 9)</td>
</tr>
</tbody>
</table>
After clearing the understanding of the general concepts about the standards, more detailed information can be observed in the following table. (Wilkinson and Dale, 2002)

| Orientation | Process, management and administration. Heavy on quality assurance initiatives and conformity of clauses | Process, management and administration. Heavy on continuous improvements and compliance with legislation |

Table 12. Micro level comparison between ISO 9001 and 14001 (Wilkinson and Dale, 2002)

<table>
<thead>
<tr>
<th>Aspect/Application</th>
<th>Extent of Application</th>
<th>ISO 9001</th>
<th>ISO 14001</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical boundary</strong></td>
<td>Activities involved in meeting customer and regulatory requirements</td>
<td>Organization or site</td>
<td></td>
</tr>
<tr>
<td><strong>Principle activities</strong></td>
<td>Planning, implementing, controlling, improving, monitoring, measuring and auditing, design and development</td>
<td>Planning, implementing, controlling, improving, monitoring, measuring and auditing</td>
<td></td>
</tr>
<tr>
<td><strong>Needs addressed</strong></td>
<td>Customer and regulatory requirements</td>
<td>Legal requirements</td>
<td></td>
</tr>
<tr>
<td><strong>Commitment and responsibility</strong></td>
<td>Top management</td>
<td>Top management</td>
<td></td>
</tr>
<tr>
<td><strong>Involvement in continuous improvements</strong></td>
<td>Those involved in the provision of products and services that meet customer requirements</td>
<td>Everyone who the organization can control and influence</td>
<td></td>
</tr>
<tr>
<td><strong>Consultation in setting of objectives</strong></td>
<td>Does not exist</td>
<td>Interested parties (including employees)</td>
<td></td>
</tr>
<tr>
<td><strong>Communication of policy</strong></td>
<td>All levels in the organization</td>
<td>All employees and public</td>
<td></td>
</tr>
<tr>
<td><strong>Awareness of the policy/procedures and their importance</strong></td>
<td>All levels in the organization</td>
<td>Employees at each relevant level and function</td>
<td></td>
</tr>
<tr>
<td><strong>Training provision</strong></td>
<td>All personnel perform activities affecting quality</td>
<td>All personnel whose work has a significant impact on the environment</td>
<td></td>
</tr>
<tr>
<td><strong>Provision of information</strong></td>
<td>Between levels and function in the organization, suppliers and customers</td>
<td>To and from employees and external interested parties</td>
<td></td>
</tr>
<tr>
<td><strong>Involvement in development &amp; review of policy and procedures</strong></td>
<td>Top management</td>
<td>Top management</td>
<td></td>
</tr>
<tr>
<td><strong>Provision of resources</strong></td>
<td>Resources to implement &amp; improve processes to address customer satisfaction including work place facilities and work environment</td>
<td>Resources essential for implementing &amp; controlling the system</td>
<td></td>
</tr>
<tr>
<td><strong>Internal audits</strong></td>
<td>Programmed, implemented including results of previous audits</td>
<td>Programmed, implemented, effective, reviewing previous audits</td>
<td></td>
</tr>
<tr>
<td><strong>Dealing with suppliers and subcontractors</strong></td>
<td>Control of goods and services. Information, verification of products. Identification and traceability. Evaluation of suppliers.</td>
<td>Identification of significant environmental aspects. Communication of requirements. Traceability of products and services</td>
<td></td>
</tr>
</tbody>
</table>
3.3 Lean Thinking

Conventional companies often get so involved in their internal organization that they lose sight of value and produce waste instead; therefore lean companies focus on value streams to eliminate non-value-adding activities. (Ward, 2007)

The concept of lean provides a way to make more and more with less and less – less human effort, less equipment, less time, and less space – while coming closer and closer to provide customers with exactly what they want. Thereby, lean can be seen and/or implemented in different cases, for example, when the progress of a design goes from concept to launch, or an order as information flows from initial request to delivered product, or the physical product as it progresses from raw material to the customer. (Womack and Jones, 2003)

3.3.1 Introducing Muda and Value

Muda is a “must word” that has to be learned and taken into consideration at any moment. This Japanese word stands for waste and can be seen in every single non-added value activity, such as: unneeded items piled up in inventory shelves, mistakes which require rectification, processing steps which are not actually needed, movement of employees and transport of goods from one place to another without any specific purpose, but mainly those activities that produce a good or service that do not meet the need of the customer. (Womack and Jones, 2003)

Muda is everywhere, but lean thinking is the antidote, which converts it into value by providing immediate feedback on efforts. (Womack and Jones, 2003)

The critical point for lean thinking is value, which is defined by the customers according to how their needs are met at a specific price and time. Activities are value-creating when they change any kind of material into products that customers pay for. (Ward, 2007; Womack and Jones, 2003)

According to Ward (2007), a basic value through the development of any project is the usable knowledge, which prevents defects, excites customers, and creates profitable operational value streams. This usable knowledge is created by three basic kinds of learning:

- Integration learning: learning about customers, suppliers, competitors, partners, etc. Helps to understand how integrated is the project’s design with the customers’ needs.
- Innovation learning: creates new possible solutions.
- Feasibility learning: enables better decisions among the possible new solutions, avoiding cost and quality problems.

Lean companies therefore generally spend larger fraction of their development effort creating knowledge and a smaller fraction creating hardware.
3.3.2 7 Wastes

The lean philosophy emphasizes in the elimination of all wastes within the production flow. Everything in the production that does not add any value to the customer is considered as waste and should be eliminated from the production, as it was mentioned in previously. According to Toyota’s Production System, there seven types of non-value-adding wastes: overproduction, waiting, transportation, overprocessing, excess inventory, unnecessary movement, and defects. However, Liker added and eight waste, unused employee creativity. (Bellgran and Säfsten, 2010; Liker, 2004)

1. **Overproduction.** When production is running without any specific order, which generates such wastes as overstaffing and storage and transportation costs because of the excess inventory, also when production runs faster or before than it is need becomes a dangerous practice (Ortiz, 2006). This waste is considered the most important since it causes most of the other wastes.

2. **Waiting (time on hand).** Operators that are just standing around waiting for the next processing step, tool, supply, part, etc, watching an automated machine, or having no workers because of stock-outs, lot processing delays, equipment downtime, and capacity bottleneck.

3. **Unnecessary transport or conveyance.** Moving materials, parts, or finished goods into or out of storage or between processes, carrying work in process (WIP) long distances, and creating inefficient transport.

4. **Overprocessing or incorrect processing.** Taking unneeded processes, incorrect processing due to poor tools and product design, causing unnecessary motion and producing defects.

5. **Excess inventory.** Excess raw material, WIP, or finished goods causing longer lead times, damaged goods, transportation and storage costs and delays.

6. **Unnecessary movement.** Looking for, reaching for, or stacking parts, tools, etc. Even walking is a wasted motion that employees perform during their work.

7. **Defects.** Production of defective parts or correction of them. Repair or rework, scrap, replacement production, and inspection mean wasteful handling, time and effort.

8. **Unused employee creativity.** Losing time, skills, ideas, improvements, and learning opportunities by not listening to employees.

According to Ward (2007), the most important wastes during the development of a lean process are wastes of knowledge. Taking into consideration that the difference between profitable and unprofitable operational value streams is how much usable knowledge is created and delivered by development. Therefore, the physical transformation (for example non-added value but necessary activities) is not the primary waste in development.
3.3.3 Lean Thinking Principles

According to Womack and Jones (2003), the first step in lean thinking is specifying \textit{value} accurately. Where value must be defined in terms of specific products with specific capabilities offered at specific prices through a dialogue with specific customers. As a second step, firms have to find the entire \textit{value stream} for such products or services. This value stream consists in all those activities that are needed to bring a specific product through the three main management tasks in any business:

\begin{table}[h]
\centering
\begin{tabular}{|l|p{8cm}|}
\hline
\textbf{Task} & \textbf{Description} \\
\hline
Problem Solving & From concept through detailed design and engineering to production launch \\
Information Management & From order-taking through detailed scheduling to delivery \\
Physical Transformation & From raw material to a finished product in hands of the customer \\
\hline
\end{tabular}
\caption{Value Stream in Management Tasks (Womack and Jones, 2003)}
\end{table}

Once the \textit{flow} of the value is running through every process within the company, the customer is able to \textit{pull} the value from each product or service that is provided by the enterprise. Finally, after these four principles (value, value stream, flow, and pull) comes the fifth one, addressed \textit{perfection}, in a sense that lean thinking will guide any lean enterprise to be perfect when all the activities are performed as stated by this way of thinking. (Womack and Jones, 2003)

3.3.4 Lean Manufacturing

One major reason for the success of Japanese companies in general, and Toyota in particular, is their ability to develop close relations and high involvement of suppliers in product development as well as in production. The Japanese companies have introduced new approaches to manufacturing, known as lean production system, which uses a smaller number of suppliers, who are participating in early product development phases and who have responsibility for manufacturing of complete sub-systems or larger modules. (Womack \textit{et al.}, 1990)

As Feld (2001) denoted in his book, lean manufacturing is constructed by five key elements that are interconnected and depended to each other. Each of them contains a set of lean principles that when they are working together, all contribute to the development of a first-class manufacturing environment. These five key elements are explained below:

- Organization: the aspect focusing on identification of people’s roles and responsibilities, training in new ways of working (workforce preparation), product-focused responsibility, leadership development, and communication planning.
Metrics: the aspect addressing visible outcomes (which is where improvements come from) using models as DuPont Model; process-driven measures (infinite continuous improvement), results-based performance measures, KPIs\(^2\); targeted improvement (goal alignment through policy deployment); and team rewards/recognition. It focuses on changing behavior and ensures alignment between cell-level shop floor activity and higher-level company business objectives. This connection is necessary for lean manufacturing improvements to appear on the bottom line.

Logistics: the aspect that provides definition for operating rules and mechanisms for planning and controlling the flow of material. This flow can be interpreted within the aspects below:

- In-bound. Improves the processes in which materials, purchased parts, tooling, engineering data (drawings) are provided to the cell.
- Internal. Improves the material flow of components to, through, and onto next cell. Includes cell leader, production engineers, operators and other physical elements as materials, tools, Kanban\(^3\), etc.
- Out-bound. Improves the customer/supplier relationships between the cell and its customer base. Considers negotiated delivery quantity of products, transportation, information, etc.

Manufacturing Flow: the aspect that addresses physical changes and design standards (layouts) that are deployed as part of the cell. Uses the following techniques:

- Product/quantity analysis
- Process mapping (i.e. spaghetti diagram)
- Routing analysis (process, work content, volume matrices)
- Takt Time
- Workload balancing and one-piece flow (comparing Takt Time to machine time, labor time, and setup time)
- Cell design guidelines (5S Technique can be applied)
- Cell layout
- Kanban sizing

Process Control: the aspect directed at monitoring, controlling, stabilizing, and pursuing ways to improve the process. Employs the following activities/methods:

- Single-minute exchange of dies (SMED)

\(^2\) KPIs: Key performance indicator (KPI) is a value which is used for comparison against either an internal or external target “benchmarking” in order to get an indication of performance (Ahmad and Dharf, 2002)

\(^3\) Kanban: An authorization begins to work when a demand signal from the customer detected. It controls the level of work in process and lead-time for products. It facilitates immediate feedback on abnormalities. (Feld, 2001)
Each element focuses on a particular area of emphasis and sorts out the activities; however, the power comes from their integration.

Besides the knowledge that comes with the books, there are some true competitive advantages that come from promoting capabilities within the workforce; which can be only accomplished as Feld (2001) pointed out as:

- Achieving demonstrated knowledge transfer by building an empowered workforce
- Engaging all employees within the business by steering their collective energies in the same direction
- Empowering the workforce with clarified expectations, common purpose, and accountability to get the job done

In order to start creating a lean manufacturing environment is important to recognize where the company currently is by understanding the need of change and all the side considerations that it might bring with. Therefore, a prior assessment should be done to the company, which will provide feedback regarding to current capabilities and reveal the areas that are considered to be lean practices. (Feld, 2001)

Once the assessment is conducted, the next step is to gather a team to design, develop, and deploy the lean manufacturing program. The selection of these team members has to be really picky in a sense of choosing the most appropriate people for this task. Where they must be full-time committed with it, plus good communication skills and other characteristics such as: open minded, effective communicator, results oriented, self-confident, group facilitator, trusted judgment and influential within the organization. (Bellgran and Säfsten, 2010; Feld, 2001)

In addition to the internal search for opportunity, the outline of a manufacturing strategy, as it is explained in the previous sections, is developed in order to assure alignment of the lean initiatives with the marketplace and to provide insight for the appropriate design criteria. Therefore, this strategy will identify which products compete in what markets and why. Moreover, it will determine where the team needs to leverage the change program to gain alignment with the current and desired customer base. (Feld, 2001)
This manufacturing strategy logic follows the goal proposed by Womack and Jones (2003), which state that a firm might adopt the goals of converting the entire organization to continuous flow with all internal order management by means of a pull system. The projects required to do this might consist of:

- Reorganizing around product families, with product teams taking many of the jobs of the traditional functions
- Creating a lean function to assemble the expertise to assist the product teams in the conversion
- Start a systematic set of improvement activities to convert batches and rework into continuous flow

As mentioned before, to be a lean manufacturer requires a way of thinking that focuses on making the product flow through value-adding processes without interruption (one-piece flow), a “pull” system that cascades back from customer demand by replenishing only what the next operation takes away at short intervals, and a culture in which everyone is striving continuously to improve. (Womack et al., 1990)

### 3.3.5 5S Technique

As Pheng (2001) mentions in his paper, the original concept of 5S was developed by Takashi Osada in the early 1980s, although 50 years ago Taiichi Ohno identified them while developing the Toyota Production System (2006). He coined the concept as the five principles to a total quality environment. The Japanese consider that the practice of the 5S principles is not only useful for the workplace but also helps them personally by improving their thinking process. Once the 5S have been implemented at home, experience is gained and each one becomes aware of the usefulness of the 5S; therefore, everybody can start implementing it at his or her workplace (or vice versa). The logic behind the 5S principles at the workplace is that these principles are the basic requirements for high efficiency in producing better quality products and services with little or no waste. These five principles according to the Toyota Way are (Liker, 2004):

1. **Seiri (sort / organization):** regards the separation of the things that are necessary from those that are not, and keeping the number of unnecessary ones as low as possible and at a convenient location.
2. **Seiton (straighten / orderliness):** give a place to everything and everything in its place, which will improve efficiency at work. It is a question of how quickly one can get the things needed and how quickly one can put these things away. (i.e. label every shelf or container)
3. **Seiso (shine / cleanliness):** the cleaning process often acts as a way of inspection that shows unusual and pre-failure conditions that could decrease quality or cause machine failure; which thereby should be the concern of everyone in the organization.
4. **Seketsu** (standardize / create rules): develop systems and procedures that continually and repeatedly maintain and monitor one’s organization, its order and cleanliness (first three S’s).

5. **Shitsuke** (sustain / self-discipline): induce the ability to do things the way they are supposed to be done. The emphasis here is on creating a workplace with good habits as an ongoing process of continuous improvement.

The five S’s together create a continuous process for improving the work environment. Start by sorting out what is in the office or workshop to separate what is daily needed to perform value-added activities from what is rarely or never used. Mark those rarely used items (tools, papers, parts…) with red tags and move them outside of the working area. Then create locations for each item in order of how much it is needed to support the user. The user should be able to easily reach every commonly used tool or part. The shine, being sure that everything is clean every single day. Standardize in order to keep control of the first three principles. And finally but not least, sustain keeps the benefits of 5S working by making a habit of properly maintaining the correct procedures, by using a team-oriented continuous improvement technique (as explained in the next section). (Liker, 2004)

After having this habit, a standard work is implemented and the process can be revised over and over again to make it even more efficient. Additionally to this, a remarkable benefit of having a standard work is that it is measurable; therefore, managers can easily evaluate operators and their operations. Thus, the importance of putting into practices the 5S technique. (Ortiz, 2006)

From time to time, 5S is confused with lean production. But lean systems use 5S to support a smooth flow to Takt time. 5S is also a tool to help make problems visible and, if used in a sophisticated way, can be part of the process of visual control of a well-planned lean system. (Hirano, 1995)

### 3.3.6 Kaizen Philosophy – Continuous Improvement

Kaizen is a Japanese term that stands for continuous improvement and basically is the process of making incremental improvements, no matter how small they are, and achieving the lean goal of eliminating all waste that adds cost without adding to value. This philosophy or technique teaches individuals skills for working effectively in small groups, solving problems, documenting and improving processes, collecting and analyzing data, and self-managing within a peer group. It pushes the decision-making down to the workers and requires open discussion and a group consensus before implementing any decisions. Improvements made through Kaizen are generally small and slight; however, their results over time can be large and long lasting. Summing up that Kaizen is a total philosophy that strives for perfection. (Liker, 2004; Ortiz, 2006)
A Kaizen event is different from Kaizen as a philosophy. Kaizen event are sometimes referred to as rapid improvement events, which involve small groups of individuals in the company that are brought together to address a particular area of the company. An ideal candidate for implementing these Kaizen events would be a full-time lean manufacturing engineer. Someone with solid lean skills and an understanding of 5S, Kaizen, and standard work will help drive the program and ensure success during Kaizen events. (Ortiz, 2006)

Operators working under new standard work should use their day-to-day Kaizen responsibilities to find ways to improve the methods, and have the authority to make improvements since a Kaizen event may not be scheduled for a few months. (Ortiz, 2006)

Kaizen not only seeks to eliminate errors in production, but also to locate their sources. Operators’ participation is crucial, through monitoring and detecting any variations in process or product. They also contribute ideas about reorganizing and improving production, and this delivers productivity improvements through incremental innovation. (Hampson, 2006)

### 3.3.7 Summarizing the Lean concept

Toyota created the concept of Kaizen as a constant improvement practice, which aims to remove waste or *muda* or also *seiri* (dirt), and this process of removal is a kind of cleaning (*seiso*). An important catalyst to Kaizen is just-in-time (JIT) production that means producing only what is needed, as nearly as possible to when it is needed, and delivering it just in time to be used. Kaizen, “leanness” and JIT converge on the mythological “zero-buffer” principle. Buffers allow linked production processes to work processes to run at speeds somehow independent of each other, and therefore enable workers to take short breaks, or to organize production irregularities without affecting adjacent production processes. Removing buffers makes visible production imbalances and other problems, prompting operators to fix them. (Hampson, 2006; Liker, 2004; Womack and Jones, 2003)

### 3.4 Production Planning

When it is time to choose the materials and production planning systems the connection to the market or demand, should be taken into consideration at different level according to the company’s strategy, due to the variety of options of producing the goods.
3.4.1 Customer Order Decoupling Point

The Customer Order Decoupling Point (CODP) is used as a business level concept with strategic, tactical as well as operational implications in the sense that the positioning of the CODP impacts many aspects of a company (Wikner and Rudberg, 2005a). The objective is to separate the flow and decide where the planning point should be. In other words, when this point goes upstream, the production is carried out according to forecasts, otherwise downstream on customer’s order. With this flow “Supply – Demand” we get the following categories of production control (according to Bellgran and Säfsten, 2010):

- Engineer to Order (ETO)
- Make To Order (MTO)
- Assembly To Order (ATO)
- Make To Stock (MTS)

In Figure 4 is displayed the different positions that the CODP can take through the flow. As it can be noticed, in the engineer-to-order category, production starts once the customer sends the order, then the manufacturer order the raw material to their supplier. In the case of make-to-order the company is supplied by the required amount of components so they do not waste time in ordering those when the customer demands the product. On the other hand, assembly-to-order and make-to-stock have a faster response towards customer demands, this is due to the previous planning of the finished good (semi-finished for ATO and completely finished for MTS). In these two cases, an accurate forecast is extremely important.

The selection of CODP affects certain capabilities of the production system, which can be seen in Table 6. Customer demands acts as guidance for production planning; which modifies the amount of production that is needed to meet the needs of the market (Bellgran and Säfsten, 2010).
Table 14. CODP and Competitive Factors (Bellgran and Säfsten, 2010)

<table>
<thead>
<tr>
<th>Comp. Factor</th>
<th>ETO</th>
<th>MTO</th>
<th>ATO</th>
<th>MTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to Customer</td>
<td>Long</td>
<td>Average</td>
<td>Short</td>
<td>Very short</td>
</tr>
<tr>
<td>Production volumes</td>
<td>Small</td>
<td>Small</td>
<td>Average</td>
<td>Large</td>
</tr>
<tr>
<td>Product variation</td>
<td>Very high</td>
<td>High</td>
<td>High</td>
<td>Low</td>
</tr>
</tbody>
</table>

3.4.2 Production and Delivery Lead-Time Ratio

All the definitions of CODP are based on a ratio concept between Production lead-time and Delivery lead-time; where both “P” and “D” are lengths of time. It is crucial to indicate that they are both independent variables, wherefore the ratio (P divided by D) does not represent a linkage between them. Rather, P is totally under control of the company and its relationship with its supply chain, whereas D is what the market demands or what the company offers. This concept can be visualized in Figure 5 (Wikner and Rudberg, 2005b).

![Figure 5. The concept of P:D Ratio. (Wikner and Rudberg, 2005b)](image)

3.5 Total Quality Management (TQM)

Total Quality Management concept was developed and introduced by quality gurus such as Deming, Juran, Crosby, etc. Since the time that TQM concept was proposed, it has been very famous and widely used all over the world especially in industrialized countries. In both global and local markets, TQM concept helps the organizations, which practice TQM, increase their competitiveness. (Powell, 1995)

Lal (2008) states that, TQM is a management idea that concentrates on quality. TQM philosophy helps the organizations to optimize and utilize their resources for all the stakeholders in the system. This managerial approach strives long term success by satisfying the customers and adding values to organizations and their members, customers and society while all the organization members contributing.
The basic principles of TQM can be observed below: (Lal, 2008)

1. Total involving: All departments and employees within the organization ought to participate at all levels.

2. Quality should not be seen just as product or service quality. It must be considered as an organizational excellence.

3. TQM should not be limited as a technical tool. It is supposed to be management discipline

Powell (1995) indicates that, both Eastern and Western World contributed and structured TQM concept by the management thinkers. Different management thinkers or “quality gurus” have different ideas and perceptions about Quality and TQM.

Powell (1995) concludes TQM factor suggestions by the quality gurus as the following:

- **Committed leadership**: In TQM, Continuous Improvement, Quality Improvement concepts, there should be a consistent, long-term commitment from top management to the philosophy.

- **Adoption and communication of TQM**: The themes and goals should be denoted clearly with the tools like mission statements or slogans.

- **Closer customer relationships**: Both internal and external customers’ needs should be determined and satisfying those requirements should be a priority.

- **Closer supplier relationships**: In order to ensure gathering the right input from the supplier, the organizations should work closely and in a cooperative way.

- **Increased training**: The trainings should include TQM principles, team work and skills and problem solving

- **Open Organization**: The traditional hierarchy should be smoothened while having open horizontal and vertical communications with empowered work teams and lean thinking staff.

- **Employee Empowerment**: Better independence in decision-making should be sustained. The number of employee involvement in planning and design should be increased

- **Zero defects mentality**: Instead of inspecting and reworking at every negative situation. As the defects arise, they should be marked by a system

- **Flexible manufacturing**: The organization should apply and retain just in time manufacturing, effective cellular manufacturing, design for manufacturability, statistical process control. This principle is only applicable in manufacturers.

- **Process improvement**: The waste and cycle times must be reduced in all areas by cross departmental process analysis.
Measurement: The performance ought be measured in an objective oriented way with the help of statistical methods

![Diagram of TQM implementation elements]

*Figure 6. Major elements of TQM implementation. (Ghobadian and Gallear, 1996)*

Ghobadian and Gallear (1996) explain the possible advantages and disadvantages of TQM activities for SMEs, which can be observed below:

**Advantages:**

- Managers or CEOs of SMEs have the opportunity to maintain leadership with a high visibility during all the processes of TQM implementation and general TQM process
- In SMEs, there is a high horizontal and vertical communication between the implementation teams which increases the commitment to the project
- In SMEs, the employees are closer to the products, suppliers and customers which enables them to be more responsible and increases the external focus
- Because of having small number of horizontal and vertical layers, the cross-functional training can be reached easily
- The goals of the organization can be perceived and employees can be encouraged to work in parallel with the objectives and come up with ideas for improving and expanding the business
- The profitability of the organization directly affects the employees which motivates employees to perform better
- Because of more efficient communication, the decision making process is simpler
- Having low standardization of processes can be seen as a negative thing but it increases flexibility with the help of easier communication
- It is easier to achieve functional integration in SMEs
Disadvantages:

- Many owners have little formal managerial training and owner or CEO may dominate the whole culture and business in a negative way.
- Because of having a small management staff, number of responsibilities per employee about different business functions with a little back up, the organizations focus on short term goals.
- The health and future of the business depend on almost all employees being motivated to provide the best service.
- It is difficult for SMEs to hire or keep high caliber employees because of focusing on short term outcomes.
- Because of financial problems and wrong managerial activities, it may be difficult to reach the best resources, knowledge and technical expertise.
- Lack of time, financial, physical constraints and unsystematic management external and internal resources cannot be used optimally which reduces the overall quality.
4 Empirical Findings

In this chapter the data collection methods (observations and interviews) that were explained in the Methodology chapter are carried out.

The observations, interviews with top managers and employees were made within the company. Additionally to this, the third interview was conducted with an ISO auditor outside the company.

4.1 Observation

4.1.1 Current Production System

As it was stated before, most of the projects that the company is carrying out are under the development phase. Therefore, the production is not considered constant or heavy-weighted, as it might be considered. There is only one project that produces, apparently, with a constant flow. Besides the creation of new products, this project is also updating previous products with the latest versions, since the testing and software changes are currently working.

The current production system of the mentioned project is carried out in different places (some of them are within the workshops) and consists of different activities. These activities are mainly software installation, soldering, assembly, and packaging.

An absence of a structured production system is denoted in its processes. In some cases, the production of finished products is mixed with the production of prototypes, which have different processes and purposes. In the case of prototyping, the production may vary from days to months, without any fixed planning.

4.1.2 Workshops

The company has two rooms assigned to manufacturing activities. One room is arranged to perform mechanical activities, which has a drill table and a complete set of mechanical tools. In the other room, it is observed that the rest of the manufacturing activities are carried out, such as soldering, packaging and assembly. This last room is approximately double size of the previous one. It also has an array of shelves that are used to store mechanic and electronic tools, raw material, measurement gauges, and office items and equipment.

The employees have agreed to clean the workshops once a week. However, sometimes is not enough to see the working tables in order. For some kind of activities, the tables are not suitable, causing an inefficient production and also waste of time while looking for free space to work.

The two workshops are quite distant, which makes the employees move from one room to another when they require tools from different shelves. It is also seen that in some cases employees take tools to their desks and do not return them after their usage, causing other colleagues search for them through all the facility.
4.1.3 Vertical and horizontal communication within the company

A fluent communication is denoted among the colleagues within different aspects. They contact each other when they have troubles or need a feedback. Most of this communication is oral, due to the physical size of the company; there is no need of sending email or calling colleagues. Therefore, the interaction between departments is really efficient.

The physical organization of the company makes some departments be together, without any wall separation. However, in some cases this might disturb other colleagues that require more concentration while doing specific tasks. Also, when someone is working in the big workshop and is making noise while performing mechanic or testing tasks, other colleagues might complain of this, causing a low harmony in the working environment.

The communication with the top management is also really good. Since the offices of the top managers are in the same floor as the rest of the employees, this makes easier to reach them and consult them immediately. Hence, the vertical communication depends on the availability of the managers due to their tight agenda.

4.2 Interviews

As primary data collection, the researchers conducted seven interviews, approximately about 30 minutes long, as the next table shows with dates and interviewee information.

<table>
<thead>
<tr>
<th>Interviewee</th>
<th>Job Position</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Torbjörn B.</td>
<td>Top Manager</td>
<td>2011-05-11, 16:00</td>
</tr>
<tr>
<td>Lars B.</td>
<td>Top Manager</td>
<td>2011-05-12, 09:00</td>
</tr>
<tr>
<td>Javier D.</td>
<td>Project Leader</td>
<td>2011-05-09, 15:00</td>
</tr>
<tr>
<td>Joakim G.</td>
<td>Project Leader</td>
<td>2011-05-09, 14:30</td>
</tr>
<tr>
<td>Stefan E.</td>
<td>Development Engineer</td>
<td>2011-05-09, 11:00</td>
</tr>
<tr>
<td>Roger G.</td>
<td>Development Engineer</td>
<td>2011-05-10, 09:30</td>
</tr>
<tr>
<td>Mehdi P.</td>
<td>ISO Auditor</td>
<td>2011-05-09, 18:30</td>
</tr>
</tbody>
</table>

4.2.1 Top Managers

4.2.1.1 Strategies

The main strategy of the company is to manufacture their own products without any third party involved; therefore they will offer the whole solution to their customers directly. Once they interact with the customers, their strategy will rely on their customers’ market.

The current marketing strategy of CombiQ is reaching their target customers indirectly. The company supplies large companies with innovative products. Thus, the company uses the large companies’ market potential and opportunities to deliver their finished goods to the end users.
As a manufacturing strategy, the company wants to have total control of the production of each product that they are responsible of developing. The managers believe that, this strategy will help them to maintain their own competitive objectives that help to reach customer satisfaction.

As it was presented (CombiQ AB, 2011), the business model of the company considers the following points:

- Interactive innovation with customers/end-users
- They earn money on products sales.
- Ideas with high business potential are allocated in separate companies.
- To speed up development venture capital is invited into the subsidiaries.
- Maintain competitive edge with core innovation or complementing solutions.

### 4.2.1.2 Competitive Factors

The management prioritizes the competitive factors. First of all, quality is the main concern in order to meet the customer satisfaction. They believe that this factor is essential and will bring other factors such as cost reduction in the long run. Their second priority is deliverability, which enables the company to be reliable attain the trust of the customer. Their third priority is to have a flexible system that can produce different products in a short time using the same tools and methods. As the top managers said, this will increase deliverability and high response to market demands. And finally but not least, the cost will be reduced in a long run, once all these processes are carried out in an optimal way.

As it is mentioned, the company is specialized in development with the following competences among their employees (CombiQ AB, 2011):

- Embedded software
- Wireless communication specialists
- Antenna specialist
- Electronic design
- Software development
- Purchase and Quality
- Business development

### 4.2.1.3 Production System

The managers presented the current situation of the production where, due to a low demand, the actions taken to improve the production are slow until it gets more serious.

According to one of the managers, the production ramp-up is a short-term goal, which is planned to take place in one year. Once the customers’ orders become constant and a forecast can be made.
As a long-term goal, the company is planning to develop their own platforms (such as software programming, electronic and mechanical testing and manufacturing). Also, they plan to develop a flexible production system that will enable the company to produce different products with the same tools and only differing in the final usage. With this system of producing, they aim a reduction in cost and time, while increasing deliverability and performance within their processes. However, the steps of how to move to this production system are still unknown. That is why, although it is contradicting with the plans of the company, there is an opportunity to outsource their production to another company. In order not to select this option, the top management is open to suggestions to design and develop an optimal production system.

4.2.1.4 **ISO Certifications**

Top management has experience working with ISO 9001 and 14001. Their main priority about ISO certifications is to maintain a management system within the company, which will enable them to have the full control. In a simple explanation that they indicated, they require to structure “how things should be done?”, track the problems from the root-cause and avoid them with a good documentation system. However, they are concerned about the level of the paperwork that will increase the workload of the whole company. As a second priority, they want ISO certifications because of its marketing impact. They believe that, by being certified, it will be much more easier to find customers and suppliers.

The top management supports the change process but want to keep the changes for the certification as simple as possible. It is especially denoted in the interview that, there is a high management commitment to the projects. For the future plans regarding the ISO certification, the company plans to inform the employees about the goals and make them understand what is required. By doing this, the management wants to maintain total involvement within the company.

The management also indicated that, they want to use external consultancy as low as possible in the certification process.

4.2.1.5 **Lean Philosophy**

During the interview with the managers, questions regarding Lean Thinking and principles were asked, and even when the managers have worked in different companies, they are not aware of such terms. However, after explaining the advantages and characteristics of these principles, they agreed on such implementation within the production system.

They commented the fact of working with quality tools and improvement techniques, but they were not aware of the relation of these activities with Lean Thinking. Additionally to this, they showed great interest to the topic and the benefits that can be obtained from it.

4.2.1.6 **Interaction with Customers and Suppliers**

Nowadays, CombiQ works quite close to the customer, thereby the need of improving deliverability and quality in their products.
They do not consider themselves as consultants; in other words, they do not want to provide only solutions. They want to produce their own products and sell them directly to their customers.

Due to a fluctuating demand from their customers, CombiQ cannot plan a production. However, they have plans with their customers to make this order more constant, once the products leave behind the prototyping phase.

After the explanation of Customer Order Decoupling Point (CODP), the managers placed the company in a situation towards the customer, which refers to Make-To-Order and Assemble-To-Order. In order to increase the response rate they think of having a safety stock, considering all the implications that this might bring with, such as an increase in their costs.

Regarding the suppliers, the managers have a close relationship with them, which improves the delivery of pre-assembly components, like electronic boards.

4.2.2 Employees

4.2.2.1 Employee well-being in the current system

In general, most of the employees feel comfortable with the work environment, which concerns of social atmosphere, physical aspects (lighting, A/C, furniture, workspace, etc.) All the employees are motivated and satisfied about their jobs because of many reasons. The reasons can be listed as: They can make their own decision on the activities that they are undertaking. Thus, they feel the full responsibility about their tasks since they are making the decisions while increasing the trust of the top management. Some of the employees indicated that this positive aspect could be stressful depending on the situation.

Besides being an SME, the social atmosphere in the company enables the employees to transfer ideas easily, which increases the quality of the job as well as the job satisfaction. Additionally to this, employees feel an optimistic attitude from other colleagues even though some projects are still in the development phase.

It is important to denote that some employees are stressful about the future steps of the company. As they explained, because of the increase in the workload once the company moves to a constant production from prototyping stage.

4.2.2.2 Top management support

All the employees feel the support of the top management. This includes the technical and managerial aspects, where the employees receive constructive feedback regarding their activities. The management provides them freedom to make their own decision as it is mentioned before. The employees do not have any problems regarding the communication with the top managers. They can talk freely about their problems and the top managers are easy to reach.

As a drawback from this top management support, employees lack of technical advice when it comes to specific problems, which they see it as a negative consequence of the free will while conducting their projects.
Another comment regarding the communication is the absence of information concerning the goals and strategies of the company in the long term, although they are aware of the short run goals.

The employees receive a weekly letter that informs them the actual situation of the company’s departments. Some of them agree with this method rather than weekly meetings. But on the other hand, other employees sense a lack of knowledge sharing and they think that the weekly meetings could improve this aspect.

4.2.2.3 Intercommunication

The relationship between colleagues flow in a good way and so far they feel comfortable with it. However, in some cases noise becomes a little bit distracting when other employees are working in the workshop.

They find really easy to ask for advices from their colleagues due to the closeness between departments. It is also indicated that the efficiency of the communication is much higher than the big companies by the employees who have work experience both in large organizations and SMEs.

4.2.2.4 Knowledge about Production Systems, ISO Certification and Lean Philosophy

In general, most of the employees do not have experience working or studying these topics, especially due to their professional and educational backgrounds. Since all of them are working in the development of projects, they do not have the time to focus in the production of them. Therefore, a couple of employees suggested the idea of hiring a responsible person that can take care of all the production process.

Regarding ISO Certifications, most of the employees are aware of what ISO standards are, but there is no deep knowledge in this subject. The main perception about ISO certification is its usage as a marketing tool. In contrast, employees who have worked at certified firms are really satisfied with the profits of it as a management system.

None of the employees have worked or been educated with Lean principles and techniques. However, they are aware of some tools and methods that increase work efficiency without knowing the relation with Lean Thinking.

Summing up these technical aspects, all of the interviewees are positive with the idea of being educated in these areas, if such training is provided by the company.

4.2.2.5 Relations with suppliers and customers

In the projects that are also taking action in the production, customer orders are carried out in a reactive structure. The responsible person for this project, considers useful having a safety stock in order to meet these demands, but is aware of the costs that this will imply. Therefore, he has to react and adjust production so the products can be delivered on the expected time. This relation with the customer is getting more formal and now the documentation of orders is filed, since the company increased its experience with customers.
The communication with suppliers is really efficient. One reason of this is because of the low amount of suppliers, where the time delivery is short and the information flow is immediate compared to some employee’s previous jobs, where they had not direct contact with suppliers.

In general, the relation with suppliers and customers is really good according to the employees.

4.2.2.6 Reaction to change

The employees are aware that they are not working with structured processes. Once they were informed about the purpose of this project, they agreed on the possible changes in the system and their tasks. All employees indicated that they would not resist in the change process because they are aware of the importance of the project for the company. The employees who have experienced change process in other companies (both SMEs and large organizations) stated that the change phase is comprehensive and difficult but required in most cases.

4.2.3 ISO Auditor

4.2.3.1 Non-conformities observed in SMEs

The ISO auditor experienced and observed several non-conformities in SMEs before and during the inspections. The most common that the interviewee faced are lack of commitment to the projects both from top management and employees, not having enough focus or not having any focus at all on continuous improvements and corrective and preventive actions. The auditor pointed out “top management commitment” as the biggest challenge for all kinds of organizations.

4.2.3.2 Challenges and benefits of ISO certifications for SMEs

The biggest challenges of ISO certifications observed in SMEs are standardization, financial side of the ISO certification process, and perception of ISO. The standardization process in SMEs is much more complicated in SMEs compared to large organizations because of not having structured processes. The respondent wanted to mention the financial side of the ISO certification implementation. It was indicated that having a QMS or EMS or both of them is not financially feasible considering the fact that SMEs have limited financial resources. Most of the top managers or leaders consider ISO certifications as a marketing tool without perceiving their management philosophies. Thus, this does not allow the companies to have a core management function and tool, which work according to the requirements of ISO 9001 and ISO 14001.

A beneficial attribute of SMEs concerning ISO certifications is, SMEs can adapt themselves to changes much more efficiently than the large companies. But the main benefit for the enterprises that do not have any management system, ISO standards make them to have a structured management system, which is a good start for the growth of the company and being competitive.
4.2.3.3 General misperceptions of ISO standards by SMEs

Most of the SMEs consider ISO certification processes as over paperwork. Another negative behavior is not being determined when a problem is encountered. In most of the companies, internal auditor who is responsible for inspecting the status of the company according to the standards either does not exist or assigned to another job so the importance is not given to the internal audits.

4.2.3.4 Operational focus

SMEs ought to define and get to know their processes accurately. Then, necessary activities can be built up around the well-defined processes. Also, internal audits are really important. Internal audits should be authorized by the top management and the staff which performs internal audits should be trained about this subject. Companies can use “Monitoring Management Systems” in order to detect non-conformities.

4.2.3.5 Consultancy

Consultancy is not necessary at every case. Considering the fact that ISO certification process require comprehensive changes in the system and operations, employee experience with ISO standards are important. Thus, it depends on the organization.

4.2.3.6 Integrated management systems

Because of having many common requirements, besides having specific requirements; QMS and EMS can be implemented together. This enables the companies reach both ISO 9001 and 14001 certifications.

4.2.3.7 Inspections after being certified

Top management commitment plays a vital role in the certification process. According to the interviewee’s experience gathered in the inspection of certified firms, many companies do not spend the same effort on working with the new system as they spent before they got certified. Thus, many of them go back to their old system and cannot pass the next audits.

4.2.3.8 Suggestions for SMEs that are in the certification process

After the companies decide on being certified, they should evaluate their current position, define cracks in the system, make decisions and plan the implementation, focus on documentation, try succeeding in the change process and being ready for the inspections.
5 Analysis

The Analysis chapter contains seven sections that integrate the empirical findings and literature review into a perspective that focuses on the current situation of the chosen company case. The following sections are the basis of Lean Production System Design framework for SMEs that share similar characteristics and situation with CombiQ.

5.1 Identifying a Manufacturing Strategy

This section of the analysis explains how to structure a manufacturing strategy for the companies in order to organize their production systems. The manufacturing strategy idea is handled with relevant concepts, which drive the companies to reach the ideal strategy.

As a plan, all kinds of companies should focus on manufacturing strategy via corporate strategy and marketing strategy in an order. After creating their business goals, they should define a plan according to the market conditions and place themselves in the relevant market. This enables them to obtain a significant manufacturing strategy that the company can base their production system on.

5.1.1 Defining a Business Model

CombiQ has a well-defined corporate strategy and business model as one of the top managers presented, which is denoted in the empirical data chapter. Also, they have well defined their business focus (RFID solutions) and preplanned its relevant structural and infrastructural issues, which are mentioned in Table 3. Mainly, capacity, facility and process technology are the structure issues that the company is aware of. On the other hand, they mentioned their current situation regarding the following infrastructure issues: organization, human resources and new products, lacking of quality policy and production control.

As for the rest of the companies that are in process of defining an optimal business model, it is essential that they should organize their actions according to some strategies previously defined. However, deciding these strategies cannot be enough; thereby the companies ought to make a direct linkage and create interfaces between them. (Hill, 2000)

When SMEs are in the process of reaching the desired manufacturing strategy, they should decide the most suitable business that they can participate, for instance the type of technology they want to produce, the type of service they want to offer and so on (Sramidass, 2000). This phase is the basis of structuring the manufacturing system. Thus, the SMEs which want to form a manufacturing strategy; they must have a core corporate strategy.
5.1.2 Aiming Customer Satisfaction

As it is well known, most companies focus on satisfying their customers’ needs. However, they might differ in the ways to achieve this factor. Therefore, it is important to analyze the competitive factors that situate the companies in the market. These factors were detailed in the theoretical background as: cost, quality, flexibility and deliverability. (Ulrich and Eppinger, 2008)

Most SMEs have a clear marketing strategy, such as CombiQ, which had made a marketing research about market conditions and prioritized the competitive factors according to their main objectives. The company tends to focus on the quality rather than the cost, looking forward to a direct contact with the customer. This condition increases the communication between both parties and gives them more freedom in the interaction and delivery deadlines. Thus, CombiQ aims on providing high quality products and later on they will try to reduce the costs once the production is steadier and the orders become constant.

The actual way of working of CombiQ, is creating innovative products that meets the customer requirement. In other words, if the customer requires a specific function for the product, CombiQ is able to modify the original concept and provide it, which proves the strong linkage between the manufacturer and the customer. However, most of the times, CombiQ is the one who provides new solutions to different situations in the market, creating a new need in customer’s mind and increasing their interest in the product. When this situation happens, the company is considered as an order winner, which is previously explained by Swa- midass (2000). Despite this consideration, the company behaves as an order qualifier when the requirements of the customer must be strictly followed.

In a general context, SMEs should discuss their relation with their customers according to the competitive factors stated in their business strategy. By prioritizing those factors, every company should be able to work in the best way that fits under the capabilities and resources. With this working method, companies can stay close to the customer or make their customers wait for their products to be released and used. Moreover, if the customer requires high quality, the core focus of the manufacturer should be based on quality factor. In this case, deliverability or cost might be placed as second and third priority if it is accepted by the customer.

In parallel with prioritization of the competitive factors, the SMEs should balance the order qualifier and order winner concepts. If they want to enter a new market order qualifier concept is more appropriate to maintain a place in a new market. Besides this, order winner helps the companies to increase their share in the market by using their innovativeness that allows them to provide elements that are not common in the current market. (Hill, 2000)
5.1.3 Determining a Manufacturing Strategy

While analyzing the connections between the different stages of the development of a production system process, manufacturing strategy has a direct linkage to the desired production system. As it is mentioned above, manufacturing strategy is structured by defining a corporate and marketing strategy while prioritizing the competitive factors, order winner and order qualifier concepts. As a complement, the production system can be built or changed in parallel to structural and infrastructure issues.

Despite the existence of production in CombiQ, continuity in their working process cannot be observed. Therefore, they are aiming to develop a structured production system that will contain all their structural and infrastructural issues, which are defined in their manufacturing strategy. In the next section, the way how CombiQ should change and build its new production is explained.

Concerning the structural and infrastructural issues that CombiQ has been handling with its current production are: facilities, process technology, vertical integration, organization, human resources, new products, and performance management. However, these issues depend directly on the actual situation of the company. For example, facilities (workshops), process technology and new products depend on the available physical resources. On the other hand, capacity, quality policy and production control ought to be handled in parallel with the new production system. The analysis of the unidentified structural and infrastructural issues can be observed in the following sections.

5.2 New production system

Once the concepts of system and production system are explained in the theoretical background chapter, it is time to go further in the description of the main steps of creating a production system. As it is denoted in the empirical data, the company does not possess a formal production system; therefore the main purpose of this section is to set the initial conditions for starting a new production system. This analysis can be generalized to different SMEs that share the same conditions as the case study of this master thesis.

The reasons of having a new production system may vary, which can be: an increase in profitability, introduction of new products, increasing the quality of the processes and so on (Bellgran and Johansson, 1995; Bellgran and Säfsten, 2010). In the current case study, the company is running from their development phase to their production phase, thereby it is essential to implement a manufacturing system.

As a preparatory step, it is important to identify the initial manufacturing conditions (if they exist), such as checking the available tools, materials, workshops and other facilities that the company has at that moment. Consequently, an evaluation of what else is needed should be done according to the purposes of the manufacturing system.
As a next step, an identification of the reasons to change must be done in order to evaluate further actions. There are two main reasons for this change to be made, which can be observed in Figure 2, one is internal initiated and other is when the change is initiated externally. In the special case of CombiQ, the top management is planning this change process, therefore it is considered as internally initiated. The previous reasons can work in parallel with the degree of change, where it is determined if the change is minor or major. For example, minor degree changes can be considered as improvements or developments in the existing production system depending on the reason for the change. As a major change, it can be classified as transformation and revolution, depending again on the reason of change, where the first one concerns the case of CombiQ. Its current situation does not require having a completely different production system. Therefore, the desired production system for the company would be similar to the existing one regarding the structural and infrastructural issues.

Summing up the mentioned concepts, the change process can be handled with transformation. This transformation decision is internally initiated and planned by the top management of the CombiQ.

After determining the reasons for change, degree of change and current situation of the manufacturing system; it is pertinent to describe the methodology that will be used to design the production system. With this methodology, the practitioner can follow a set of steps in order to design their production system according to their needs. However, it is important to clarify that these steps are related to the case study of this report.

The design process is carried out according to the presented in the Framework for Production System Design chapter. (Bellgran and Säfsten, 2010)

1. Models of design and development processes. The aim of this section is focused on preparing the company to design an adequate methodology in order to reach the desired production system. By following this section, an overall understanding of all the development process can be attained.

2. Methods and techniques to be used within these processes. Across the report, different methods and techniques are presented. These models are mainly can be observed in the sections about Lean Thinking and ISO Certifications.

3. A system of concept and corresponding terminology. Finally, as the whole system concept, a connection between ISO Certifications requirements and Lean Thinking is performed. Thus, this system concept is addressed as Lean Production System Design.
5.3 Design Methodology

While designing a methodology, SMEs guarantee an outcome with optimal quality and the coordination and management of the project will flow as effective as possible. As it is denoted in the theoretical background, the Production System Development Process consists of several stages, which are analyzed below according to the concepts proposed by Bellgran and Säfsten (2010):

5.3.1 Planning and Managing the Structured Methodology

At this stage, top managers should discuss prepare the investment request in order to start the production system development process. A decision must be made according to the type or operations, where it can be day by day or in a long-term process. Hence, the methodology should adapt to the objectives of the company, which in the case of this report is towards a production system, rather than a product life cycle. Once the top managers have decided whether to proceed or not with the process, they can acquire external support in order to improve the quality of the development. For such support, this report may help and guide SMEs throughout the planning and design of their own production system.

It is strongly recommended to assign a project leader, who will be full time committed to carry out the process and if human resources are available, to make up a team with experience in production field. This team should have analytical abilities in order to understand what are the initial manufacturing conditions and seek for new solutions that will improve the situation, always heading towards the manufacturing strategies of the company.

5.3.2 Preparatory Design

The mentioned team should research externally and internally for similar processes that can assist the current design. The aim of this research is to provide relevant knowledge and ideas, so the project leader can obtain the most valuable concepts from them and adapt them to the design requirements. For example, taking a look to other companies’ production systems might help to attain a general perspective of how production systems can operate under different conditions and different goals; therefore the most similar systems can be analyzed in order to enrich the design. Another example is to review current processes inside the company that can be related to the new production system. Normally these processes are oriented to the organization targets and provide an accurate feedback.

As an outcome of this research, the team should provide the requirements that are needed to have a detailed design of the production system.
5.3.3 Design Specification

When the company is aware of the requirements, it is time to search for tools and methods that will cope with these requirements. According to the manufacturing strategies, a set of methods and techniques are chosen. That is why this thesis proposes Lean Thinking as a methodology that provides useful techniques as 5S and Kaizen, which are linked to ISO requirements. However, SMEs might differ from each other, so they have to choose the most suitable techniques that meet their own goals.

The mentioned techniques reduce the complexity while designing workspaces, layouts, operations and other factors. By this implementation, the communication within the company and outside of it, such as the relation with suppliers and customers is highly improved. Thus, the main characteristics of each tool are described further down in this chapter.

Now, is up to the project manager to design the work tasks according to the chosen system design. Consequently, an evaluation of the conceptual production system is conducted and discuss among the different departments of the company that involved in this process.

5.3.4 Implementing

The implementing stage starts with the final system solution that drives the process to the purchase or manufacturing of the production system. At this moment, the team should evaluate suppliers according to the equipment/tools they have to buy. Right after the purchase or manufacture, a proper installation of the components should be done, followed by its verification and testing.

The next step is to fix training program to the personnel that is involved in the system. Providing a thorough explanation of the tools, methodology and strategies, so all the employees work in a common direction.

Finally, the company should be able to perform the start-up and its relevant evaluations of the performance. This evaluation should offer a constructive feedback to the project team and the rest of the involved people in order to operate in a continuous improvement structure.

5.4 Adaption to ISO requirements

As the top managers of the company stated, being certified by ISO 9001 and 14001 is one of the main goals for CombiQ. The company wants to achieve the marketing power of ISO standards and management systems that are required in the certifications.

In order to achieve their goals, the company ought to get familiar with the concepts and the requirements for certification. Thus, they would be aware of possible adjustments in the change process, which should be considered starting from the planning stage of the production system design. Therefore, the limited resources of the company can be organized in order to achieve the preset objectives.
In the theoretical background chapter, comprehensive information about ISO standards can be observed in several perspectives. One of those perspectives is the integration of ISO 9001 and 14001 by Karapetrovic and Willborn (1998). This idea is also supported by the ISO auditor who was interviewed.

The gathered theoretical and empirical data indicate that, besides having specific requirements, QMS (ISO 9001) and EMS (ISO 14001) share a remarkable number of requirements. Thus, Integrated Managements System is an appropriate concept, where QMS and EMS can be carried out together. In Table 16, specific and common requirement paragraphs for both ISO 9001 and 14001 are listed in a sequenced way.

In the current situation of CombiQ, the company should follow a well thought-out plan and steps in order to maintain satisfactory QMS and EMS. As Wilkinson and Dale (2002) suggested, CombiQ can connect and integrate both of the concepts in order to reduce the workload and significant duplication of the tasks for the common requirements. Besides, there must be a deep focus on specific requirements independently.

### Table 16. Relevancy of ISO 9001 and 14001 requirements by paragraphs

<table>
<thead>
<tr>
<th>ISO 9001</th>
<th>ISO 14001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific requirements of each certification</td>
<td>Common requirements that can be organized together</td>
</tr>
<tr>
<td>4.1.1 Quality policy</td>
<td>4.2 Environmental policy</td>
</tr>
<tr>
<td>4.2.1 General requirements</td>
<td>4.1 General requirements</td>
</tr>
<tr>
<td>4.2.3 Quality planning</td>
<td>4.3 Planning</td>
</tr>
<tr>
<td>4.3.2 Responsibility and authority (legal requirements and objectives)</td>
<td>4.3.1 Environmental aspects (legal requirements and objectives)</td>
</tr>
<tr>
<td>4.2.2 Quality management program</td>
<td>4.3.4 Environmental management program(s)</td>
</tr>
<tr>
<td>4.3 Contract review (communication with stakeholders)</td>
<td>4.4.3 Communication</td>
</tr>
</tbody>
</table>

| 4.1.3 Management review | 4.6 Management review |
| 4.5 Document and data control | 4.4.4 Environmental documentation |
| 4.2.2 Quality system procedures | 4.4.5 Document control |
| 4.1.2 Organization | 4.4 Implementation and operation |
| 4.1.2 Organization | 4.4.1 Structure and responsibility |
| 4.18 Training | 4.4.2 Training, awareness and competence |
| 4.4 Design control | 4.4.6 Operational control |
| 4.6 Purchasing | 4.4.6 Operational control |
| 4.7 Control of customer-supplied product | 4.4.6 Operational control |
| 4.8 Product identification and traceability | 4.4.6 Operational control |
| 4.9 Process control | 4.4.6 Operational control |
| 4.10 Inspection and testing | 4.5 Checking and corrective action |
| 4.11 Control of inspection, measuring and test equipment | 4.5.1 Monitoring |
| 4.12 Inspection and test status | 4.5.1 Monitoring and measurement |
| 4.13 Control of nonconforming product | 4.5.2 Non-conformance and corrective and preventive action |
As the specific requirements fulfillment for each certification type, the company should define and establish a quality policy and an environmental policy “separately” in a detailed way with the commitment of the top management (Copes with ISO 9001; 4.1.1, 4.2.1 and ISO 14001; 4.2, 4.1). Having defined policies would lead the company to determine the responsibilities and processes necessary to achieve both quality and environmental goals. During this determination phase; a complete resource planning, establishment of methods to verify the efficiency and legal requirements must be examined well. (Copes with ISO 9001; 4.2.2, 4.2.3, 4.3.2 and ISO 14001; 4.3, 4.3.1, 4.3.4). Additionally, the system should be also beneficial for the stakeholders of the system, so the relevant partners should be well informed about the changes. (Copes with ISO 9001; 4.3 and ISO 14001; 4.3.3)

Specific requirements, which are explained above, must be satisfied individually with the high commitment of the top management. According to the interviewed ISO auditor, lack of top management commitment is the biggest challenge in the ISO standards implementation. Top managers of the company stated that they have working experience with ISO 9001 and 14001. The awareness of the philosophy of certifications will help them to be committed to the change processes in a management responsibility perspective, which is a common requirement (Copes with ISO 9001; 4.1.3 and ISO 14001; 4.6). One of the main demands from CombiQ is to keep the change process as simple as possible. Consequently, the integration of common requirements can be considered as one of the best options.

The integration of common requirements for ISO 9001 and 14001 helps the companies to reach quality and environmental performance. (Karapetrovic and Willborn, 1998)
In the integration process, it is important for CombiQ to plan and document all activities that affect the overall quality and environmental issues (Copes with ISO 9001; 4.5, 4.2.2 and ISO 14001; 4.4.4, 4.4.5). The system capacity and mechanisms should be adjusted according to the customer requirements (Copes with ISO 9001; 4.1.2 and ISO 14001; 4.4, 4.4.1). It is essential to train employees and assign them to the tasks that are relevant with their competencies (Copes with ISO 9001; 4.18 and ISO 14001; 4.4.2). The company should define and apply methods to verify the effectiveness and efficiency of each specific process while having control on the operations (Copes with ISO 9001; 4.4, 4.6, 4.7, 4.8, 4.9, 4.15, 4.19 and ISO 14001; 4.4.6). In the change process and for the future of the certified company, to have a continuous program of a performance evaluation of the system and its parts and having a control and corrective action system which measures, monitors and reports non-conformities while correcting and preventing them is necessary (Copes with ISO 9001; 4.10, 4.11, 4.12, 4.13, 4.16, 4.17, 4.20 and ISO 14001; 4.5, 4.5.1, 4.5.2, 4.5.3, 4.5.4)

5.4.1 A TQM approach to ISO requirements

Psomas and Fotopoulos (2009) point that; the required quality management system required by ISO standards share the same philosophies with TQM. Their study shows that companies who want to be certified by ISO can use TQM approach as a management idea because of contributing to same objectives with quality management principles concerning customer focus, leadership, and involvement of people, process approach, systematic management approach, continuous improvements and mutual benefits in the relationships with suppliers.

The expectations of CombiQ regarding the desired production system can be maintained by using TQM. As a management idea TQM organizes and sustains the resources and activities within the company while trying to satisfy the customers.

If CombiQ is analyzed in line with the basic principles of TQM,

Total involvement: The empirical findings show that both the top managers and employees are ready to act in the change process without any resistance.

Quality perception: Quality is seen as the most important competitive factor. With the introduction of the new production system, the perception of quality should go beyond product or service quality that would lead the company to organizational excellence.

TQM perception: The top management of CombiQ should not consider TQM as a tool that maintains the quality. TQM principles should be well understood as a management discipline because they serve the main goals of the company including satisfying QMS requirements of ISO. By doing this, the company would have a disciplined system that would also be ready for the yearly ISO inspections.

In the following paragraphs, the present condition of CombiQ is analyzed according to the suggested TQM factors.
Committed leadership: The top management is willing to commit to any concept that they decide to use. Regarding this study; in the whole steps in the transformation phase, the board of management should be consistent with the predetermined goals and on the processes that lead them to objectives.

Adaptation and Communication of TQM: In the empirical findings, the employees denoted that they are aware of short-term goals but there is an absence of getting informed by the top management about long-term goals of the company. There must be a total involvement in TQM, since it is one of the basic principles of the idea. Total involvement cannot be achieved when there is lack of communication about the goals. Thus, management of CombiQ should give more importance on letting the employees know about the goals, ways and methods in order to reach those goals.

Closer Customer Relationships: Top managers and employees in the company represented that the relations with the customers are increasing. The company works closer to the customers. As it was denoted in company’s competitive factor perception, customer satisfaction has a high priority.

Closer Supplier Relationships: CombiQ is satisfied with their supplier relationships. It was stated that the relationships are efficient because of having a small number of suppliers. The company gathers the right input from the suppliers on time. Both top management and employees does not have complaints about them.

Increased training: Since the overall awareness of the techniques that are used in this research is not enough for a satisfactory implementation and change process, the managers should provide training to the employees. Concerning the teamwork and intercommunication within the company, there are no remarkable problems. But as it is said before, in order to provide problem-solving skills to the employees about TQM concept, employees should be trained.

Open organization: All feedbacks about vertical and horizontal communication were positive. According to the employees, the hierarchy with the management is smoothened. They are satisfied with the communication with the top management but adding that they do not feel enough technical support. Therefore, the management should try to provide the required technical support, if it is needed.

Employee empowerment: The employees in the company are very satisfied about their freedom in decision-making, where they are highly involved in the design of the products or other technical tasks.

Zero defects mentality: The company should have a monitoring system in order to mark the defects, which avoids inspecting and reworking in the unexpected situations.

Flexible Manufacturing: This idea is one of the long-term goals of the company. The company should be practiced and well informed about the application of the desired attributes of chosen flexible manufacturing system.

Process improvement: When the company starts to have a constant production and the definition of the processes is made, the wastes, cycle times, etc. should be reduced.
Measurement: The company should have a measurement system in order to evaluate the overall and specific performances with the help of the statistical methods.

5.4.2 ISO implementation framework

The information gathered ISO certifications in the empirical findings chapter was about general knowledge about the certification system. The managers and employees who work with the certifications were satisfied with it as a management system. The main concern in CombiQ is the implementation phase of the standards. The members of the company who worked in the implementation phase of the standards have negative opinions about dealing with many requirements and paragraphs. That is why; the top management wants to keep this phase as simple as possible.

According to the ISO auditor that was interviewed, general perception about ISO standards among the SMEs is that change process contains over paperwork. Also, they question the financial feasibility of the certification process.

In order to reduce those negativities in real life while implementing the requirements needs being determined, organized and patient. As a result International Organization for Standardization (1996) and also the interviewed ISO auditor suggest a structured implementation plan.

Decide to proceed: CombiQ is in this stage as a current situation. The company has decided to act for the certification process. They should make themselves ready by understanding the requirements of the certification and organize its resources according to the plan.

Assess current position: The company has decided to be certified by ISO 9001 and ISO 14001. So, the management and employees should be informed about each requirement and make an assessment about their situation towards the requirements. The possible adjustment areas should be determined and all processes should be prepared to find shortfalls.

Determine shortfalls. This step can be called as gap analysis as well. CombiQ should keep on analyzing itself in a more detailed way to point out the gaps or shortfalls. This step will lead the company to develop an implementation plan. In this step, each requirement should be questioned and examined in current circumstances and company should not ignore any of them.

Develop an implementation plan: In this step, CombiQ should built and plan the implementation phase according to the data they gathered from previous steps.

Perform the documentation process: Depending on the standard, CombiQ should develop all required documents. The company should develop its quality manual for being certified for ISO 9001 as well as environmental manual for being certified by ISO 14001. In this process, a help form International Organization for Standardization provides consultancy. The company should make sure that the created manuals assure the common understanding.
Manage transitional activities: This step can be explained as managing the change process. CombiQ ought to adjust the company according to the new environment of ISO. The core focus in this step should be on changing management style according to the requirements, trainings on the required documentation and conformity of the processes.

Validate compliance to ISO: Internal audits should be conducted in this stage. This leads the company to assess if they are ready for the certification or not. By doing this, the company can also test Internal audits requirement of the desired ISO certifications. Findings in this process would provide a constructive feedback about the progress of the company.

Pass the registration audit: This step is the stabilization of the changes in the system. In order to perform in the registration audit, CombiQ should complete corrective actions before the final inspection.

5.5 Selecting and practicing relevant LEAN techniques

In this section, the concept of Lean Thinking and its main techniques are explained and analyzed according to the purposes of the production system design. The reasons for selecting the techniques and the relation with ISO Certifications are described below.

5.5.1 Introducing Lean Thinking

As it is suggested by Womack and Jones (2003), the idea of Lean Thinking is to do more with less resource. But more than a few managers ask how to implement an idea?, how to ground this way of thinking?, is it possible to make it tangible and obtain profits?

Several companies assume that, by implementing some tools/techniques they will become Lean; which drives the concept of “being lean” into a misunderstanding (Liker, 2004). This philosophy has to be attached to the backbone of companies, to cope with all the process and has to be part of the way of thinking of all the employees within the company. That is why, when big companies try to transform their systems into lean systems, they fail on the process. The lack of communication and training takes any company to an erroneous implementation, causing a loss of time and resources.

Another misconception of this philosophy is when companies skip taking a thorough review in the processes that do not give added value to the final product or service. Thus, CombiQ should focus on improvements by understanding the value concept in this process. The value adding activities should be determined and developed in order not to make improvements without estimating the outcomes of them.

A remarkable advantage of CombiQ and many other SMEs compared to big companies is the fact of starting a production system from “scratch”, where they can focus on designing a new production system with a new philosophy, without the necessity of making extensive changes.
In summarize, according to Liker (2004); Womack and Jones (2003); Bellgran and Säfsten (2010), waste elimination is denoted in the reduction of non-added value activities that are identified in the production processes; consequently, the lead time will also be reduced. This is the part of the process, where most of the wastes are seen and where managers can take more corrective actions. After making such corrections, the quality of the process is improved radically. When it comes to the managers to discuss these aspects, there is no need to make complex changes, due to the simple solutions that lean thinking provides.

5.5.2 Value and Waste Analysis

The empirical findings at CombiQ showed actions that generate waste in their processes. After describing the seven wastes, plus the eighth one added later on by Liker (2004); it is clearly observed that CombiQ presents four main wastes: waiting, overprocessing, unnecessary movement and defects. The rest of the wastes cannot be observed due to a lack of constant production, low level of facilities/workspace and high employee empowerment (overproduction, unnecessary transport, excess inventory and unused employee creativity). All these wastes are analyzed below:

Waiting: It usually happens when the overall workload is high and employees have to wait for a while until they have access to free workstations, this is because of a scarce of facilities in CombiQ.

Overprocessing: Since the company is running through a product design phase, several updates of software versions are made as overworking, subsequently to debugging and testing. This is a consequence of the usage of complex products that implements high technology in their production process.

Unnecessary movement: A disorder is observed in the main working room of CombiQ, which is caused mainly by the different projects that are running at the same time, where tools and parts are in current use. This situation drives employees to start looking for those missing tools and parts from their original position in the shelves and delaying their activities.

Defects: Because of non-existing quality procedures/department in CombiQ, mainly due to low human resource, the finished goods do not have a final inspection regarding the quality of their functionality. Consequently, the same design engineers have to recheck, retest and repair the products, causing a loss of time and resources.

On the other hand, the wastes that cannot be observed are due to the following reasons:

Overproduction and Excess inventory: Nowadays, the production demand is low and without a continuous pace; moreover the company starts production when the customers require a certain amount of products, which makes impossible to overproduce or to have excess in the inventory.
**Unnecessary transport**: A convenient factor of SMEs, as for CombiQ, is the location size and distribution, where the offices (computer rooms) are quite close to the workshops (mechanical rooms). This turns out to be an advantage for the employees that need to be in constant movement from their desks to the workstations for testing, soldering, packaging or any other activity that cannot be performed on their desks. Furthermore, having the stock shelves beside the workstations, reduce the transport time of raw material and stocking time of finished goods.

**Unused employee creativity**: In SMEs, it is common that employees take care of many other roles besides the main one; such is the case in CombiQ. Employees quite often involved in developing, supplying, dealing with the customer, testing, producing or any other task that might not be in their job description. However, due to the low amount of human labor, they have to deal with those activities. Subsequently, the employees can develop their creativity and ideas in order to cope with many things that concern to the company’s processes, both managerial and operational.

### 5.5.3 Lean Techniques selection

While analyzing the current operation of manufacturing in CombiQ, either for prototyping or for production of finished goods, several non-conformities can be found.

The empirical data provides a general view about the main processes that the company carries out in their current situation, where many of them do not follow a standardized way. Therefore, the efficiency of the operations can be questioned. The standardization of the processes cannot help to reach the efficiency by itself, besides that, the way of thinking and knowledge of the management and employees should be improved; as Pheng (2001) claims 5S principles is not only useful for the workplace but also helps them personally by improving their thinking process.

The next examples show a straight relation with 5S technique and followed by a suitable solution approach according to its characteristics.

While observing the behaviors of employees, the researchers denoted a loss of time while looking for tools or parts in the workshops. The employees spend few minutes almost every time they want a specific tool, especially those who are of common usage. This loss of time can cause delays in other process, such as order delivery or unfinished tasks during the working hours. But once the lean principles are taken into practice, these kinds of troubles will be reduced drastically. For instance, two “s” from the 5S technique are directly linked to these problems, which provide an easy solution to order (seiton) and clean (seiso) the workspaces in advance and with continuous action (Kaizen). If the employees give a place to every tool they use and they return it back to its original position after using it, the next employee will not have these kinds of problems. Additional to this, the workspace will look neat and tidy, which makes the company to be ready for both internal audits and ISO inspections.
In the production of prototypes, a constant reworking of process can be excused due to the necessity of testing different components in order to obtain the higher performance of the products. But, when it comes to production of finished goods, the act of reworking consumes valuable time that is needed for other activities, making this act a waste of labor and time. For these cases, CombiQ does not have a quality department that conducts inspection to finished goods; thereby the same engineers are responsible for the quality inspection. But this factor can be reduced, if the company improves the standardization of processes, so when the same task is performed by different engineers, the problems will not occur again. Having standardized (seketsu) procedures for all operations is a practice promoted by 5S technique that must be repeated in a continuous flow, as Kaizen indicates.

Another issue that CombiQ faces is the lack of training for their employees regarding to new technologies, processes or in this case, the introduction of new concepts in manufacturing. After a well-based training of the main tools and working methods, every single employee is now self-disciplined (shitsuke) and responsible to do the operation in the right way. The importance of this behavior is to enhance the habits among the colleagues as an ongoing process of continuous improvement (Kaizen).

On the other hand, in order to cope with short-term goals that require rapid improvements, the technique of Kaizen Event can be used. As it is explained by Ortiz (2006), this event reacts more in detailed rather than the holistic view of Kaizen’s philosophy. The importance of having these events is to help the company react to short problems while the whole production system is being developed. Therefore, a quick training about Kaizen should be performed at the beginning of this project.

In conclusion, it is found out that 5S and Kaizen are most suitable techniques for the company present situation and its future development. This decision has been taken not only because of the previous examples, also because of the power that these techniques bring to any kind of process. One of the main reasons of choosing Kaizen is its philosophical approach towards incremental improvements. In many techniques, the importance of continuous improvements is mentioned. That is why CombiQ should perceive Kaizen as a way of thinking and its applicability with different procedures such as ISO certification and TQM. One of the main requirements in ISO considers a continuous improvement technique in order to keep up working in the same structure and do not let this down after being certified.

5.5.3.1 Contribution of 5S to ISO requirements

CombiQ has to consider 5S as a path to ISO 9001 and the Quality Management System, which is supported by TQM. As Pheng (2001) suggests that there is at least one or more “s” in the requirement clauses of ISO 9001. Using 5S is a different viewpoint to satisfy the requirements of ISO 9001.
In the following paragraphs, the readers can observe which “s” copes with which ISO 9001 requirement. As it is mentioned by Karapetrovic and Willborn (1998), the common requirements of ISO 9001 and ISO 14001 can be handled together. So, common requirement satisfaction is valid for ISO 14001. In the Appendix 9.4, complete information about this topic can be examined.

Seiri (Organizational) is compatible with the clauses that demonstrate stratification management as well as the clauses that contain plans, schedules, procedures and criteria required for quality management. In conclusion, this “s” contributes the requirements for “how the organization should operate”.

<table>
<thead>
<tr>
<th>Usage</th>
<th>Degree of need (Frequency of use)</th>
<th>Storage method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Things not used in the past year</td>
<td>Throw out</td>
</tr>
<tr>
<td></td>
<td>Things used only once in the past 6-12 months</td>
<td>Store at a distance</td>
</tr>
<tr>
<td>Average</td>
<td>Things used only once in the past 2-6 months</td>
<td>Store in central place</td>
</tr>
<tr>
<td></td>
<td>Things used more than once a month</td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>Things used once a week</td>
<td>Store near worksite or carried by person</td>
</tr>
<tr>
<td></td>
<td>Things used everyday</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Things used every hour</td>
<td></td>
</tr>
</tbody>
</table>

Seiton (Neatness) is compatible with the clauses on systematization and documentation of processes, procedures and other matters. This “s” can be used with control of documents to ensure traceability as well as it guides the organization to report and communicate to ensure the performance follow-up actions, where necessary.

Seiso (Cleaning) is compatible with the clauses about non-conformities by leading the organization to remove non-conformities, and it guarantees that there are no contributing factors that result in defective products. In every stage of the product realization process, each defect or non-conformity should be corrected and assured. Also, CombiQ can use Seiso to deal with the clauses about accountability by assigning responsibilities to capable personnel.

Seiketsu (Standardization) is important for CombiQ after getting certified by ISO, because the company can ensure the possible changes by standardizing them. This promotes consistency in the operations and organization itself.

Shitsuke (Self-discipline) is compatible with many clauses. With Shitsuke the company can review and evaluate the changes and guidelines to improve the quality management system. CombiQ can cope with total involvement and top management commitment, organization of internal audits and maintain the conformities.
5.6 Key Elements of Lean Manufacturing System

The backbone of the proposed production system is Lean Thinking. For CombiQ; in order to reach the structured production system certified by ISO 9001 and ISO 14001, integrated management system assists the design process in a constructive way. TQM maintains overall quality of the system, which is in parallel with ISO requirements and Lean Thinking. However, there must be complete composition of the concepts in the manufacturing process. Hence, the manufacturing system should be adjusted by the key elements that Lean philosophy proposes. This system is called Lean Manufacturing System as Feld (2001) suggests.

### Organization
- The top managers of SMEs must inform their employees with the proper job role and responsibilities. Because of the size of the companies, for instance CombiQ, the same personnel have to do several tasks that might not be directly related to the ones which they were hired for.
- At the same time, training must be provided and afterwards, this knowledge has to be shared among employees, increasing its flow around the company.

### Metrics - KPIs
- While running the production system, the company must define key performance indicators (KPIs) in order to measure different processes. Basically, these indicators can be denoted in the following two fields:
  - Manufacturing (OEE, maintenance, cycle time, quality, flexibility, cost…)
  - Supply Chain Management (forecasting, inventory, delivery lead time, cost…)

### Logistics
- Coordinating the flow of material is extremely important once the company starts handling a formal production system. The planning and control of this flow has to be shown with the supplier, then inside the manufacturing facilities and finally with the customer. For instance, CombiQ’s suppliers and customers have a direct contact, which helps the coordination of this material flow, reducing delivery times and production lead times. However, they still do not have a fixed position in the production process, where it can be balanced by demand and forecast.

### Manufacturing Flow
- The manufacturing departments in SMEs are relatively limited, such as the case of CombiQ, where the usage of one common workshop is oriented to different manufacturing operations, reducing its availability which is against continuous flow principle in lean thinking. Thereafter, the workplace organization should be performed by process mapping, workload balance, routing analysis, and workshop layout design.
- The short distance between workshops in CombiQ, helps the flow of operations and reduces time while selecting parts from the inventory to the workstations.

### Process Control
- In all production phases, CombiQ and other SMEs should have a process control policy. The controls should be made with different tools depending on the purpose (monitoring, stabilizing and tracking). According to the needs of CombiQ in the long run, the following tools could be implemented as a part of Lean philosophy: JIT, TPM, 5S, Visual Controls, Poka-Yoke and 6σ.
5.7 Production Planning

Nowadays, CombiQ works in an Assembly-To-Order class in Customer Order Decoupling Point (CODP). This is observed when the employees preassemble cases and electronic boards in order to reduce lead time when customer sends the order. Thus, the forecast plays an important role in their current situation. However, it cannot be accurate all the time due to the fluctuating demand by the customer as the employees pointed out in the interviews.

According to one of Lean principles by Womack and Jones (2003), production planning must operate with a pull system, where the orders are satisfied as soon as possible, increasing the flow of value and reducing time in the manufacturing process. But, in order to accomplish this way of working, CombiQ has to work closer with its customers and foresee a possible order.

In this case, the company should pull the value stream in an efficient flow in order to achieve a Lean Production System, where the coordination between forecast and demand is controlled. Moreover, one of the goals of CombiQ is to have a flexible manufacturing system, where they have one common module that can be adapted to different products. Thereby, having this module will enhance the speed of satisfying customer’s demand.

As an inventory management policy, the company could use safety stock concept as one of the employees agreed. Hence, CombiQ should have some stock as a safety stock in order to react faster to the orders. The company should place themselves where the effect of demand is higher than the effect of forecast. Therefore, the company could shift towards MTO and ETO. Depending on the product type or relation with customers, MTO and ETO could be chosen after a detailed analysis that the company must do, by which customer demand uncertainty can be coped with.

With an accurate CODP identification, CombiQ would be able to calculate the ratio between production lead time and delivery lead time, which defines its position in the supply chain and the relationship with the different elements. (Wikner and Rudberg, 2005b)
6 Discussions and conclusions

In this chapter, discussions about the chosen method, discussion about the analysis and findings, also conclusions and suggestions for further researches can be found.

As it is mentioned in the Method chapter, an exploratory single case study with qualitative approach and inductive reasoning was carried out through this project. The validity and reliability concepts should be discussed according to the selected approaches. Due to the fact of being a single case study, reliability can be increased if the study is applied more than one company. On the other hand, single case study concept enhances the perception of a specific phenomenon and entails detailed insights, which ensures the validity of the study. This makes preferred approach the best option according to the requirements of the project. As an external validity point of view, qualitative research approach is less reliable than quantitative approach in terms of generalizability. But, inductive reasoning can be applied to the SMEs that share the same conditions and characteristics with CombiQ.

According to the characteristics of this case study, observations, interviews and literature review are the most suitable data collection techniques. The data was collected focused on the research questions. For primary data collection, all the related personnel were interviewed inside the company, where valuable data was collected and used for its analysis as well as an ISO auditor. Within the company, not being a native speaker was a disadvantage for the empirical findings in terms of language barrier, where the quality and reliability of the context affected. Nevertheless, the interviews were handled in English since everybody was capable of expressing himself. A remarkable advantage in the data collection process is the eight-month experience of one of the researches in the company as a worker, which enriched the observations via his knowledge about the current operations and mechanisms of two of the main projects. These empirical findings were supported by the relevant literature in order to provide a synthesis for the analysis of the case.

As it was highlighted in the empirical findings chapter, the overall knowledge about the concepts in theoretical background chapter can be discussed. The structure of the interviews was performed in order to cover a sequence of relevant topics that are included in the theoretical background chapter. This sequence starts with an overall perspective of the company, which consists of business model, manufacturing/marketing strategies, competitive factors and employee well being. Then, the interviews follow a theoretical part where the managers and employees showed their knowledge regarding ISO Certifications and Lean Thinking, among other parallel topics. Therefore, the presented theory of the thesis complements the deficiencies of the empirical findings. The main aspects were covered and described as simple and informative as possible, so it can be used as a framework for the readers and practitioners. By having this description, this paper drives the project of a production system design into an implementation and the continuation of the development process as it can be found in Figure 3.
The analysis was made in order to achieve the answers of the research questions. Regarding the first question, it was answered by solid explanation about the steps that can be taken in order to design a lean production system with the company’s characteristics and conditions. After understanding Figure 3, the reader can detect that design phase is part of the production system development process. Thereby, this project focuses on the design phase, providing the proper guidance and tools that help SMEs, in this case a company in the electronic industry. The researchers believe that implementing Lean Thinking in the operations of this kind of companies is extremely beneficial due to the effectiveness of its techniques. Moreover, this project drives the companies into a set of steps. To explain the main steps briefly, the company should have a manufacturing strategy in order to design a production system. The SMEs should create their manufacturing strategy by defining their marketing strategy and business model, which are constructed by the prioritization of competitive factors. When the company reaches the production design phase, in this case lean production system design; preparatory design and design specification phases should be organized with the help of lean philosophies and techniques that were suggested. In parallel with lean ideas, the company should adapt itself to the requirements of the desired ISO certifications (ISO 9001 and 14001) and take actions to reach this goal with full commitment from both managers and employees. The companies should plan their production by balancing customer demand and forecast. In the case of lean production systems, SMEs ought to focus on a pull system rather than a push system. According to the demand situation, the companies should make an accurate assessment of placing their Customer Order Decoupling Point (CODP).

Regarding the ISO certifications, a comprehensive investigation about the certification requirements was made. The analysis was performed according to the current situation of CombiQ supported by the empirical data gathered from an ISO auditor and relevant literature. The study shows that, companies should perceive ISO 9001 and 14001 as a management system rather than a marketing tool. As it is mentioned before, there must be a full commitment and determination in the certification process that would lead the company to reach the desired management system. The common requirements of ISO 9001 and 14001 can be handled together. This enables the companies to use Integrated management systems to have a common management system for both certifications while handling the specific requirements separately. Additionally, a general ISO certification framework was suggested as a guideline with several steps, which can be used as a road map in the certification process.
Concerning the second research question, different lean techniques that enhance the design and development of a production system in the certification process were studied and suggested. In the tool selection process, a value and waste analysis constructs the basis of the tool selection as well as the requirements of ISO certifications. The current system of CombiQ directed the researchers to come up with two applicable lean techniques that would ease the certification process in terms of requirement satisfaction. Continuous improvements are obligatory in order to be certified by ISO. For this case, Kaizen is appropriate as a mentality, which can be reflected to all processes and actions in both operational and managerial perspective. The companies can support all the techniques with Kaizen. In the case of CombiQ, the supported technique is 5S. This technique is useful in both current situation and future steps of the company. In general, 5S enables CombiQ to structure and handle its processes with a support in workplace organization, reducing reworking, standardization of processes and training. Additionally, these mentioned benefits of 5S help the ISO certification process by contributing the requirement satisfactions in quality management, systematization and documentation of processes, correction and reduction of non-conformities, and internal audits. As a complement to quality management system requirements of ISO, lean ideas and future steps, Total quality management concept was analyzed. The findings indicate that TQM approach is appropriate for both sustaining a quality management system for ISO 9001 and integrated management systems. The company can develop itself in a TQM perspective in combination with lean if going beyond ISO 9001 is desired.

The figure below is the reflection of the overall process of this thesis in three main blocks:

1. The three bottom layers form a solid structure, where the company should state their Mission and Vision, followed by a Business Model. This bottom layer supports the Competitive Factors that form the Manufacturing Strategy. The last layer of the basis ensures that the presented model operates with a Lean Thinking philosophy.

2. The middle block contains two main pillars and two auxiliary pillars. The main ones consist of Lean Principles and ISO Requirements, which are assisted by Lean Techniques and TQM pillars. As a group, the middle block can be considered as a path for the practitioners to walk through in order to achieve their objectives from their basis.

3. Finally, the presented framework will ease the desired outcomes of the company, firstly by managing a Production Planning and Control. Consequently, the company will be sufficiently prepared to be certified by ISO and last but not least, the way of working will improve their Competitiveness and therefore the Customer Satisfaction.
As suggestions for future researches, this study can be extended for the whole production system development process. Once the proposed design is performed, the company can continue with its implementation according to recommended steps, which would lead the company to experience the production start-up.

Besides the techniques that are used in this study, new ones can be examined and implemented according to the needs. The researchers ought to add quantitative approaches for the further decisions in order to measure the performance of the developed production system and increase the overall reliability of the project.

Throughout the whole project, the companies and researchers should involve deeply and believe in the changes for the ISO certifications. This attitude should be maintained after being certified.

It is recommended for the researchers, who would like to carry a similar study out, to use multiple case study design approach in order to work on different systems that would provide more insights and contributions to the external validity of the study.
7 References


CombiQ AB (2011) http://www.combiq.se (Acc. 10 May 2011)


8 Search terms

5S .......................................................... 40
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9 Appendices

9.1 Inductive and Deductive Reasoning

According to DePoy and Gitlin (2005), we can indicate the major characteristics and differences of deductive and inductive reasoning with the table below.

<table>
<thead>
<tr>
<th></th>
<th>Deductive</th>
<th>Inductive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acceptance of a priori truth</td>
<td>No acceptance of a priori truth</td>
<td></td>
</tr>
<tr>
<td>Truth is constructed with one set of conclusions</td>
<td>From data, alternative conclusions can be made</td>
<td></td>
</tr>
<tr>
<td>Theory testing</td>
<td>Theory developing</td>
<td></td>
</tr>
<tr>
<td>Relations are checked via discrete phenomena</td>
<td>Relations are inspected via unrelated pieces of data</td>
<td></td>
</tr>
<tr>
<td>Atomistic perspective</td>
<td>Holistic perspective</td>
<td></td>
</tr>
<tr>
<td>Based on single and separate reality</td>
<td>Based on multiple realities</td>
<td></td>
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</tbody>
</table>

Deductive reasoning leads the researcher from general principles to understand specific cases. In other words, the theory becomes the basis and hypotheses are tested formally according to them. (Williamson, 2002)

Inductive reasoning leads the researcher from specific cases to understand general principles. In other words, the specific cases become the basis and generalization is made via them and general statements are made. (Williamson, 2002)

Granzino and Raulin (2004) suggest that a researcher who starts the research with empirical observations and then constructs a theory is using inductive reasoning. Inductive reasoning is case oriented. Since, inductive reasoning enables the researcher to gain deep understanding the character of a particular phenomenon in a holistic perspective; we have chosen Inductive reasoning as our reasoning approach.

4.1 Management responsibility
4.1.1 Quality policy
4.1.2 Organization
4.1.2.1 Responsibility and authority
4.1.2.2 Resources
4.1.2.3 Management representative
4.1.3 Management review

4.2 Quality system
4.2.1 General
4.2.2 Quality system procedures
4.2.3 Quality planning

4.3 Contract review
4.3.1 General
4.3.2 Review
4.3.3 Amendment to a contract
4.3.4 Records

4.4 Design Control
4.4.1 General
4.4.2 Design development and planning
4.4.3 Organizational and technical interfaces
4.4.4 Design input
4.4.5 Design output
4.4.6 Design review
4.4.7 Design verification pg.48 schema
4.4.8 Design validation
4.4.9 Design changes

4.5 Document and data control
4.5.1 General
4.5.2 Document and data approval and issue
4.5.3 Document and data changes

4.6 Purchasing
4.6.1 General
4.6.2 Evaluation of subcontractors
4.6.3 Purchasing data
4.6.4 Verification of purchased product
4.6.4.1 Supplier verification at subcontractor’s premises
4.6.4.2 Customer verification of subcontracted product

4.7 Control of customer-supplied product
4.8 Product identification and traceability
4.9 Process control
4.10 Inspection and testing
4.10.1 General
4.10.2 Receiving inspection and testing
4.10.3 In-process inspection and testing
4.10.4 Final inspection and testing
4.10.5 Inspection and test results

4.11 Control of inspection, measuring and test equipment
4.11.1 General
4.11.2 Control procedure

4.12 Inspection and test status

4.13 Control of nonconforming product
4.13.1 General
4.13.2 Review and disposition of nonconforming product

4.14 Corrective and preventive action
4.14.1 General
4.14.2 Corrective action
4.14.3 Preventive action

4.15 Handling, storage, packaging, preservation and delivery
4.15.1 General
4.15.2 Handling
4.15.3 Storage
4.15.4 Packaging
4.15.5 Preservation
4.15.6 Delivery

4.16 Control of quality records
4.17 Internal quality audits
4.18 Training
4.19 Servicing
4.20 Statistical techniques
4.20.1 Identification of need
4.20.2 Procedures

ANNEX 3: Steps towards a quality system
ANNEX 4: Brief outline of certification/registration
9.3 ISO 14001 "Environmental Management System Requirements" (Zeng et al., 2005)

4.1 General Requirements

4.2 Environmental Policy

4.3 Planning
   4.3.1 Environmental aspects
   4.3.2 Legal and other requirements
   4.3.3 Objectives and targets
   4.3.4 Environmental management program(s)

4.4 Implementation and operations
   4.4.1 Structure and responsibility
   4.4.2 Training, awareness and competence
   4.4.3 Communication
   4.4.4 Environmental management system documentation
   4.4.5 Document control
   4.4.6 Operational control
   4.4.7 Emergency, preparedness and response

4.5 Checking and corrective action
   4.5.1 Monitoring and measurement
   4.5.2 Nonconformance and corrective and preventive action
   4.5.3 Records
   4.5.4 Environmental management system audit

4.6 Management review
### 9.4 Checklist for implementing 5-s principles and ISO 9001:2000 requirements (Pheng, 2001)

**ISO 9001:2000**

<table>
<thead>
<tr>
<th>Clause</th>
<th>Requirements</th>
<th>Seiri</th>
<th>Seiton</th>
<th>Seiso</th>
<th>Seiketsu</th>
<th>Shitsuke</th>
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<td>Management commitment</td>
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<td>Customer focus</td>
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<td>Product and service operations – validation of processes</td>
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<td>Control of measuring and monitoring devices</td>
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Measurement, analysis and improvement

8.1 Planning | X | X | X |
8.2.1 Measurement and monitoring – customer satisfaction | X | |
8.2.2 Measurement and monitoring – internal audit | X | X | X | X | X |
8.2.3 Measurement and monitoring – measurement and monitoring of processes | X | |
8.2.4 Measurement and monitoring – measurement and monitoring of products | X | X | X | X | X |
8.3 Control of nonconformity | X | X | X | X |
8.4 Analysis of data | X | X | |
8.5.1 Improvement – planning for continual improvement | X | X | X | X | X |
8.5.2 Improvement – corrective action | X | X | X | X | X |
8.5.3 Improvement – preventive action | X | X | X | X | X |

**Note:** *Seiri* (organization); *seiton* (neatness); *seiso* (cleaning); *seiketsu* (standardization); *shitsuke* (discipline)

**Figure 9.** Checklist for integrating 5S principles and ISO 9001:2000 requirements. (Pheng, 2001)
9.5 Interview for Top Management

1. Can you define your Company Strategy?
   a. Prototyping (development) and Production phase

   Corporate Strategy: What set of business should the company be in?
   Business/Market Strategy: How should the company compete in given business/market?
   Manufacturing Strategy: How can the manufacturing function contribute to the competitive advantage of the business?

2. Can you explain the current Production System compared to the desired Production System? How do you plan to reach it?
   a. Improvements
   b. Opportunity Areas
   c. How do you see your production in the short (3 years) and long (>5 years) term?
   d. Production Planning (Towards the supplier or customer)

3. What is your knowledge regarding ISO 9001 and 14001? (Requirements)
   a. Do you have any opinion about Quality Management System and Environmental Management System?
   b. How are you working with Quality issues:
      i. Control
      ii. Methods
      iii. Tools (Mention TQM)
      iv. Philosophies

4. Why do you want to be certified by ISO (relations with mentioned strategies)?
   a. How are you planning to achieve the certification?

5. What is your perception regarding Lean thinking and applications? (Objectives, tools, methodologies, philosophy)
   a. Kaizen
   b. 5S

6. From your perspective, how is the interaction between CombiQ and its customers/suppliers?
9.6 Interview for Employees

1. Can you evaluate your working environment?

2. Can you define your level of motivation in your daily activities?

3. Can you define your job satisfaction?

4. How do you feel the support from top managers?

5. How do you define the communication within the company?

6. What is your knowledge regarding:
   a. Production Systems
      i. Production Planning and Control
   b. ISO Certifications (9001 and 14001) and requirements
   c. Quality Management
   d. Lean Philosophy
      i. Kaizen
      ii. 5S

7. How do you deal with customer orders / suppliers?

8. From your perspective, how is the interaction between CombiQ and its customers/suppliers?
9.7 Interview for ISO Auditor

1. What are the most common mistakes that you observe during the inspection?

2. Which main opportunity areas are found in SMEs?

3. What are the most difficult obstacles concerning certification achievement?

4. Mention three of the most important areas or topics that SMEs should have a dedicated focus on? (Some of them take more time, i.e. documentation)

5. Do you think that consultancy is a must in the certification process?

6. Do ISO 9001 and 140001 require completely different actions? Can they be implemented in parallel?

7. If ISO is not considered as a marketing tool and philosophy or not well perceived by the top management and employees, what kind of problems can the company face?

8. What can you suggest for the companies that will proceed in the certification process?