Quality
- a Consequence of Organizational Culture

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Abstract

Title: Quality – a consequence of Organizational Culture

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Issue of study: Quality Systems are frequently used within companies. These systems can be useful to make companies more efficient. The successfulness of the implementation of these systems varies between organizations. The key to quality success has been proved to be a change in the employees' attitude and behavior. These changes are difficult to make and must start at the top level and thereafter be spread throughout the organization.

Aim: The aim of this study is to identify the critical success factors for the creation of behaviors, which are favorable for quality. This study also aims to present how these factors are related.

Method: This is a qualitative case study which is done out of an abductive approach. The empirical data is gathered, at the case company, by interviews, observations and reviews of internal documents.

Conclusion: The critical success factors for quality are; Leadership, Quality Department, Training, Peer Involvement, Employee Ownership, Incentives, Data and Reporting, and Supplier Management. The factors' relations show their contribution to quality and are presented in a model, where Leadership and Employee Ownership are of biggest importance.

Key words: Human Errors, Organizational Culture, Quality, Behaviors, Values and Norms, Leadership and Employee Ownership.

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By performing the study as a case study being located at the Case Company has given us insights in great parts of the organization and valuable experiences for our future. We would like to thank all employees at our case company for their participation and contribution to this study. A special thanks to our supervisor at the Case Company for initiating the idea of this study.

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1. Introduction

The first chapter gives an introduction of the topic of the master thesis, followed by a problem discussion within the area. Out of the given information the purpose to the study is set. Assumptions & Limitations, Target group and the outline of the report is also presented in the chapter.

1.1 Background

After World War II members of the union Japanese Scientists and Engineering, JUSE, came to understand that quality will pay an important role in the future. JUSES's purpose was to find how to increase quality, and at the same time keep the costs low. In the 1970 their research had a breakthrough in several industries. Western countries realized that the only way to compete with Japanese companies was to follow the same way, and pay more attention to quality. Quality has since this time period been an important key for the industry in the West (Lagrosen & Lagrosen, 2010).

Today there are growing similarities between countries' distribution channels, infrastructure and buyer's needs. This, in combination with falling tariff barriers, a fluid global capital market, and the technological revolution, has led to a widespread globalization and the intensity of competition has risen (Porter, 1986). Customers have expectations on the product's quality, and if this is not met it could lead to dissatisfaction, deteriorated image, lost market shares, reparation costs and sometimes even tort money for the company. Therefore, poor quality should be identified before the product leaves the company and reaches the market (Lagrosen & Lagrosen, 2010).

Targets of performance are set in order to tell the company what they should do, and the measurement tells the company how well they are performing. Different methodologies and quality systems are tools that enable the company to reach these targets. Total Quality Management, TQM, is one method saying that quality should be integrated in all activities within the company. The Western World has established a set of international standards, for instance ISO 9000 regarding quality management system (Lagrosen & Lagrosen, 2010). Six Sigma is a framework consisting of different tools that are established in order to reduce defects in production, and receive a high level of quality, in other words reduce the number of variation (Klefsjö, B; Wiklund H.; Edgeman, R.L, 2001). In addition to this, Lean Production aims to eliminate the factors in manufacturing that does not add any benefits for the customer (Linker, 2009).

In order to improve the manufacturing and the company´s performance, companies implement the aforementioned methodologies. Commonly, companies initially pay

great attention to the method, but once the quick wins are won the systems tend to be seen as complicated and cumbersome. The key to success has been proved to be a change in attitudes, and these changes are difficult to make. These changes must start at top level and thereafter be spread throughout the organization. To receive the wished result it is necessary to make changes in attitudes, by everyone in the organization (Sörqvist, 2011).

1.2 Problem Discussion

Companies today have an extensive knowledge of how to run improvement projects in order to, in a technical way, improve their processes and, thereby, increase both quality and efficiency. Even though the knowledge exists there is still dispersal in the success of these improvement projects. One explanation, to why the same changes in two different companies do not give the same result, is that there is an internal life in a company, a unique organizational culture. Lately, this organizational culture has been proofed to have a greater influence on the success, quality and efficiency than realized before (Bentell & Wiberg, 1999; Sörqvist, 2011).

Common for all companies, even those who are more industrialized, is that there are employees involved directly or indirectly, in all processes. People make decisions, communicate, develop and perform their tasks in a good, or not so good, way. People affect the quality of the product by the way they act and behave. Their motivation and competence determents how well they perform their job. It is not enough to focus on quality improvement systems if there is a lack of motivation and competence amongst the employees (Steininger, 1994).

Two studies, investigating what impacts quality performance, have shown that soft factors, such as top management support and workforce management, influence the quality performance to a greater extent than harder factors, meaning data, information and quality control systems. Goldstein, Linderman, and Schroeder (2008) show with their study that good leadership, employee involvement, teamwork and communication have a significant positive effect on manufacturing performance. What their study also shows is that there is no significant correlation between quality information and manufacturing performance (Goldstein, Linderman, & Schroeder, 2008). The same reasoning is done by Dow, Samson, and Ford (1999) saying that softer factors, like shared vision and committed workers, impacts the quality outcome in a more significant way than hard quality tools do (Dow, Samson, & Ford, 1999). A united vision, created by shared values and norms is, therefore, needed in order to improve the quality output.

These studies show that soft factors have a bigger impact than hard factors. Which are these factors that are critical for a company to create a behavior amongst their employees that is favorable for quality? How are these factors related to each other and which of these factors will have a direct impact on quality? The indirect factors, how will they affect the quality output?

1.3 Aim and Objectives

The aim of this study is to identify the critical success factors for the creation of behaviors, which are favorable for quality. This study also aims to present how these factors are related.

To achieve the aim the following objectives have been identified:

1. Identify the critical success factors for creating behaviors favorable for quality.
2. Analyze a Case Company using the identified critical success factors.
3. Through the analysis of the Case Company, understand how the critical success factors are related to each other.

1.4 Assumptions and Limitations

Quality is, in this study, seen from a technical perspective. The technical perspective sees quality as the ability to perform according to preset targets and directives. Customer focus is excluded in this study. The product produced is assumed to serve the customers' purpose and product design is, therefore, not included as an area of research in this study.

The study does not include process design, techniques and machines used for production.

1.5 Target Group

The study's primary target group is the management team at the Case Company. Employees working at either the Human Resource department or Quality department could also have an interest in the study. Finally, researchers and students working within the topic are considered as a target group.

1.6 Outline of the report

Chapter 1: Introduction

In the first chapter the background and problem description to the topic will be introduced, as well as the aim & objectives, limitations and the study's target group.

Chapter 2: Methodology

How the study was performed will be explained in the second chapter. The strategy, research method, design of the study, data collection and analysis method, that have been used, will be presented.

Chapter 3: The Case Company

This chapter introduces the study's Case Company. The company and its history, and the Group it belongs to will be presented as well as the company's current situation regarding the quality problems.

Chapter 4: Human Errors
In order to understand the Case Company's quality problems, this chapter will explain the concept of Human Errors. Questions that will be answered are; What characterize a Human Error? How could a Human Error be categorized? Why do they occur?

Chapter 5: Basic assumptions, Values & Norms and Artifacts
In this chapter it will be explained what an organizational culture is and the relation between basic assumptions, values & norms and artifacts.

Chapter 6: What is Quality?
In the sixth chapter Quality, from different perspectives and definitions, will be presented. Since the Case Company is in a regulated industry, the company needs to follow Good Manufacturing Practice, GMP, which is a quality assurance tool. How GMP affects the company's processes and the products' quality will be explained.

Chapter 7: Critical Success Factors for achieving Quality
This chapter will introduce factors impacting the quality at the company. The empirical research will be based on a selection of those factors and these will, therefore, be explained in more detail. The critical success factors are; Leadership, Quality Department, Training, Peer Involvement, Employee Ownership, Incentives, Data & Reporting and Supplier Management.

Chapter 8: Case study
Out of the selected factors, presented in the seventh chapter, the empirical data gathered at the Case Company will be presented. The factors will be presented and analyzed, one by one, in order to understand the weaknesses and strengths with the current situation.

Chapter 9: Conclusion
In the last chapter, the academic result as well as the company specific result is presented. These are followed by a discussion of the result, the chosen methodology and recommended areas for further research.

2. Methodology

This chapter describes the methodological approach for the thesis. Choices taken will be motivated, and the chapter will be summed up with a discussion regarding the trustworthy and credibility, together with a discussion about difficulties experienced when performing the study.

2.1 Work Process

The study has been conducted in different phases in order to fulfill the purpose. Each phase is presented below and summarized in Figure 2.

2.1.1 Introduction

Firstly, the aim was to receive an overall picture of the Case Company, its products and the manufacturing process. Since the Case Company is in the pharmaceutical industry information about what it means to be in a regulated industry was needed.

2.1.2 Gathering Theory

According to Bryman & Bell (2011), it is initially suitable for a qualitative research to search for information in a wider range (Bryman & Bell, 2011). Therefore, a basic screening of quality systems, organizational culture and total quality management was conducted in order to give the authors a first impression. A decision was thereafter taken to focus on the following areas; *Organizational Culture, Human Errors and Quality*. These areas are presented in Figure 1. The reason for this choice was that these areas covers for behaviors that affecting quality, since organizational culture gives an understanding of values and norms that creates behaviors, human errors are errors that is a consequence of these values and norms, and for the understanding of what to strive for it is necessary to understand what quality is.

Figure 1. Visualization of the theory areas for this study.

2.1.3 The Case Company's situation

Interviews and observations were mainly conducted to be able to understand the current values at the Case Company, within the areas, from theory, identified as important for quality. From the interviews and observation the authors gained information about what systems the Case Company has and how they are used, at the same time as getting the employees' perceptions of the company and its working processes. In addition to this, reports and internal documents have been read.

2.1.4 Analyze of the Case Company relative to the theory

The analysis was based on the gathered empirical information and theory. The analysis resulted in an understanding of problem areas at the Case Company.

2.1.5 Conclusion

Out of the analysis similarities within the analyzed areas were found and presented to the director of Quality Operations and the management team. Further, the factors presented in the framework were put in a model, which explains the relation between the factors. A discussion about suggestions for further research is held together with a discussion about work process.

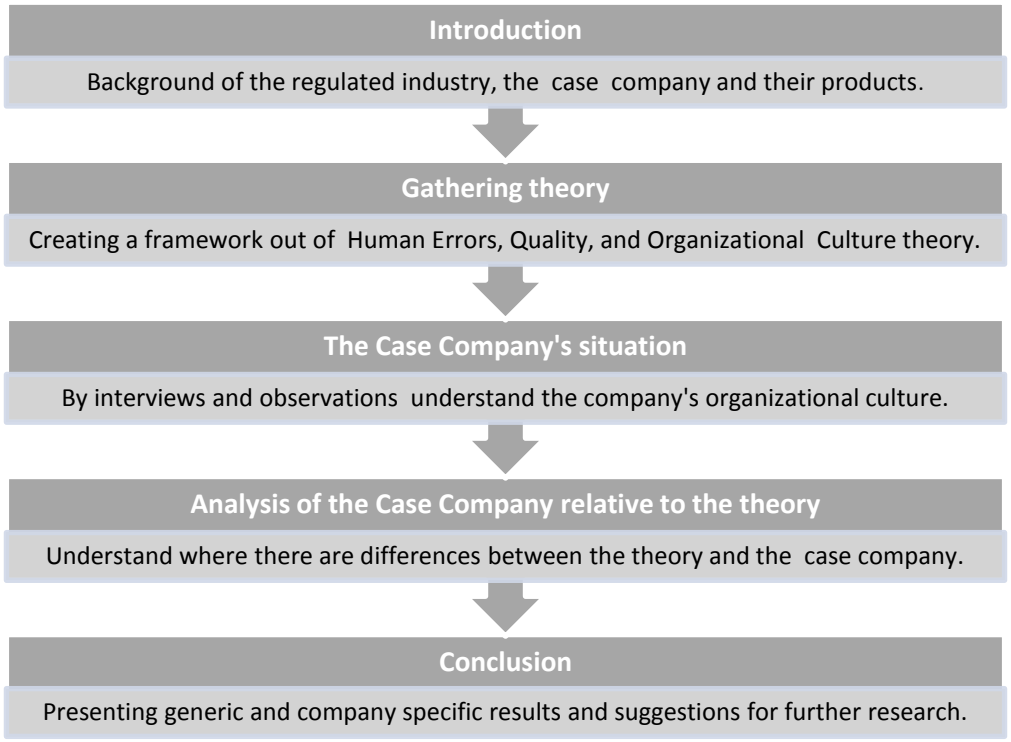

Figure 2. A summary of the study´s work process.

2.2 Methodological Approach

According to Arbnor and Bjerke (1997) there are three different types of methodological approaches; *the analytical-, the systems-,* and *the actors approach* (Arbnor & Bjerke, 1997).

This study has been conducted out of the actors approach. This approach assumes that the best output is received when all the components, one by one, are optimized. In this approach the components can be analyzed individually and thereafter merged to one whole picture being more meaningful with all pieces together than the individual components separately (Arbnor & Bjerke, 1997).

The critical success factors were individually analyzed in this study. Later on they were put in a model with the purpose of explaining the relation between them. This relation visualized the importance of those factors without direct effect on quality, which otherwise would be meaningless from a quality perspective.

2.3 Research Strategy

> *"The general principle is that the research strategy or strategies, and the methods, techniques employed, must be appropriate for the questions you want to answer"* (Robson, 2002) .

To get the required information, necessary for performing a research, four different research strategies could be used; *case study, survey, experiment* and *action research* (Robson, 2002).

In this study a case study strategy has been used. A case study provides details and knowledge about a single "case" or sometimes a number of cases that are related to each other. Individuals, groups or a specific situation is of great interest in this strategy. The details of the study's design commonly emerge throughout the process, during the collection of data or analysis. The required information to a case study could be gathered through different methods such as interviews and observations (Robson, 2002).

A case study was the most appropriate strategy for this thesis since the Case Company had identified an area that they wanted the authors to investigate. The study's design emerged throughout the process. The picture of the current situation got clearer when more information was gathered, which lead to a shift in what to investigate. The methods for gathering information normally used in a case study, interviews and observations, fitted well for this study.

2.4 Data Collection

There are two types of data, primary and secondary data. Primary data is when the researcher itself has collect the information by experiment, interview or observation. Secondary data is existing information that has been gathered for another purpose, and not primarily for the study. Because of this, there is a risk that the data get misinterpreted by the researchers. It is also difficult to know what information that is left out while collecting the data in first place. The usefulness of secondary data depends on how and why the data is collected and this could be difficult to know (Höst, Regnell, & Runesson, 2006).

When performing a case study multiple sources, at least two, should be used in order to increase the possibility that the correct information is gathered. This is especially important when asking about someone's perception of a situation, since the perception could vary between individuals. Another recommendation while performing case studies is to save findings in a database or document for later analysis. During a case study a lot of information is gathered and it is important for the researchers to remember this information and their perception while collecting it (Yin, 2009).

Information for a study could be gathered in many ways. According to Yin (2009) six different sources are commonly used in case studies; *interviews, documentation, archival records, direct observations, participant-observation* and *physical artifacts*. In this study the four first mentioned sources are used.

2.4.1 Interviews

Interviews are a common way to gather information in a qualitative research. An interview could be conducted in three different ways; unstructured, semi-structured, and structured (Bryman & Bell, 2011). In this study the authors have used semi-structured interviews because before the interviews the authors had limited information about the areas of expertise of the respondents. Therefore, semi-structured interviews fitted well since it enabled some guidance from the authors and in the same time it was possible for the respondent to give information about what he, or she, found necessary for the authors to know. When conducting interviews the purpose has been twofold; the interviewers wanted information about the expertise area, but also personal thoughts from the respondent about the current attitudes in a certain field.

All interviews in this study has been recorded and transcribed to prevent information loses.

2.4.2 Documentation

Letters, e-mails, agendas, news and formal studies are examples of documentation, usually available online, on the intranet or the Internet. Documents should be used as a complement to the information gathered from other sources. The strength of documents is its accessibility – it could be reviewed numerous times. One risk with documents is that it could be misinterpreted and that the information could be incorrect (Yin, 2009).

In this study documents have been collected from the Case Company's intranet to increase the understanding of the company. Formal studies have been used for gaining knowledge about the pharmaceutical industry, but also about the three major theory areas.

2.4.3 Archival Records

Archival records refer to records with processed data. The data could be gathered by the state or the government, or the organization itself. Examples are data from the Central Bureau of Statistics, employee survey, performance charts, and process maps (Yin, 2009).

In this study performance charts and statistics have been used as historical information to judge the involvement of the employees and the frequency of usage of certain tools, but are not used as the primary source for analysis.

2.4.4 Direct Observations

Direct observations should be performed in the natural setting of the Case Company, in order to identify behaviors and environmental conditions. Arbnor and Bjerke (1997) mention four types of direct observations visualized in Table 1.

Table 1. Arbnor's and Bjerke's four types of direct observations describe different interactions between the observer and the observant (Arbnor & Bjerke, 1997).

		Observant´s knowledge of being observed is	
		High	*Low*
Observer´s interaction with observant is	*High*	Observing with participation	Participative observation
	Low	Observing without participation	Complete observation

What differ between the four types are the interaction of the observer and the knowledge of the observant being observed. In this study all four types have been used. During guided tours in the production area the authors have observed with participation. The authors have attended educations as a participative observation. Observing without participation has been done during meetings, and finally complete observations have been conducted due to the authors' location at the Case Company. From the complete observations information about the daily work, interactions between employees and departments, facilities and working climate have been collected (Arbnor & Bjerke, 1997).

2.5 Research Method

Research is usually divided into two different methods; qualitative- or quantitative method. What method to use depends on available and, or, needed data. How to conduct the research study will depend on whether a qualitative or quantitative method is used (Bryman & Bell, 2011).

This study has been done out of a qualitative method. The focus in a qualitative method is to understand the social world and the interpretations of humans. The data collection and analyzing phase, in a qualitative method, could be conducted simultaneously and interactively. Information is mainly gathered by observations and interviews. The collected information in a qualitative method differs from the quantitative since the outcome is words rather than numbers (Bryman & Bell, 2011).

The authors chose a qualitative approach because they found it suitable when trying to understand the behaviors, which were a consequence of the values and norms, shared within the company. To gain this understanding the authors felt that interviews were a better method than questionnaires since during interviews the interviewers could perceive feelings, thoughts and attitudes which is not possible to do when using a survey.

2.6 Scientific Reasoning

Research that should result in new knowledge could be done out of a deductive or an inductive research approach. A combination of these two approaches is also possible, called an abductive approach. An abductive approach is suitable when performing a case study since it allows an iterative process of matching existing frameworks to observations (Spens & Kovács, 2005).

In this study an abductive approach was chosen based on the study being a case study. The first theory screening gave an overview of the areas; Organizational Culture, Human Error and Quality. When applying the theories on the Case Company new areas, for example within Quality were discovered because of the Case Company being in a regulated industry. Theory, data collection and analysis were conducted simultaneously.

2.7 Validity, Generalizability, and Reliability

Information is credible if there are no imperfections of the measurement, or the data gathering method. To secure this, validity, generalizability, and reliability should be evaluated (Bryman & Bell, 2011).

The validity could be analyzed asking the question*:* Are the results based on the correct measurements? This means that the validity secure that the findings of the study are regarding what they appear to be about. Generalizability is concerned with whether the study's findings could be useful outside the study and transferred to other areas or industries. Without testing the conclusion on more than one study the result is not sufficient to draw general conclusions from. Reliability answer the question: If the same study was done once again, would the same result then be obtained? (Bryman & Bell, 2011)

To secure the validity multiple sources have been used. When collecting information about one specific area several people have been interviewed. In that way, the validity in the given information has been tested. When possible, numbers and quantitative data given in interviews have been checked with other sources such as documents on the intranet. The information given during interviews has been verified by the interviewees afterwards. To increase the validity both interviewers were present at the interviews to minimize the risk of misperceptions.

As for the generalizability the factors affecting the behaviors that influence quality are, to a large extent, based on the framework produced by CEB. They have worked with more than 140 companies on improving the Culture of Quality, which implies that the factors are general and not specific for a certain company or industry.

This study is based on two extensive frameworks, one being applied on more than 140 companies and the other being complied out of the most prominent theories in the quality field. This gives reliability to this study.

3. The Case Company

This chapter contains a short description of the Case Company used in the study. The purpose of this chapter is to create an understanding of the industry, and why the Case Company is used in this study.

3.1 The Group

The Case Company is part of a group, in this thesis called the Group, which contains 260 companies and 465 brands globally. The Group is active in three divisions; Pharmaceuticals, Medical Devices & Diagnostics, and Consumer Products. The Group was founded in the United States and the first business idea was to produce antiseptics for wound care. During this time many patients died of infections after surgery and there was a need for treatment.

3.1.1 Vision, Strategy, and Guiding document

Since the start, the Group has worked strategically to become *Broadly Based in Human Health Care*, one of the four strategic principles. The other three are *Managed for the Long term, Decentralized Management Approach* and *Our People and Values.* One result coming from this strategy is that 70 % of the Group's sales come from products being no. 1 or no. 2 in the global market.

All companies within the Group are united under a guiding document describing the principles of responsibility and behavior. The guiding document informs about the Group's responsibility towards, and in this order; consumers, employees, society and shareholders. This is a way to think about the company in long terms, and by fulfilling the responsibility for the first three categories of stakeholder, the shareholders will be satisfied too. The guiding document is used as a moral guideline when facing big and difficult decisions, and every year all companies within the Group evaluate how well the guiding document is lived.

3.2 History of the Case Company, a company within the Group

The Case Company was founded in the end of the 19th century in the United States. The company is famous for production of broad range of products including prescription drugs, Over-The-Counter (OTC) drugs and other Consumer and devise products. OTC means pharmaceuticals for purchase without prescription from doctors, normally available in stores but also in drugstores and pharmacies.

Products distributed under the Case Company's logo are pain killers, treatments for cold and flues, allergy, sleeplessness, digestives and other areas for OTC products.

3.3 Production site in Sweden

The production site has been at its current location for around 100 years. During the years the production site has been subject to a fem acquisitions and mergers. The current Group took ownership of the site in 2006. After the acquisition, the company name was changed to the name it has today.

The production site in Sweden is focused on solving one medical problem for consumers. For meeting the customer demands the site produces six different products for the global market, solving the same medical problem, but in different ways. During 2011 the products produced at the Swedish production site sold for 525 MUSD.

About 340 people work directly in the production, and in all 540 employees work in the Supply Chain division. The Case Company also keeps its R&D at the Swedish site, employing around 100 people. This is the global research center for this type of product within the Group, and has the capability to go from product idea all the way to market introduction.

3.3.1 Why the Case Company is part of this study

When the Case Company was acquired by the Group, the quality requirements changed as well as the focus of the new business. The product and the production process were not changed, but the criteria set from the Group, customers and consumers were different.

The production processes are validated. This means that the processes are governed by strict regulations and Health authorities requirements, intended to ensure that companies produce products with the correct quality, in a consistent manner. While quality problems are not uncommon in any production process, the Case Company wants to take a strategic approach to improve Quality as a key enabler to improve Customer and Company requirement. A large part of the current company quality challenges has already been identified by the company as being related to humans. At the moment, the Case Company is looking into different solutions to this problem. One is to investigate the current attitude towards quality, and to see how this attitude could be changed towards more quality focused behaviors within the organization.

4. Human Errors

Chapter four will introduce the reader to the concept of human errors, different types of errors, and explain possible root causes. This chapter will also highlight the human errors that are connected to values and norms.

In all organizations there is always a risk that human errors will occur. At first thought, human errors could be associated with manufacturing. But even in automatic environment humans are integrated, not necessarily in the actual production, but for e.g. the setup of the production line, the programming of robots and in the surveillance of the process. The same is true for service companies. Wherever humans are involved there is a risk for human errors. To understand why human errors occur and how a company could prevent them, it is first necessary to understand what a human error is. A definition of human error and identification of categories of reasons are needed in order to sort out the issue.

4.1 Definition of Human Errors

Authors and researchers active in the field of human errors tend to, more or less, agree on the definition. James Reason (1987) says that "a human error is any act which is counter-productive with respect to the person's private or subjective intention or goals" (Reason, 1987).

Sanders and McCormick (1987) have another definition saying almost the same as Reason. To their definition they add that an error is something that has an undesired effect, or potential effect. Adding *potential* to the definition means errors that are reversible and corrected will be included. These corrected errors still count as human errors (Sanders & McCormick, 1987). With this said it is clear that a human error is an error caused by a human and its action. Since Sanders' and McCormick's definition covers corrected errors, this definition of human errors will be used in the rest of the study:

> *"A human error is an inappropriate or undesirable human decision or behavior that reduces or has the potential for reducing, effectiveness, and safety and/or system performances"* (Sanders & McCormick, 1987).

4.2 Classification of Human Errors

It is important to find the reason for the human error in order to be able to correct and prevent it from happening again. Even if the outcome, or effect, of two errors could be identical the reasons could be completely different.

A simple classification is done by Swain and Guttman (1983). This includes four classes of errors:

- Errors of omission
- Errors of commission
- Sequence errors
- Timing errors

Errors of omission are human errors that occur when forgetting to do something. The error is a lack of action; for instance if one step in the process is not conducted, this result in an undesired situation. *Errors of commission* are actions performed incorrectly. The reason for the incorrect performance could for example be inadequate information or training, lack of concentration, or stress. *Sequence errors* are right actions performed in the wrong order while *timing errors* are right actions performed in right order but taking too long or short time. Sanders and McCormick (1987) agree to the first two classes but find sequence and timing errors being part of errors of commission instead of separate classifications (Sanders & McCormick, 1987).

Baybutt (1996) agrees with Sanders and McCormick but add one more classification. His third class is *extraneous error.* He describes this class as non-required actions performed instead of, or in addition to, required actions (Baybutt, 1996). He means that it is possible to perform all intended, necessary, actions in the right way, not mixing the order nor doing it with incorrect timing, but still make errors by adding non-required actions.

To do a non-required action instead of required action could qualify in the class of errors of commission, if the task is performed with the intention of doing what is required but failing. If a non-required action is done because the right action is forgotten, then it qualifies as an error of omission. What Baybutt refers to is non-required action that is performed without the knowledge of the action being incorrect. Errors of commissions in literature seem to be exemplified as action being performed incorrect but with the performer being aware of the mistake. This indicates that the last classification by Baybutt covers a new category of errors.

These categories or classifications are used as the first step in understanding human errors, even if it does not reveal the reason or cause. To be able to take the right actions when an error occur it is necessary to be more specific about the reason. It is important to not only be content with identifying who was responsible for the error but also examine why that person made it (Sanders & McCormick, 1987).

4.3 Reasons for Human Errors

There are attempts in literature of creating generic frameworks for human errors. At first each error could seem to be unique but after deeper studies some more frequent origins appears as active *failures* and *latent conditions*. An active failure is an error or violation committed by operators/maintenance personnel. The errors are often specific and get a direct consequence. Latent conditions are designed into the process, created by the organization or government rules, and do not get exposed until it is combined with an active failure. The mechanism behind a human error can be described as; slips and lapses, mistakes or violations. This covers for both active failures and latent conditions (Contra Costa Health Service, 2011).

4.3.1 Slips and Lapses

A slip is an action of correct intentions which fails. The operator knows how to execute the task but fails, due to lack of concentration or another disturbance, while performing the task. Lapses are when an action is forgotten by the operator. Reasons for this could be the same as for slips but it results in the task being undone, instead of being wrong. If an operator assembles parts for a car and gets disturbed while working, that could result in parts being put together incorrectly – a slip. It could also result in parts missing when passing the work forward – a laps (Contra Costa Health Service, 2011).

4.3.2 Mistakes

Mistakes are defined as task being performed according to plan, but the plan itself was wrong from the start. If an operator is doing his job following the instructions, step by step, but still produces the wrong product, there is a mistake in the instructions. Since the mistake is in the instructions, and not made by the worker performing the task, it is necessary to remember that the actual source, or reason, for the mistake is the person writing the instruction, and not by the worker performing the task (Contra Costa Health Service, 2011).

4.3.3 Violation

If an intended action is taken that is against rules, restriction, and procedures, it is a violation. There are three categories of violation; routine, optimization and necessary. *Routine* is a regular violation that has become the normal way of performing a task. A short-cut to the desired result, often because the instructed way feels unnecessary and complicated (Contra Costa Health Service, 2011).

An *optimization* means that the process is pushed to the limits to get maximum output. An example could be that a reactor only is allowed to be filled to a certain level, but that level is violated in order for the process to increase the output. The reason for the limit might be a safety precaution. When violating this limit there might not be direct visual impact on the equipment but it could result in later errors and breakdowns (Contra Costa Health Service, 2011).

A *necessary* violation is when there is no other way of performing the task. A necessary violation should indicate that an improvement of the process is necessary in order to prevent it to be done again (Contra Costa Health Service, 2011).

4.3.4 Personal Interpretations and Misremembering

James Reason (1987) discusses human errors that occur due to humans' capacity of processing information. Individuals who receive information could perceive it differently and draw different conclusion out of the given information. *Inferential errors* are errors that occur due to the employee's incorrect reasoning. Another error is *errors of judgment* which are caused by misjudgments. *False sensations* occur because of a difference between the employee's subjective experience and the objective reality. Finally, an *inaccurate recall* is based on misremembering sentences, stories, places, faces or events. A similar error is *misperception* – mishearing or misreading text, signs and instrument and misperceptions of people (Reason, 1987).

4.4 Why Human Errors occur

Human errors must, to some extent, be accepted. To forget, to misinterpret, to be disturbed and, therefore, make errors is human, and hard to overcome completely. One reason for these errors could be a stressful environment. By adding more resources or by adjusting the workload it is possible to reduce these types of errors.

Violation errors are tightly connected to behaviors. Since the employee is aware of he, or she, making an error these errors are caused by the employee's decision, and indirect caused by employee's values and the company's norms. In this case, the company needs to work with improving the values and norms held within the company if wanting to improve the quality (Asch, 1955).

Errors could also be connected to training, education or lack of understanding. A lack of knowledge by the employee could result in errors. The reasons for why the employee is lacking knowledge could, from information presented in this chapter, for example be:

- The company is not providing education, or information, to its employees. The company does not think that education is necessary.

- The company is giving education, but the content is not correct or could be presented in a way that does not support understanding. The company teaches its employees incorrectly, which results in quality flaws.

- The company gives education, with correct information, but the employees are unmotivated during the education and they do not learn. It could, for example, be that the company does not inform the employees of why the education is necessary and important. In other words, they do not “sell” the education to the employees. Another reason might be that the employees do not agree with the company on why the education is necessary.

Human errors that occur due to the employees’ individual values and the company’s norms are errors that could be prevented by having other norms and values. With a focus on quality, deeply based in the organization, these types of errors could be avoided. A deeper understanding of values and norms is necessary before understanding how these values and norms could be affected.

5. Basic assumptions, Values & Norms and Artifacts

This chapter will discuss the elements within an organizational culture. This will contribute to an understanding of how behaviors are related to these elements.

Culture is originally from the Latin language and means "soil cultivation". In social anthropology the word is explained as how human act, think and feel (Hofstede, Hofstede, & Minkov, 2010). When talking about culture within a company, it is named organizational culture. The most prominent researcher within the area of organizational culture is Edgar H. Schein. According to Schein (1984) organizational culture is:

> *"… the pattern of basic assumptions that a give group has invented, discovered, or developed in learning to cope with its problems of external adaption and internal integration, and that have worked well enough to be considered valid, and therefore, to be taught to new members as the correct way to perceive, think and feel in relation to those problems"* (Schein, 1984).

Firstly, Schein means that members of an organizational culture have a shared view of basic assumptions. Secondly, the culture is developed by learning, which means that culture will be developed along with new experiences and changes. The basic assumptions, that the group share, will develop over time. And finally, the culture will be taught to new members as the correct way to understand, think and feel. New members of the organization will, thereby, learn what is correct and not correct within the group. Organizational culture is, as Schein says, not just about what a person experience and think. Feelings also have an impact on how a person molds their perception of reality (Schein, 2010).

5.1 What an Organizational Culture consists of

Organizational culture could be divided into different components. In Schein's organizational culture model three levels has been identified; basic assumptions, values and norms, and artifacts. Basic assumptions are always taken for granted, and are seen as the truth for an individual who is a member of the culture. The challenge with the basic assumptions is the difficulty in isolating them from the second level; values and norms. When a value is shared, within a group, it will develop into a norm. A norm is an unwritten rule in the group and, in the same way as basic assumption, it will not be questioned. A value can be individual for an employee, and if these values deviate from the norm, the employee will be socially punished. Deviating from the norm is to break the unwritten rule. The third level, which consists of artifacts, is easier to observe since it consists of physical expressions of

the culture such as verbal and behavioral expressions, architect, furniture, and dress code. This level could be analyzed when trying to understand the organizational culture since it is the result of values & norms. The organizational culture's levels are visualized in Figure 3 (Bang, 1999).

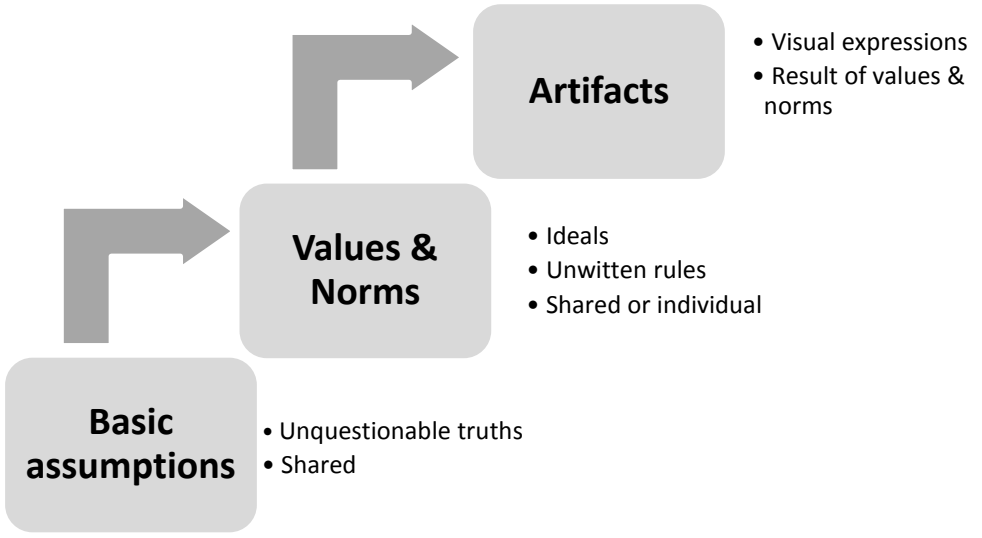

Figure 3. Three levels of organizational culture and their interaction (Bang, 1999).

5.1.1 Basic Assumptions

A culture consists of a number of "truths" that no one in the culture is questioning, which is defined as *basic assumptions.* Basic assumptions will develop over time and are results of problem solving within the group. The problems could be both internal and external, and the solution to the problem has developed into a truth, since that solution has turned out to be functional (Bang, 1999).

Basic assumptions are often chosen solutions to a problem that the group, or organization, has experienced. The chosen solution is not the only solution to the problem; it is just the one solution that this specific organization has chosen. For example, meetings are held following a certain ritual. This ritual is instituted because it solves a problem that the organization had before. It could be that all cell phones are switched off when entering the meeting. Within that specific organization that is what all members are doing, and that rule is not questioned (Bang, 1999).

5.1.2 Values

A value will decide what decision to make in a certain situation. With shared values the same decision will be made by a group of people. Values are described as a stable goal, ideal, and priority, that are established according to stories and/or behavioral patterns (Hofstede, Hofstede, & Minkov, 2010). There is a close connection between the values an individual express and the basic assumptions the individual has. What is good versus bad is often a consequence of one's basic assumptions (Jacobsen & Thorsvik, 2008).

Hofstede (2001) means values are one of the "mental programs" used by human, in how to orient themselves in the environment. Three different levels of "mental programming" is possible. T*he universal level* is the same for almost all people. *The collective level* is common for people within a group or company, and is characterized by cultural values and specific ways of how to behave and talk. Finally, *the individual level* depends on the individual's personality (Hofstede G. , 2001).

To clarify what a value is, some examples could be given. If there is an assumption that humans are lazy, the values would say there is a need of controlling. Another example of value occurs if a person believes conflicts increase the competition and the level of innovation and creativity. This person's value is that conflict is preferable for problem solving (Jacobsen & Thorsvik, 2008).

Usually values are expressed when decisions are taken, plans are made, or when looking at the philosophy that the organization is based on. In other words, values have been consciously chosen in the organization to show what is a correct and wished for behavior, and indirect what is incorrect and an unwanted behavior. It is challenging to create common values that are shared by all employees. Managers have the possibility to influence the employees in how they act in different situations. This is not the same thing as saying that the managers have changed the values within the group. To change values is very difficult, and it is also difficult to know if a value has changed. Employees could behave in a certain way because they know that the manager would like them to act that way, but that does not mean that the employees' values are in line with that behavior (Hofstede, Hofstede, & Minkov, 2010).

Tough strategies, systems and measuring have for years been common tools used when doing company changes. The trend, nowadays, is rather to pay more attention on softer parameters, which should result in values shared by all employees within the organization (Thompsson & McHugh, 2009). To establish common values, it is not enough that the management team write down the wished for value and print it out, or e-mail, them to the employees. Humans are complicated, and to change their values is difficult. Problems occur when the company's values differ from the employees' values. The company's values are called espoused theories and the

employees' values are theories-in-use. Espoused theory stands for the, by the company, expressed values, or the values the employees are aware of. The espoused theories could be found in the company's goals, management philosophies, or visions. Theories-in-use are the real values that support the employees' actions. To counteract these differences concrete actions should be taken when trying to establish new values. So, it is not enough to tell the employees what the values are, the management team needs to live by these values and employees should be rewarded when theories-in-use conform to the espoused theories (Bang, 1999).

5.1.3 Norms

A norm is usually explained as an unwritten rule about what is correct to do in a specific social situation. It is important to separate norms and behaviors from each other since the behavior is a result of the norm. If people have been part of a group for some time, expectations of how to behave, and not to behave appears. What is expected, accepted and supported from the group belongs to norms. When a behavior has turned into the expected one it becomes a norm. It is not necessarily so that the norms have been out-spoken. A norm is the normal behavior in a situation, and when a norm is followed no one will notice it. But when someone deviates from the norm some sort of punishment will take place. The punishment could be social, legal, or both (Bang, 1999).

Norms are connected to values. A norm is created when a certain value is shared by a group of people, over time. When a group acts identically in a situation, and to act differently would be seen as an incorrect action, the group has created a norm out of their shared values. Norms are expressed by rules and routines which have been clarified for all employees within the organization, either out-spoken or by the members' common behavior in a certain situation. Ethical norms could be; we keep our promises, we follow the laws, we behave honestly and we do not talk derogatory about others (Jacobsen & Thorsvik, 2008).

To summarize; a value is a person's view of what is right, or wrong to do. Shared values will generate a norm. The norm is the guideline and rule for a behavior in a situation. When one employee has values that deviate from the norm there will be some sort of punishment.

5.1.4 Artifacts

Artifacts are what are visible and visual in the organizational culture. Artifacts are expressions of values and norms, but also of basic assumptions. Artifacts could for instance be physical objects, used language, texts or behaviors. Members in a group, or an organization, will behave in a certain way depending on the values and norms. These behaviors are cultural expressions and have its root in the underlying cultural elements. Identify artifacts could be easy, but to analyze and draw conclusions out of them is much harder (Jacobsen & Thorsvik, 2008).

Different types of artifacts could be identified within a company, and categorized into three sub categories (Jacobsen & Thorsvik, 2008). These will be presented below:

- *Artifacts could be what people say*
  What people say and how they say it indicate their values. Language consists of a great numbers of symbols. The words used, the professional terminology, and the humor or jargon could be an indicator of the culture.

- *Artifacts could be peoples' behavior*
  How people behave, greet each other, and show respect, are good indicators of values and norms. Managers giving a hand when help in production is needed, show that the hierarchical distance between floor and office is quite small.

- *Artifacts could be physical objects*
  The physical objects are the most obvious artifacts to observe. Examples of physical artifacts are; the architecture of the building, the artistic expressions, written material or the use of uniforms. The dress code sends signals of the culture, and it creates an atmosphere that could be unique for one organization compared to another

Thompson and McHugh point out the importance of the management team's awareness of the company's values, language, rituals and myths. The active usage of artifacts can result in increased motivation and enthusiasm by the employees (Thompsson & McHugh, 2009). Same discussion is done by Deal & Kennedy (1982) that argue for established symbols, heroes and rituals since they believe they are necessary, in the long run, to create a strong culture (Deal & Kennedy, 1982).

To summarize this chapter, the core to the organizational culture is, as has been mentioned before, shared values within the organization. Decisions are based on values and these values needs to be in line with what is favorable for the company. Important is, therefore, to establish an ideology that clarify the wanted values within the organization. It is also necessary for the employees to know what the correct decision to make is. For a company, with a quality focus, decisions favorable for *Quality* need to be explained.

6. What is Quality?

Chapter six explains the concept of Quality. The definition of Quality, further used in the study, is presented. Since this study's Case Company is active in the pharmaceutical industry, this chapter also contains information about Good Manufacturing Practice, the guidance for pharmaceutical production.

Quality is a complicated term because it lacks a united definition. Quality is connected to expectations, and expectations vary between people and situations. Quality is also connected to experiences, and experiences are, in the same way as expectations, different amongst people.

6.1 Perspectives on Quality

Firstly the different perspectives on quality must be clarified. To whom is it quality? A product of high quality according to the standard set for the production might not be seen as a high quality product by the customer. If the consumer has different expectations on the product, than the requirements set by the company producing the product, there will be an asymmetry in the perception of quality.

According to Garvin there are five perspectives. The first is the *transcendent* perspective, and with this perspective quality is something that only can be experienced, but not defined. Users feel if the product is a quality product/service or not. The next perspective is the *product – based* view saying that, in contrast to the transcendent perspective, quality could be measured in exact measurements. When quality is measurable it is possible to keep track of variations and deviation in production. The *user – based* perspective focus on the user as being the one judging the level of quality. The fourth perspective is the *manufacturing – based* view and this refers to quality being an effective production with absence of wastage. This perspective is focusing on producing the right stuff in the right way. The last perspective mentioned by Garvin is the *value – based* one meaning that quality is related to cost or price and that high quality is when one is receiving the desired features to an acceptable price. Value for money is a term describing this perspective (Bergman & Klefsjö, 2010).

In the producing industry the product – manufacturing – and user-based views are the most popular one. Since quality could be a competitive advantage for companies it is necessary to measure the quality of what is produced. When there is a quality difference between the same products there is an unwanted variation. Variation is the same as lack of quality, using the product-base view. To avoid variation there is a need for a standardized production process. With a standardized process, giving the same output every time, quality could be measured and actions could be taken to make improvements. If changes are made before the process is stable it is not

possible to say whether the variation depends on the change, or something else in the process. A stable process is necessary if effective improvements should be done (Bergman & Klefsjö, 2010).

Using the manufacturing-based view on quality, reduction of wastage and capacity utilization is of high priority. A process with low variation, low amount of wastage and high percentage use of its capacity, is considered highly efficient and desirable for manufacturing companies. If the product also satisfies the customer needs, a perfect mix of product -, manufacturing - and user-based views is created. It is necessary to keep in mind, when talking about quality, which from whose perspective quality is considered, since the view of quality differs.

6.2 Definition of Quality

In the same way as there are different perspectives, there are different definitions of quality. The definitions are either written from a producer's, or a consumer's, point of view. Juran (1988) defines quality as *Fitness for Use*. He focus on the consumer, or user, since it is the user who decide if the product is fitted for the intended usage and, thereby, becomes a quality product or not. To make his definition clearer he has two subsidiary definitions to *Fitness for use*. They are *Features,* and *Freedom from Deficiencies*. By features he refers to the design of the product. The features should be those that the customer is asking for. And, with freedom from deficiencies, he indicates that a product needs to function properly in order to be a quality product (Isenberg & Bisgaard, 2008).

Another definition that focus more on the producer is ISO 9000's definition. ISO 9000 states that quality is "*the degree to which a set of inherent characteristics fulfill the requirements"*. Quality in this sense is when products are produced according to the standard and when no deviation could be found (Hoyle, 2009).

Edward Deming says that "*Quality should be aimed at the needs of the customer, present and future*" taking the same perspective as Juran. Bergman and Klefsjö agree with both Juran and Deming and chose to define quality of a product as "*…its ability to satisfy, or preferably exceed, the needs and expectations of the customer"*. Bergman and Kelfsjö (2010) mean that this is the way new customers are recruited. When expectations are exceeded people are more likely to talk to others about their experience compared to when expectations are only met (Bergman & Klefsjö, 2010).

The pharmaceuticals industry has its own quality definition. The industry is strictly regulated by International and National regulations enforced by local Health Authorities and International Agencies. The Food and Drug Administration, FDA, defines quality as *"the suitability of either a drug substance or drug product for its intended use. This term includes such attributes as identity, strength, and purity*" (FDA, 2006). Since the Case Company's is active in the pharmaceutical industry, their definition is:

"High quality is a drug product suitable and safe within its intended area of usage" (Case Company, 2013).

Both FDA's and the Case Company's definition are similar to Juran's, only more product specific. Quality in pharmaceuticals is the right medicine, i.e. correct substance and concentration, treating the right illness in the right way.

What is not considered in the Case Company's definition is how to compete against companies trying to satisfy the same customer segment. Customer focus is important, as stated in most of the definitions discussed in this chapter. Still, for this paper, and since the Case Company's definition is of a technical character, the customer focus is outside of this study's scope.

As for all companies active in the pharmaceutical industry, the Case Company is regulated under GMP, Good Manufacturing Practice. This is a collection of Regulatory guidelines, with the purpose of securing the safety for the users. Before being able to completely understand the quality definition, more knowledge about GMP is necessary.

6.3 Good Manufacturing Practice, GMP

6.3.1 Definition

Good Manufacturing Practice, GMP, is a guideline for companies producing pharmaceuticals for either humans or animals. The guideline consists of global recommendations for how to run the manufacturing. The purpose of GMP is to provide a defined system for assuring and controlling quality in accordance with International law and country specific regulations. (ICH, 2000).

6.3.2 Quality management by GMP

For GMP to work as a quality assurance tool there are recommendations for quality management that should be in place for the following of GMP. The most important principle in GMP is that everyone involved in manufacturing is responsible for quality. For this to be a reality, active participation from both senior management and manufacturing personnel is necessary (ICH, 2000).

In GMP, documentation is important. All activities related to quality must be defined and documented. It should be clear how these activities should be performed, and also why. Since the production process is validated, and thereby should be performed according to that description, it is important that quality related activities are performed as they should. Quality related activities must also be recorded at the time they are performed, meaning that checklist and other control tools should be used during the control and not filled in later on (ICH, 2000).

A Quality Unit, independent of production, is a specific requirement in GMP. This unit should have the responsibility over quality assurance and quality control. There are many assignment connected to the Quality Unit. One is release of API, intermediates and finished products. In GMP the person responsible for these releases should be specified and authorized. To keep Quality Unit independent of production is a way of ensuring that impartial decisions are made. The Quality Unit acts as a safety barrier for customers. They should assure that no harmful or incorrect products reach the market. More about the Quality Unit and its functions will be discussed later on (ICH, 2000).

To investigate deviation is the fourth corner stone in GMP. Any deviation from established procedures should be documented. Critical deviations should be investigated. This investigation, and its conclusion, should be documented. "Deviation from established procedures" indicates that not only deviation with a direct effect on the quality of the *finished product* should be investigated. All deviations from what is stated in the validated process do, per definition, affect the quality (ICH, 2000).

These four areas are recommendations in GMP and are summarized in Figure 4.

Figure 4. The main areas covered by GMP (ICH, 2000).

6.3.2.1 Quality Unit

To have a Quality Unit is a requirement in GMP. The purpose of having an independent Quality Unit is to facilitate the decisions, necessary if there is a quality problem. The Quality Unit should function as a barrier between the company and the market, with its primary task to ensure that the products entering the market are of right quality, and thereby safe for the users. The responsibilities that lie within

the Quality Unit are summarized in Figure 5. These are the required responsibilities but other tasks might as well be placed in the Quality Unit if the company would like so (ICH, 2000).

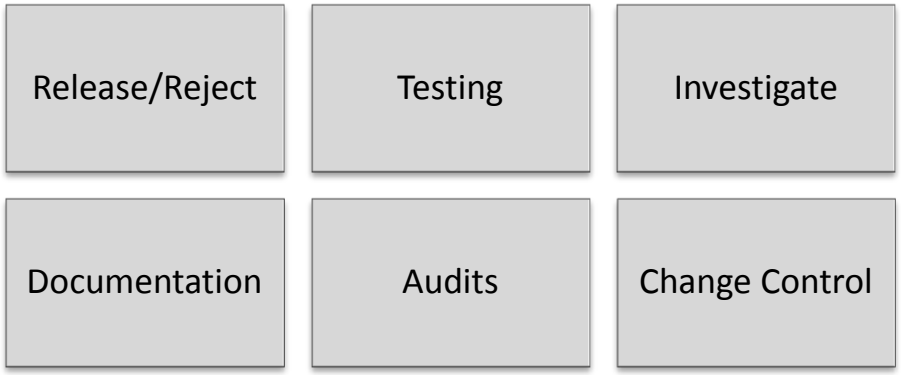

Figure 5. The Quality Unit's responsibilities (ICH, 2000).

The first area, release and reject, is something strongly associated with the pharmaceutical industry. There is no straight pipeline from the factory out on the market. All batches must be tested and cleared before release. If there is a quality problem with a batch it might get rejected, completely or partly. Before API or packing materials enter the process they must be released. To determent whether to release or reject a batch or material, testing is necessary. The term testing also includes testing and calibration of equipment, and not only testing of incoming and outgoing products (ICH, 2000).

All companies regulated by GMP are required to investigate deviations. The Quality Unit is responsible for making sure that all critical deviations, usually called non-conformances, are investigated so that the root cause can be found. All deviations do not result in a batch being rejected. Some deviations do not have a direct effect on product quality, but still, these deviations need to be investigated. They do have the potential of harming the product quality since quality according to GMP also includes following the process according to the description (ICH, 2000).

Another responsibility that, in GMP, is assigned to the Quality Unit is the approval of quality documentation. This is closely connected to Change Control. Since all quality related activities are documented, and these descriptions should be obeyed, if there is a change in the procedure the Quality Unit must be involved. The Quality Unit will, or will not, approve the suggested change. Documentation of the new procedure is the responsibility of the Quality Unit (ICH, 2000).

Changes that affect the process validated by authorities, such as FDA, will require a new validation. The Quality Unit should possess the knowledge to decide whether a certain suggested change will affect the process so that a new validation is necessary or not (ICH, 2000).

Audits, internal and external, are controls of actual working procedures. To perform internal audits, but also external on suppliers, is the Quality Unit's responsibility. When being audited by others, like customers or authorities, the Quality Unit assists and supports. Since there is extensive documentation of all steps in a process, these documents can be used as a key, a correct way to perform. When doing an audit, the actual working procedure is compared with the documentation. Internal audits are a way to prepare before an external audit, but also a tool for self-control. If, during an audit, complaints are noticed the company will be asked to perform corrective actions. A new audit, for following up, will be performed afterwards. Audits are a quality assurance tool that covers for more than just in-house processes. How often an audit is performed is regulated by GMP and depends on how close to the API the target of the audit acts (ICH, 2000).

6.3.3 Other requirements according to GMP

There are other requirements besides having a Quality Unit, document all activities and investigate all deviations. A lot of these topics include documentations since everything needs to be documented. The reason for why they are still mentioned is that they are more important in GMP than in other quality assurance literature and, therefore, deserves to be highlighted (ICH, 2000).

6.3.3.1 Quality review

Annually a quality review should be performed. In this review rejects and deviations should be followed up. The purpose is to learn from mistakes and see if there are any trends in deviations. With this information education actions should be addressed to areas with higher frequency of deviations. Recalls and complaints are also followed up, basically for the same reason (ICH, 2000).

Something else that also should be reviewed is those corrective actions suggested during earlier audits. The reason for why a corrective action is suggested is for it to improve the process so the quality will increase. During a review changes, due to corrective actions but also from suggestion of improvements, are followed up. Did the change have the intended effect on productivity, safety, or what it now intended to affect? If not, what should be done about that? To review the last year based on situations that have had an effect on quality is a tool for quality assurance. If wanting to improve, one need to evaluate what have been successful and what have not (ICH, 2000).

6.3.3.2 Personnel requirements, both for employees and consultants

For being allowed to work in manufacturing regulated by GMP, appropriate education is needed. The education and training should contain information about both the particular operation connected to one's role and those parts of GMP that affects the role. Without proper education the quality will be jeopardized since quality, according to GMP definition, also is to perform all procedures as described in validated working descriptions (ICH, 2000).

Hygiene is mentioned as a chapter in GMP because, when producing pharmaceuticals, the hygiene of the employees affects the quality of the product to a larger extent than for non-regulated industries. Clothes for avoiding contamination should be worn, and if carrying an infection or open lesions no work in production is allowed. These rules are the same for employees and consultants (ICH, 2000).

6.3.3.3 Facilities

The manufacturing area should be fitted for its intended use. This includes not only running the production, but also to enable proper cleaning and maintenance of manufacturing equipment. The equipment should be used as intended, and optimized in order to prevent mix-up and contamination. The building, and the surrounding area, should fit the process, and not the other way around (ICH, 2000).

6.3.3.4 Storage of records

Traceability, the possibility to trace a certain package back to its original batch, date of production and specific purchase of active ingredients, is regulated in GMP. This requires storage of records and samples until, and past, the expiry date. Records of test results, laboratory reports, production – and batch information are those kinds of documents that need to be stored. How long a record should be stored depend on what document it is and to what product it is connected (ICH, 2000).

6.3.3.5 Laboratory control

Laboratory control is the Quality Unit's responsibility. The reason for why it is highlighted here is that it is a specific part of the Quality Unit and one of the most effective tools in GMP. The laboratory control is a way to, with quantified test results; give the current status on quality (ICH, 2000).

6.3.3.6 Validation

A validated process is a reproducibly process, meaning that independently of what day or year, who is working and the weather outside, the result of the process, the product, will be the same. With the technical definition of quality, the one used in GMP, a validated process without deviations will result in a quality product (ICH, 2000).

Necessary to mention is that process parameters that are not related to quality do not need to be included in the process validation. That could for instance be process

parameters measured for decreasing electricity consumption. If that parameter will fluctuate it still does not affect the quality (ICH, 2000).

6.3.3.7 Complaints and recalls

Complaints and recalls should be reviewed in the same way as deviations and the other things mentioned in *Quality review*. What is special about complaints and recalls compared to normal deviation is that these deviations have not been noticed before the product has entered the market. If a life-threatening situation appears, or has the potential of being so, due to quality flaws on a product, which already is on the market, the company is forced to inform local, national and/or international authorities (ICH, 2000).

So, these are the requirements according to GMP. GMP needs to be followed in order for the quality to be correct. Therefore, the quality that needs to be used in this study is a combination of GMP and the Quality definitions. The used definition of quality, in this study, is presented below together with an accompanying explanation.

> *"Quality is when a product is produced according to GMP standard, meaning that the finished products are correct, the process is performed as stated in the GMP validation and all employees have followed their GMP rules and regulations".*

With this said, quality can be measured by controlling if the product is correct. This can be done in laboratories checking the right levels of included substances. Quality is also when the process is performed as described in the GMP validation. This means that the steps in the process, affected by GMP, cannot be changed without a new validation if the product should be able to live up to the quality standard. It also means that regulations for employees according to GMP must be followed. There are regulations for training, signing and control. If these regulations are not followed the quality is not good enough.

The difficulty in this technical definition is that, even though it is technical, humans are involved in the process, making humans responsible for quality. It is their values and norms that will determine the quality output. If these values and norms are not in line with the requirements there will be a quality problem. The company must make sure that its employees are unanimous when it comes to quality. How a company can work with quality, and what parameters that are most important when it comes to quality, will be discussed in the next section.

7. Critical success factors for achieving Quality

Chapter seven presents two theoretical frameworks for Quality. These are compared and merged into one new framework. The factors, used in this new framework, are described, and will later be used in the case study.

7.1 Comparison of existing frameworks for Quality

For coming up with the factors necessary for achieving quality, two frameworks, created with the purpose of measuring just these quality factors, are compared. The first framework is created through a review of literature about quality, written by all the prominent authors in the field. This review is performed by Saraph, Benson and Schroeder (1989). The second framework is created by the Corporate Executive Board Company, CEB, which is an organization that provides advisory services to companies. Their framework is developed by a combination of research and empirical data (Callaway, 2013).

7.1.1 Framework created by Saraph, Benson, and Schroeder

The famous theorists in the quality field; Juran, Deming, Ishikawa, Crosby and others, are not only writing about what quality is, but also about how to create, and maintain, quality. They have, to some extent, different views on quality, which results in different tools for creating quality.

Literature studies on quality, with the purpose of summarizing thoughts and ideas, have been conducted. One study doing this, performed by Saraph, Benson, and Schroeder (1989), has compiled views from the most prominent theorists in the field of quality. This study has resulted in a matrix where the theorists' ideas are organized with the purpose of labeling areas, or critical success factors for quality. The following factors have been identified;

1. The role of top management leadership
2. The role of the quality department
3. Training
4. Product/service design
5. Supplier quality management
6. Process management
7. Quality data and reporting
8. Employee relations

This framework has the purpose of measuring the critical factors of quality management. The theorists, that this framework is based on, have different methods for improving quality. It is all from Deming's 14 principles, Jurans' quality planning, quality improvements, and quality control to Ishikawa's total quality control and Crosby's 14-step zero-defect quality improvement program.

7.1.2 Framework created by CEB

This framework has been developed by the Corporate Executive Board Company, CEB. CEB is a company offering a number of best-practices and advisory programs, and this framework has been used at 140 international companies.

The input to the framework's factors came from a survey, performed by CEB, which had 855 respondents within different levels of seniority, functions, and industries. The survey was complemented with quality literature, but also with literature and research on organizational culture and its development.

The identified factors for quality, by CEB, are:

1. Best Practice Sharing
2. Employee Ownership
3. Incentives
4. Leadership Emphasis
5. Message Credibility
6. Peer Involvement
7. Quality Management Systems
8. Tools and Training

7.2 Merging the two frameworks into one

The authors of this thesis have evaluated the two frameworks described above with the purpose of identifying similarities and differences. The merge of the two frameworks will result in a new one, and the factors that will create this framework will later be used in the case study at the Case Company. The merge is visualized in Figure 6. For the analysis in the next chapter, the merged framework will be used. The eight new categories; Leadership, Quality Department, Training, Peer Involvement, Employee Ownership, Incentives, Data and Reporting, and Supplier Management, will be the areas used for evaluating the performance of the Case Company.

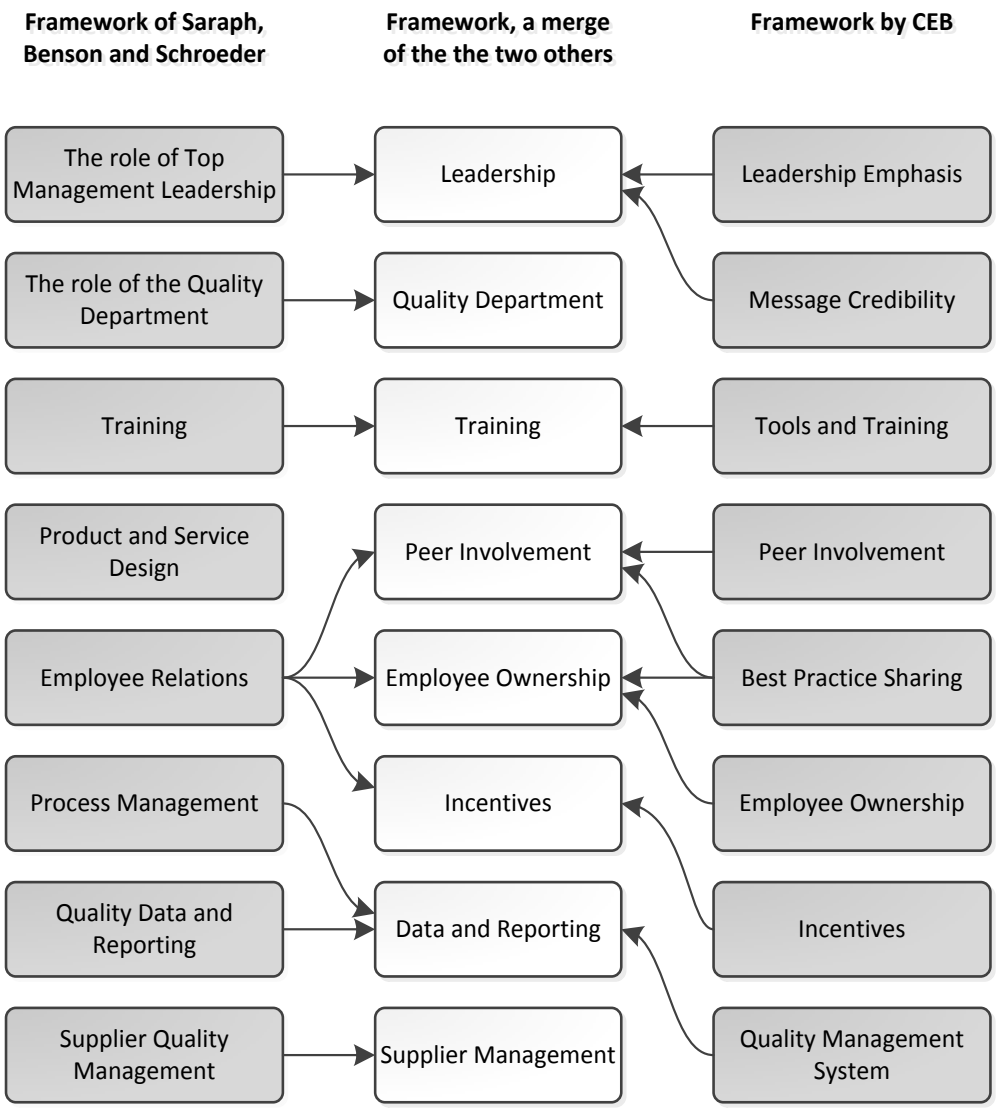

Figure 6. The creation of the framework used for analyzing the Case Company. This framework is a merge of those being presented earlier.

7.2.1 Leadership

Both frameworks discuss the importance of leadership. Leadership is also mentioned in literature about, both, organizational culture and quality. The management team needs to focus on quality in order for the company to improve on that parameter. If quality is part of the strategy it is more likely that the company will succeed. Visible leadership with a dedicated management team sets the agenda (Hofstede, Hofstede, & Minkov, 2010).

What the management team pay attention to, measure and control is an indicator of their values, of what they find important. The managers' visible behaviors send signals about their values. The behaviors in a critical situation would be interesting to analyze, since when taking decisions in these situation, their true values will be reviled (Schein, 2010).

From the CEB framework Message Credibility, one of the factors, is in this merge added into leadership. "Walking the talk", as mentioned above, is one good leadership tool, which makes Message Credibility fit well under the Leadership factor. The merge of Leadership factors are visualized in Figure 7.

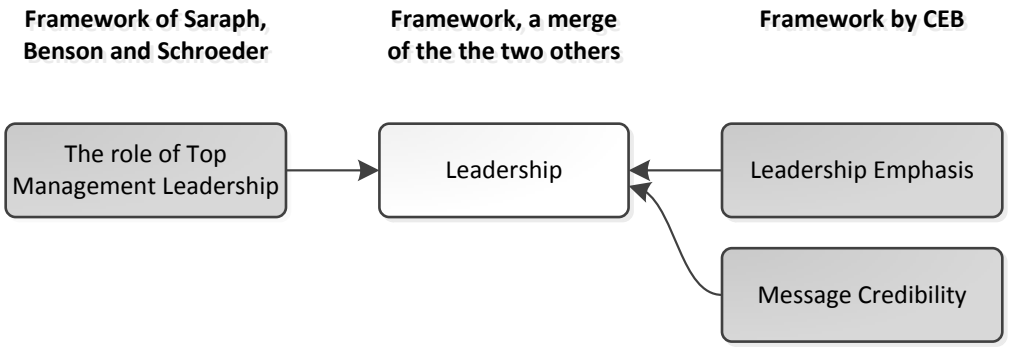

Figure 7. Merge of Leadership factors.

7.2.2 Quality Department

The first framework mentions Quality Department as one factor. This factor cannot be found in the CEB framework. The reason for why it is kept as a factor is the need for it according to GMP, but also that Juran, in his Quality Control Handbook, advocates a Quality Department (Juran, 1988). The creation of the new framework concerning Quality Department is shown in Figure 8.

It is from the framework by Saraph, Benson, and Schroeder (1989) said that the Quality Department must be visible and have the autonomy to make, sometimes unpopular, decisions. One task assigned to the Quality Department is the performance of audits. For an audit to be useful, it must be allowed to look at the

manufacturing with a critical view. The purpose of an audit is to identify potential hazards and, therefore, to announce these findings must be acceptable. Audits are also one important quality tool according to GMP.

The Quality Department is a support function and should be used as such a function. Coordination is necessary because the improvements, identified by the Quality Department, must be conducted out in the organization. A production unit can improve with help from the Quality Department, but it is not the Quality Department on its own that is responsible for the improvement (Bergman & Klefsjö, 2010).

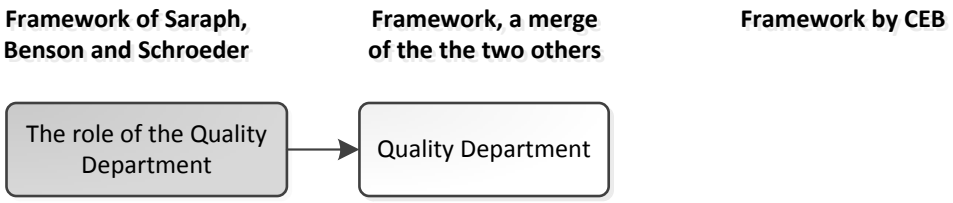

Figure 8. Merge of the Quality Department factor.

7.2.3 Training

Both frameworks raise the importance of training, see Figure 9. To be able to perform a proper job it is necessary to possess the right knowledge of how the job should be done. Validated quality means that the process is being performed identically every time, and that requires extensive training of all employees. To ensure that tasks are being performed correctly, even after finished education, it is important to explain why, and not only how the job should be done. The knowledge of why creates a deeper understanding, and in situations when in doubt the understanding ensures that the right decision is made.

Lindmark and Önnevik (2009) present that competence depends on knowledge, wish, and opportunity. The most important is knowledge, because without knowledge there is no value in a wish or an opportunity. If an employee should be competent it is necessary that the employee has the required knowledge within that specific area. Secondly, there is a need for the employee to want to use the information and, finally, that there are opportunities for usage of the information (Lindmark & Önnevik, 2009).

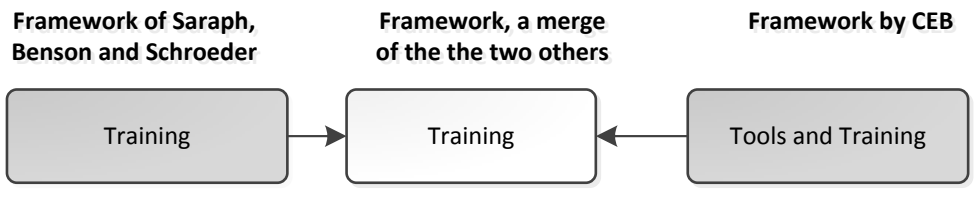

Figure 9. Training is part of both frameworks, and therefore a factor in the new framework.

7.2.4 Peer Involvement

Peer Involvement, one of the CEB factors, is the importance of collaboration between employees. In the first framework, that by Saraph, Benson, and Schroeder (1989), the interaction between colleagues is included in the Employee Relations factor. Participation, communication, involvement and recognition are emphasized by all authors within the quality field. In Lean Manufacturing, Quality circles are one way to involve the employees. Cross-functional teams are similar tools. In these teams you, as a represent from your department, are put in a position where you are expected to participate and contribute. The feeling of being needed, of making a difference, is a way to engage the employees.

With a shared approach towards responsibility and improvements, the employees will be able to develop the processes, and make the company perform better. This requires a willingness amongst the employees to feel united. If all employees identify themselves with the company the loyalty towards the employer will increase and, thereby, also the motivation to do a better job (Alvesson, 1991).

Cooperation and teamwork within, and across, departments are essential. To achieve a team spirit, and social integration, within the company the company must create a method for communication. The spreading of knowledge and information is needed (Trompenaars & Hampden-Turner, 1997). Best Practice Sharing, one factor mentioned in the CEB framework is included in the Peer Involvement factor, see Figure 10. System for sharing is necessary, but also that what is being shared is absorbed, and used, in other parts of the organization.

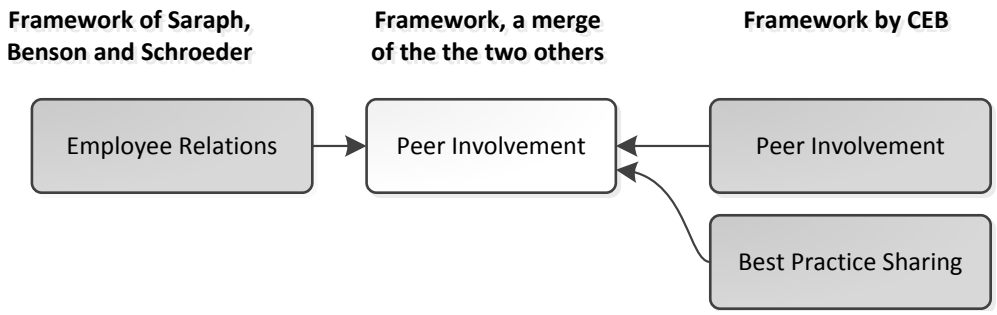

Figure 10. Creation of the Peer Involvement factor.

7.2.5 Employee Ownership

Employee Ownership is, by the CEB framework, the most important factor for creating an organizational culture with focus on quality (The Corporate Executive Board Company, 2012). To include this factor is, therefore, important when creating a framework for analyzing the quality focus within an organization. In Saraph, Benson, and Schroeder's framework the taking of responsibility by the single

employee is included in Employee Relations, but the usage of the term Employee Ownership will more strongly reflect what is meant. The merge of the factors are visualized in Figure 11.

To take ownership of one's work, to make decisions that will be correct for quality, is a reflection of one's values and norms. It is also connected to training, and as written about training; to be able to do what is correct one must know what is correct. But for ownership and responsibility, the employee must want to do what is correct (Lindmark & Önnevik, 2009). The employee must also feel secure enough to raise concern, and ask questions that will challenge the directives, in order for the quality to improve (The Corporate Executive Board Company, 2012).

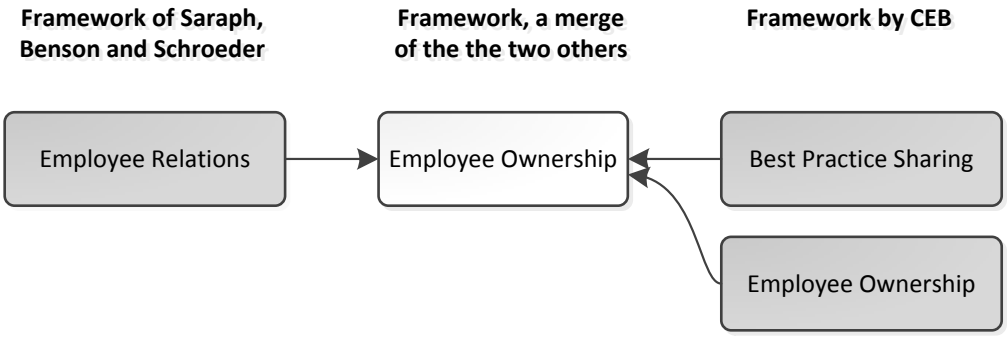

Figure 11. The creation of the Employee Ownership factor.

7.2.6 Incentives

One way of creating employee relations, and participation in quality work, is by incentive systems. There are different methods for how to reward employees. Rewards could except for money also be praises, status, increased job satisfaction or social acceptance (Thompsson & McHugh, 2009). It is important to consider what type of reward systems to use, and what criteria to have for receiving an award. This since employees learns what is correct and incorrect in the organization through the reward system (Schein, 2010). The main purpose with rewards is to give a feeling of attention to the employee and the achieved result (Bang, 1999).

In the CEB framework Incentives is one factor. In the framework by Saraph, Benson, and Schroeder (1989) incentives is included in Employee Relations as a method used for increasing the relations and the responsibility taken by the employees, see Figure 12. To use incentives is a leadership tool for reinforcing of a certain behavior. For an incentive to be effective, and fulfill its purpose, it is important for the employee to understand the connection between the award and the performance, or action, which is the reason for the award. Employees will try to understand what those who are receiving an award, like increased salary, but also a warning, has done. With a

clear connection between behavior and rewards, managers indicate their priorities, values and norms (Schein, 2010).

Suggestion systems, systems where employees can give suggestions for improvements, are one effective way to identify improvement areas and get the employees involved. This is often connected with a monetary reward. Key success factors in a suggestion system are fast response to a given suggestion, high ratio of implementation of ideas and only small economic rewards. To get employees to continue generate idea for improvement it is important to realize what is needed from the company to encourage that behavior. A fast response sends a signal that ideas are taken seriously. Implementation of ideas, even those who does not generate direct financial profit, tells the employees that the company finds the ideas useful, and this will lead to more generated ideas. By limiting the economical reward ideas could be developed by input from others in e.g. Quality circles where groups of colleagues share thoughts on quality improvements. Even a good suggestion might be improved by input from others (Bergman & Klefsjö, 2010).

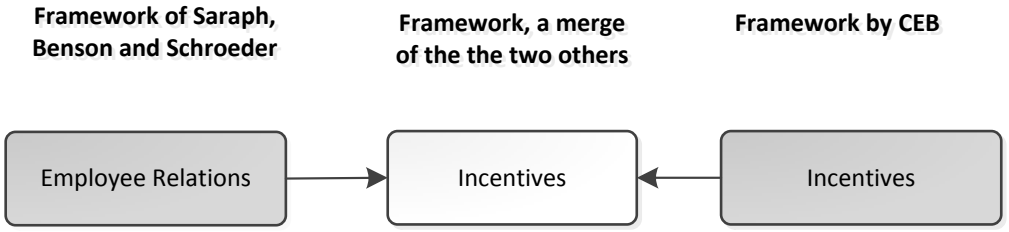

Figure 12. Creation of the Incentive factor

7.2.7 Data and Reporting

Quality Data and Reporting is one factor mentioned in the framework by Saraph, Benson, and Schroeder (1989). Another is Process Management. For the CEB framework Quality Management System is mentioned as a factor. These three are merged into Data and Reporting. Focus on data and statistics is strong within the first framework. For an author like Deming, with a background in statistical mathematics, data is important. By showing, statistically, the extent of errors and defects in different areas, the choice of where to start an improvement project is facilitated. By this approach the company is not guessing, but actually choosing using correct information (Bergman & Klefsjö, 2010).

Showing and presenting data is a management tool for creating focus of what is important. To create the right focus, the intended one, it is necessary to reflect on what data to present. The reason for why it is presented must be to create a certain behavior among the employees. The direct, or indirect, measurement must be something that the employee can affect by the way they perform their job (Bergman & Klefsjö, 2010).

Process Management and Quality Management System are system for managing quality and the production process. Quality systems, like ISO 9000, GMP, Lean Manufacturing, and Six Sigma, are systems with the purpose of ensuring the quality of the product and process. This is connected with data and reporting, since keeping track on quality it is often necessary to measure different quality parameters (Bergman & Klefsjö, 2010). These systems are hard factors, and just as it is stated by CEB, these systems will not improve the quality by them self. Instead, they are useful for getting employees to identify improvement areas and have them to notify when there is a quality deviation. But to not mention them as factors that are influencing quality would be incorrect. Therefore, and since both frameworks are using them, Data and Reporting will be used as a factor in the merged framework, visualized in Figure 13.

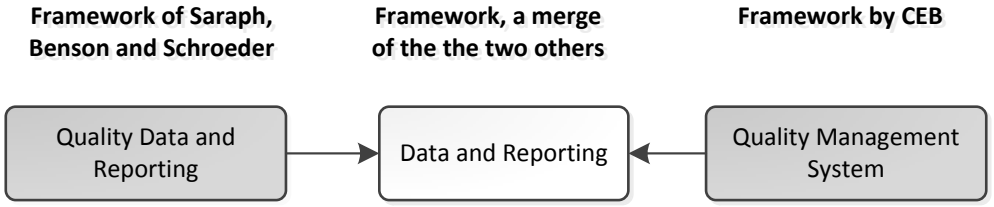

Figure 13. Creation of the Data and Reporting factor

7.2.8 Supplier Management

Supplier Quality Management is mentioned as one factor in Saraph, Benson, and Schroder's framework. CEB does not have any factor that is related to the supplier management, see Figure 14. Still, how a company works with its suppliers is important for the quality, and also the ability to deliver in time.

Management of suppliers is important for every company to be able to supply their customers with product. If raw material does not get delivered to the factory the whole production process stops. If raw material is delivered but not within right quality it still affects the production and jeopardize the delivery to customers. Inadequate service from the suppliers could lead to misunderstandings, frustration and, thereby, also risk the delivery. Finally, if the price from the suppliers is too high, this will result in either a raising price on final product or a decreasing profit for the producing company. To maintain a good and healthy relationship to suppliers is critical in order to stay successful as a company (Bergman & Klefsjö, 2010).

Even though specifications are necessary in the communication between buyer and supplier, it is even better if the supplier also understands where, and to what, they contribute to the final product. To enable this it is necessary to share information in an open and trustful way. A producing company must feel responsibility, not only over what is produced in-house, but also over what is delivered by their suppliers.

The end customer will always turn to the last part in the supply chain, holding them responsible for total quality and service. This relationship, where buyer and supplier are closely connected with a high dependability on each other, leads to higher product quality, due to better fit and faster feedback. It also ensures delivery punctuality, since a buyer buying bigger volumes is of great importance to the supplier. The cost of each component will drop when purchasing volumes increase and this, together with a more specialized production process at buyers and suppliers result in increased profit for both parts (Bergman & Klefsjö, 2010).

As for strategies for handling suppliers the three most common strategies are; single sourcing, dual sourcing and multiple sourcing. There are risk and benefits connected to each one and what is the most preferable strategy depends on the company's situation and its relationship with suppliers. For critical raw material single sourcing is a big risk. What will happen with your production line if there is a fire at the supplier's production site? Multiple sourcing give the opportunity to choose based on current prize but it does not create the same close relationship as single or dual sourcing could. An example of multiple sourcing is the supply of gasoline. For car drivers this is preferable. The function of the product is the same and you can choose based on prize. Dual sourcing is preferable when the amount of suppliers of raw material, to some extent, is limited and you cannot risk missing a delivery (Yu, Zeng, & Zhao, 2009).

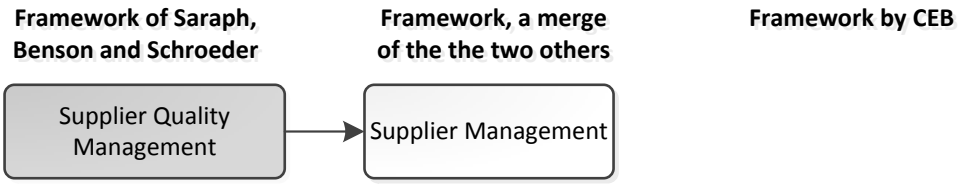

Figure 14. Supplier Quality Management is merged into the factor Supplier Management.

7.2.9 Factors not added in the merged framework

Product and Service Design, mentioned in Saraph, Benson, and Schroder's framework, is not added in the framework created by the merge of the two original one. In order to deliver quality to customers, the product or service design is perhaps the most important part. As for quality definitions focusing on the customer perspective, like Juran's *fitness for use*, it is necessary to thoroughly understand what the customer wants (Bergman & Klefsjö, 2010). But according to the limitations set for this paper, the quality of the product is assumed to be high enough, and fulfills the needs of the customer. An evaluation of the product quality is not within this paper's scope and will, therefore, neither be added in the framework nor analyzed.

8. Case study

This chapter contains the case study. The empirical material, gathered during interviews and observations, are presented and analyzed. The areas analyzed are the same as the eight factors in the framework.

The information presented in this chapter is gathered at the Case Company by interviews and reviews of internal documents. Due to the Case Company's confidentially policy, sources of information will not be revealed. Persons interviewed in this study have the following positions, presented in Table 2:

Table 2. Interviewees at the Case Company.

Business Support Training	Machine Operator
Coordinator of Group Managers	Manager Compensation & Benefits
Director of Quality Operation	Manager Learning & Development
Division Manager of Quality Assurance Systems	Manager Material Management
Division Manager of Quality Control	SOP/Production document administrator
Education Coordinator	SOP System & Total LMS Administrator
GMP Educator	Quality Assurance Release Officer
Group Manager Packaging	Quality Engineer

Empirical data is collected and sorted under each factor, presented in the framework in chapter 7. In all factors the empirical data is presented and followed by an analysis.

8.1 Leadership

8.1.1 Strategy

Different tools are used within the Case Company, which signalize what is important for the company. These are presented below.

8.1.1.1 Visual Road Map

The Case Company has created a document that contains the guidelines for the company's work and focus areas during the two coming years. This document is called the Supply Chain Roadmap, and has six different focus areas. The Road Map is structured by guiding principles, responsible departments, the year's target and what major activities to use for reaching the target. The focus areas and the

principles are presented below in order to give the reader an indicator of which areas the Case Company is seeing as the most important.

- *Customer First* – Keep our promises
- *Safety, Health & Environment* – Work safe and stay healthy
- *Quality & Compliance* – Zero Defect
- *Simplify & Standardize* – Keep it simple
- *Value People* – Proud to work here
- *Value Creation* – Be competitive

8.1.1.2 Safety, Quality, Delivery

According to the Case Company, and the Group, the company is following three key words. These are; Safety, Quality, Delivery, and should be followed in that order. The key words are shown in Figure 15. This is the order used during the Daily Management meetings, and when different decisions are made. These three words should permeate the whole organization, independent of working in office or production. The idea about this order is that with safety the employees are able to perform their job without accidents and injuries. That will make it possible to produce a product with high quality, and more important, everything that is being produced is of correct quality. When everything that is being produced is correct the delivery plan will be held. So, with safety, quality will follow, and quality will result in delivery. This, all together, will generate a positive financial result for the company.

Figure 15. The Case Company's key words in the correct order.

8.1.1.3 Passion-to-Win

Passion-to-Win is a tool used to symbolize the values the Case Company stands for, and what they want their employees to comply to. The Passion-to-Win has its core in the Group's guiding document, and has out of this highlighted some important areas. These areas are; Cooperation & Communication, Result and Follow-up, Innovation & Continuous Improvements, and Engagement & Individual Drive.

During 2012 Passion-to-Win was highlighted by numerous activities and campaigns. The purpose of these campaigns was to enlighten the employees about what type of behavior the company wish among its employees. Passion-to-Win, and the areas mentioned above, is used when setting target for the employees for receiving the

yearly bonus. More about how the bonus system works will be found in section Bonus system 8.6.1.

8.1.1.4 Quality Policy

According to GMP it is necessary that a Quality Policy exists. The Case Company has developed a one pager with three areas seen as the key areas for quality. These areas are; customer focus, management engagement, and employee engagement. The customer focus has partly been based on the guiding document which says the company has a responsibility to customers, employees, community and shareholders, and in that order.

The Quality Policy could be seen on the wall in every department. All employees within the department have signed the policy, which should indicates that they all agree with what it says. Unfortunately, what has been told during interviews with both managers and production workers, is that these strategies, mainly referring to the Quality Policy, seems to be more for show than actually mean something to the employees.

8.1.2 Daily Management

One of the tools used at the Case Company is Daily Management, DM, and these meetings are held at four levels, reaching from the production line up to highest management level. The purpose of these meeting is to create a pipeline for information through the company. It starts with DM 1, held on a production line, and continuous with DM 2, where attendants from these different lines inform about the current situation and how that will affect the surrounding lines. Next level, DM 3, is on the department like Quality Department, Product A manufacturing or packaging. The highest level is DM 4 and this is where representatives from production areas and support functions meet, together with the CEO. The idea of Daily Management is to share information, escalate critical issues and agree daily priorities amongst those it concerns. Questions that need to be passed up are transferred to the next meeting by the attendants. DM has been used as a tool in the company since May 2008 with some minor changes since the start.

After DM 4 most of the participants stay for some minutes, to discuss more detailed information concerning the different departments and production lines face-to face with those who it concerns. Priorities of staffing are discussed in order to facilitate backlogs and optimize if construction work is being done in one line. In DM 4 there is a clear focus on the performance of the entire production plant, not only on one's own production line or area.

8.1.3 Top Managements actions in Critical Situations

Poor quality on the products has been a major problem for the Case Company. It has given the company numerous negative consequences, in terms of lack of trust from

customers, large rejects and loss of income. For pointing out the importance of improvement, the CEO held a general meeting for all employees within the company. At this presentation the CEO highlighted the current problems, and compared the financial loss with the cost of 40 luxury cars. The general meeting was seen as a warning of what could happen, and since many employees have mentioned this meeting during interviews, the message seems to have come through.

Since the problems in the production did not decrease, and parts of the production still did not reach the minimum level of quality more actions were needed. The management team decided to take, what they call, a "Quality Time Out", to really investigate the situation and find the root causes. More resources were dedicated to solve the problems. Management clearly outlined that if something indicates a too high quality risks the production will stop immediately. A wish by the management team was to involve the employee and get their input on how they perform their tasks, and what risks they see in their daily work.

8.1.4 Managers walk-the-talk

The Case Company has approximately 50 managers who are responsible for different areas, and have different experience. Listed below are key findings where the authors identify that conscious actions reflect leadership.

- The authors have seen that the whiteboards, used for the Daily Management meetings, not always are used as they are intended to. By observations it has been found that the whiteboards, in numerous places, were badly updated. Since the whiteboards are used every morning, it is obvious that managers must be aware of that they are not completely followed and up-to-date.

- The SOPs should be used as an instruction of how to perform a task. In both the office and in the production it has been said that the SOPs are not used in the intended way. Several people have told the authors that the SOPs are too extensive. The employees believe that it, in many cases, is obvious for the managers that the SOPs not always are followed. Though, no greater actions have been taken by the managers, which mean that there are no consequences for the employees when not following a SOP.

- The top management team used to be placed up on the fifth floor in the building. Now the top management team has moved down and are divided, and integrated with the other employees. This has resulted in the top managers coming closer to the rest of the organization, and, therefore, being more visible.

8.1.5 Analysis of Leadership

The DM-meetings held at the Case Company is a good way to share information, and be aware of the company's current situation. What is expressed at these meetings is dependent on what should be filled out at the whiteboard, and that is depending on where the meetings are held around. Schein (2010) says, what the management team wants to measure and control, gives the employee a greater understanding for what they should pay attention to. It is, therefore, good, that the construction of the whiteboards signalize that Safety, Quality and Delivery is the preferred order, since the Case Company's management believes this is of great importance. The same reasoning could be applied for the KPI used at the Case Company. The KPIs, expressed at the whiteboard, are the ones the management team has found to be of greatest importance.

The authors Thompson & McHugh (2009) and Schein (2010) agree that the management's reactions and actions tell the rest of the employees what their values are. It is especially in critical situations, that the management team's values get visualized (Thompsson & McHugh, 2009; Schein, 2010). Both according to interviews, and to the actions taken by the top management, there is a shared responsibility amongst the top management team regarding quality at the Case Company.

The general meeting for all employees was a good action by the top management team that showed the employees that these critical situations need to be taken serious. The general meeting showed that quality is of high priority, and that the company, and all its employees, needs to take responsibility in this situation. The Quality Time Out was another action needed to show the seriousness of current errors in the production. The shared responsibility in the top management team shows the rest of the organization that every employee needs to be responsible and act when there is a quality issue. These two situations, the general meeting and the Quality Time Out, indicate that the managers walked-the-talk, as Schein (1985) advocates. To say that the managers walk-the-talk in a more general way is difficult since to walk-the-talk requires consequent actions in all situations. Though, what can be said is that is these two situations, when the top management team was united in the quality question proved good leadership.

According to the internal policy documents and strategies, which all are well-developed, includes quality, and other important parameters that are essential for a company with high quality. Bang (1999) highlights the importance of internal documents being clear and not just empty words. Employees from different levels within the company, has mentioned that there is a problem with these documents. They are mostly created for the satisfaction of the Group, and unfortunately not rooted in the company. One example is the Quality Policy, signed by all employees. But as said during interviews, to just sign the paper does not mean that the

employee agree, or has changed his, or her, values and behaviors. However, the Case Company has documents that are useful in their work, for example Passion-to-Win was created by the Swedish site. This document is used in appraisals for managers and employees. The key for its success has been that this document has been useful and solved problem that the site identified, and not being a document required from the Group.

It should be mentioned that leadership is a never ending job and, as Hofstede, Hofstede, Minkov (2010) say, it is difficult to change the values and norms within an organization. It takes time and it is difficult to understand when the employees follow the values, and when the values are actually lived. A typical example from the Case Company is a manager seeing the employees holding the hand rail when the employee is aware of being watched, but do not do it when not being aware of the manager observing the employee. This shows that the employee, in this case, does not have the same values as the company, and to hold the hand rail has not become the norm among the employees. Still, when being observed, or controlled, the company values are followed, but without being controlled another behavior will be the norm.

The middle management should be seen as the messenger between the top management and the rest of the organization. The question is if the top management's values have permeated through the organization? The authors suspect, from observations and interviews, that this is not the case. For instance, the whiteboards for DM are not filled out, and line managers seems to be aware of that SOPs are not followed, but do not take any actions. It is hard to say whether this problem is strictly connected to middle management or if it reaches the whole way to top management. The problem could be located at the top management team but it could also be that the organization is experiencing a transformation of the leadership structure, and that this change has not yet reached the wished effect. As Hofstede, Hofstede, Minkov (2010) say, changes takes time, and the middle management's behavior could be a result of earlier leadership, which is visualized in Figure 16.

Figure 16. It could take time to receive the effect from a leadership action.

To summarize Leadership, the Case Company has well-developed strategies, and a top management team that take good decisions for the quality, and could, thereby, be seen as good role models. When it comes to the middle management, the authors have suspicions that not all these managers have the same quality mindset, as is required for having a high quality within the whole organization. And with the size of the company it will take time for the top management's ideas to permeate the organization. Anyway, it seems like the leadership have good opportunities to continue developing in the right direction.

8.2 Quality Department

The Quality Unit at the Case Company, within the company referred to as Quality Department, has the responsibility over several different tasks related to quality. The department consists of five sections shown in Figure 17.

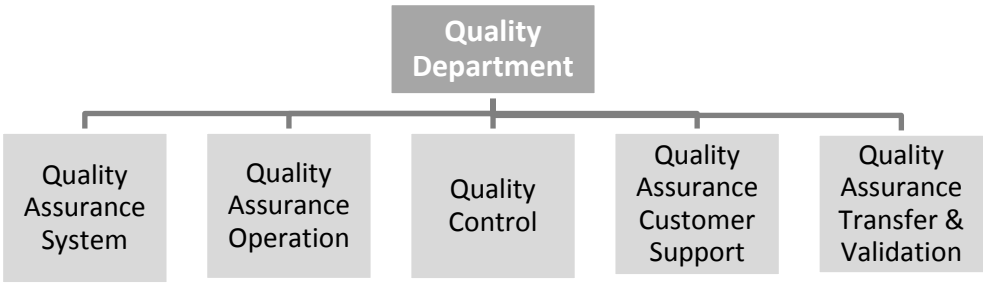

Figure 17. Organizational structure of the Quality Department at the Case Company.

8.2.1 Quality Assurance System

Quality Assurance System is responsible for audits, both internal and external, SOPs, education and Change Control. Regarding audits, the section makes sure that the audits are planned, performed, and also that the result is followed up. Depending on the result, different actions for the audited company is necessary. The same is true for internal audits. Internal audits are a way for the Case Company to both ensure that the quality is good enough, and to prepare for audits performed by an external part, like an authority. When the Case Company is being audited, the Quality Assurance System section is present and responsible for taking care of the auditors.

The educations that Quality Assurance System is responsible for is those with connection to GMP. In the section 8.3 about training more information about the GMP education, and how it is conducted, can be found.

Change Control and SOP are connected. Change Control is the process for making changes in a validated process. When a validated process is changed, an update of the related SOPs is necessary. This process is also directly connected to production,

because the knowledge of exactly how the process is run is more often found in production than at the office.

8.2.2 Quality Assurance Operation

Quality Assurance Operation is responsible for two main areas. These are Master Documentation and Release. Master Documentation refers all documents connected to production. All batches are tied to production documents for the traceability after finished productions. These documents, that later are filled in during production, is created by the Quality Assurance Operation section. The other area, Release, is the release of products from the manufacturing site out on the market. It is also release of incoming material, both packing and raw material, into production.

One important responsibility related to release, is the investigations of reported non-conformances. Quality Assurance Operations will, when a non-conformance is reported, start an investigation to reveal the root cause, and after that, also make sure that action are taken, in order for prevent the error from occurring again. The process for identifying the root cause at the Case Company is the 5M process. 5M refers to; Man, Machine, Medium, Mission, and Management. In the category Man the Case Company investigates further, and tries to isolate the reason for the occurrence of the human error. Internally, the Case Company has started to use a method for categorization in five categories. These categories are;

- *Learning* – The employee do not possess the correct knowledge for performing the task. The reason could be that the employee has not learned what has being taught during the education, or the education did not consist of the right information. The solution is either that the employee attends the education again, or that the education content is being improved.

- *Memory* – The employee forgets how to perform the task. Either the task is completely forgotten, or it is being replaced with a wrong action. If the employee normally knows how to perform the task, the mistake could be a result of stress or tiredness. It is still the employee's responsibility to ask colleagues for help, when having forgot how to perform a task or feeling too stressed.

- *Wrong Performance* – The employee performs the task in an incorrect way, but realizes it and corrects it. The non-conformance should still be reported.

- *Unconsciously* – The employee does not know that the task is being performed incorrectly. The reason for this could be that the employee has misinterpreted some information, or that wrong information is given during education or instructions.

- *Wrong Decision* – The employee knows how to perform the task, and is possible to do so, but decides to deviate from the instructions. It could also be that the employee knows that he, or she, is not in possession of correct information, or the permission to perform the task, but decides to do it anyway. If an employee is aware of being sick, or something else that would jeopardize the production, but goes to work anyway, this is also a human error that will be categorized as a wrong decision.

These categories have been implemented in order for the company to work in a preventive way, once one human error is identified. A lot of effort has been put into making this investigation to something that will help, both the company and the single employee, without only identifying the "black sheep".

8.2.3 Quality Control

Quality Control is the laboratories within the Case Company. Incoming material is being tested before it can be release into production. The Quality Control section will not perform the release. They will only inform the Quality Assurance Operation section about the laboratory result.

Control of finished product is another area for the Quality Control section. All batches are being tested with three samples. The first, one in the middle, and the last sample is being collected from production, and transported to the laboratory for testing. If no non-conformances are found, the batch can be released out to customers. The Quality Control section will just perform the laboratory analysis. The release is still the responsibility of the Quality Assurance Operation section.

For products with an expiration date, samples must be stored throughout this time, and tested within a given time interval. Quality Control is also responsible for testing of the production environment, the air and water quality, and the presence of microorganisms. Regular tests are taken within the whole production site area.

8.2.4 Quality Assurance Customer support

Quality Assurance Customer support is, as the name tells, responsible for the contact with customers, in case of a complaint or recall. This section receives the complaints and investigates if an actual error has occurred. The investigation includes analysis of batch documents, interviews with operators, and laboratory analysis.

8.2.5 Quality Assurance Transfer and Validation

This section is a support function when transferring a new product from research and development stadium into regular production in supply chain. When introducing a new product the whole process needs to be validated, and this is an extensive procedure. These projects require coordination with all functions within the Quality Department, as well as with other units.

8.2.6 The Quality Responsibility

During interviews, it has been revealed that, the Quality Department sometimes feels lonely in the company's strive for archiving quality. It was also mentioned that there were difficulties amongst the employees in the Quality Department to enable other employees, not connected to the Quality Department, to take responsibility over quality. What is experienced could be a consequence of Quality Department's behavior. As said during one interview:

> *"To take the responsibility over something, one must be given that responsibility"(Director of Quality Operation, the Case Company, 2013).*

With the measurement of quality, used at DM 4, the closing of non-conformance investigation is one task with high priority in the Quality Department. This task is typical "firefighting", even though it is necessary. The Quality Department has a wish of working more proactive, but the current situation, with a high number of open non-conformance investigations, have made it stressful to ensure that the root cause is being identified.

8.2.7 Analysis Quality Department

When comparing the Quality Department at the Case Company, and their duties, with what is said according to GMP it is clear that the group works with the correct tasks. All six areas; release/reject, testing, investigating, being responsible for documentation, performing audits, and being responsible for change control, are found at the Case Company just as they should be, for following GMP correctly. To analyze the Quality Department out of a GMP perspective is easily done. GMP is a guide that informs a company of what tasks to work with, but is not specific about how. It is more interesting to look deeper into the Quality Department and see how the collaboration with the rest of the organization works.

The Quality Department has, with its work on categorizing human error, spot on with what the theory says. The Case Company's categories for reasons for human errors are connected with those being mentioned in Chapter 4. Wrong performance is related to slips and lapses. The error could be corrected by the employee directly, and if not, the employee still realizes the mistake at once. Interpretations, or making unconsciously mistakes, are mistakes that the employee is unaware of doing. The same is true for Mistakes, as Mistakes are defined as performance according to instructions, but the instruction is incorrect. The most interesting category, for this thesis, is the category Violations, or as it is named at the Case Company; Wrong Decision. To make a decision, that the employee knows is against the regulation, is a sign of he, or she, having values that conflicts with the rules and regulations. How often this occurs has not been investigated by the authors, because it has not been found important for the study. What, instead, is interesting is the finding that the Case Company is working in a correct way for identifying the root cause of the

human errors that occur. These investigations, and the following action, have the potential of improving the quality of the product, or process.

The Quality Department is, geographically, located in the office building, separated from the production. According to what GMP say about the Quality Unit, it is important that the unit is impartial, to ensure that decisions made are what are the best for the patient safety, and not for the short term earn. To be impartial does not necessarily mean being physically separated from the production. The Quality Department should, as described in the framework created by Saraph, Benson, and Schroeder (1989), be visible for the rest of the organization. If not part of the daily work in production, there is a risk that the Quality Department starts being seen as a division that only is present when there is a quality problem. This creates uncertainty amongst those employees working on a production line when having the Quality Department present.

Also, when not located close to the production, there are difficulties in identifying areas that could be worked with proactively. The Case Company is experiencing a time when the Quality Department is working more with firefighting than with preventive quality actions. All reviewed theorists in the quality field advocated the importance in all employees taking responsibility over quality, and this is also the main message throughout this thesis. For taking responsibility over quality one must also be given the responsibility. This was said during an interview, and is confirmed as correct by Lindmark and Önnevik (2009). An employee must know what the correct action, for ensuring the quality, is. This knowledge is given by the Quality Department during education. Next step is that the employee must want to do what is best for quality. This is where values and norms will reflect. And finally, the opportunity to take responsibility must be available. Without the opportunity of doing something right, both the knowledge and the wish to do so, will faint. To give responsibility to other departments is something that the Quality Department must continue working with, in order for the overall quality to rise. It is also important that the Quality Department start seeing oneself as a support function, and not the only department responsible for quality.

8.3 Training

The Case Company uses an electronic system for managing the employees' educations. The system gives the employee an overview of up-coming study activities and previous done educations.

As newly employed the employee will be assigned a specific "role" in the education system. The role depends on working tasks and which department the employee belongs to. For each role it is pre-registered which information and study activities that are required for the employee. Some parts of the obligatory training package

are common for all employees, and some parts differ regarding if the employee is a blue or white-collar.

Different training methods are used at the Case Company to learn the needed knowledge. The company offers classroom training, written work descriptions, On the Job Training, and e-learning. External training is also offered, but requires the employee to specially ask for the education. How each one is used at the Case Company will be presented in the text below.

8.3.1 Classroom Training

Classroom training is internally training, performed at the Case Company. The obligatory course package of educations consists of a basic course in GMP, required for all employees, independent of what position he, or she, has. This course should be attended in the employee's first four weeks at the company. Further on, the number of classrooms training depends on what position the employee has. However, this means all employees attend the classrooms training.

8.3.1.1 Educators

The educator of a classrooms training is an employee from the Case Company. To be a qualified educator the employee needs to be observed by the person responsible for the educational system at the Case Company.

The educators could receive help from the Learning and Development department when developing the content to the course, if the educator wishes so. Regardless if the support is wanted or not, the observer observes the first held course, in order to give the educator feedback about how the education was performed, how the educator acted, and how the information was given. In addition, attention is paid to how the course participants acted, and their reactions on what was told. After the classroom training the observer holds an interview with the course participants. This gives the participants an opportunity to give their comments of the course content, what they found relevant, as well as not relevant, and if their understanding of the topic has increased. If participants are happy with the content the education, and the educator, is approved. Otherwise, changes need to be done with respect to the given feedback.

8.3.1.2 Course Outline

In the course description it is written what goal(s) each course has. Specified is also, what is required of the participant to be approved on the course. Sometimes the requirement is to actively participate. In other cases a test will be held, and the percentage of correct answers needed is then specified in the course description.

All course outlines for the employees are available in the education system. This means the employee always has the opportunity to read about the training's content and aim, before attending the course.

8.3.2 Work Descriptions

Two different work descriptions are used at the Case Company. These are; Standard Operating Procedure (SOP) and point list, called EPL's. An SOP is a document, describing and informing how different tasks should be performed. All together the Case Company has 766 SOPs that are available on the intranet. How many of these SOPs an employee needs to read, depends on the employee's position and working tasks. A SOP should always be updated when there have been a change in the process described. The updated SOP will be re-posted in the education system, and sent to the affected employees, who need to read it within two weeks, and memorize the changes. If it is not read within this time period an over-do symbol will be visual for both the employee and manager in the education system.

As a complement to the SOPs, EPLs are created. The purpose of an EPL is to have bullet points describing, in a very short and clear way, how to perform a task in a specific situation. The EPLs are placed where they are needed. For instance if the EPL describes how to stop the machine, the EPL should be placed where the machine is. From the employees' point of view the EPLs are seen as a helpful tool. Unfortunately, the control over the amount of EPLs is inadequate. With the EPLs up on the wall out in the production, it is very difficult to ensure that they are all updated to the latest version. There is a risk that one EPL is updated, but that an earlier copy is used somewhere else. The following of working descriptions is important, but in order for the task to be correct, the correct work description is necessary.

The employees have a more positive attitude towards EPLs than to SOPs. This is mainly because of the length of the document. To read a SOP when having a question is complicated and time consuming. Instead, to call a colleague is the normal solution to the problem. EPLs, when found in the production, will help in the same way as calling a colleague.

8.3.3 Practical Training

Specified in the GMP standard is that a person performing a GMP critical task needs to get practical training, be tested, and approved, before performing the task on its own. Therefore, all operators or machine technicians at the Case Company need to have a certificate before they are accepted to perform the tasks in the production. The practical training is called On the Job Training, OJT, and the employee should, during the OJT-time, be supervised on the production line. The duration of the OJT is from two weeks to six months depending on the task's complexity and how often it is performed. In addition to the practical OJT, readings of SOPs and classrooms training are required to receive the knowledge needed for the certificate.

8.3.3.1 Supervision of OJT

The supervision regarding the OJT was changed for six years ago, in 2007, due to the lack of control of the certification tests. Before, all employees at the production line

had the possibility, after a pedagogical course, to educate and approve each other. This made it hard to regulate the knowledge, since the certifiers had, to some extent, different knowledge and routines. Today the Case Company has a smaller amount of certifiers, which makes it easier to secure that those who are being educated get the same information, and that this information is correct. There are some differences between departments and production lines when it comes to certifiers and educators, some line have only one being responsible for the education, and on other lines all employees can educated. Still, only a few employees have the authority to perform the certification. This ensures that, even though different people participate in the education of the new employee, the employee possesses the correct knowledge. And this gets controlled by the certifier.

When the employee feels confident of how to perform the task, it is time for the "test". The certifier has a document where it is specified what to check when observing and questions to ask. Possible results of the test are; pass the test or fail. If failing, the actions taken are depending on which part that the employee failed. The actions could be to continue the training, which means more OJT, reread SOP's, or participate at a classroom training once again. In worst case the certifier realize that the employee has not the potential to learn the task.

8.3.4 E-learning

E-learning is Internet based training, which the employee individually does in front of a computer. The e-learning is an interactive way to learn. Throughout the education orally told information is mixed with exercises and questions to answer, which is a way to make sure that the employee has understood what has been said.

8.3.5 Following up the Knowledge

Identification of the production mistakes is always done in order to understand why the error has occurred. The process for identifying the root cause is described in section 8.2.2 concerning the Quality Unit. When having identified the root cause, and come to the conclusion that the root cause is connected to a human error, it is taken one step further by finding out why the human error has occurred. With the reason being a learning gap more education is one solution.

Another way to secure that the employees have the needed knowledge to perform their work in production, is by making a re-certification. The re-certification is necessary for employees that have been out of the production, or not performed the task, during the past six months. By the re-certification the Case Company secures that the employees are aware of the task's risks, remembering how to perform it in a correct way, and are updated with the latest updates.

According to employees at the HR-department, there is a lack of control on the knowledge given on the education within the company. Once, the Case Company tried to follow-up the learned information from the education by sending an

evaluation form to the participants. The employees were asked to reply with three things they had learned that they afterwards had found to be useful in their daily work. The educator received no answers and no more tries were done since it became a question of resource to send reminders or contact the participant in other ways.

8.3.5.1 Further Education

The HR department decides which educations that is mandatory for the employee. This is beforehand registered in the education system, and connected to each role, which already has been mentioned. Additionally, the manager is responsible for deciding if more training is necessary for the employee. At the appraisal or half-time-review, a discussion between the employee and manager can be held to decide if more education is wished, or required. The Case Company offers courses both within, and outside the company. If an employee has a need of specific training, which not is offered by the company, an application could be sent to the management team, with a motivation of why the employee needs this course. The company has a special fund dedicated to external education, and the management team decides if the application should be approved or not.

8.3.6 Expectations on Training by the Employee

It seems like the employees have different attitudes towards the training. In general the internal education is less motivated than the external one, which also is possible for the employee to attend. According to the developer of the educational system, a wide range of educations are offered at the Case Company. The perception by some employee is that the Case Company has too many educations.

The views on the courses are different; some are seen as “needed-to-have” and some as “nice-to-have”. When experience hard pressure on the manufacturing, employees feels that the nice-to-have-courses take important time from them. This view is, most likely, shared by the managers. Educators suspect that the managers do not “sell” the educations very well to the employees. In order for the employees to feel motivated it is necessary to understand why the education is given, and what the education will give to the employee in the daily work. As initially was mentioned, upcoming study activities are visible in the education system. When an employee get the invitation to an education, the information given regards what course to attend, in what format it is given, and which date, time and place to attend. This means that, in many cases, the employees are not aware of what to learn, the purpose of the course, or how they will use the knowledge afterwards. For instance; will the employee get other tasks or more responsibility after taken education? Educator experiences that employees, firstly after the course introduction, are aware of what the course should include. Educators see this as a problem, since it decreases the attendants’ motivation.

8.3.7 Analysis of Training

As has been mentioned in the empirical data, the Case Company has a lot of different methods to educate and secure the knowledge and competence possessed by the employees. The methods, being both theoretical and practical, show variation and would make it possible for all types of learning styles to find something that fits. But what have been heard, from several people, is that the employee's motivation factor is low when having a training session. One educator being interviewed has often experienced that employees do not know, when arriving to the training session, why to participate. As have been understood, the invitation to the training lesson only includes the practical information, and one interviewee mentioned that the managers perhaps do not sell the education that well. As is written in the theory, the employees need the knowledge itself, as well as a wish to use it and opportunities to use it. If the employee not knows when to use the knowledge, or do not have situations to use the knowledge in, this will decrease the employee's motivation and wish to learn.

Minimizing the numbers of certifiers for the OJT makes it easier to control, that what it taught by the certifiers is correct, and uniform. During certification, a template for ensuring that those being certified possesses the correct knowledge is used. The Case Company has with these actions shown that the company values quality, and that they find it important that those working in production perform their job equally.

Regarding the SOPs, the attitude towards those is often negative. Several employees see the SOPs as something needed due to the GMP regulation, and not as a primary source for information gathering. Even employees involved in administrate the SOPs are aware of that the SOPs are not read or followed as they should, within the organization. A SOP should be seen as a reliable source where answers could be found. What instead have been obvious is that the SOPs are seen as something necessarily evil, and that clarifies that the values regarding the SOPs do not support a quality mindset. This means that in situations when an employee is in doubt of how to perform a task, the SOP is not the obvious choice.

What could be said according to the training is that the Case Company has several tools for understanding what type of education that is needed, different education methods to educate and secure that the employees within the company gets the needed knowledge. The lack of correct values according to the training seems to be the most problematic, both by the managers and employees. As have been described in section 0 the managers have a great influence of the rest of the organization and needs to walk-the-talk, in other words; argue for the importance of follow SOPs and participate at trainings etc. In total, the authors could see that the attitude, both workers' and managers', towards education is not completely in line with a quality mindset.

8.4 Peer Involvement

To facilitate networking, the Case Company is using tools such as e-mail, office communicator, intranet, and shared hard drives for internal documents. These tools facilitate the communication and knowledge sharing. Official meetings, as well as more unofficial gatherings, are other ways for the employees to interact.

8.4.1 Daily Management

Daily Management is, as have been described before, a tool used for networking and interaction, both internally in the department and between departments. With short, daily, meetings the most important information is spread throughout the organization. This spreading of information increases the knowledge of what goes on at the company's different departments.

8.4.2 Management of improvement projects

Every week all lines have meetings regarding improvements. Participants at this meeting are; the shift, line manager and support functions. Since the company is, normally, using three shifts, all shifts contribute to the meeting with information, but only the shift working when the meeting takes place participates. The suggestions from these meetings go further to the monthly management meeting. At these monthly meetings the line managers from each production line meet, in order to decide which projects to focus on, and what actions to take.

8.4.3 Round Table

In February 2013, the Case Company started a networking tool called Round Table. The concept is that 10-12, randomly selected, employees from different department, both from the office and the production, sit down with the CEO, and sometimes more people from Board of Directors, to talk about a, for that meeting, specific topic. The meeting is held on a monthly basis with new participants every time. The idea is to decrease the distance between top management and employees, and to show that the employees' thoughts and inputs are important to the company. The response from the first meeting was positive. An article was published on the intranet, with the purpose of informing about the meeting, what was discussed and how the reaction was. Before this meeting, there was some anxiousness among those who were selected. But after the meeting, all participants spoke with positive words about it.

8.4.4 Facilities

The Case Company is located on a tight area with limited possibilities for expansion. Still, the company has grown since the start, resulting in both offices and production lines being located on many floors. Also, the need for the production area to be clean has increased the complexity, and created a segregated factory. Still, the limited area has led to buildings being built together, or with just a few meters distance if walking outside. The dining hall works as a center for the plant, and around 50 % of all employees take their lunch in the dining hall every day. The dining

hall also serves as a location for DM 4, and the data presented on the board at DM 4 is visible to everyone passing the dining hall.

8.4.5 Observations of Peer Involvement during the study

Since the authors have been located at the Case Company, observations of the natural behavior of the employees have been possible to perform. The company's office building contains offices separated with walls and doors. The doors are normally opened but the offices are not shared. For some areas plan offices are used. These work places are separated with screens. What puzzled the authors was that, in the beginning of the study, it was normally just as quite in those plan office areas as in the other areas with separate offices connected with a hall. But as the time elapsed more interaction was noticed.

Another area, observed by the authors, is the dining hall. As said, around 50 % of the employees take their lunch in the dining hall every day. Unfortunately, almost no mixing of people occurs, even though around 300 people eat there. This indicated that the employees do not feel a very strong fellowship within the whole company, but only within the department or smaller group.

When entering in the morning all employees use their access card for unlocking the door. Therefore, all people who are coming in, without the receptionist opening for them, are employees. Despite this fact, the welcoming in the reception is vaguely and avoiding.

8.4.6 Analysis of Peer Involvement

Bergman & Klefsjö (2010) talk about systems, aimed to bring suggestions, as a good way to find improvement areas, and get people involved within the company. The DM-meetings are a good way to involve the employees. The employees have there, an opportunity to express their opinion and come up with thoughts and ideas. The meetings; daily, weekly and monthly, are good complements to each other since their purposes differ. The daily meeting considers the daily problems, the weekly suggestions and monthly takes care of greater suggestions to implement. This means, all ideas from the employees has a forum where they can be discussed, regardless if the idea will improve the company in a short or long term.

Another benefit with the structure of DM and the monthly meetings is that it allows discussions within the department, as well as between the departments. A cross functional team have the possibility to consider more aspects than just one single employee. Other benefits these meetings bring are knowledge sharing, and the possibility to learn from each other.

The DM is set up by the management team, and this action symbolizes which values and behavior they enhance. As Hofstede, Hofstede and Minkov (2010) explain, values are expressed when plans are made and decision taken. The decisions are the

management team's way to show the rest of the organization what is a wanted and unwanted behavior. When looking into what DM symbolizes, the meetings indicate that all employees' opinions are important, and should be expressed. The greatest knowledge is in the production, and an idea should, therefore, go from the bottom and up. Finally, the meeting structure urge to take both the responsibility and decisions at the own department, and just take bigger problems further up to higher management levels.

The gap between the production and the office at the Case Company should be mentioned. It is a physical barrier, because of the GMP and the regulated industry, but to just accept the situation is not good enough. The blue collars wish that employees from some departments, for instance the Quality Department, should be more visible on the floor. To be visible is, as stated in the framework by Saraph, Benson, and Schroeder (1989), important and enables collaboration. The authors of this study talked to one employee in the Quality Department, and were told that the employee had not been visiting the production during the last five years. The general perception by several blue collars is that it is a lack of white collars in the production. The segregation within the Case Company is a serious problem. Since the Case Company has common goals, the segregation could be troublesome. Dow, Samson, and Ford (1999) are talking about, that a shared vision, and committed and united workers, impacts the quality outcome in a great way. This needs to be considered by the Case Company.

The Case Company's attempt to decrease the distance, using Round Table as a tool, is in line with quality literature. The usage of DM for creating participation in the daily work is another tool. The communication within a department is no bigger problem, but the collaboration between is. This separation may partly depend on physical barrier, but in those situation where this is not a problem, for instance in the dining hall, the separation still exists. The opportunities to work more cross-functional should be considered, which could lead to better solutions being found.

8.5 Employee Ownership

The framework uses the factor Employee Ownership to describe how the single employee takes responsibility for work, knowledge, development and improvement. This is a direct reflection of the individual values, and when these correlate with the values and norms shared within the company the employee is said to take ownership.

8.5.1 Employees take responsibility for education

The Case Company works with documents called Standard Operating Procedure, normally referred to as SOP, which has been presented before. Every task has its own SOP and the use of SOP is required according to GMP, Good Manufacturing Practices. The purpose of GMP is to ensure the safety of the patients using the

product and the SOP should be followed to ensure that the production process is identical every time.

When something is changed in the production, which is described in a SOP, the SOP needs to be updated. When there is a change in the working process it is necessary that the employees take responsibility over these changes, and announce this to a support function within production, which then will update the SOP. The Case Company is experiencing some difficulties with gathering information about these changes. All SOPs are updated every second year, and normally smaller deviations are found during this review.

After the update of SOPs, all employees that are using the SOP will have to reread it, and learn the new changes. At the HR department, responsible for education of employees, statistics over finished education in time is available. In 2013 the percentage of employees reading SOPs within the assigned time was between 66% and 74%. The Case Company has a target of 90% finished within time. The reason for the target being 90% is that sickness and vacations will make it impossible to reach 100%.

As mentioned in section 8.3.5.1 about training and education, the employee has the possibility to request further education when needed. Unfortunately, there is no data available on the number of employees who ask for education, and these cannot be separated from those being registered automatically.

8.5.2 Responsibility in production

Except the controls integrated in the production systems, there are numerous of manual controls being performed. In the pharmaceutical industry there is a need for extended documentation. Standardized templates are used within production for tasks where one or two persons, depending on the importance of the task, should sign.

During interviews, it has been mentioned that these controls are not always performed as supposed. The control documents could have been signed afterwards, instead of when they were supposed to be signed. When samples should be collected and sent to laboratory, there are times when these tests are collected after finished production, instead of when, according to the document, they should have been collected. One reason for this, suggested by one blue collar, is that the trust amongst employees will tend to increase this behavior, since it feels unnecessary to check the work when the colleague normally performs it correctly. This results in the controls being inefficient. Another reason for not performing the controls correct might be stress, caused by inadequate staffing or by tight delivery plan.

For the reporting of non-conformance, the company has a target of all non-conformances being reported within 48 hours. This could be seen as a measurement of the employees taking responsibility over quality. The purpose of reporting a non-conformance is to ensure that an investigation is done, and that the root cause of the non-conformance is revealed. If the root cause is found, and corrective actions are taken, the same error should not occur again, and the process would get closer to a quality production. Statistics for 10 weeks in 2013, visualized in Figure 18, shows that only every second non-conformance is reported within the target time of 48 hours.

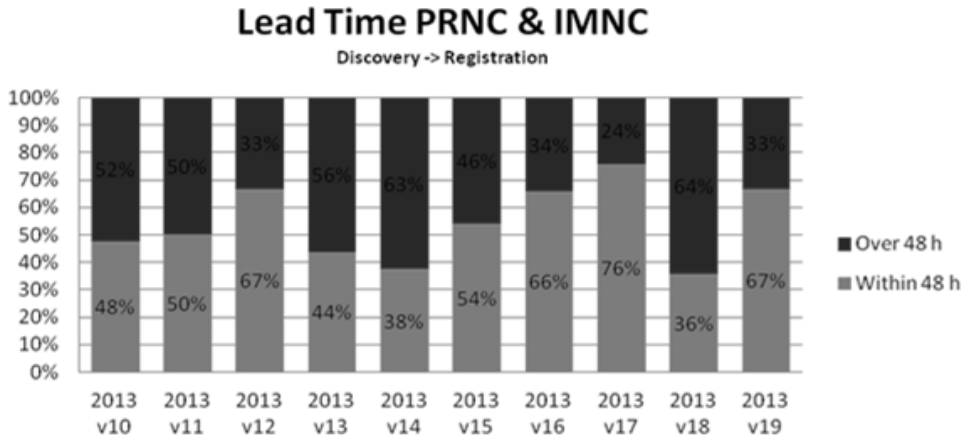

Figure 18. Percentages of how many non-conformances that are reported, and not reported, within 48 hours (the Case Company, 2013).

8.5.3 Analysis of Employee Ownership

CEB means that the most important factor, for creating behaviors favorable for quality, is employee ownership.

As written in the section about training, section 8.3, the popularity of SOPs is low. The perception, the feeling of the SOPs being complicated and time consuming, leads to an unwillingness to update these work descriptions when needed. This indicates that the employees do not see the purpose of using SOPs, since they do not see it as a meaningful source of information. This leads to several negative consequences; if no one wants to update the SOPs, the information is not reliable and, therefore, there is no need of reading it.

One explanation to why some SOPs are poorly updated is that experienced operators do not have the same need of detailed documentation as newer operators do. That is one reason for why, in some cases, the description is not as detailed as necessary. This is difficult to avoid because, in order to get the correct information, the description needs to be written by someone who is well familiar with the process. That could result in some implicit parts being excluded. These kinds of gaps

are usually identified when a non-conformance is investigated, and the root-cause is connected to the SOP.

To present the data over how many employees that are reading the SOPs is good, because it signalize that the company finds this type of education important. Though, should it be mentioned that the numbers presented do not express if the employee has either understood the information, or remembered it. The authors mean that having more control, if the employee has read the updated SOP or not, are necessarily not the best way. More controls mean that all responsibility is taken from the employee and could signalize that the company do not trust their employees. What the company needs to strive for is that the employees themselves should feel a need of learning the knowledge. Though, if a smaller number of controls should be beneficial, it requires that the employee's values regarding quality are high, and that the employee takes responsibility for its knowledge and behaviors.

Employee Ownership is connected to training, and as written about training; to be able to do what is correct one must know what is correct. It is difficult by the single employee to understand what required knowledge that is missing. If knowing, it is potentially possible for the employee to ask for needed education. Doing this is, according to the theory, one way to take responsibility for its own contribution. As is written in the Training part, section 8.3, there exist an opportunity to apply for a specific education. Whether those participating in an education are those who are being told to do so, or they have been asking for the education themselves, have unfortunately not been possible to find data of. This could otherwise be a sign of Employee Ownership.

To take ownership of one's work, to make decisions that will be correct for quality, is a reflection of one's values and norms. In the Human Error chapter *violation* was explained. This is when the employee is aware of how to do, but do not follow the rules anyway. This is something that is a problem at the Case Company, mentioned in the empirical data. One reason for this is the trust amongst the employees. Another reason, given to the authors during interviews, were the tight production plans, which indicates that the employees' values are that producing the right number of batches, is more important than producing batches with right quality.

In CEB's framework about Employee Ownership, they highlight the importance of employees raising concerns and ask questions that will challenge the directives, in order for the quality to improve. To dare to stop the production when noticing a deviation in production is, therefore, essential. If doing so, this indicates that the quality is more important than producing the higher amount of product, for the employee. Another indicator of how important the quality is for the employee is the data about how quickly a non-conformance is reported. As the data shows, only

about 50 % of the non-conformances are reported within 48 hours. What the employees may not be aware of is that, as long as the root cause to the non-conformance is not found, there is a potential risk that the same error will happen again. Both the documentation and the non-conformance reporting are examples that confirm that there is a lack of correct values regarding quality within the Case Company.

Employee Ownership will reflect in several other factors mentioned in the framework. This makes it difficult to analyze Employee Ownership separately. The Employee Ownership is visualized by taken actions, which are based on the employees' values. It is hard to say if the Employee Ownership is good or bad since the effects is spread to other factors. The Employee Ownership is, to a great extent, affected of the individual's personality, which also makes it more difficult to generalize this factor. However, if people are having the same type of values, the feeling of responsibility would be shared among them, and the actions taken will be similar, no matter who makes the action.

8.6 Incentives

8.6.1 Bonus system

All employees, recruited by the Case Company, are connected to the company's bonus system. The bonus system is constructed in the same way for all employees, regardless if the employee is working in the production or at the office. The date for the payment of the yearly bonus will vary depending on when the company knows the result from the previous year. Sometime the bonus payment reaches the employees in March and sometimes in September or October.

8.6.1.1 Selection of criteria aimed to evaluate the employee

Yearly all employees have an appraisal with the closest manager. The manager has a guidance of what to include in these meetings, and what is the foundation of the bonus.

Firstly, the manager and employee make an agreement about eight goals, which the employee should try to fulfill during the year. The goals should have a link to the company's goals, and the employee's position, and be SMART, meaning Specific, Measurable, Approved, Realistic and Time bound. The company goals are described in the Supply Chain Road Map in the section 8.1.1.1.

Secondly on the appraisal, the employee and manager should identify which "Passion-to-Win"-competences the employees should focus on, in order to fulfill the set goals. Even if the company expects the employee to fulfill all of the Passion-to-Win competences, two should be chosen and seen as more important for the employee.

The quality and relevance of the goal is important, and the goals are, mainly, on an individual level, but could be for the whole department. In Table 3 the Passion-to-Win competences are specified, together with a shorter definition.

Table 3. Passion-to-Win competences used for individual setting of goals (the Case Company, 2013)

Passion-to-win	Competency	Definition
Guiding document	Live our values within the guiding document	Build trust. Tell the truth. Advocate openness when having problem. Take care about humans. Strive to put the guiding document firsthand when discussing.
Result and Follow-up	Result and Performance oriented	Create result and solutions. Focusing on customer values. Personal responsibility and ownership.
	Energetic	Work in prevention. Identify and react on problems and opportunities. Strive to shorten the lead time. Absorb the information quickly.
Innovation and Continuous Improvements	Curiosity	Find opportunities, try and “cultivate” new ideas.
	Risk Awareness	Courage to seize opportunities. Dare to take decision. Want to learn from mistakes.
Cooperation and Communication	Cooperation and Team Work	Manage to work in different team and with different functions. Supporting good relations and try to build effective teams. Is an inspiring colleague.
	Self-awareness and Adaptability	Is humble. Can adapt and change depending on what situation it is. Learn by others.

8.6.1.2 Evaluation of goals

After one year, when employee and manager have the yearly appraisals, an evaluation of the past year will be done. The goals aimed to be evaluated are the eight SMART-goals and the Passion-to-Win criteria. For receiving the yearly bonus, the performance must exceed what is expected in that position.
Each goal will be evaluated out of a nine-step-rating. Each step describes how well the goal is met. Step one to three stands for goal are not met. Above step four the performance level is constantly over what was expected of the managers. It is possible that the employee reaches seven or eight during one year, but this is an indicator of that the employee needs new challenges. Step nine has never been met within the organization. The result of each goal's evaluation will together be weighted into one number which will represent how well the employee reached the set goals.

8.6.2 Reward systems

8.6.2.1 Encore

A reward system, called "Encore" was established at the Case Company in 2012. To receive a nomination the employee's contribution should have had importance for the company. Though, the contribution cannot be something that is expected in the employee's role at the company.

To receive the reward the employee should have performed in line with the Encore-criteria. These criteria are:

- Has customer focus
- Business sense
- Consider the strategy
- Act with determination
- Has a good judgment
- Act with integrity and confidence
- Not afraid of risks
- Support colleagues
- Reach result

The nomination should be considered by the mangers of the employee's managers, so called *grandfather principle*. Five different levels of the reward are available. For the smaller performances the employee gets a "Thank You" without a financial compensation. To receive the greatest reward, and a financial compensation of 5140 SEK, the performance should have had a measureable effect on a division, subsidiary or operating group. The level of reward is based on how great impact on the company the employee's performance has.

The encore rewards and a diploma are given to the employees during an official ceremony. How many Encores, of each level, that have been given, from the start in 2010, are visualized in Table 4.

Table 4. Numbers of Encores, specified by level, that haven been given to the company's employees.

Year	Thank You 0 SEK	Bronze 1290 SEK	Silver 2570 SEK	Gold 3860 SEK	Platinum 5140 SEK	Total
2010 Q3-4	0	0	0	4	3	7
2011	4	22	43	62	12	143
2012	1	43	13	7	6	70
2013 Q1	1	4	17	12	2	36
Total	6	69	73	85	23	256

8.6.2.2 Leadership Award Programme

The Case Company uses an incentive system called "Leadership Award Programme", with a bigger financial reward. All employees within the company have an opportunity to be nominated, not only the managers. To receive a nomination the employee has to show good leadership that is in line with the Group's Global Leadership Profile. The aim with the Leadership Award Programme is to increase the positive behavior within the organization. Even in this case, the grandfather principle is used for appointing the reward winner.

8.6.2.3 Suggestions of improvements

The Case Company has a system for handling suggestions of improvements. Before, every suggestion that was handed in was rewarded with a small symbolic reward, around 50 SEK. This resulted in a big amount of suggestions, but unfortunately the quality of the suggestions varied. To solve this problem improvement meetings was implemented, and are now held on a weekly and monthly basis. Improvements given at these meetings do not generate a reward to the suggestion giver, but other rewards like Encore could be given.

For improvements that could result in big saving for the company, a monetary reward system is kept. Suggestions could be handed in by any employee, and it should contain a solution describing how to solve the problem, and not only point out that there is a problem in a certain area. To receive a reward, the suggestion should concern areas outside one's own work area. This means that improvements of systems or processes might be included in the work description, and to just perform the work according to the description does not generate a reward. Most of the suggestions handed in come from operators or technicians. Normally,

improvements are limited in their work descriptions, compared to work descriptions of managers, and that is the reason for why they are more active handing in suggestions.

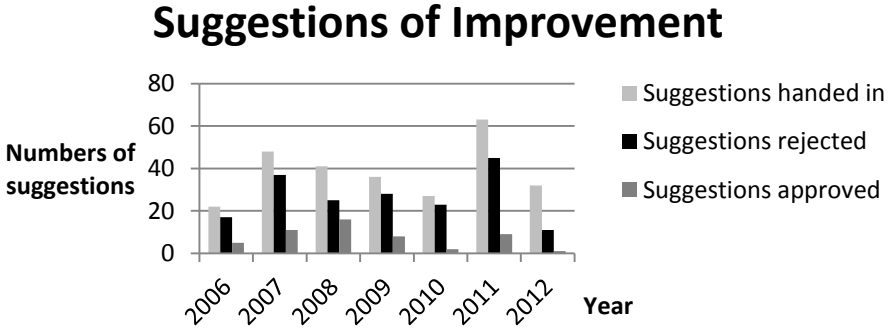

Figure 19. Presentation of data over suggestion of improvements at the case company (the Case Company, 2013).

The size of the reward is calculated as the saving generated by the improvement that the company makes in one year. The reward is not approved until the improvement has been shown. This give a delay in the statistics since some improvement requires testing and verification. As seen in Figure 19, around 20 % of the suggestions result in a reward. The amount being paid varies. The biggest reward was one payment of 400 000 SEK.

When interviewing employees who have handed in suggestions, what is being told is that the feedback from the group working with deciding about the reward is too slow. For a suggestion handed in during October still, 6 month later, no response have been given, not even about how the process is running. The group is having meetings every second month, but have recently suffered from internal problems due to employees leaving the company for other duties, resulting in a delay of handling cases. It has also been said that the interest from group managers, who are involved in the process of deciding whether the suggestion is good or not, is not that high. According to the coordinator of this group, this is another reason for why the process is being slow. Still, the employees handing in suggestions are confused and the motivation for handing on more suggestion is getting decreased.

8.6.3 Analysis of Incentives

When analyzing the Case Company's bonus system and its criteria, it is obvious that these criteria have a strong connection to the company goals, described as Supply Chain Road Map, Passion-to-Win and the key words; Safety, Quality, Delivery. Having these connections between the strategy and the bonus system reinforce the

credibility for the strategy, and clarify which behaviors that are appreciated within the organization.

Schein (2010) says that an award will be effective, and fulfill its purpose, when the employee understands the connection between the award and the performance, or action. The Leadership Award Programme is a great system for indicating the appreciated behavior among leaders. The ones that walk-the-talk will be rewarded, which is in line with what Bang (1999), says about credibility. The Leadership Award Programme is, therefore, one way for the company to affect how their role models act, appreciating the following of the company goals and values.

Encore is another good example of a reward system at the Case Company, where the employee will be rewarded if their behaviors are in line with the company's values. Encore has many criteria that are beneficial for the quality mindset, the behaviors, and the business itself. This means Encore is covering many essential areas within the Case Company. The financial amount is also in line with what Bergman and Klefsjö (2010) say; it could be a small financial reward, since the reward is more of a symbolic contribution for the performance.

As shown in Table 4, it is obvious that the amount of nominations as well as rewarded employees has greatly decreased between 2011 and 2012. The authors cannot find that any conscious actions have been conducted, in order to get this decreased number of nomination to Encore. The authors speculate that one reason for this decrease could be that too many Encore rewards have been handed out, since it under 2011 handed out 143 rewards and the number of employees in the Company is around 600. To give a reward to more than 20 % could reduce the exclusiveness.

The feedback time is another factor, which could influence the employee's ability to understand the connection between the performance and the bonus. As was mentioned before, the bonus at the Case Company is yearly calculated, and will be paid around the next coming year's summer. This feedback time could be seen as quite long, which could make it hard for the employee to link the bonus to their performances.

The manager for compensations and benefits believes that the bonus, nowadays, is something that is expected by the employee, and is taken for granted. The bonus system has, thereby, lost its main purpose. The employee means that it is hard to see the effect which the bonus is supposed to give the company. The interviewee believes the employees have been spoiled to always get a bonus payment. Always getting a reward is a reason to why the bonus has started to be something that is expected. Another reason for why the employees cannot connect their contribution

to the bonus could be the big amount of criteria. It may be hard for the employee to actually understand what the Case Company wants the employee to focus on.

Regarding the suggestion, the new system with Weekly Management is, according to Bergman and Klefsjö (2010), more beneficial than handing in all suggestions, as before. Weekly Management involves more employees, which enables further development of the suggested improvement. What drives the upcoming suggestions at the Weekly Management is the employees' willingness to be better, and get noticed in front of the group, rather than the financial reward. Another advantage with Weekly Management is the quick feedback on the given suggestions.

Unfortunately, the other suggestion system with bigger financial rewards, fails concerning the time for the feedback and response. Even though, as was mentioned before, it takes time to evaluate an idea, some kind of information or feedback of how the process is going could be given to the employee. As mentioned by both Bergman and Klefsjö (2010) and an as interviewed employee say, the motivation goes down when not knowing what is happening with the given suggestion. The silence could indicate a lack of interest from the company in having its employees to give suggestions of improvements.

The authors could see come difficulties with having a suggestion system, in a regulated industry, because it is harder to change the process since it, once again, needs to be validated. Regarding the size of the financial reward for suggestions of improvements, the Case Company could consider it. With big amounts employees tend to keep their ideas to themselves, instead of developing them with input from others. This could both mean that it takes longer time for the company to experience the advantage given by the suggestions, but also that the ideas are not as good as they could be if more employees were involved in the process.

Overall, the Case Company's view on incentives is in line with theory; small financial rewards, official announcement, rewards for unofficial leadership, and goals that correspond to the company's strategy, for just mentioning a few things. The possibility to reinforce the wanted behavior among the Case Company's employees is good.

8.7 Data and Reporting

8.7.1 Daily Management

As have been mentioned before, there are four different levels of Daily Management. DM 1 and 2 is more of a daily planning meeting, where the different tasks are divided between the employees, and KPIs are evaluated. The used KPIs within the company are different, depending on department. DM 3 is more similar to DM 4, with brief information from the sub divisions, but more focused on the

performance of the whole department. This information is later transferred to DM 4 to contribute to the whole production plant's performance.

Every Daily Management meeting is held in front of a whiteboard, presenting data over Safety, Quality, and Delivery. These whiteboards should be updated before, or during, every meeting. The whiteboard is divided into different parts. When going from left to the right, the order is; Safety, Quality and Delivery, or production. This order is chosen to reflect the company's view of what is important.

8.7.1.1 Data in production

Both Safety and Quality are daily marked with one color depending on what happened yesterday. Possible outcome for Safety are; green - no accidents, yellow – potential accident and red – occurred accident. For Quality the same colors are used but stands for; green – quality target met, yellow – an incident that is reversible and do not affect the GMP requirements, red – quality deviations that are affecting the GMP requirements. If a deviation has occurred, that should be reported within 48 hours.

If the line has noticed a deviation, and reported it at the DM 1, the deviation is taken further and being discussed at DM 2. For deviation defined as non-conformances, these are reported back and should be stored on a list at the line whiteboard. The reason is that the non-conformances should be investigated at the line, by those working there, together with the Quality Department. These lists, referred to as Quality lists, are used as a visualization tool for keeping the employees aware of current quality problems.

On the whiteboard the weekly production is also visualized. How the production went is compared with what was planned to be produced. Green stands for production target met, yellow for risk of deviation from plan, and red is when the production plan failed.

Observations show that several of the Case Company's whiteboards are poorly updated, and employees say that too much information is to be put up on those boards, and not all this information is useful or followed up. Found during observation was that Delivery was updated, but the information that was lacking, at numerous places, was data about Safety and Quality.

8.7.1.2 DM 4

At DM 4 representatives from all production areas and support functions participate. The meeting is held in the dining hall where the result of DM 4 is visualized for all employees. The result is visualized on a wall, placed in the middle of the room, where each product area is individually presented. This gives the employee an

indicator of how the previous day in production went. How the result is presented will be described below.

At DM 4 the current status and performance of the factory is presented. The production for the biggest product, per volume and sales, is divided into manufacturing, coating and packaging. For the other products the whole production and packaging is included in the judgment of the performance. All these products are evaluated, using the methodology of a traffic light where green represent good, or satisfaction, yellow is for potential deviation from plan, and red is for not meeting the targets. Here, the evaluation order is safety, quality and delivery, as mentioned above.

Quality is judged based on the number of open non-conformances. What are reported on DM 4 are the number of opened, new, and the number of closed non-conformances for every product. The number of new and closed non-conformances is counted from the last meeting. Every production area has a target stating the acceptable number of opened non-conformances, and when meeting this number quality gets judged as green. The targets are different for each production area since the volume of product being produced differs. Unfortunately, the data of the Quality, visualized at DM 4, is not stored, but by observations, the authors have seen that the overall quality judgment has been red, mostly depending on quality at the biggest product's manufacturing, coating and packaging. For other production areas, it has most of the time been green, which means the number of accepted open non-conformances is not exceeded. But since there is one product, which is bigger, both per volume and sales, the judgment of this product performance will override the other products' performance, and the overall quality gets judged as red.

The delivery plan is based on weekly plans. The number of batches to produce is calculated based on orders, and broken down to what to be produced every day. This is followed up on DM 4 by giving the probability to meet the delivery target. Yellow light symbolize that there is a risk for not meeting target, while red is when the target is out of reach. Delivery performance is presented for every product, in the same way as the data for Safety and Quality. Delivery is highly dependent of the quality performance, which gives that the Delivery result follows the same pattern as Quality. The overall judgment has been red during the observation time.

8.7.2 Intranet

On the front-page on the intranet, the result of the DM 4 meeting, held in the morning, is visualized. This result is the overall judgment for the Case Company's all products regarding Safety, Quality and Delivery. Since the result presented is the same as for DM 4, the result during the whole observation time has been green for Safety and red for Quality and Delivery.

Presented, on the intranet, is also the number of days since the last accident occurred at the plant. The overall judgment has been green for more than 193 days by the 2013-05-08.

8.7.3 Analysis of Data and Reporting

As Bergman and Klefsjö (2010) say, data should be visualized. DM is a great tool for visualizing the result, both within the department and in the common areas as dining hall and on the intranet. To openly share the result with all employees enable them to have a dialogue about the result, regardless if they are satisfied with the result, or not.

The same reasoning could be used here, as was held in the Leadership analysis. The structure of the whiteboards, used for Daily Management is in line with the priority order; Safety, Quality, Delivery. As Bergman and Klefsjö (2010) express, the data could secure that the right focus is held on the meeting. Since the meeting is held out of the whiteboard, the meetings will be quite equally, regardless of what department or production line it is held on. A standardized meeting is a way for the top management to minimize the risk that managers put a personal touch on the meeting, and discuss what they think are the most important areas. The whiteboard "forces" the manager to talk about what happened yesterday, out of the whiteboards order; Safety, Quality, and Delivery, and this shows credibility to the employees that this is the actual applicable order the company is following.

When doing observation in production it became clear that the whiteboards were not used as they are supposed to. This means that the employees and, or, the line managers do not, completely, understand the purpose of some parts of the board. If translating these behaviors, the authors could see that there is a deviation according to the importance of quality. The authors cannot explain why the whiteboards are not used, but it is clear that, at some lines, the quality and safety are not as important as following up the daily production. This conclusion comes out of those two areas not being documented on the whiteboard to the same extent as the daily production. This shows that the employees' and management team's values regarding Safety, Quality and Delivery differ.

The method for measuring quality is different at different levels of DM. The measurement for quality at DM 1 and 2 is the amount of new reported non-conformances, in comparison to DM 4, where the total amount of open non-conformances is measured. The authors are wondering if open non-conformances is a 100 % correct KPI for measuring the quality? There is a good point in keeping track on open non-conformances, since this means problems in the production have occurred without understanding why. Since this leads to a potential risk that the same problem will occur again, it shows that there is a lack of quality within the production. The downside with just calculating the amount of open non-conformances is that wrong signals could be given. For instance, if the production

has worked without any errors in one week, but no old non-conformances have been closed, this still gives bad signals of quality and a red color at the DM 4 board. If the employee has "we-feeling" with the production line, the different measurements of quality could lead to a frustration of all mistakes other departments are doing. If the employee has "we-feeling" with the whole company, hopelessness over constantly bad quality could occur. It is important that the company is aware of what signals the quality symbols send. With the current method, calculating open non-conformances, there is a risk that the responsibility is connected to the Quality Department, since their task is to close non-conformances. A risk is, thereby, that the production feels a limited responsibility over this, even if the error occurred in the production.

What should be mentioned is that it is of great importance to be clear when communicating the result. As have been mentioned by Reason (1987), one reason to why a human error occurs is that the employee has done personal interpretations, called inferential errors. So a risk when visualization results and not explaining them is that it could be misleading. Especially for new recruited, it is hard to understand what the colors stands for. This was something that the authors initially experienced, for instance in the dining hall and on the Intranet, since the colors of Safety, Quality and Delivery not are explained. The authors' first impression was that there were severe quality problems within the whole company, and not only on some production lines.

To sum up Data and Reporting the authors could state that the company has good tools for visualizing data. Though, it is important to make sure that all data are meaningful for the employees, and that they understand the importance of the data. If the understanding increases, this could result in the whiteboards are filled out more thoroughly. The company and the managers need to continue their work to promote the usefulness of the whiteboards, especially for the people that not feel that they have the need of knowing the data. It needs to be clear, what gains that could be achieved, when using the whiteboards.

8.8 Supplier Management

At the Case Company in Sweden the Supplier Department's role is to hold the daily contact with the suppliers. The European office is responsible for negotiation and to create the contracts. Though, the Case Company in Sweden has the opportunity to give input, since they possess insight in the cooperation in daily work, and know what problems the supplier have had before.

For packaging material, the Case Company uses dual sourcing. This means that they often have two sources and, therefore, secure the delivery of material. For some material, especially raw material, it is hard to find more than one supplier due to the products complexity or availability. In these cases, the Case Company is forced to use the strategy of single sourcing, even though dual sourcing is the preferable

strategy at the Case Company. When choosing supplier of raw material the product specification is described in a Pharmacopoeia. A Pharmacopoeia is, as described in section 6.3, a written specification of substances. The Pharmacopoeia ensures that the quality of the raw material is as high as required.

8.8.1 The relation to suppliers

The Supplier Department holds the daily contact to their suppliers. The department has different KPIs that are used for analyzing the suppliers. For instance is the opportunity to deliver measured, as well as numbers of variation or complains. Every month the 15 greatest suppliers are evaluated by the Case Company in Sweden and the European office, in order to take action if problems have occurred.

When problems occur, actions are taken. One action is to hold meetings more frequently in order to follow up and solve the problem. When the supplier have hard to reach the quality requirements extra tests could be the temporarily solution to check the quality before delivering to the Case Company.

The relation to suppliers could either be seen as how integrated the Case Company is in the supplier's production, or how integrated the suppliers are in the Case Company's production. According to interviews, there is an internal proudness by the employees at the Case Company, which leads to that external help is not always seen as the most obvious choice. Traditionally, the Case Company possessed enough knowledge of the complete process, machines and raw material, but now the technology development has rapidly increased and become too complex. The competence within the Case Company is, therefore, not in all areas as good as the supplier's competence.

When there is a problem with one of the supplier's products in the production at the Case Company, the bought packaging material, label, or blister, for just mentioning some products, tend to get the blame for being the cause. The manager of material management told the authors that sometimes, the materials are used incorrectly. This incorrect usage is often noticed by the supplier, if they are invited to take part in the problem solving process at the Case Company. In other cases, the production line is just too complicated and complex, creating problems with the products.

8.8.2 Choice of suppliers – the process

According to the Supplier Department at the Case Company in Sweden, the price has played an important role in the selection of suppliers. The Group has three product areas; Consumer Products, Medical Devices, and Diagnostics, and Prescription Products. Since the Case Company's products are not on prescription, they belong to consumer products. The problem with this is that the material requirement differs between pharmaceuticals and consumer products, and this was not considered when choosing suppliers. Even if the Case Company's products still belongs to consumer products, a clarification has been made that the requirements on the

material to the Case Company need to be as high as it is on the pharmaceutical products. This has led to an increased cooperation between the product categories, which before not existed.

When a new supplier should be chosen the European office is responsible for this process. Firstly, the interested suppliers are invited to the European office. At place, they are told which requirements the Case Company has on the suppliers, and a specification, which includes product specification, buyer volume, and lead time etc. is presented. The suppliers will then return to the Case Company with their price and possibility to deliver according to the specification. Thereafter, one supplier is chosen that is seen as the most suitable. The last step, before the supplier can start their delivery, is an external audit, performed by the Case Company.

8.8.2.1 External audit by the supplier

Auditing the suppliers is included in the GMP requirements. An audit is performed at all new suppliers and thereafter on regular basis for the existing suppliers. The auditing is also a way for the Case Company to secure that the gods delivered to the company has the right quality, before using it in the production.

The audit is done out of the praxis in the industry. The requirements of the supplier depend on how close to the Case Company's product the supplier's product will be. There are three possible results of the audit:

- Acceptable
- Conditionally Accepted
- Unacceptable

With the result Acceptable the Case Company may continue doing business with the supplier as normal. If the result is Conditionally Accepted this will generate more extensive testing of the delivery, and no other products will be bought from the supplier. After a follow-up-audit, and when the supplier return to the status Acceptable new items can be added to the buying list. In those cases, if a supplier will be rated as Unacceptable, it is allowed to, temporarily, continue doing business, but with even stricter controls of incoming material and more frequent meetings are held with the supplier. The supplier must immediately show improvements, but still, the normal case is to start looking for another supplier.

The Case Company has, during audits, experienced differences between suppliers regarding their willingness to change and adjust to the Case Company's demands. The willingness will depend on how big, or small, customer the Case Company is to the considered supplier. In the pharmaceutical industry, the supply chain requirements are extensive. For suppliers, who deliver to customers within different industries, the requirements needed for continue delivering to the Case Company

might be too tough, and that could reflect in the willingness to adjust after an audit with negative result.

8.8.3 Analysis Supplier Management

As Yu, Zeng & Zhao (2009) express, dual sourcing is preferable when the amount of suppliers of raw material is limited, and the company cannot risk missing a delivery. This is representative for the Case Company, which have tried to find two suppliers, for the products where it is possible. Unfortunately, it has been difficult to find two suppliers of some material. There have been occasions when the Case Company has found two suppliers, but later on one of them has be acquired by the other. Still, the authors see it as positive, that the company is aware of the situation regarding the suppliers, and work with a strategy of decreasing the numbers of suppliers and work closely to those they have.

Having external audits at the suppliers, as the Case Company has, before buying the product from the new supplier, is a good tool to make sure that the supplier's manufacturing enables high quality on their products. As has been written in the Leadership section 8.1.1.2, the key words within the Case Company are Safety, Quality and Delivery. As also have been mentioned before, when describing CEB's framework, is message credibility. In other words it is an indication of how well the given information correlates to what is actually followed. The authors have analyzed the choice of suppliers, and they reacted on that the external audit by the new supplier is conducted after the supplier has been chosen. This means that the supplier has been selected out of the quotation, but if the supplier meet the requirement or not is not clear, since this has not been checked by the Case Company. The authors mean this indicates that price goes before quality. If the external audit would have been performed earlier the decision could have been based on both the quality and price. According to one Quality engineer, the Case Company has done some kind of agreement already before the external audit is conducted. The authors also speculate if this, somehow, could impact the decision of the result when doing the external audit. If the supplier does not meet the requirement at the auditing, the Case Company put the auditor in an uncomfortable position, which means the selection process needs to be remade. An auditor explains that it is hard to come back with the result of that the supplier does not meet the requirements, but that is what is included in the job of an auditor. In addition, the auditor express that it would be preferable to make the audit earlier in the process.

What came up at the interview with the Quality engineer is that internally the Quality Department is seen as an intermediary between the production and the European office. This could be hard for the Quality Department, when the production is unsatisfied with the material, and the European office selects the supplier. The problem may occur due to that the requirements are not clear. Another reason, for why poor quality of the material reaches the Case Company,

could be that the company's unique process, and its' very specific machines. The authors see the difficulty that appears when setting too high requirements with limited choices of suppliers available. One solution could be to change the Case Company's own process, and their specific machines, if the supplier cannot meet the requirement, since this could open up for more available suppliers. As Bergman & Klefsjö (2010) have written, it is essential to have a good relationship with the suppliers and to be aware how the suppliers can contribute to the manufacturing. To ask the supplier for help, and to modify the process, are possible solutions. At one interview it has been said that it is an internal proudness within the Case Company, and to get external help from the suppliers who know the material, is not very common. The authors mean that getting help from suppliers would be beneficial, since having the competence internally is quite hard due to the technical development.

Bergman and Klefsjö (2010) explain that a producing company must feel responsibility, not only over what is produced in-house, but also over what is delivered to their customers. This is due to the reason that the end customers always will hold the last part in the supply chain responsible for the quality. They also mean a close connection between the supplier and customer will increase the quality of the product. The authors of this thesis have seen that it is not always easy to receive the wanted quality. When looking at the Case Company, active in a regulated industry and with several suppliers who are not, some problems could occur. The Case Company has most of the time, higher requirements than other customers the supplier deliver to. In those cases, where the Case Company is a small customer, it could be hard to change the production at the supplier. The combination of being a small customer, and in the same time have a lot of requirement, is not a beneficial situation because of the lack of possibility to influence the supplier. In those situations be understanding and supporting to the supplier are characteristics the authors think could be of importance.

One thing that the authors have noticed is that it is common to always strive for better quality. Especially within the Quality Department, this is a phenomenon the authors identified. The relation between quality and price needs to be considered. The most important is to meet the minimum requirements. It is not meaningful to choose a higher quality if this does not give the customer a surplus, since it, in this case, just will increase the company's and, most definitely, the customers' costs.

The greatest finding, within Supplier Management, is the working order of the process or choosing suppliers. The Case Company says, through the strategy and key words, that focus should be on quality. Here is, though, evidence that this not always is the case. The choice of supplier does not follow the same order as the key word represent, since the supplier is chosen out of the price, and not out of the result of external audit, in other words, the result of quality.

9. Conclusion

Chapter nine contains the result of the analysis, which reveals three areas for the Case Company to focus on, if to improve the quality mindset. Also, this chapter contains a model for describing the relation between the critical success factors. Suggestions for further research and a discussion is also part of this chapter.

9.1 General findings

During the authors' work with both the creation of the framework and the usage of it for analyzing the Case Company, a clearer picture, of how the factors correlate to each other, evolved. These relations are put together in a model, shown in Figure 20. The authors believe that this model could be used as a general model for describing the connection between factors, necessary for quality success. These factors, and the model presenting the relations, are developed with one important limitation. The product design, important for the customer's perception of quality, is not considered, either in this model or in the rest of the thesis. Product design is seen as a prerequisite, and because of that the quality definition is of technical character. Quality, in the model as well as in the framework presented earlier, is the correct product, produced according to the correct process, and with the employees involved in the process following the set rules and regulations.

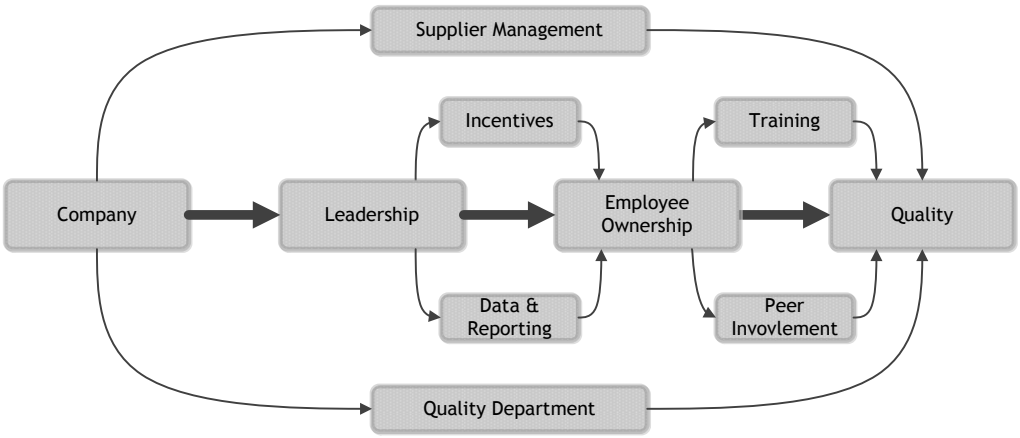

Figure 20. Model of the relation between the critical success factors.

This is the relation that, through the analysis of the Case Company, the authors has found being the most dominant and important. The straight line, from left to right in the model, is the link from Company to Quality that the authors believe is the strongest, and has the most direct result on quality. The argument for this is that the

company appoints the managers that the company think are the most suitable for the job. These managers' leadership will have a direct influence on the employees, which the managers work with. Managers who act as good role models will affect the employees and the employees' feeling of responsibility. This will then lead to certain decisions taken by the employee, which will have a direct effect on the quality of the product.

Leadership tools, discussed in this thesis, are Incentives and Data and Reporting. These are ways for the managers to create the behavior within the company, which is favorable for the quality output. The incentives, and the reporting of data, do not have the same direct effect on quality. These factors must be used for changing, and improving, the employees' willingness to make better choices. Incentives, and Data and Reporting are tools for the management to affect the employee, meaning that these tools are a link between Leadership and Employee Ownership.

With a feeling of Employee Ownership, there are more ways to improve quality than just by what the employee does in his, or her, daily work. By taking responsibility over needed education, the employee creates a possibility for improvement of knowledge, which could lead to increased quality. With cooperation with other employees, the overall quality could increase. When working together, having discussions, and learning from each other, a more uniform work process could be developed. Necessary for both Training and Peer Involvement to function as factors, for the increase of quality, is that the single employee is engaged in these activities. Without engagement there will be no improved result for quality from either training or actions for creating more collaboration.

The factors Supplier Management and Quality Department are factors that the company must be responsible for applying correct. How these factors should be used could depend on which company the model is used on, and also in which industry the company is active in. Important is that the company must possess a strategy for the usage of these factors, because the factors will not increase the quality if not applied properly. What is meant with properly depends, as said, on the industry, but should not be hard to identify once performing a case study.

9.2 Result at Case Company

The key findings in the case study possess some similarities that tend to be repetitive at the Case Company. These three are; Communication, Cooperation and Responsibility. A further discussion about these three areas will be held below.

Communication

In many factors, the authors have seen that there is a lack of communication within the company. For instance, the values are not united by the top management group and middle management group. It is also not communicated enough, to the employee, why to attend training. The different KPIs, as Quality, are not described

when presented, either at Intranet or at the dining hall board. Another area, where it is obvious that there is a lack of communication, is regarding the bonuses. Since employees expect a yearly bonus, this could indicate that the understanding of why the employee receives the bonus is unclear. The examples, which have been mentioned above, show that communication is one area where the company can improve. Increased communication could improve many of the factors mentioned above.

Cooperation

It has been mentioned, several times, that the cooperation within the Case Company is inadequate. The greatest barrier seems to be between the office and the production. There is a wish, especially from the production, to be more integrated and have a closer connection to some of the departments within the office, for instance the Quality Department. With a closer connection more problems could be solved in earlier stages and with a better fitted solution. Also, between departments in the office building there are difficulties with the cooperation. An increased cooperation, both between departments and between office and production, would be beneficial since different knowledge, skills and experiences could be shared and contribute when working with improvements and problem-solving.

Responsibility

Throughout this study the authors have seen a lack of employees taking responsibility for their work contribution. This has been seen, for instance, within Training and Data & Reporting. Several times, at interviews and observations, the authors have experienced that employees have ideas of things that could improve the company's processes, but do not do anything about it. The most important factor, with direct effect on quality, is Employee Ownership, and with employees taking responsibility over their work quality can become a reality.

What the Case Company must consider is the difference between having their employees' involved in the company, and having them committed to the company. Being involved is what the authors have found being the current state at the company. The employees go to their job, they participate in meetings, but there is a lack of commitment. With commitment the employees would take the responsibility over quality, making decisions which constantly are good for quality, and the performance of the company.

9.3 Further research

The authors have come up with a few suggestions for further research. Firstly, the framework presented in the thesis needs to be tested on other companies, in order to be validated. The factors need to be evaluated through the analysis of these companies. Special attention should be given to the factor *Quality Department* since this factor could have been overrated due to the strong directives of GMP.

Another area, which the authors recommend for further research, is the factor *Employee Ownership,* and especially the relations Employee Ownership has to Leadership and Quality. One suggestion is to perform interviews with employees, preferably on other companies, in order to receive reliable answers. Information given under interviews could reveal insight in what path that is the strongest link in the model shown in Figure 20. To test the model, and also perform a deeper investigation of what creates Employee Ownership, would be interesting.

9.4 Discussion

During the whole process with writing this thesis the authors have been located at the Case Company. The purpose of this was to enable a good collaboration and to get access to information. The Case Company did not have a clear aim with what the result of the thesis should be, which gave the authors free space to create the structure and limitations on their own.

The authors started with focus on Human Errors, and their first thought was to investigate one line in production, to thoroughly understand what type of errors that occurs, and what the root cause for them where. What resulted in the change of direction for the thesis were several reasons. Firstly, since there was no clear aim, from the Case Company, in what to achieve, the authors and the supervisor saw potential difficulties in resourcing. Secondly, when starting the literature review, the authors found interest in a wider perspective of human errors and their effect on quality. The authors wanted to attack the problem in a more general manner, to be able to say more about the overall company performance, and not only about the performance on one production line. With this perspective the authors were hoping to give the company a product that focused more on the understanding of how to influence employees, instead of giving the company information about their current problem, which they, to a large extent, already were aware of.

After finishing the thesis, with the method described in Chapter 2, the authors still advocates a qualitative method for collection of data and information for this study. Information given under interviews was more than just words, and the impressions that the authors received from interviews and observations have been useful for the analysis. The written information, used as empirical material, has many times required further explanation from the source, to ensure that the correct conclusions were drawn. The authors could, after the performance of this thesis, really see the potential danger in only using written information like surveys.

The downside with the chosen method is that a qualitative method often is time consuming. This has had an impact on the result of the analysis of the Case Company. The proportions between time spent on literature review and on collecting empirical material have been somewhere around 70/30. This limited time, spent on collecting information about the Case Company, requires a more critical perspective when drawing a general conclusion for the whole company. There are

several parts of the company, mainly in production, that have not been thoroughly investigated in this study. One explanation is that there are difficulties in finding time to talk to machine operators while they are working. It is easier to book a meeting with someone working in the office building. What also contributes to this uneven distribution of sources for information is that, for the authors to be allowed to visit the production area, one guide must be appointed to them and follow them around. There are limited resources for this as well.

One factor, which suffered hardest of the limited time spent on empirical gathering, is Employee Ownership. This is the factor that, according to CEB and also by the authors' model, has the greatest impact on quality. To be able to perform an analysis of Employee Ownership at the Case Company more information, then being collected in this study, is necessary. The analysis of this factor is, therefore, not specific about the Case Company in this thesis, and, as written in suggestions for further studies, it needs to be evaluated concerning how the factor both is affected, and affects other factors. If wanting to give a company specific judgment on the performance within this factor, a more extensive empirical material is necessary, compared to what has been collected in this study.

Bibliography

Alvesson, M. (1991). Corporate Culture and Corporatism at the Company Level: A Case Study. *Economic and Industrial Democrazy*, 347-367.

Arbnor, I., & Bjerke, B. (1997). *Methodology for Creating Business Knowledge.* California: SAGE Publications Ltd.

Asch, S. E. (1955). Opinions and social pressure. *Scientific American*, 31-35.

Bang, H. (1999). *Organisationskultur.* Malmö: Studentlitteratur.

Baybutt, P. (1996). *Human factors in process safety and risk management: Needs for models, tools and technology.* Columbus: Primatech Inc.

Bentell, L., & Wiberg, L. (1999). *Kvalitet, Produktivitet & Lärande.* Tierp: Tierps Tryckeri AB.

Bergman, B., & Klefsjö, B. (2010). *Quality from Customer Needs to Customer Satisfaction.* Lund: Studentlitteratur AB.

Bryman, A., & Bell, E. (2011). *Business Research Methods.* New York: Oxford University Press.

Callaway, J. (2013, April 9). Senior Director of Advisory Services, CEB. (E. Petersson, & L. Runesson, Interviewers)

Contra Costa Health Service. (2011). *Human Factors Program Guidance.*

Deal, T. E., & Kennedy, A. A. (1982). *Corporate Culture: The Rites and Rituals of Corporate Life.* Reading: Mass Addison-Wesley Pub Co.

Dow, D., Samson, D., & Ford, S. (1999). Explodig the myth: Do all quality management practices contribute to superior quality performance? *Production and Operations Management*, 1-27.

FDA. (2006). *Guidance for Industry, Q8 Pharmaceutical Development.* ICH.

Goldstein, S. M., Linderman, K. W., & Schroeder, R. G. (2008). The role of culture as driver of quality management and performance. *Decision Sciences*, 671-702.

Hofstede, G. (2001). *Culture's consequences: comparing values, behaviors, institutions and organizations across nations.* Tousand Oaks: SAGE Publication, Inc.

Hofstede, G., Hofstede, G. J., & Minkov, M. (2010). *Organisationer och kulturer.* Lund: Studentlitteratur.

Hoyle, D. (2009). *ISO 9000 Quality Systems Handbook - Updated for the ISO 9001:2008 Standard.* Elsevier Science Ltd .

Höst, M., Regnell, B., & Runesson, P. (2006). *Att genomföra examensarbete.* Lund: Författarna och Studentlitteratur.

ICH. (2000). Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients . *Internal Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use* (pp. 1-43). ICH.

Isenberg, E. M., & Bisgaard, S. (2008). Quality Management and Juran's Legacy. *Quality Engineering*, 390-401.

Jacobsen, D. I., & Thorsvik, J. (2008). *Hur moderna organisationer fungerar.* Lund: Studentlitteratur AB.

Juran, J. (1988). *Juran's quality control handbook.* New York: McGraw Hill.

Klefsjö, B; Wiklund H.; Edgeman, R.L. (2001). Six Sigma seen as a methodology for total quality management. *Measuring Business Excellence*, 31-35.

Lagrosen, S., & Lagrosen, Y. (2010). *Mänsklig kvalitetsutveckling.* Lund: Studentlitteratur AB.

Lindmark, A., & Önnevik, T. (2009). *Human Resource Management- organisationens hjärta.* Malmö: Holbergs i Malmö AB.

Linker, J. K. (2009). *The Toyota Way - Lean för världsklass.* Malmö: Liber.

Porter, M. E. (1986). *Competition in Global Industries.* Boston: Harvard Business School Press.

Reason, J. (1987). A framework for classifying errors. In J. Rasmussen, K. Duncan, & J. Leplat, *New Technology and Human Error* (pp. 5-14). Chichester: John Wiley & Sons Ltd.

Robson, C. (2002). *Real World Research.* Oxford: Blackwell Publishing.

Sanders, M. S., & McCormick, E. J. (1987). *Human factors in engineering and design.* McGraw-Hill.

Saraph, J. V., Benson, G., & Schroeder, R. G. (1989). An Instrument for Measuring the Critical Factors of Quality Management. *Decision Siences*, 810-829.

Schein, E. H. (1984). Coming to a New Awareness of Organizational Culture. *Sloan Management Review*, 3-16.

Schein, E. H. (2010). *Organizational culture and leadership.* San Francisco: Jossey-Bass.

Spens, K. M., & Kovács, G. (2005). A content analysis of research approaches in logistics research. *International Journal of Physical Distribution & Logistics Management*, 374-390.

Steininger, D. J. (1994). Why quality intiatives are failing; The need to address the foundation of human motivation. *Human Resource Management*, 601-606.

Swain, A., & Guttman, H. (1983). *Handbook of Human Reliability Analysis with Emphasis on Nuclear Power Plant Applications.* Washington DC: Nuclear Regulatory Commission.

Sörqvist, L. (2011). *Kvalitetsbristkostnader.* Malmö: Holmbergs i Malmö AB.

The Corporate Executive Board Company. (2012). Establish an Environment Where Employees "Live" Quality. Washington, DC, United States.

Thompsson, P., & McHugh, D. (2009). *Att arbeta i organisationer: ett kritiskt perspektiv på organisation och arbete.* Malmö: Liber.

Trompenaars, F., & Hampden-Turner, C. (1997). *Riding the waves of culture – Understanding cultural diversity in business.* McGraw-Hill.

Yin, R. K. (2009). *Case Study Research: Design and Methods.* California: SAGE Publications Inc.

Yu, H., Zeng, A. Z., & Zhao, L. (2009). Single or dual sourcing: decision-making in the presence of supply chain disruption risks. *Omega*, 788–800.

Interviews

Business Support Training, the Case Company, 11 March 2013.

Callaway, Jennifer**,** Senior Director of Advisory Services, Council Executive Board (CEB), Washington, DC, 9 April 2013.

Coordinator of Group Managers, the Case Company, 15 March & 4 April 2013.

Director of Quality Operation, the Case Company, 9 April 2013.

Division Manager of Quality Assurance Systems, the Case Company, 5 April, 2013.

Division Manager of Quality Control, the Case Company, 22 March 2013.

Education Coordinator, the Case Company, 6 March 2013.

GMP Educator, the Case Company, 10 April 2013.

Group Manager for Packaging, the Case Company, 24 April 2013.

Machine Operator, the Case Company, 10 April 2013.

Manager of Compensation & Benefits, the Case Company, 12 March 2013.

Manager of Learning & Development, the Case Company, 1 March & 13 March 2013.

Manager of Material Management, the Case Company, 17 April 2013.

SOP/Production document administrator, The Case Company, 19 March 2013.

SOP System & Total LMS Administrator, the Case Company, 13 March 2013.

Quality Assurance Release Officer, the Case Company, 20 March 2013.

Quality Engineer, the Case Company, 19 April 2013.