Organizational Alignment
Perceptions, Processes and Strategy

Per Johannesson
Abstract

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The purpose of the study and following thesis is to investigate how employees in a R&D department perceive the product development process. Review of present process documentation aims at identifying potential discrepancies between the process as it is designed and the way it’s used. The company is operating in a regulatory environment and have recently merged with another company. The company is aligning different processes and work teams. The result indicates that the organization will benefit from working with processes with an inclusive approach, i.e. involve employees working in the process. The process studied is a global process i.e. the process is used at multiple sites. This presents challenges for local adaptations. By actively involving employees a common understanding of the challenges can be achieved which will increase engagement and commitment. The organization will also benefit by looking at the organization from a process perspective.

Aligning process goals with departmental goals can be achieved by developing process and department strategies based on overall organizational objectives and the organizational context. The underlying principles for the study are the foundations of TQM. Relevant tools, such as the improvement wheel (PDCA) and GAP-analysis, that can be used for business improvements are presented.

Keywords: cost of poor quality, gap-analysis, pdca, perception, processes, strategy, tqm
Acknowledgments

This thesis is based on a study conducted in a R&D department at a company developing and providing medical devices. A big thanks to the whole department for providing me with invaluable information to gain insights to the challenges facing the department and for letting me do my thesis in your department.

I would also like to thank my tutor at Uppsala University, Pierre Thorell for providing invaluable guidance.

Last but not least I owe my tutor/sponsor at the company, Johanna Löberg, a big thank you. You have not only guided me and willingly and tirelessly proofread my sometimes hopelessly confused sentences but also been an inspiring speaking partner spanning over many areas.

Per Johannesson
Kungsbacka November 2017
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**Abbreviations/explanations**

Benchmarking – A way of comparing one organization with another to identify areas of improvements

CoPQ – Cost of Poor Quality

DC – Design Control (are required controls in the development process)

FDA – Food and Drug Agency

GIP – Global Innovation Process

GIP Accolade (GIPA) – Project Management Tool

GSOP – Global Standard Operating Procedure

Input – Input to a process

Ishikawa or C&E diagram – Cause and Effect diagram

ISO13485 – Quality Management System for medical devices

KPI – Key Performance Indicator

LSOP – Local Standard Operating Procedure

NPD – New Product Development

Output – Output from the process

PDP – Product Development Process

Procedure – Describes how something is done

Resource – Needed for the process to be able to deliver wanted result

SOP – Standard Operating Procedure
1. Introduction

Medical devices industry is regulated by authorities around the world. The consequence of this is that if a company wants to sell its products it has to comply with regulatory requirements in respective markets. As people grow older and older the need for medical devices is thought to expand but at the same time customer’s knowledge about offerings and products are increasing. This presents challenges for companies looking for a competitive advantage. The developing world is increasing its wealth which are potential viable markets. As the world is not static it is necessary for companies to be vigilant to not miss out on potential markets as well as to be flexible regarding the regulatory environment. The organization studied explores different markets and has a clear strategy about where it wants to position itself.

1.1. Background

The company where the study have been conducted is a global company operating all over the world. In total there are approx. 12000 associates worldwide with headquarters in the USA. The company is divided into different Strategic Business Units (SBU) for respective markets. The study have been conducted at the headquarters of one of the SBUs located in Mölndal, Sweden. The SBU has associates in both Sweden and Germany and the department where the study has been conducted is the R&D department. The department has 42 associates and managers, 23 associates are located in Sweden and 19 in Germany. The organization has experienced both a merger and reorganizations in the last few years. A pre-study was conducted at the department to identify potential areas of improvements that is related to the department’s productivity. Of the identified areas the design control process was considered having improvement potential. During the present study it became apparent that the design control process is in fact not a suitable process to investigate. Design controls can be viewed as mandatory activities in the product development process rather than a process per se. Together with the management team it was concluded that there are other process related issues that is considered more pressing and a change of research questions was deemed necessary.
As the organization operates in a regulatory context it is of interest of how the internal aspects of the organization, i.e. processes, copes with future challenges as well as how this is perceived by employees.

A CEO survey done in medical device industry made by Frost and Sullivan (2017) reveals that CEO’s in med tech industry have a number of concerns/challenges regarding the industry. There are three points of interest for the study presented in this thesis:

- Restrictive regulatory environment is the major external challenge according to 58.3% of respondents (this relates to strategy and processes)
- 50.0% of respondents believe that personalization and customization will have the most disruptive effect (this relates to issue of flexible processes and agile strategies for organizations)
- 45.8% believe that their company will rely on strategic partnership as a driver for growth. And they believe that digital transformation will be expediting this need. (this relates to alignment of processes)

The concerns presented above is interrelated with the internal context of the organization, i.e. employees and managers. The organization where the present study has been conducted has grown both organically as well as with mergers during the last 6 years. When the regulatory environment changes it can have big implication for companies in the industry. Fulfillment of requirements is a prerequisite for the operation of organizations. Customization may have a big impact on companies operating in the specific market. This can be matched by having flexible processes. And finally strategic partnerships and the reliance on digital transformation for the partnership can present challenges when integrating operations. The above challenges are all related to flexibility, processes and strategy.

1.2. Purpose and research questions

The purpose of this study is to investigate how employee’s perception of the organization and its processes are related to the chosen strategy.

The following research questions are used as guidelines in the study:

1. How does employees perceive the Product Development Process?

2. What is the connection between strategy and the development process as documented?
3. What is the connection between the development process and the department’s goals?

1.3. Assumptions, scope and limitations

Assumptions includes that the organizations strategy is conveyed to employees and that this strategy is known by senior management. There is an assumption that process development is actually wanted by the organization.

The scope of data collection is limited to the Swedish R&D department.

There are a number of limitations that are of interest due to assumptions and scope of the study. First the data collection is based only on Swedish employee’s perception of processes. If German associates where included in the study there might be a more nuanced view of the organization. Implications of not interviewing senior management can be far-reaching as strategy on high level sets the stage for strategies closer to the day to day operations.

2. Theoretical framework

_in this chapter the theoretical framework is presented. The theories presented herein are used in the forthcoming analysis of the result. The disposition of the chapter is divided into three theoretical areas and is concluded with a presentation of previous research._

2.1 Perception

Perception is based on how we perceive different things. It can be how we interpret an event or an object. A classic example is two people who sit on opposite sides of a table and looks at a paper with the number 6 (or 9) written on it. One of the two will see the number 6 and the other argues that it’s number 9. Knowledge can be divided into the two main categories of knowing and skills according to Sandberg and Targama (2013, p.94). They view knowing as an “object” that can be transferred from one individual to another. As an object it can also be stored, e.g. as a process map. Bergman and Klefsjö (2012, p.52) presents what Deming called profound knowledge which is important for organizational change. Profound knowledge are areas that are considered relevant for organizations that embark on an improvement journey. Profound knowledge includes (ibid.);

- Understanding of variation
- Psychology
- Improvements techniques
- An understanding of systems.

These areas are superimposed on the traditional knowledge areas that are required for a given job, i.e. it is not only about being to be good at your job, it is also necessary to understand the organization in a broader perspective. Sandberg and Targama (2013, p.59) argues that individuals act in accordance with their understanding of the reality. There is a relationship between a common understanding of the organization and the aforementioned profound knowledge. Bergman and Klefsjö (2012, p.40) presents the cornerstones of what they call “offensive quality development” (hereafter called TQM).

![Figure 1: Cornerstones in TQM according to Bergman and Klefsjö (2012, p.40)](image)

Figure 1 should be interpreted as an integrated model where the cornerstones are the foundation of the organization or functions as guiding values rather than something that is superimposed on the organization. The cornerstones are explained in some detail below (Bergman & Klefsjö, 2012, p.40-50):

- **Customer focus** should be an integral part of every aspect of the organization. Value creation from a customer perspective is a central theme and both external and internal customers are considered.

- **Working with processes** is important as transformation of inputs to outputs is done in processes. Processes can be viewed as the lifeline of the organization where a general classification of processes can be done by identifying:
  - Core processes (e.g. develop products/services, produce products/services etc.)
  - Management processes (e.g. develop strategy, set objectives etc.)
- Support processes (e.g. evaluate clinical impact, maintain production facilities etc.)

Core processes are defined as having external customers and management and support processes have internal customers.

- **Fact based decisions** is used to minimize random effects that potentially can have an impact on the organization. Facts are essential for effective management of the organization.

- **Continuous improvements** can be seen as a prerequisite for sustaining competitive advantage. The organizational context is constantly changing, be it market-, regulatory- or competitive change. It is important for organization to keep up with these changes.

- **Employee involvement** is important in TQM as employees (probably) know the processes best. Empowerment and being listened to is important aspects of involvement and participation of employees.

- **Engaged leadership** is a cornerstone as leaders/managers have the biggest opportunity of influencing culture of TQM. In TQM this is manifested as visibility, clarity and personal commitment.

Having a holistic view of the organization is a central aspect of TQM (Bergman & Klefsjö, 2012, p.51). From a leadership perspective, the principal-agent problem is of interest in a TQM context. The root-cause of the principal-agent issue is arguably asymmetric information and states that the agent (i.e. the employee) always have more information than the principal (i.e. the manager) (Scott, 2016, p.3/15). This implies that employees have more information about how things are actually done in the organization than the manager. Not only can this be of great interest because of the asymmetric information per se but this can also be a good opportunity to involve employees, i.e. by listening to them.

**2.2 Processes**

The firm can take different stances when working with processes; disregard their existence, accept their existence but choose to do nothing, identify processes but not understand their importance and finally identify, understand the importance of processes and improve them. Bergman and Klefsjö (2012, p.462) argues that there is some confusion
regarding different process concepts. The authors presents different concepts such as; process focus, process view, process management and process orientation. They make a distinction between the different concepts and they view process focus and process view as synonymous with the cornerstone of working with processes in the TQM model. Process management is thought of as a methodology that supports the cornerstone working with processes in the TQM model. Process management includes identification and improvements of processes. Process orientation is the concept that Bergman and Klefsjö (ibid.) believes is the most far reaching concept. It means that the organization is organized and structured based on the processes. The point is that processes exists regardless if they are identified or not (Ljungberg & Larsson, 2012, p.43). It is in the processes that value is created, for both customers and other stakeholders (Ljungberg & Larsson, 2012, p.51). When discussing processes it can be useful to start with a definition of what a process is and what it is not.

In this study a process is defined as (Ljungberg & Larsson, 2012)(Bergman & Klefsjö, 2012)(Isaksson, 2016):

*An ordered network of activities with a defined beginning and end that is used repetitively and that uses resources to transform inputs to outputs for stakeholders.*

In the definition there are certain keywords that are worth explaining. A process is considered a network of activities. A network is different from for example a flow. A flow is considered as sequential whereas a network allows for concurrent activities. A process have a clearly defined beginning and end. This is important as the start is the trigger point for the process and it is necessary to know when work in the process is finished. Repetitiveness ensures that the process is used in the same way and produces the same result every time it’s used regarding process metrics e.g. quality, cost and time. Ljungberg and Larsson (2012, p.62) points out that regardless of how a process is defined it is important not to forget that the process is foremost about creating value for stakeholders by fulfillment of their (different) needs.

Ljungberg and Larsson (2012, p.21) argues that being interested in processes is to be interested in:

- How value is created and customer satisfaction.
- Efficiency and effectiveness in the organization
- Efficient use of resources and competence in the organization

When working with processes it is important to identify metrics and how these relate to the organization´s objectives. When developing metrics it is important that these metrics do not stand in contrast to other potentially important metrics already in use in the organization. It can be difficult to identify contrasting metrics and/or goals if they are used in different contexts. For example, metrics and goals for a department may not be useful when evaluating the process and this can lead to discussions of who has the most power in the organization. On total this can lead to sub-optimization in the organization and that different aspects of the organization does not work together towards a common goal. See figure 2 below.

![Diagram](image)

Figure 2: One way of graphically visualize the connection between internal processes/structures and the organization´s mission, adapted from Bruzelius and Skärvad (2011, p.129)

For organization´s to be effective and efficient, able to adjust for changes and for increasing wealth, it needs to align all factors affecting the organization. One factor that in a natural way connects the different factors affecting the organization are processes (Bruzelius & Skärvad, 2011, p.129). Principles for structural change that resonates well with Bruzelius and Skärvad are presented below (Bolman & Deal, 2015, p.128):
- Develop a new understanding of the alignment of organizational strategies and objectives with current circumstances and challenges that the organization faces.
- Detailed study of how things actually are being done in the organization (i.e. processes, roles and relationships).
- The starting point when designing a new structure is changes in objectives, technology and surroundings.
- Double loop learning by experimenting and rejection of what does not work.

![Diagram showing organizational alignment](image)

**Figure 3:** The organization has aligned its processes and structures to support the firm’s mission, adapted from Bruzelius and Skärvad (2011, p.129)

Figure 2 and 3 illustrates how aligning processes, resources and structures as well as softer issues such as HR policies and cultural aspects with the firm’s mission are related to achieving/sustaining competitive advantage.

### 2.3 Strategy

Strategic prerequisites are increasingly viewed as a product of social processes rather than objective analysis. This opens up for aspects of strategy development that traditionally has not been considered, for example the political arena and power in the organization (Sandberg & Targama, 2013, p.85). Sandberg and Targama (2013, p.87) argue that there is increasing focus on the day to day operations and the factors that cements current practices. The consequence of this may present a hinder for (necessary) change. This accords well with a process view of organizations which can been seen as an alternative and more contemporary view of traditionally structured organizations. Strategy can be argued to be made up of two sides; configurations and transformation (Mintzberg, Ahlstrand & Lampel, 2009, p.318).
The configuration side is concerned with the states of the organization and its surrounding context. The transformation side is concerned with strategy-making process.

An organization can be described as a political organization that is not able to settle on a stable system of power if it has experienced some sort of transformation. The inability to settle can be a consequence of a new configuration, e.g. in a merger situation as is the case in the studied organization (Mintzberg et al, 2009, p.326).

The political organization can be temporary for an otherwise stable organization if it is put under stress for example during a transformation such as in a merger. The principles of the configuration school of strategy (adapted from Mintzberg et al, 2009, p.321-322);

- Organizations are most of the time in a stable configuration (i.e. no “big transformations”)
- The stable periods of time are interrupted by transformations
- Over time can this form a pattern of sequences (e.g. following the cyclic nature of the industry)
- The key to strategic management is to sustain stability but at the same time have a sense of when transformation is (or can be) necessary, and be able to manage this without destroying the organization
- Being flexible to be able to identify the most viable approach (of strategy development) depending on pressures
- Understanding that each perspective on strategy will lead to a different outcome

In a merger the change initiated is primarily a top-down change and employees have (in most cases) not so much to say about the change per se. This is not to say that employees are unimportant as the principal-agent issue is a reminder of. Mintzberg et al (2009, p.352) presents a process for reengineering a mature organization that touches on many aspect of TQM.
There is no formula for transforming any organization, and that includes the very notion that the organization needs transforming in the first place (Mintzberg et al, 2009, p.355). This statement implies that it can be useful to reflect over the necessity of change. In a merger/acquisition (M&A) situation some form of change is inevitable. The issue then becomes how the transformation is interpreted by employees.

Two driving forces for change are economic/financial and organizational development as a driving force according to Beer and Nohria (2000, p. 134). The different driving forces are possible to use at the same time but this needs to be planned for. In a process improvement project both driving forces are probably present. Economics are the driving force for businesses and the development of the organization (as a workplace) is of great importance for employees. The holistic viewpoint of TQM connects the two and in a (organizational) change context there are different aspects that might be considered important (Beer, Eisenstat & Spector, 1990, p.160):

- Coordination is needed for identifying opportunities for competitive advantage
- Commitment is necessary as change is disruptive in its nature
- (New) competencies are necessary as the work more often will be done in teams

These aspects are related to aforementioned types of driving forces of change.

All of these factors are needed for a change to be effective; if only one or two factors are being addressed by the organization the change effort will not be effective (ibid.). Scott (2016, p.3/16) points out that means and ends need are different, i.e. what is to be done must be differentiated by how it is done. In a strategy context it is important to
define where the organization wants to be in the future. Disaggregated organizational objectives are the foundation of strategies further down in the organization and these need to be aligned both horizontally and vertically. This implies that that strategy planning is not relevant only for top management but also for middle level management.

Figure 5: Illustration of performance gaps with current and altered strategy, based on Scott (2016, p.3/7)

Potential performance gaps can be visualized with a GAP analysis for each aspect considered important, e.g. economic or organizational implications. It is necessary to identify relevant metrics in order to use a gap analysis effectively, this resonates well with process metrics. The GAP analysis is effective as it focuses on differences in performance rather than cash flows explicitly. When evaluating projects it is necessary to assess changes in cash flows if the project is done. In an improvement project the question is how much more can be “produced” with the same amount of resources or what amount of resources is needed for the same output. This is a strategic issue that is not easily separated from the company’s strategy as the organization cannot forget the strategic position in the market place and this is closely linked to products (and product development). All business have limited resources and it is important to identify how to exploit these resources in the most efficient way in accordance with the chosen strategy. Porters generic strategies can function as a reminder of the importance of actively choose a strategy. An augmented model for generic strategies are presented in figure 6 below.
The generic strategies presented in figure 6 is based on the competitive advantage and scope of the organization. Scott (2016, p.7/15) presents Porters arguments of organizations that do not specialize will continuously react to changes in the market place by adjusting competitive focus i.e. not having a defined advantage and/or scope. This will lead to a “Stuck in the middle” strategy that potentially can lead to organizational under-performance and wealth destruction in the long run.

A stuck in the middle strategy can also lead to a general sense of confusion as the changes in market place affects what is considered important. This may also be enforced if the organization has been influenced by merger activities. Porter continues by stating that the scale of operations is not large enough to generate a cost advantage and the product is not differentiated enough to justify a price premium (ibid.). Although this may not be the case in the studied organization it can still be worthwhile reflecting over how organizational context can influence the organization.

**2.2. Previous research**

A Search in the digital scientific archive (DIVA) for process management in articles, conference papers and doctoral and licentiate thesis returns 361 hits. When the term medical is included the return rate drops to 7 hits. The same search when medical device is included in the search term returns no hits. The search in DIVA reveals that there are very few directly applicable theories specifically for process management/development in medtech industry. Although this is not
an exhaustive literature search this can be seen as an indicator that the area of process management in medtech industry is not researched to any greater extent.

Searching the internet reveals that there are some previous research done in medtech regarding process development but there are relatively few concrete suggestions. This may very well be due to the fact that there is a consultant industry that targets medtech companies and the knowledge is part of their competitive advantage.

There seem to be predominantly focus on project methodology rather than processes in the medtech industry in general. Marinov (2013) have researched measuring results of new product development, although his research is not specifically targeted to medtech. Marinov’s research points to general aspects of measuring new product development that have relevance for medtech industry.

Pietzsch et al (2009) has studied the Stage-Gate Process for the Development of Medical Devices and they observe that “While various models may exist in the device industry, no comprehensive development model has been published.” (p.1).

Ham (2010, p.16) has researched how process mapping can be used in medical device companies. He concludes that process mapping as a tool can be beneficial for companies in medical device industry. The medical device development cycle is not well defined and that there is a lack of common language. This is contrary to the findings from the internal document review conducted in this thesis. However, this is by no means sufficient evidence to draw any conclusions regarding the industry as a whole.
3. Method

In this chapter the research method is presented. The chapter starts with presentation of the strategy and methods of data collection. A presentation of reliability and validity follows on data analysis. Reporting of ethical considerations concludes the chapter.

3.1. Research Strategy

The department where the study has been conducted is primarily knowledge based and a qualitative approach was considered most appropriate. There are primarily two reasons for this; (1) the research question indicates that employee’s perception of a phenomenon in a given context may be instrumental, and (2) it was concluded that it could be difficult to derive conclusions related to the research questions from (quantitative) data based on previous projects completed by the department (due to process complexity and lack of quantitative process metrics.)

Denscombe (2009, p.21) concludes that there are no single correct strategy but rather degrees of appropriateness of the strategy. He continues to state that good research are based on choices made are reasonable and explicitly disclosed in the research report (ibid.).

The availability of respondents has been instrumental for the research. The department have been exceptionally accommodating and individuals have been available for both interviews and follow up questions. Data retrieved from the intranet has formed the base for the initial mapping of the process, identification of potential metrics and contingencies of process inputs.

Action research is based on the foundation of improving problems in the “real world” (Denscombe, 2009, p.169). Denscombe (2009, p.170) presents the characteristics of action research:

- Practical approach
- Change is an integrated part of the research
- Cyclical process
- Participation of individuals taking part of the study

The above characteristics accords well with a modern view of organizational development/improvement.
Figure 7: Illustration of Action Research as a cyclical process with result from the pre-study as input to the thesis and suggestions of improvements as outputs, based on Denscombe (2009, p.173).

Practical issues that makes action research a preferable strategy includes; identification of improvements in the studied process and to highlight potential changes in the context/structure that may hinder necessary changes (Denscombe, 2009, p.176).

The resemblance with the PDCA (see next section) makes it a natural method for this study because of the inclusiveness of participants.
3.2. Method of Data collection

Bergman and Klefsjö (2012, p.228) presents Plan, Do, Check, Act (PDCA) as the improvement cycle. The PDCA is because of its simplicity an effective tool that is easy to use and accords well with the cyclical characteristics of Action Research.

*Figure 8:* Graphical illustration of the PDCA-cycle with tools and actions, based on Bergman and Klefsjö (2012, p.228-229)

In the first step of the cycle, emphasize is on planning activities including identification of improvement areas and/or specific problems. Depending on the extent of the problem different approaches can be necessary. On an aggregate level it can be difficult to identify root causes and the problem may have to be disaggregated and dealt with separately. Brainstorming is a useful event which can lead to ideas of root causes of the problem (Bergman & Klefsjö, 2012, p.229). Another useful tool is 5 why, which begins with the question why a given phenomenon arises. In the study this was used as a screening tool during the interviews. The question of why the Design Control Process is not considered established led to an answer that eventually led to the root cause that there is in fact no Design Control Process.

When the root cause are thought to have been found a work group should be assembled to develop solutions to rectify the problem, this is the Do-phase in the cycle.

In the Check phase the implemented solutions are verified, i.e. did the problem disappear or did the implemented have solution have insufficient effect.
In the Act phase the decision is made if the solution is considered effective in which case the solution is cemented in the organization. Otherwise the improvement cycle needs to be iterated on the same problem (Bergman & Klefsjö, 2012, p.229).

The PDCA has been used with great success in the present study and the iterative nature revealed that the original research question in fact was not suitable. This change in research question led to a different approach to the study as it was clear that there were multiple views of processes in the department, see section 1.1 and 1.2.

The research questions are based on a perceived need from the organization to investigate why a certain process does not perform as expected. This is to a certain degree subjective and interviews of employees and managers who work in the process reveals any discrepancies between both employees and managers view on the one hand and the process documentation on the other. These interviews were conducted as qualitative/unstructured interviews and started with an open question regarding the originally research question which led to other questions during the interview (Yin, 2013, p.138). Respondents include the following individuals:

- 2 design Engineers
- 1 CAD Engineer
- 1 Senior Project Manager
- 2 Senior Department Managers
- Department Director
- 1 R&D Engineer from “sister company”

The result from the interviews is compared with existing process documentation to identify discrepancies between the process as documented and individual’s perception of the process. Selection of respondents has to a large extent been chosen by the department. This is regarded as a positive selection as the respondents allocated are the individuals that are most familiar with the process.

Existing process documentation including relevant SOP: s available in the organization’s intranet has been reviewed. The industry is regulated with mandatory traceability of documentation which means that needed documents can be searched for with revisions clearly stated in organizations documentation systems.
Informal discussions with different colleagues constitutes as a source of secondary data which contributes to a holistic view and a “feel” for the process studied (Yin, 2013, p.153).

Initial literature review forms the initial base for the study and subsequent definition of research question (-s). Literature review also constitutes the foundation for subsequent synthesis.

To be able to view processes as well as the organization holistically, a maturity analysis using the PEMM-framework was conducted (Hammer, 2007). The framework consists of questions regarding the maturity of the enterprise and its processes and can serve as a starting point for evaluating the organization from a process perspective.

3.3. Data Analysis

The original research question of why the Design Control Process is not established by concurrent data collection and analysis led to the change in research question. Backman (2008, p.61) argues it is not uncommon in qualitative studies as the (researchers) interpretation of the collected data occurs in a context. The PDCA cycle has been used as a tool for both data collection (by means of follow up questions) and in the analysis process (by means of change in research question).

Analysis has been conducted by interpreting data from interviews to identify underlying structures related to the (original) research question. The analysis of the data has been performed in an inductive logical process (Denscombe, 2009, p.369). Transcripts from interviews revealed keywords that are related to the research question and forms the base of the analysis. The keywords are used as codes that enables categorization and theme development. The last step in the process includes development of concepts and general statements of the phenomenon studied (Denscombe, 2009, p.374).

Although the research question changed during the study the initial analysis of data has not been in vain as insights from the interviews partly led to the change of research question. This accords well with Yin´s (2013, p.128) statement that an inductive approach will potentially lead to a revision of research question (-s).
3.4. Reliability and validity

Reliability refers to what extent the result would be the same if the research where duplicated by another researcher. It is related to the instrument used for data collection and how robust and neutral it is regarding influencing the data collected (Patel & Davidson, 2011, p.103). In a qualitative study it is difficult to assess the reliability as it is the opinions of respondents that are of interest and these can change over time for different reasons. Patel and Davidson (2011, p.104) concludes that reliability can be high when using structured observations or interviews. As the interviews in this study have been unstructured and resembles conversations, it is difficult to judge the reliability. In a qualitative study the reliability should be viewed in a particular context/situation, one way of judging the reliability may be to assess the interview situation. The interviews have been conducted in a relaxed and trustful environment with a great deal of openness. The question of reliability then becomes how well the results reflects the uniqueness in the given situation, this is regarded as more important than that the respondent’s answers are the same every time (Paturel & Davidson, 2011, p.106). In this respect the reliability of the study is considered adequate.

Generalizability refers to what extent the result from the study can be transferred to other instances of the same phenomenon rather than being applicable to the specific context (Denscombe, 2009, 379). The generalizability of the study is difficult to assess but as respondents mentioned that the new organization has had some influence in the way work is done it is likely that the result is relevant in other instances/processes in the organization. The process that is studied spans over many departments so in this regard the generalizability may be questioned as the views presented only represents the R&D department in Sweden.
Validity refers to the credibility of the study. In a qualitative study it can be difficult to validate a study according to Denscombe (2009, p.265). The response rate is 100% which is considered high and this increases the validity of the study.

Denscombe (2009, p.266) presents ways to increase the validity of the study:

- Verify data with different sources
- Verify transcript with respondents
- Verify if the data is reasonable
- Look for themes in the transcript

In this study different sources have been used as different individuals working in the process as well as senior managers have been interviewed. Process documentation retrieved from the intranet has also been used. This can be seen as triangulation of data to further increase the validity of the study (Patel & Davidson, 2011, p.107).

Verification of reasonability of data have been done automatically as respondents consists of experts in their respective field as well as informal discussions with different colleagues related to the process. Lastly, themes have been developed from transcripts that forms the base of the analysis. The themes are broader in nature and serves as an aggregate view of the respondents.

Yin (2013, p.85) presents different ways the researcher can increase the validity, in this study particularly the notion of “competing explanations” are useful. Competing explanations is more than just alternative interpretations of a phenomenon. Yin (ibid.) argues that it is not possible for competing explanations to coexist. In the study different views have been expressed by respondents but the most evident competing explanation came from the PEMM-analysis.
3.5. Ethical considerations

Ethical considerations are important in research. It is important to respect the rights and dignity of participants, not to harm participants due to the research and to perform the research in an honest and respectful fashion regarding participants (Denscombe, 2009, p.193).

Denscombe (2009, p.178) presents ethical considerations when conducting action research including transparency and having an open mind for suggestions during the research process, having permission before any research is conducted and securing that information is handled confidential. In this study these considerations together with the general ethical considerations for research has formed guiding principles in the research process.

During the data collection I have been open for suggestions as the nature of the research question (-s) more or less requires an open mind. The change in research question is an example of both openness and participation of respondents. Regarding permission it has been a natural part in the interviews, for example when respondents have not wanted the interviews to be recorded the recorder has been turned off. Information from respondents are only known to the researcher, this includes informal discussions in private. The organization where the study has been conducted will not be disclosed in the report.

Bias in research can stem from different sources and in a qualitative study it can be difficult to determine the level of bias. Action Research, as used in this study, starts with critical reflection based on the result from the pre-study which potentially minimizing bias. As I am employed in the organization there may be risk of bias in the research from my own prejudice as an employee. However this is considered offset by the fact that although I do know the respondents I have, previous to the study, had very little knowledge of the product development process. Because I am employed, respondents have perhaps opened up more in the interviews than they otherwise would have done which may have led to a more honest view of the process.

The fact that I have been aware of bias in objectivity, the risk of interpretation- and analysis bias has potentially been minimized.
4. Result

The initial research question were based on the notion of Design Control as a process. Design Controls are integrated in the development process as a way of ensuring that mandatory activities in the development process is conducted and documented appropriately. This is clearly defined in the process documentation.

4.1 How does employees perceive the Product Development Process?

Developing codes from keywords identified in the transcript revealed that there are six main areas of concern which form the base of two themes, clarity and support systems. Keywords, codes and themes are presented in table 1 below.

Table 1

<table>
<thead>
<tr>
<th>Repeating ideas/keywords from interviews</th>
<th>Codes</th>
<th>Theme</th>
</tr>
</thead>
<tbody>
<tr>
<td>GIP</td>
<td>Definitions</td>
<td>Clarity</td>
</tr>
<tr>
<td>GIP Accolade</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Design control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>V&amp;V</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concept development earlier in process</td>
<td>Process</td>
<td></td>
</tr>
<tr>
<td>GSOP/LSOP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Room for improvisation in the process</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implicit requirements</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stakeholder involvement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time management</td>
<td>Project</td>
<td></td>
</tr>
<tr>
<td>Unclear/changes in project charter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Difficult to &quot;learn on the job&quot;</td>
<td>Craftsmanship</td>
<td>Support systems</td>
</tr>
<tr>
<td>Difficult to find &quot;correct&quot; documentation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Collaboration between sites</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Process establishment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Late changes affects the project</td>
<td>Change Management</td>
<td></td>
</tr>
</tbody>
</table>

Note: The table shows development of codes and themes from repeating ideas and/or keywords identified from interviews.

Employees consider the product development process as unclear and difficult to understand. Employees interviewed believe that it is difficult to see the process from a holistic viewpoint. There are no consensus regarding what is the Global Innovation Process (GIP), Global Innovation Process Accolade (GIPAccolade or GIPA) and design controls.
The training material for new product development projects is extensive and covers all aspects of a project. The material also covers some definitions that are relevant, for example the definition of project and project management in the organization. A project is a temporary endeavor undertaken to create a unique result or outcome (product, service, etc.)

Project Management is the application of knowledge, experience, tools and techniques to simultaneously manage scope/performance, cost and schedule of the project by guiding team in problem solving and timely decision making (internal document).

In the training material the Global Innovation Process is defined as a business process based on Stage – Gate project management principles which is consistent with Design Control principles. GIP ensures that:

- Sound business case is identified upfront
- Professional, User and Clinical evaluations are planned and completed prior to market release
- IP and Regulatory submission & clearance is planned for and not an afterthought
- Product Stability & Shelf Life studies are accommodated

There is also an explanation of what GIPA provides:

- Clear visibility to timeline & tasks (ownership, status, due date, etc.) to drive reduce time-to-market
- Common framework to collaborate across all SBU's

In the training documentation it is clearly defined what activities are mandatory as well as activities that may or may not be necessary in a project. In GIP Accolade it is possible to use predefined templates when setting up a project. The templates includes much information to use as guidance. This information is however not in the form of SOP:s.

One respondent remarked that the design control is based on the GIP, another thinks that the design control should be integrated in the GIP.

GIP and GIP Accolade is generally referenced synonymously, there is an indication that not all use GIP as the process for product development but rather GIP Accolade which in fact is a portfolio system that enables reporting of projects as one respondents conclude.

There is consensus that there is a low level of process development done in the studied department. In contrast the “sister organization” have adapted GIP to their context,
although they have a somewhat different document handling system which is more integrated in the process. One respondent remarked that as.

“...the process is not generally known it is possible to improvise in the process.”

This is confirmed by other respondents that concludes that, GIP is not always used as designed and sometimes it is felt necessary to use workarounds rather than using formal channels.

The respondents agree that it is difficult to learn the job based on the documentation available, this is to a certain degree because some activities are not possible to document in a meaningful way. For example is the transfer of user needs to design input considered a craftsmanship that is not easily written down and that one has to “learn on the job”.

Employees also emphasize that changes and/or adding of product features late in the projects is not uncommon and this is costly and jeopardizes the project outcome as well as potentially disrupting the time to market. From a cost perspective this is confirmed in the documentation of GIP, see figure 9 below.

- Maximum leverage earlier in the process
- Periodic review and agreement to avoid surprise at the end

![Figure 9: Cumulative investment cost is presented in relation to the ability to influence the project at each stage in the project (Internal document)](image)

Late participation of other stakeholders in projects is also a source of concern as they can have a different view of what the process should deliver and how it should be delivered. This can have an impact on previous work in the process.
One comment regarding responsibilities between departments was that “- well, I suppose they need to sit down and talk to each other” this can be interpreted as a typical sign of when the processes are not established and managed purposefully. Much time is spent on determine who will do what and who´s responsible.

4.2 What is the connection between strategy and the development process as documented?

This chapter presents findings from the review of relevant process documentation and the connection with strategic considerations. The GIP is not disclosed as this process is a core process contributing to competitive advantage.

The company presents the complete Global Innovation Process as shown in figure 10 below.

*Figure 10: Graphical illustration of GIP (internal document)*

Process documentation is broken down in sub-processes for each stage of the project model. The documentation is extensive and provides guidance as to how the process is designed with both graphical illustrations and in text.

The strategy of the organization is an input to the GIP and can be viewed as a guide and includes the “normal” strategic directions, i.e. line extensions, new markets, market changes, competitive position etc. Innovation and strategy is considered mutually influential. And it is recognized that innovations can have a big strategic impact on the firm. The number of activities/deliverables can be used as an indication of the extent of complexity and hence the potential implication for strategic planning. A review of an actual completed project (as designed), review of a sister organizations adaptation of GIP, the GIP as designed and the product development process (PDP) before the merger are presented in table 2 below.
Table 2

*Number of activities and deliverables in respective stage in a new development project*

<table>
<thead>
<tr>
<th>Stage</th>
<th>Discovery</th>
<th>Proposal</th>
<th>Development</th>
<th>Validation</th>
<th>Launch</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actual project</td>
<td>N/A</td>
<td>31</td>
<td>54</td>
<td>24</td>
<td>54</td>
<td>163</td>
</tr>
<tr>
<td>Sister organization</td>
<td>36</td>
<td>77</td>
<td>77</td>
<td>74</td>
<td>73</td>
<td>337</td>
</tr>
<tr>
<td>GIP</td>
<td>27</td>
<td>55</td>
<td>45</td>
<td>48</td>
<td>65</td>
<td>240</td>
</tr>
<tr>
<td>PDP before merger activities</td>
<td>10</td>
<td>14</td>
<td>13</td>
<td>17</td>
<td>3</td>
<td>57</td>
</tr>
</tbody>
</table>

*Note:* In table 2 are findings from documentation review of the development process presented. The number of activities/deliverables represents an aggregate, every activity/deliverable are not relevant in all projects. In the row for PDP before merger activities only activities are presented i.e. the numbers do not reveal how many deliverables there are in that process.

The number of activities and deliverables for GIP is extracted from the (global) process design. When compared with activities/deliverables in both the actual project and the adapted process from the sister organization it is evident that the process has a great deal of room for local adaptation. The total amount of activities/deliverables in the actual project is for example 68% of the designed process and the sister organization assess that they need 40% more activities/deliverables than the designed process to complete a new product development project.

It should be noted that the activities and deliverables in the actual project for the discovery phase is not accounted for.

There is no evident connection between the document handling systems and information in GIP/GIP Accolade, i.e. document numbers used for traceability of procedures that are necessary for the execution of activities in the process.
4.3 What is the connection between the development process and the department’s goals?

No explicit process goals have been found during the inventory of process documentation. There are a number of goals that are used for both portfolio management and for project monitoring but none are specifically related to the GIP. The department goals are based on activities that the department should finish (in order to reach organizational objectives) and are divided into hard and soft goals.

Hard goals are predominantly related to projects in the project pipeline, i.e. this is what is to be done.

Soft goals are set to improve collaboration in the department and making sure that meetings are efficient and SOP:s are relevant.

There are development goals for the organization but it is unclear how these relate to processes. None of the department goals are directly linked to the development process per se except for goals regarding different SOP:s. Departmental goals are broken down and linked to individual goals.

The SBU analysis indicated that there are areas that can be improved regarding process management. This is true for both the processes themselves and how well the organization is prepared for process development and management. It is however perceived that work has begun towards process development and management in a structured manner.
The most prominent process enablers to develop, based on the PEMM analysis, are presented in table 3 below. See appendix 2 for full presentation of the analysis.

Table 3

Areas of improvement for process enablers

<table>
<thead>
<tr>
<th>Enabler</th>
<th>Aspect</th>
<th>Statement P-1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design</td>
<td>Context</td>
<td>The process’s inputs, outputs, suppliers, and customers have been identified.</td>
</tr>
<tr>
<td>Infrastructure</td>
<td>Human resource systems</td>
<td>Functional managers reward the attainment of functional excellence and the resolution of functional problems in a process context.</td>
</tr>
<tr>
<td>Metrics</td>
<td>Definition</td>
<td>The process has some basic cost and quality metrics.</td>
</tr>
<tr>
<td>Metrics</td>
<td>Uses</td>
<td>Managers use the process’s metrics to track its performance, identify root causes of faulty performance, and drive functional improvements.</td>
</tr>
<tr>
<td>Performers</td>
<td>Knowledge</td>
<td>Performers can name the process they execute and identify the key metrics of its performance.</td>
</tr>
<tr>
<td>Performers</td>
<td>Skills</td>
<td>Performers are skilled in problem solving and process improvement techniques.</td>
</tr>
</tbody>
</table>

Note: In table 3 are scores for process enablers presented from the PEMM analysis. The enablers and aspects presented in table 3 have all scored low or very low in the evaluation.

The other aspect of PEMM is how well prepared the organization is regarding process management and development.
The result for the lowest scoring capabilities are presented in table 4 below.

Table 4

*Areas of improvement for enterprise capabilities*

<table>
<thead>
<tr>
<th>Capabilities</th>
<th>Aspect</th>
<th>Statement E-1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leadership</td>
<td>Awareness</td>
<td>The enterprise’s senior executive team recognizes the need to improve operational performance but has only a limited understanding of the power of business processes.</td>
</tr>
<tr>
<td>Leadership</td>
<td>Alignment</td>
<td>The leadership of the process program lies in the middle management ranks.</td>
</tr>
<tr>
<td>Leadership</td>
<td>Style</td>
<td>The senior executive team has started shifting from a top down, hierarchical style to an open, collaborative style.</td>
</tr>
</tbody>
</table>

*Note:* In table 4 are scores for enterprise capabilities presented from the PEMM analysis. The capabilities and aspects presented in table 4 have all scored low or very low in the evaluation.

The PEMM analysis in table 3 and 4 represents opinions from one group, this is elaborated in section 5.1.1.
5. Analysis and discussion

This chapter presents the analysis of the result based on the theoretical framework. The disposition follows the research questions and starts with an analysis of employee’s perception of the GIP. Conclusion and discussion follows the research questions and a proposition for continued research concludes the chapter.

5.1. Analysis

5.1.1. Perception of the product development process

As a way to identify and analyze the organization level of maturity, two PEMM analysis were conducted. One with managers and one with engineers. This was to identify potential discrepancies between how management and employees view process management and the organizations maturity. Maturity models can be discussed whether they are an effective instrument for analyzing an organization. This has been taken into considerations as it has been presented as one way of viewing the organization and the result should not necessarily be thought of as an absolute truthful view of the organization. This is not say that the result is useless. On the contrary, the result can lead to ideas on potential new ways to develop the organization. This is a part of the action research approach where involvement of participant is central and the research can lead to new insights for participants as well as the researcher. The analysis used the SBU as context in one case and the department in the other. As the result from the analysis are strictly subjective no statistical inferences can be drawn from the analysis, neither is it considered meaningful to present descriptive statistics.

The analysis with managers revealed that there are areas where the organization can develop. The result indicates that there are process related issues that the organization may want to define and actively work with. Infrastructure, design and metrics are considered areas for improvements as perceived by participants. This can be an indication that the level of process establishment is not on a satisfactory level. Especially design and metrics should be investigated further as both areas potentially can have a big impact on employee’s perception of the (design and development) process. Regarding the enterprise, leadership is considered an area that can be developed. Sveningson and Sörgärde (2014, p.46) presents three perspectives on organizational change:

- Tool perspective.
- Process perspective.
- Critical perspective.

From the tool perspective on change, focus are on technical aspects of change that can be used, e.g. different maturity models. This perspective is normative in nature and can be viewed as being in stark contrast to principles of TQM. This particular aspect is however a narrow viewpoint and is easily accounted for by inviting employees to participate in organizational analysis.

The analysis with engineers led to the decision that a PEMM analysis was not meaningful as no common process could be identified. The session turned into a group discussion instead which led to further insights. The development process is expressed as a combination of verbal agreement and experience which implies that process documentation is either insufficient or not known to employees working in the process.

Respondents agree that there should be only one product development process. It is, however, perceived that there are multiple processes where the SOP for Design Control is considered the formal process for product development and not GIP. This, together with conflicts in systems, led to the perception that the maintenance of systems are more important than to develop products. The PEMM analysis is a clear indication that there are different views regarding both processes and maturity of the organization.

The different views can be explained by the fact that the subject of analysis, i.e. SBU vs. department, are different. An alternative explanation can be that managers primarily focus on issues related to systems, planning and control whereas employees focus is on interpretation, dialogue and interest. This may not be so per se but the point is that the differences in perception can stem from different viewpoint of the organization (Sveningson & Sörgärde, 2014, p.46).
The organization where the study has been conducted uses a stage-gate model for its GIP. Edgett and Jones (2013) presents ten tips for successful implementation of a stage-gate product innovation process:

1. Have a well-designed and credible process design
2. Give visible and meaningful leadership support
3. Be sure you have sufficient and appropriate resources
4. Create defined roles and responsibilities
5. Have a strategic implementation approach
6. Be effective with your communication and marketing
7. Track your performance
8. Appoint an executive sponsor of the product innovation program
9. Understanding the impact on your company’s culture
10. Seek effective change management

From the interviews some of the above issues were raised by employees, for example the process design is not seen as credible as the process is not used the same way by everyone, every time it’s being used (this accords with Ljungberg and Larsson’s established process (2012, p.161)). Communication and marketing of the process is not efficient as not all employees know of the process. Tracking of the process is done on a project-rather than process level, company culture is not readily considered as the process is primarily developed at a remote department (although there are no formal boundaries that hinders participation of process development) and finally process change management is sought after but hindered by day to day operations.

By working with processes actively and with inclusiveness and strong management support it is likely that employees will feel a sense of purpose and commitment which will contribute to work satisfaction, Scott (2016) states that:

“A workforce that is well informed, where individuals feel part of the process are committed to organizational objectives is clearly a precondition for the implementation of an effective value chain”. (p.6/44)

This accords well with opinions of employees where the study was conducted, there is a degree of frustration which is interpreted as a lack of not being felt as part of the (development of the) process.
5.1.2. Product development process and strategy

All activities in the product development process include some sort of documentation, either as an input/control or as an output. The connection between process and documentation is missing in many cases and this is what makes the process difficult to understand. The consequence makes it difficult to view the process holistically which leads to confusion amongst employees. This also affects the coordination of activities within the process, this is however somewhat offset/rectified by project management.

![Diagram of process and object properties]

*Figure 11*: Example of how process and object properties can be related to the activity of transfer user needs to Design input, based on Ljungberg and Larsson (2012, p.227)

In figure 11 the process effect is interpreted as to what extent the user needs have been successfully translated to design inputs as perceived by customers. The figure exemplifies the connection of an activity in the development process (object in, activity and object out) and the usage of resources (from different departments). The object in needs to be of sufficient quality. In this example this can be interpreted as clarity of user needs, understandability and handoff of the object in itself. The length in time of the activity is also of interest and the object out is of interest for downstream activities. These are process
and object properties. Strategic implications has to do with alignment of affecting factors as presented in figure 2. For example, it has to be clear when the handoff is to be made and to whom. If the strategy of the department that delivers the object in do not align with the receiving departments strategy, gaps in the handoff may occur which can influence both process and object properties. The more complex the process is the more handoffs are necessary which in turn increases the importance of strategic alignment. Figure 11 is an example of relationship between object/process properties and resources. Figure 11 presents one way of viewing an activity and is not exhaustive and should be viewed in the context of value creation and/or resource efficiency.

Respondents perceive GIP as a complex process and this is confirmed by the amount of process documentation. There are a number of questions that can be relevant to reflect over when discussion process complexity (Ljungberg & Larsson, 2012, p.346):

- Proportion of value-/non-value added activities in the process
- Number of different process related documents (in the studied department this is naturally high due to regulatory concerns)
- Number of decision forums are involved in the process (this can be related to the extent of empowerment and trust in the organization)
- Time to introduce new employees (respondents has confirmed this as relevant in the studied process)
- Number of organizational levels involved in the process (this can indicate the level of internal focus)
- Waiting time for decisions on aggregate
- Number of IT-system are used in the process (this can lead to fragmentation of information)
- Number of exceptions (this is a measurement of how often a project and/or activity is treated as a special case)

Ljungberg and Larsson (ibid.) argues that the complexity of a process does not necessarily mean that it is unnecessary complex and continues to state that the process complexity have to be in parity with process requirements. One way of reducing fragmentation is to let a team take a collective responsibility for the execution (and development of the process) (Ljungberg & Larsson, 2012, p.340). When designing and
documenting the process, the question of how to make it so good that employees choses to use it every time it is used is pivotal (Ljungberg & Larsson, 2012, p.164). The process documentation is not only relevant for the development of the organization, it also serves as a guide for introduction of new employees, i.e. this is how things are done here (Ljungberg & Larsson, 2012, p.189).

A potential starting point to create a more holistic view of the process and the organizations objectives can be to define process strategy based on disaggregated SBU objectives as described in figure 12 below.

*Figure 12: Illustration of how SBU strategy can be disaggregated into process strategy, critical success factors and process goals, based on Ljungberg and Larsson (2012, p.185)*

Process strategies refers to how the organization’s processes supports the overall objectives of the firm. Process strategies should be developed for (at least) the core processes (Ljungberg & Larsson, 2012, p.118). Identification of critical success factors based on the process strategy is used when developing process goals.

The organization chart basically shows how resources are spread, reporting channels and power structures, it does not show how things are getting done nor does it show the different connections within the organization or the organization and other
stakeholders (Ljungberg & Larsson, 2012, p.127). The process perspective presents an alternative view of the organization that is based on what is done in the organization and where value is created.

Ljungberg and Larsson (2012, p.139) points out that the lack of focus on management processes are to a large extent dependent on the day to day operations which draws attention from management activities. Obviously the day to day operations is important in the short term but there is a risk that this is on the expense of long term efficiency and development of the organization. It is important that an analysis of the calculated benefits are compared with the assessed costs of process (development) projects. From a strategic point of view it should fit within the project portfolio as well as with overall strategic objectives (Ljungberg & Larsson, 2012, p.318). It might be worth reflecting over meetings in the department (organization). Isaksson (2016, p.91) points out that an organization that have a need for many meetings have process related issues.

5.1.3. Strategy and the department

Bergman and Klefsjö (2012, p.423) presents their view of Total Quality Management as a combination of Values, Methodologies and Tools. Examples of values (called principles by Isaksson, 2016, p.6) are the corner stones of TQM, i.e. focus on customers, develop processes, fact based decisions, create availability to participate, continuous improvement and develop an engaged leadership. Examples of methodologies includes; process management, benchmarking, six sigma etc. TQM should be a strategic consideration as it requires senior management attention and support to add to competitive advantage. However, it is important to realize that the cornerstones presented (or the ones the organization develops) should be integrated in all parts of the organization. The effect of TQM will decrease significantly if principles and methodologies are applied in isolated areas of the organization.

Bergman and Klefsjö (2012, p.46) argues that cost of poor quality can be as much as 10-30% of revenues. The basic principle of quality development is that there is always a way to achieve better quality at a lower cost (ibid.)

Cost of poor quality (CoPQ) can be categorized as presented in figure 13 below.
By increasing the preventive costs, the cumulative costs of poor quality will actually decrease. Bergman and Klefsjö (2012, p.71) argues that only internal and external CoPQ should be used in a model for CoPQ. In this study preventive costs are considered investment costs (for process improvement projects) and should be accounted for as they will lower cumulative CoPQ.

Bergman and Klefsjö (2012, p.461) discusses the importance of not seeing everything as processes and they make a clear distinction between project and process. They also presents issues that potentially contributes to difficulties of process improvement initiatives, including; confusion within process related definitions and that the level of process integration for which there are no standardized definitions needs to be defined (Bergman & Klefsjö, 2012, p.462).

The illustration of cost of poor quality can be used together with GAP analysis when building a business case for process improvements initiative.

Respondents in the present study have not discussed/mentioned strategy more than occasionally, there seem to be a disconnect between strategy and process. This may be because the department’s goals do not involve process improvement initiatives.
Figure 14: Illustration of relationships between objectives, processes and strategy (author’s own interpretation)

Figure 14 implies that it is important to connect and align both internal aspects of the organization (processes, departments etc.) as well as with the organizational context. The department is set out to work with the efficiency of meetings which accords well with one of the methodologies that Isaksson (2016, p.7) presents as an example of TQM.

Figure 15: Illustration of aspects when constructing a business case for process change (Harmon, 2014, p.207)
Ljungberg and Larsson (2012, p.274) presents a framework for establishing processes. Their framework includes Harmons suggestion for business case construction presented in figure 15. The framework includes establishment of the process and follow up activities. They concludes that the maturity level of both the organization and process as well as how explicit process goals are formulated have a big impact when establishing processes (ibid.).

There is a difference when dealing with local and global processes which can have an impact on both how they can be developed and how they are related to local departments (Ljungberg & Larsson, 2012, p.275). Global processes presents more extensive considerations for establishment which is the case in the studied department. It is important that all employees who work in the process, regardless of where they work, feel involved. An important part of the establishment is the measurement system for the process and it is of great importance that this is designed in accordance with the organizations strategy, i.e. the metrics used should reflect overall objectives. As process metrics are not used today in the department it can be difficult to apply GAP-analysis but as the analysis is an effective strategic tool it will be presented. What factors that are considered most influential is a matter of debate and this is a central point of the Ishikawa diagram. It is an excellent tool for creating a common base for further analysis. The Ishikawa diagram is presented in appendix 1.
5.2. Conclusions

GIP Accolade is the software used for project management. As a tool it is used to support the innovation process. The (possible) metrics in Accolade are not related to the day to day operations of the department as perceived by employees working in the process. There is a common belief that there are not sufficient metrics for process management. Metrics used are based on a project management perspective and these are not necessarily the most appropriate from a process perspective. The metrics has to be related to objectives broken down from aggregate objectives of the organization. Thus, there are all kinds of possibilities for the organization to integrate and adapt the global innovation process in the day to day (local) operations of the department. For this to be possible it is necessary for senior management to discuss how the metrics should be used (at a disaggregated level) in relation to the day to day operations as well as their relationship with strategy.

It may not be possible (or desirable?) to separate process development/management with strategy as they are closely linked. This is however not the only way to view the organization, Scott (2016, p.3/16) discusses the difference between means and ends as an alternative to aggregate and disaggregated objectives. The difference may at first seem obvious but there are many aspects in organizational life that affects decision making and what is seen as important in the company. For example can process development be a means to reach an end (e.g. the end is to reduce time to market by 15%). However, a prerequisite is considering process development when developing the strategy as process development requires resources. These resources might not be available if not considered during strategy development. It is vital that employees are involved in changes of the way work is done (Beer et al, 1990, p.163). It is also important that metrics are developed and used to track changes (ibid.). In the studied organization it is not clear whether or not the GIP is supposed to be used as a template for local adaptation or if it is presented as is (i.e. top down). This can have big impact on how employees perceive their ability to influence how work is done. Procedures (i.e. SOPs) are used as guidance when activities are performed. It is essential that these are connected to and aligned with the process and easily accessible and understood. In a global/local context it is important for employees to know when to use one another, this is clear from the interviews. This is directly linked to what strategy is being pursued for GIP as well as the integration of the different support-systems.
The formal stance of cumulative investments in projects presented earlier (see figure 9), does not seem to accord with employee’s perception of changes in projects. Employees generally agree that it is not uncommon for late changes in projects. This is an indication that the formal process is not established (these project changes are in principle CoPQ). Cost of (late) changes in projects is potentially a viable way of getting the necessary attention of senior management regarding process costs. In the organization changes are more likely to be regarded as project costs as opposed to process costs. The organization could potentially benefit by start viewing the organization from a value creating perspective, i.e. process perspective. One way of tackling this problem is to have a dedicated resource that has process responsibility and together with other resources develops the (local) process. If the opportunity cost, i.e. using resources from product development, is considered higher than the potential benefits from process improvement initiatives it can be difficult to allocate sufficient resources to improve the processes. This is probably related to the principal-agent problem discussed earlier in the thesis (see section 2.1). The question of opportunity cost and benefits from process improvement can be viewed as a short term view. A possible reason for this is that it is encouraged by current reward systems and the focus on departmental objectives. Ljungberg and Larsson (2012, p.256) argues that metrics used in process oriented organization are different than that of the traditional organization. They continue to state that focus has to change from the department to the process (ibid.). For this to be meaningful it is necessary to have a process based view of the (development of the) organization (Ljungberg & Larsson, 2012, p.259).

The goals of the department are set strictly from a functional perspective although the development work is predominantly done in a process. This can lead to contradictions regarding what employees perceive is important as individual goals are set based on functional premises. Of course there are things that has to be done in order for the process to function properly but the question is if it is possible to achieve this with a functional focus. It can be argued that it has to be done in a collaborative fashion including related functions and with a common view of the processes and value creation. Thus the question can be funneled down to resource management and it’s relation to organizational objectives and what strategies are used to achieve these objectives. That is, are processes considered
from a strategic perspective? The complexity of the (product development) process can potentially have a big impact on the competitive position if competitors are more agile.

The PEMM analysis indicates that there are a number of areas that the organization can begin working with. It is however probable that from the employee’s viewpoint the most important area to begin working with is to clarify Design Control and GIP and to relate metrics in GIP to the day to day operations (without discarding departmental objectives).

It is difficult to differentiate process development/management from other issues related to leadership, culture, structures, economics and the organizational context. This is due to the fact that all of these areas affects the process in one way or another. This resembles very much the stance on strategy development and implementation, which is notoriously difficult as the organizations environment constantly changes (Scott, 2016, p.1/27). And to reconnect with Ljungberg and Larsson´s (2012, p.50) statement that it is easy to fall into the it’s just “common sense trap” when discussing processes. Processes touch on many different aspects of organizational life that at first sight seem unrelated. Processes contributes to connect the present with the future (Bergman & Klefsjö, 2012, p.44). In this regard the strategy is an important part as it generally deals with how to achieve a desired state.

General economic theory suggest that something is worth doing (to maximize profits) as long as marginal cost is less or equal to marginal revenue (Lumsden, 2015, p.7/9). In a development project/process it is likely that there is a great deal of uncertainty in the changes in cash flows which can make it difficult to judge the break point of marginal cost and marginal revenue. Subsequently it can be difficult to assess how much resources is worth allocating from a wealth creating perspective. Ljungberg and Larsson (2012, p.116) points out that it is a slightly cynical notion that the business model is a description of how the organization is expected to make money as it is in the processes that value is created.
5.3. Discussion

Although it is not within the scope of the study, it can be insightful to reflect over aspects of process ownership. Ljungberg and Larsson (2012, p.291) presents what they believes is the responsibility of the process owner:

- Effectiveness – The process deliver what the customer (stakeholder) want, i.e. doing the right thing.
- Efficiency – Ability to deliver with minimum resource usage.
- Flexibility – Ability to adapt to changing circumstances.
- Level of establishment – To what extent is the process used as designed by users.

In the department it has not been possible to identify anyone with a (local) responsibility that resembles that of a process owner as presented by Ljungberg and Larsson. This is somewhat surprising as the importance of the new product development process is a critical process for sustainable advantage. The notion of CoPQ in a process that does not directly produce physical products such as the case with a product development process help the organization understand the importance of improvements throughout the organization. Ljungberg and Larsson (2012, p.242) argues that traditional metrics in organizations are to financial focused, this accords well with Lindvalls (2011, p.36) view of modern business management (see table 5 below for a summation). I share this view but I believe that it is a too narrow view of organizations that does not take into account shareholders and other capital suppliers that require a return on invested capital.
Table 5

*Differences in philosophy between Traditional Economic Management and Modern Business Management. (Lindvall, 2011, p.164).*

<table>
<thead>
<tr>
<th>WHO HAS ACCESS TO INFORMATION</th>
<th>TRADITIONAL MANAGEMENT</th>
<th>MODERN MANAGEMENT</th>
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<td>“EMPOWERMENT”. Both Manager and employee</td>
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<th>Goal/objective oriented</th>
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<th>MODERN MANAGEMENT</th>
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<td>Reactive, await deviation</td>
<td>Proactive, foresee deviation</td>
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<td>Both – And.</td>
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<th></th>
<th>TRADITIONAL MANAGEMENT</th>
<th>MODERN MANAGEMENT</th>
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<tbody>
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<td>E.g. either decentralization OR centralization</td>
<td>E.g. both decentralization AND centralization</td>
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<th>MODERN MANAGEMENT</th>
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<tr>
<td>Systems OR Norms</td>
<td>Systems AND Norms</td>
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<thead>
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<th>TRADITIONAL MANAGEMENT</th>
<th>MODERN MANAGEMENT</th>
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<tbody>
<tr>
<td>Cost focus</td>
<td>Value creation</td>
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Note: The table is not exhaustive and presents only central aspects of differences between traditional and modern views of management.

When reviewing literature about business improvement from a “modern” perspective it is easy to forget the economic aspects of organizations. One can get a sense that everyone “should” simply understand the necessity of change but I believe this is a far too simple view of people in organizations. There is always an opportunity cost to consider and resource owners have to see the benefit of potential changes. If resource owners have no incentive to change their area of responsibility, change will likely not occur. One can argue that bottom up change is possible, however this will likely only occur when performance falls and resource owners consider it necessary to change.
The research has revealed that in the studied organization different views of reality exists. This is not remarkable in any way but in the day to day operations it is easy to forget this fact. The connection between perceptions, processes and strategy has been in focus in the study and from the interviews many interesting viewpoints has been revealed which can benefit the organization. Not all views has been relevant for this study and is therefore not presented, but there is a great will in the department to make the workplace better and more efficient. This can be explored further and a possible way forward is to discuss strategic issues from a process perspective without changing the present hierarchical structure.

Involvement is a central theme in most contemporary theories about organizations and development. In the studied department it is often felt that there is no time to develop the organization because there are so many projects that has deadlines. This is not to say that the projects are less important but for the organization to continue to have a competitive advantage it may be necessary to reflect over efficiency and effectiveness.

Senior management views on the research questions has not been in the focal point which may lead to bias towards employees view. On the other hand did the process review confirm many aspects of process management as perceived by employee’s, i.e. importance of involvement, development of metrics, connection with strategy etc. Nonetheless, it would have been interesting to delve into the strategic implications of the SBU as seen from senior management. I strongly believe in the involvement of relevant stakeholders as well as in the importance of relating the business objectives to the processes where value is actually created. In investment projects cash flow estimation is central and may be one explanation to why process development projects are difficult to assess as it is actually a decrease of cash outflow, i.e. an increase in efficiency. When developing business cases for process improvement projects it may be useful to use changes in the discounted rate of resource use (i.e. the efficiency benefits/resource costs rate) instead of cash flows per se. It can also be relevant to reflect over the notion of sunk costs (e.g. costs that have been spent on a project) as these can affect the profitability of projects (Scott, 2016, p.5/3). It is in the shareholders interest that the wealth of the company increases with (at least) the cost of capital, this is also true for process improvement projects. Without delving into details is it never the less relevant to reflect over these issues as much of this potentially can have a great impact on the business and its operations.
5.4. Summary

Respondents perceive the Product Development Process is difficult to see holistically, this implies that there are certain areas that can be improved for increased efficiency. The organization should try and identify synergies between local and global processes and as the PDP is rather well documented there is a solid foundation for this. The issue can likely be reduced to resource management and priorities within the department.

There is no apparent connection between strategies and the PDP per se in the SBU. Although connection between strategies and PDP are likely to exist on corporate level. This is an area that the organization may want to explore further to identify potential efficiency gains in the SBU.

The organization may want to explore how process improvement can benefit efficiency. This is not necessarily easily done and require an understanding that it is not something that can be done without a certain amount of focus and support from senior management.

5.5. Propositions for continued research

The study has put the spotlight on some important issues as perceived by employees and managers. The documentation review revealed that there are aspects of the GIP that the organization would benefit in improving. The organization can continue to develop these ideas as part of a strategy. There are many tools and methods available to the organization but the arguably most important aspect is to develop a strategy for the organization and making the connection to processes more visible and inclusive. This work has begun in the studied organization but it is difficult to allocate necessary resources if it is not considered by senior management. The financial perspective of process improvement projects as well as potential financial benefits from changing perspective to process orientation would be very interesting to investigate. This is likely to be dependent on individual company specifics but the development of a framework for the financial assessment regarding process improvements would likely lead to a bigger interest from shareholders. This in turn can help managers when deciding on resource allocation for process improvement projects. Financial aspects/metrics of processes will likely lead to a more “natural” connection to the company’s strategy as seen by senior management and shareholders.
The comparison of activities/deliverables presented in table 2 (page 26) of the studied organization and the sister organization is not absolute as the two organizations are different structurally and geographically. However, it may present a way to benchmark against a partner that is not in a competitive position and invites to investigate how the global innovation process can be adapted to local circumstances in the studied department.
References


Appendices

Appendix 1. Ishikawa diagram of identified factors potentially affecting process management

What factors affect process Management in the organization

Management
- Process understanding
- Commitment
- Relationship strategy/process goals
- Short term focus
- Unclear responsibilities

Method
- Established SOP
- Improvisations in process
- Unclear definitions
- Involvement of stakeholders earlier

Man
- Resistance To change
- Process not defined
- Activities not coordinated

Machine
- IT systems not harmonized

Regulatory context
- Complex regulation
- Design control is not perceived as integrated in the process

Culture
- Two sites
- Process development Not prioritized
- Not sufficient time for planning
- Quick results

Measurement
- Process metrics not defined
- Other metrics are used

Responsibility
- Unclear responsibilities
- Quick results
- Process not defined
- Design control is not perceived as integrated in the process
- Other metrics are used

Regulatory context
- Complex regulation
- Design control is not perceived as integrated in the process
- Other metrics are used

What factors affect process Management in the organization
Appendix 2. PEMM analysis

**Processes**

<table>
<thead>
<tr>
<th>Enablers</th>
<th>Aspect</th>
<th>Statement P-1</th>
<th>Statement P-2</th>
<th>Statement P-3</th>
<th>Statement P-4</th>
<th>P-1</th>
<th>P-2</th>
<th>P-3</th>
<th>P-4</th>
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</thead>
<tbody>
<tr>
<td>Design</td>
<td>Documentation</td>
<td>The documentation of the process is primarily functional, but it identifies the interconnections among the organizations involved in executing the process.</td>
<td>There is end-to-end documentation of the process design.</td>
<td>The process documentation describes the process’s interfaces with, and expectations of, other processes and links the process to the enterprise’s system and data architecture.</td>
<td>An electronic representation of the process design supports its performance and management and allows analysis of environmental changes and process reconfigurations.</td>
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<tr>
<td>Design</td>
<td>Purpose</td>
<td>The process has not been designed on an end-to-end basis. Functional managers use the legacy design primarily as a context for functional performance improvement.</td>
<td>The process has been redesigned from end to end in order to optimize its performance.</td>
<td>The process has been designed to fit with other enterprise processes and with the enterprise’s IT systems in order to optimize the enterprise’s performance.</td>
<td>The process has been designed to fit with customer and supplier processes in order to optimize interenterprise performance.</td>
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<tr>
<td>Design</td>
<td>Context</td>
<td>The process’s inputs, outputs, suppliers, and customers have been identified.</td>
<td>The needs of the process’s customers are known and agreed upon.</td>
<td>The process owner and the owners of the other processes with which the process interfaces have established mutual</td>
<td>The process owner and the owners of customer and supplier processes with which the process interfaces have established</td>
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<tr>
<td>Infrastructure</td>
<td>Information systems</td>
<td>Fragmented legacy IT systems support the process.</td>
<td>An IT system constructed from functional components supports the process.</td>
<td>An integrated IT system, designed with the process in mind and adhering to enterprise standards, supports the process.</td>
<td>An IT system with a modular architecture that adheres to industry standards for interenterprise communication supports the process.</td>
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<tr>
<td>Infrastructure</td>
<td>Human resources systems</td>
<td>Functional managers reward the attainment of functional excellence and the resolution of functional problems in a process context.</td>
<td>The process’s design drives role definitions, job descriptions, and competency profiles. Job training is based on process documentation.</td>
<td>Hiring, development, reward, and recognition systems emphasize the process’s needs and results and balance them against the enterprise’s needs.</td>
<td>Hiring, development, reward, and recognition systems reinforce the importance of intra- and interenterprise collaboration, personal learning, and organizational change.</td>
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<tr>
<td>Metrics</td>
<td>Uses</td>
<td>Managers use the process’s metrics to track its performance, identify root causes of faulty performance, and drive functional improvements.</td>
<td>Managers use the process’s metrics to compare its performance to benchmarks, best-in-class performance, and customer needs and to set performance targets.</td>
<td>Managers present the metrics to process performers for awareness and motivation. They use dashboards based on the metrics for day-to-day management of the process.</td>
<td>Managers regularly review and refresh the process’s metrics and targets and use them in strategic planning.</td>
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<tr>
<td>Metrics</td>
<td>Definition</td>
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<td></td>
<td>The process has some basic cost and quality metrics.</td>
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<td>The process has end-to-end process metrics derived from customer requirements.</td>
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<td></td>
<td>The process’s metrics as well as cross-process metrics have been derived from the enterprise’s strategic goals.</td>
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<tr>
<td></td>
<td>The process’s metrics have been derived from interenterprise goals.</td>
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<table>
<thead>
<tr>
<th>Owner</th>
<th>Activities</th>
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<tbody>
<tr>
<td></td>
<td>The process owner identifies and documents the process, communicates it to all the performers, and sponsors smallscale change projects.</td>
</tr>
<tr>
<td></td>
<td>The process owner articulates the process’s performance goals and a vision of its future; sponsors redesign and improvement efforts; plans their implementation; and ensures compliance with the process design.</td>
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<td></td>
<td>The process owner works with other process owners to integrate processes to achieve the enterprise’s goals.</td>
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<tr>
<td></td>
<td>The process owner develops a rolling strategic plan for the process, participates in enterprise-level strategic planning, and collaborates with his or her counterparts working for customers and suppliers to sponsor interenterprise process redesign initiatives.</td>
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<table>
<thead>
<tr>
<th>Owner</th>
<th>Identity</th>
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<tbody>
<tr>
<td></td>
<td>The process owner is an individual or a group informally charged with improving the process’s performance.</td>
</tr>
<tr>
<td></td>
<td>Enterprise leadership has created an official process owner role and has filled the position with a senior manager who has clout and credibility.</td>
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<tr>
<td></td>
<td>The process comes first for the owner in terms of time allocation, mind share, and personal goals.</td>
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<tr>
<td></td>
<td>The process owner is a member of the enterprise’s most senior decision-making body.</td>
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<table>
<thead>
<tr>
<th>Owner</th>
<th>Authority</th>
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<tbody>
<tr>
<td></td>
<td>The process owner lobbies for the process but can only encourage functional</td>
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<tr>
<td></td>
<td>The process owner can convene a process redesign team and implement the new design and has</td>
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<tr>
<td></td>
<td>The process owner controls the IT systems that support the process and any projects that</td>
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<tr>
<td></td>
<td>The process owner controls the process’s budget and exerts strong influence over personnel</td>
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<tr>
<td>Performers</td>
<td>Behavior</td>
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