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Managing the balance between quality assurance and flexibility in production

A case study at Wellspect HealthCare investigating how to enable rapid continuous improvements under high regulatory demands

Master's thesis in Quality and Operations Management

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To Prince Haakon and Dr Zjivago

Abstract

Introduction – Companies within the medical technology production sector operate under very strict regulatory demands. This has resulted in these companies historically mostly focusing on quality compliance within production to pass authority revisions, with little focus on efficiency of production. Wellspect HealthCare, Mölndal Sweden, is a world leading producer of hydrophilic catheters and has ordered this thesis work to investigate how high quality assurance in production can be combined with flexibility and agility in order to improve the overall efficiency. The purpose of this thesis is to perform a current state analysis of Wellspect HealthCare to investigate what the current status is, how it can be improved and what need to be changed. It will also investigate the possibility of enabling standardized working processes within production as a part of the efficiency improvement. Finally the thesis will develop a new complementary solution that facilitates the changes that are needed.

Method – This thesis will utilize a number of methods to gather all the data that is needed and to evaluate both existing processes and developed solutions. These include work studies at the production floor, semi-structured and unstructured interviews, benchmarking of companies in similar situations and a pilot to test the proposed solution in the production. The thesis will be conducted as a case study with some action research influences.

Results – The current situation analysis showed that the organizational structure as a whole is not an issue but it is rather the document handling and approval system where issues arise. The common perception of changes in documents is that the process is slow and rigid, therefore many expressed that changes might as well be scrapped on beforehand. The benchmarking showed many useful things regarding document structure and handling in production, but the issue of updating and revising still remained unanswered. The knowledge gained from these investigations were combined to create a new kind of instruction. In addition to this instruction, a regulatory document controlling the instruction was created, all so that no problems with quality assurance would arise. This new kind of instruction was designed to consist of a simple step by step layout where operators always can look for support, new and old employees alike. Included in this instruction template is room for tips and tricks as well as time measurements of each step, these factors enable an increased efficiency mindset by measuring the process and to provide information of how actions are best carried out. The template was used to create a set of instructions for a part of the production line and a small scale pilot was conducted there. The pilot was unfortunately ended before the last steps could be evaluated due to time limitations and troubles on other parts in production but many useful insights were gained anyway as the thesis was concluded.

Discussion – As was wanted out of the thesis, a thorough and perspicuous current state analysis was conducted and provided. This analysis showed clearly which strengths, weaknesses, opportunities and threats that existed for Wellspect HealthCare in its current state. The thesis also delivered a tested and proven viable solution for the question of enabling standardized working processes in production. The main question of how to balance between quality assurance and flexibility in production may be somewhat centered around the specific case at Wellspect HealthCare but it is fair to assume that it can be applied to most companies in similar situations.

Keywords – *Standardization, Working instructions, Quality management, Change management, Organizational structure, Current state analysis, Standardized working processes, Agile production*

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Glossary

AVIX	A computer software used for evaluating processes in production
Benchmarking	The process of comparing ones business to the industry and best practices
BSI	The company that handle revisions for the European market.
Change request	A formal process initiated whenever a proposed change will affect the product or the process directly
FDA	U.S. Food and Drug Administration
Gemba	"Where the value is created"
Hydrophilic catheter	A catheter is a thin tube used within medicine to drain fluids, in this case urine. The hydrophilic coating makes the surface slippery when in contact with water for safety and comfort
LoFric®	Wellspect's first hydrophilic catheter, still in business after 30 years
Major change	A change that will require 100 man-hours to implement or that will cost more than 100.000SEK
PDMLink	The new document handling system used at Wellspect in addition to WIP
Rapid Event (RE)	A two-day focused change project driven by Lean Support
SHE	Safety-Health-Environment
SOP	Standard Operation Procedure
SWOT	A method used to evaluate strengths (S), weaknesses (W), opportunities (O) and threats (T)
TIA	Specialized group in Astra Tech working with Lean Production, now called Lean Support
WIP	The older of the two document handling systems currently used at Wellspect
5S	A Lean Production method used to organize the work space for efficiency

1 Introduction

1.1 Background

In the modern era of production it is widely acknowledged that the methodologies developed by Toyota regarding Lean Production, i.e. waste reduction, improved flow and increased efficiency, are extremely efficient and profitable. Wellspect HealthCare (from here on called Wellspect), at the time called Astra Tech, was early inspired by this philosophy and slowly started working accordingly, but as the production volumes grew so did the need for a specialized group working solely with Lean Production. The result of this was a group called TIA who were responsible for developing an own philosophy based on Lean Production, also called TIA. TIA is a philosophy which builds on trying to understand what the customer really want, to take part in the processes, to remove waste and to plan long term.

In 2011 a new corporate ownership resulted in a name change from Astra Tech to Wellspect and a rebranding of the company. TIA was also affected by this change thus it went through a total remodeling. This resulted in the TIA group changing name to Lean Support, a new philosophy was developed called The Wellspect Way and a new model was created (the lighthouse) which is shown in Figure 1 below.

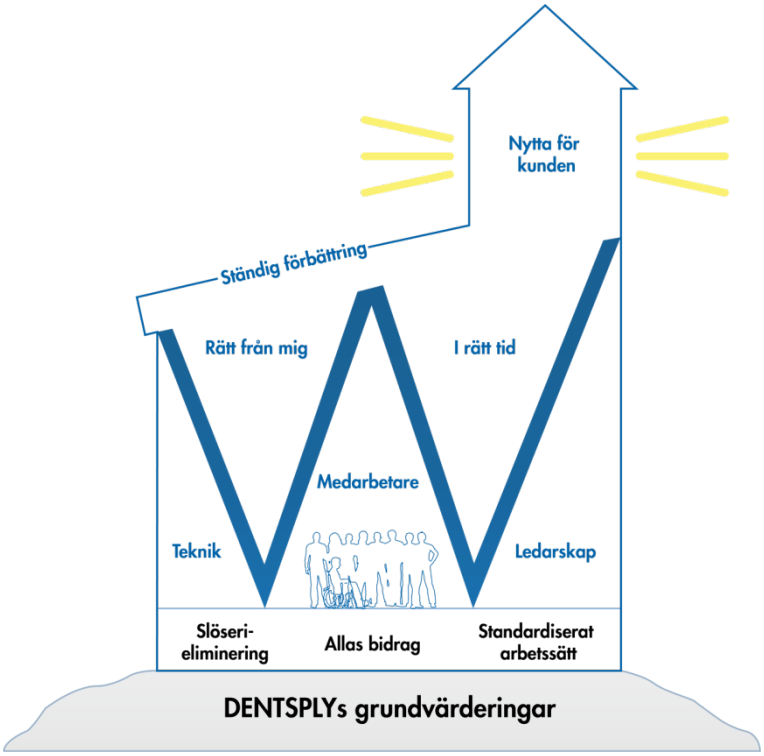

Figure 1: The Wellspect Way.

This is the value model that Wellspect follows and it clearly displays the core values and strategies that permeate the entire company business. In order to continuously improve and provide value for the customer, many things must function. The work must be done correctly in the right time and the right leadership, technology and people must work together to accomplish it. To facilitate it all, everyone needs to contribute, waste need to be reduced and the work must be standardized.

With this background it is evident that an instruction that enable standardization, which at the same time simplifies the continuous improvement work, is of great interest and importance for Wellspect. As a first step towards reaching these goals the Lean Support group at Wellspect ordered this thesis work to be done.

1.2 Company introduction

The company was founded as Astra Tech in 1948 and has ever since been an innovative producer of products in the healthcare business that raise the quality of life for its customers. In 1983 the company developed the first hydrophilic catheter in the world, LoFric®, and it was an immediate success. Having been on the market for over 30 years LoFric® has constantly been developed and improved. This has resulted in several new types of LoFric® catheters that have been introduced to the market, all with the same surface coating technology. Wellspect is now a leading global provider of innovative urological and surgical products and services. The largest part of the production is in the Urology Department where catheters are produced and distributed to hospitals and end users worldwide.

There are currently five different kind of catheters produced in the factory located in Mölndal, Sweden. Each kind of catheter got its' own specific market segment to cover and has one or multiple specific production lines allocated for its production. The different lines has various degree of automation and at the end of the process the catheters ends up in packages ready for delivery to the customer. A lot of effort is put into creating an experience that is as trouble free as it can possibly be for the customer, which means that both the design of the catheter itself and the packaging is really important. This adds to the complexity in the production where the mix of manual and automatic work must be coordinated to deliver great precision throughout the processes.

Wellspect has throughout the years delivered products that are of sufficient quality and has never failed to deliver in any authority control revision. This is due to the high quality their products have and also the carefulness throughout the processes. The general attitude is to better be safe than sorry and not to take any unnecessary risks. This attitude can be found throughout the entire organization, all the way from the production to the top management.

Wellspect currently employs about 1000 people and is represented in countries all over the world. The company vision is "We passionately strive to make a real difference every day to everyone who needs our products and services" and this permeates the entire business, from R&D to production and distribution. The company vision together with the high quality and customers satisfaction forms the picture that Wellspect provides to the outside world.

1.3 Problem definition

The medical technology sector has been a steady business for many years, with relatively high profit margins and low competitiveness in comparison to other sectors. The main focus has always been quality compliance to ensure customer health and satisfaction and to pass the strict authority control revisions that permits sale of the products at the specific market, such as FDA's revision for the American market. To lose permission to sell on a market would mean a major cutback in financial terms and it may take years before a new evaluation is issued and the permission to sell is regained. Therefore, the operations throughout the entire organization have been evolved around quality compliance, which has made other factors such as efficiency and speed in the production second class factors. This, together with the fact that the company has grown fast in recent years, has led to

lagged efficiency where many processes have become bureaucratic, complicated and slow. Now, time start to catch up and in order to stay profitable, retain a leading position at the market, and keep the production located in Sweden, increased focus on efficiency is required. The Lean Support group at the Operations Department has previously tried to introduce the concept of standardized work but has encountered big challenges along the way. In order to accomplish a shift towards standardized work in the production the current working instructions need to be adapted to the concept. Today this is complicated due to the long lead times for document updates and the strict restrictions of how the instructions are to be written. These challenges has led to a trade-off between having an agile and lean process, in which standardized work can act as the foundation for improved efficiency, and still retain the high level of quality assurance needed. In the current situation this trade-off will always favor the strictly quality assuring path, leading to that a new way of linking the development of instructions together with the quality aspects is needed.

1.4 Purpose

The purpose of this thesis is to explore the benefits and challenges of implementing standardized work in production. It should also deliver a method that complements the existing working instructions with more detailed standardized working instruction as well as enable a more flexible and agile update procedure for these standardized working instructions. The method shall further ensure that today's focus on quality compliance is preserved while also including additional instructions of how to perform the working sequence in an efficient way. Furthermore, the method should be designed with the production lines as recipients so that they can use it independently and continually. In addition to this the thesis will investigate how the balance between quality compliance and flexibility in production can be handled.

1.5 Research questions

How should a methodology of developing working instructions be designed to result in standardized work at Wellspect?

1. What is the current methodology?
    a. What are the expected benefits of implementing standardized work?
    b. How can quality compliance be assured by this methodology?
    c. How can an increased efficiency be reached by following this methodology?
2. How can the balance between quality control and flexibility in production with high regulatory demand be handled?

1.6 Delimitations

This master thesis is to be conducted from the start in January 2015 to the expected finish in June 2015. In the scope of this study Wellspect production site at Mölndal, Sweden will be analyzed and the study will be limited to the Urology Department. Impressions and knowledge will be gained from all of Wellspect's functions but the current situation analysis, the delivered methodology and the pilot will be conducted on one of the production lines in the catheter factory. This since these lines are in suitable condition regarding production process, performance and location that will help minimize the possible impact from external noise factors on the outcome of this study. This is also where the main production and headquarter of Wellspect is geographically located, which facilitates the possibility to develop the outcome in collaboration with other important functions of the organization. For example, the outcome of this study needs to be developed in close collaboration with the Quality Department to ensure the regulatory validity of the result.

Further, this study will only consider instruction documents connected to already available machines or processes. Hence, only changes coming from "bottom-up" will be considered, i.e. changes issued from the production floor. Instructions created from scratch for new machines or products will not be in the scope of this study.

1.7 Project outline

This study will start with presenting the theoretical framework that has been used as the foundation of theoretical knowledge. The next section in the thesis is divided into two major parts. In the first part all needed empirical data is gathered and in the second part the new methodology is developed and tested. This division was made since there were several components in the empirical data that were needed before the delivery of this thesis could be designed in the second part. Therefore, in the first part the main focus is to gain knowledge and collect information needed in order to understand the present circumstances at Wellspect and gain insight of how other companies deal with the matter. When all necessary empirical data is gathered the forming of a solution for Wellspect can begin. In this second part knowledge from creating and implementing a new methodology in the specific context will be gained.

The two major parts will together with the theoretical knowledge provide the information needed to perform the last part of this thesis. In this part everything will be combined to form the base for the conclusions drawn in this study. At last recommendations will be given to both Wellspect in particular as well as in the topic of this thesis in general.

2 Theoretical framework

In order to get a solid ground for this study to stand on a literature study will be conducted. The project will use both a current situation analysis of Wellspect today and a benchmarking analysis of other companies in similar situations as a foundation of understanding how the working instructions should be constructed, it is important that the underlying structures and cultures are understood. Hence a literature study on organizational structures and their effect on production will be included. As the desired outcome of the project is a methodology that enables standardized working processes to promote efficiency and quality, as well as an instruction template for this, the area of standardized work will occupy a substantial part of the literature study. This section will cover not only why standardized work is useful but also how it should be constructed and implemented to be as efficient as possible. Potential pitfalls and drawbacks connected to standardization are also included in the analysis.

Furthermore, change management will be studied in order to better understand the psychology behind implementing change and how to inspire people to follow it.

2.1 Organizational structures

In the article by Nadler and Tushman (1978) their concept of an information processing organization is as an open social system that deals with environmental uncertainty and organizational uncertainty. Environmental uncertainty is that which is based on factors that cannot be controlled within the subunit or the organization (e.g. extensive rules and regulations) thus having large amounts of environmental uncertainty reduces the ability of developing rules or standard operating procedures (SOPs) in the subunit (Nadler and Tushman, 1978). Further they state that fundamentally an organization is built upon subunits and that processing information within and between these

subunits is one of the major functions that the organizational structure must perform. It is desirable to reduce the perceived uncertainty within the organization in order to create rules and standards, this way the amount of information a subunit needs to process for the working tasks to be executed can be reduced (Nadler and Tushman, 1978).

In the article by Mintzberg (1980) he divides an organization into five basic parts that together constitutes the entire business, these parts can be seen as the subunits discussed by Nadler and Tushman (1978) and they are as follows:

- the operating core which consists of the operators or employees that produce the basic products or services
- the strategic apex that is the top management and their staff
- the middle line which are the middle managers who sit between the strategic apex and the operating core
- the technostructure which consist of analysts outside the formal structure who design the process and adapt it to its environment
- the supporting staffs that are units that indirectly support the organization through its services, this could be the legal counsel or the cafeteria.

-Mintzberg (1980)

These five basic parts of an organization are configured differently depending on what type of organizational structure the company has applied or developed. In the article Mintzberg (1980) continues by distinguishing five types of structural configurations based on the five parts, all of which has an "ideal" structure for a specific setup of assets, preconditions and strategy. These five structural configurations each have a prime coordinating mechanism, which more or less is what the entire structure builds on. The key part of the organizations also differ for the five configurations as different prime coordinating mechanisms depend on different functions, the same goes for the type of decentralization. The five structural configurations are as follows:

- *The Simple Structure*: This organizational structure is built as the name proposes, simple. There is little technostructure and very few supporting staff, there is no clear division of types of work and there is not very much hierarchy in the structure. These kinds of organizations are very informal and direct in their line of communication. It is a clear case of an organic structure, and most decisions are made top-down from the strategic apex which not seldom only consists of one single person. Thus the CEO strictly supervises the work. This structure is common in young and small organizations due to the dynamic nature of an organic structure and the fact that it probably has not had time to develop any considerable bureaucracy yet. The typical case is an entrepreneurial firm.
- *The Machine Bureaucracy*: This configuration of organizational parts is characterized by being very specialized and formalized in its procedures, it also has large units in the operating core that rely a lot on routine operating tasks. The decision-making is fairly centralized and the line and staff are sharply separated. Machine bureaucracy is mostly found in mass production firms and so it relies most of all on standardization of the work, as the technostructure of these firms hold most of the analysts responsible of the standardization it plays a very important part. The analysts in a machine bureaucracy gain a lot of power through their formalization and standardization of the work at the expense of the operators and the line managers, this is a direct consequence of the extensive rules and regulations

that are applied. This focus permeates the entire company and the structure if often rather formal with all major decisions being made in the strategic apex. A machine bureaucracy is often found in an environment that is both stable and simple, so that it more easily can be standardized and is predictable. The strive for stability also shows in the size of the supporting staff, here large resources are put in order to closely control the support services to increase autonomy. In addition to all this, machine bureaucracy is typically associated with high external control, as this tends to drive companies towards a centralized and formal structure. Companies associated with machine bureaucracy are e.g. mass production firms or companies with large safety requirements.

- *The Professional Bureaucracy*: This organizational structure is defined by the standardization of skills. Here highly trained professionals make the foundation of the operating core and these have a very high degree of autonomy. This structure is often found in schools or hospitals where a high complexity of work tasks can be handled through extensive education and training of operators. In addition to this complexity, the environment is also characterized by stability that enables the complex procedures to become standardized. The operating core is very large and has considerable power, both formal and informal. The technostructure is almost non-existent while the supporting staff often is quite large, although the latter in this case mostly work with simpler tasks to help the professionals. An interesting trait of the professional bureaucracy is that the customers are grouped after functionality, that is e.g. cancer patients in the cancer department of the hospital or physics students in the physics department at the university.
- *The Divisionalized Form*: This structure is often described as "market-based" as the organization can be mapped as a central strategic apex controlling different divisions working in different markets. This means that there is little to no interdependence between the divisions which all have a high degree of autonomy. The middle lines of each division emerge as the key parts of the organization and the main concern is to find a way to align all divisions' goals with those of the entire organization. The strategic apex and the technostructure are very small in these organizations while the supporting staff is of medium size. The focus of the latter is mainly services that all divisions share, such as legal counsel. Within the divisions the typical structure is machine bureaucracy, this mostly as external power promotes this and the strategic apex here constitute said power on the divisions.
- *The Adhocracy*: In organizations that deal with groundbreaking innovation a fifth organizational structure is needed, this is where adhocracy comes in. It is characterized by an organic structure, extensive job specialization based on training and education and a tendency to use these professionals in cross-functional teams for their projects while having them grouped by function organizationally. The difference between line and staff is vague as the project groups are given authority. There are two types of adhocracy, the operating adhocracy and the administrative adhocracy. The former of the two is typically a consultancy firm working directly on behalf of the client using a multi-disciplinary team to find an innovative solution to each unique problem, here planning and execution is merged into the project work. This in contrast to Professional Bureaucracy consultancy firms focusing on having a broad base of standardized skills to match each client problem. In the latter of the two adhocracy types, the administrative adhocracy, the distinction between administration and operation is very clear and differentiated. The operators are often completely separated from the rest of the company so that the administration can function individually. Most companies using the adhocracy structure are young and not yet matured. This since the adhocracy structure is quite vulnerable as there is no clear customer feed and that time therefore promotes an evolution towards increased bureaucracy. An example of this is an

> Operating Adhocracy deciding which areas or competences should be their area of expertise or niche and thus start changing towards a Professional Bureaucracy in that area instead.
>
> -Mintzberg (1980)

Table 1: Mintzberg's five structural configurations.

Structural configuration	Prime coordination mechanism	Key part of organization	Type of decentralization
Simple structure	Direct supervision	Strategic apex	Vertical and horizontal centralization
Machine bureaucracy	Standardization of work processes	Technostructure	Limited horizontal decentralization
Professional bureaucracy	Standardization of skills	Operating core	Vertical and horizontal decentralization
Divisionalized form	Standardization of outputs	Middle line	Limited vertical decentralization
Adhocracy	Mutual adjustment		Selective decentralization

These five organizational structures clearly show the benefits of applying the most suitable structure based on a company's specific strategy, market situation and preconditions. Thus these aspects are useful to keep in mind when analyzing what internal forces are most prevalent in an organization and how this affects the outcome and performance. It is very rare to find an organization that fits these descriptions to the letter but according to Mintzberg (1980) the literature on this area shows that in most cases one of the five structures dominate the other four. This indicates that all organizations strive for organizational harmony and that it is found in these structures (Mintzberg, 1980).

2.2 Standardized Working Processes

Standardized working consists of detailed step-by-step instructions for every job that specifies work sequences and enables measuring and calculation of expected cycle time (Lander and Liker, 2007). The theory of documenting and analyzing processes to reach one common standardized way that improves productivity and reduces lead times has its origin in Taylor's theory of scientific management from the late 40s (Adler, 1993; Marksberry et al, 2011). However, the theory has evolved from the pure productivity centered to also add emphasis on the employees and how their well-being and knowledge can be used to be beneficial for the organization (Adler et al, 2009). Toyota has with their Toyota Production System (TPS) for many years acted as the role model for the modernized view on production, which emphasizes on quality, efficiency and waste reduction. Standardized work is one of the fundamental parts in TPS, and is a powerful tool and a necessary precondition for performing continuous improvement in the production system (Marksberry et al, 2011). Toyota sees standardized work as a tool to maintain productivity, quality and safety at a high level as well as provide the needed foundations for working in the desired takt time and highlight possible improvement areas in the production (Marksberry et al, 2011). To be able remove waste to a large extent in a process the different steps needs to be defined and an accurate way to measure the time and quality of the product is required (Lander and Like, 2007). This purpose is fulfilled by standardized work as it is the preferred way to map and analyze the working processes.

2.2.1 Benefits of using Standardized work

Standardized work is seen as the foundation for many companies' improvement models. Researchers have concluded that standardized work acts as the base for continuous improvements (Adler, 1993; Marksberry et al, 2011), see Figure 2. The cycle illustrated in the figure represents the continuous process of identifying the best practice, standardizing it and then evaluating it in order to find further improvements. Standardized working processes naturally leads to a more consistent documentation of the current processes, which simplifies training and improves organizational learning (Marksberry et al, 2011). Adler (1993) adds that standardization is an essential requirement for learning due to the implication that in order to improve a process, one must first understand it. As the knowledge about the process and each and every step of the procedure are documented and understood it is also possible to broadly take safety into consideration. Potential dangerous step is located and addressed and it is possible to find the working procedure that provides the best ergonomic operation available (Marksberry et al, 2011; Adler, 1993). Since the employees initiates the development, safety and ergonomics is empathized and developed for all kind of available personnel so that the task procedures are appropriate designed for everyone. Assigned together with an appropriate job rotation schedule, this can increase the well-being among employees by declining injuries, leading to decreased absence and improve flexibility to cover for absence (Adler, 1993; Marksberry et al, 2011).

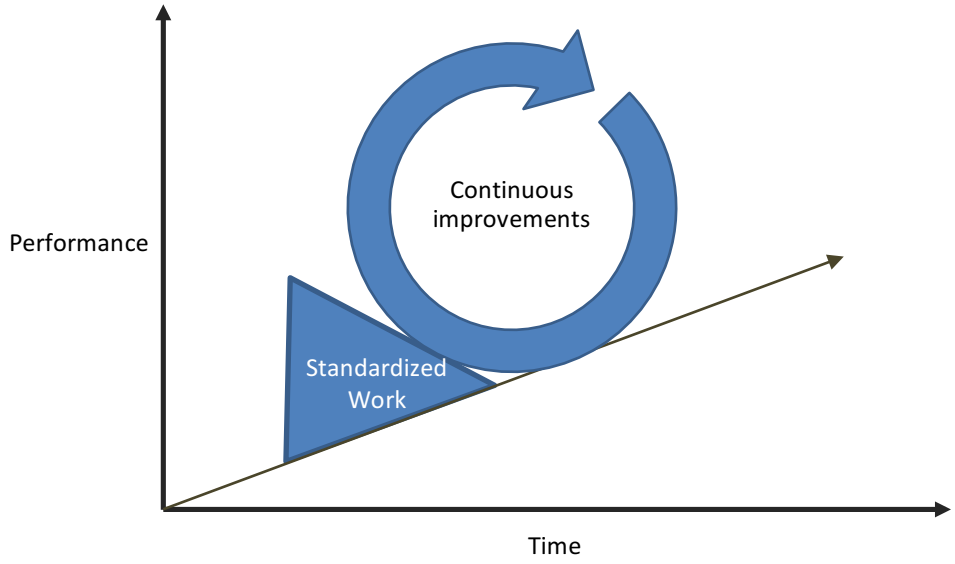

Figure 2: Illustration of the role of standardized working processes.

Standardized work can also be used to achieve increased performance in more measurable hard factors. These factors are usually more easily measured and provide a solid proof for which benefits standardized work can mean for the production performance. For example, as the standardized methods are learned variability in both accomplishment time and quality of performance is reduced (March, 1991; Marksberry et al, 2011). This effects leads to more products being produced and that those produced are of higher quality, leading to higher efficiency and cost reductions (Marksberry et al, 2011). Once a company has successfully implemented standardized work and the procedures have been studied and developed, other improvement possibilities such as better materials and equipment can quickly appear and be addressed (Adler, 1993).

One of the fundamental parts of standardized work is to involve the employees affected by the working instructions and make them the owners of the instruction document update process. This leads to a higher level of self-management among the employees by refining the control structures and will in the long run lead to a reduced hierarchy and need of managerial involvement (Marksberry et al, 2011). This gives control of the development to the people that know the processes best, hence leading to better processes and more empowerment to the work force (Adler, 1993). The team members will become more committed to perform the tasks accordingly to the agreed standard (Adler, 1993), and make better use of the human capital (Marksberry et al, 2011).

2.2.2 Drawbacks and pitfalls of standardized work

Standardizes work comes with a number of possible drawbacks that one need to be aware of in order to avoid potential pitfalls and achieve positive outcome. One important challenge is to manage the perception and ownership of the development of standardized work. Highly exploited standardized work is one theory that fits well with Taylor's scientific management (Adler, 1993). If the standardized work is also developed by engineers autonomously and pushed down on the workers to follow, it will become alienating and probably lead to that the workers opposes the instructions and only follow them while being examined (Adler, 1993). Instead, the process of developing standardized working instructions should be done by the line workers who have the most experience and knowledge about the work (Adler, 1993; Adler et al, 2009). By moving the development of instructions down to the workers who will perform the operations, the workers are motivated by the logic of learning instead of coercion and the organization benefits by encouraging learning, capturing and communicating innovations and supporting continuous improvements (Adler, 1993).

It is important to remember that a standardized way of working is not to be interpreted as the end state of the development of instructions. There is a trade-off between achieving higher efficiency through standardized work and the risk of losing flexibility and the ability to innovate (Adler et al, 2009). March (1991) describes two different ways of learning and developing. The first way is the exploiting way that makes use of knowledge already available and exploits it to an as far extent as possible. The second way is exploration, where entering new previously unknown ground discovers new knowledge. Standardized working processes may affect the organization's ability learn and innovate, and leaves the organization guided by old knowledge, which may cause them to collapse when not being able to adapt to shifts in the market environment (Adler et al, 2009). Further, the focus on routinization of process management tends to favor short-term measures that further leads to exploitative development rather than explorative (Adler et al, 2009). This is supported by Mintzberg (1982), who means that efficiency in practice means the greatest measurable benefit for the cost, and that cost is more easily measured than other benefit, leading to that efficiency often are diminished to a short-term economic viewpoint. One way to handle these trade-offs is to let the workers develop the standardized work instructions in a continuous way, which will lead to higher motivation and self-esteem among workers, better power balance between workers and management and a higher level of achieved explorative learning (Adler, 1993). Preferably, the workers should be cross-trained in the teams' different assignments and should be rotated between the tasks (Adler, 1993).

2.3 Change management

Careful planning of the design and implementation of the pilot need to be conducted. Not only the actual change need to be considered, this is an external process that theoretically can be

implemented immediately, but the internal change of the employees, the transition, is a delicate matter that requires attention (Bridges and Mitchell, 2000). When performing a structural change the people involved are forced to let go of their old ways and enter the so called "neutral zone", this is an uncomfortable phase but according to Bridges and Mitchell (2000) it is vital for the outcome of the project. It is often in the neutral zone that people, when striving to get through it, develop the real innovations and transformations that lead to the success of the entire process; the change program can continue according to schedule but if the transition is not handled with care the entire change initiative may fail (Bridges and Mitchell, 2000). Keeping people informed constantly, including them in the decision making and emphasizing the benefits of the change are factors that help ease the transition (Franckeiss, 2012).

Garrow (2012) compare organizational change and social movements in the aspect of getting the people to embrace a change process in order for it to succeed. In the article Garrow identifies four central parts of each change process that need to exist for it to become successful, they are as presented below:

1. *Values*: ''Framing'' a persuasive message that resonates with individuals' values and experiences.
2. *Identity*: Building a collective identity where individuals begin to feel part of something bigger.
3. *Mobilization*: Coordinating action through leadership, sound organization and providing clear ways to participate.
4. *Outcomes*: Demonstrating improvements from quick wins to longer term beneficial change.

- Garrow (2012, p.254)

In order to get past the neutral zone, engaging all employees towards a common cause is the way to go, thus creating a common value. Agreeing upon the areas of improvement enables the employees to become truly engaged in the common cause of improving these. Involving and empowering the employees into driving the change themselves is a big challenge for all leaders of change, but success here will ease the transition significantly (Garrow, 2012).

For the identity part it is important to make everyone feel included in the project and this is something that Franckeiss (2012) holds as a key reason for success. Having a clear dialogue with all involved employees through active participation and engagement, both in the design phase and in the implementation phase, is a recipe for success (Franckeiss, 2012). Here a stakeholder analysis is useful to identify all the people who are affected by or interested in the change initiative so that these may be included (Garrow, 2012). An introductory meeting or event is useful to make everyone feel part of the movement. Using this event for action planning so that everyone has a clear task or part to play helps the transition, this also helps in the mobilization as everyone gets to participate (Garrow, 2012).

Another important part of the mobilization is that the leaders of change need to accept and recognize their roles and the responsibilities that follow (Franckeiss, 2012). Understanding that it is the transition that might be holding people back and not the change itself is an important realization that the leaders must acknowledge to aid the employees properly and keep the project moving forward (Bridges and Mitchell, 2000). In the article by Garrow (2012) she summarizes many change projects that engaged and empowered the people and which lead to successful sustainable changes.

Considering the mobilization part many of the projects had several structural requirements in common; a board level sponsor of the project, a team focusing on steering the change in the right direction and a leader assigned full time to facilitate and motivate the change work (Garrow, 2012). In addition to this, the successful results also came from external help in form of an initial training before the implementation started on the methodology and theoretical background of the change initiative, as well as external coaching to help solve problems and keep the work on track (Garrow, 2012).

In order for the change to become sustainable and successful in the long run, the outcomes of the project play a very important role. Here both short term and long term improvements are crucial, the former to inspire and motivate the employees and the latter to anchor the changes in the corporate culture (Kotter, 1995). The most important factor for achieving this is to establish key measurements early in the planning state so that these can be followed (Garrow, 2012). Data is needed to identify improvements that have been made, the spread of the changes throughout the company and also the sustainability of the change that has been achieved (Garrow, 2012).

Focusing on the four vital parts of the change process that has been presented above and following the suggestions that are given will most likely aid the process and heighten the quality of the result. In addition to this methodology Bridges and Mitchell (2000) propose a short communication plan for helping the employees passing the neutral zone which should be used as an iterative process throughout the entire change operation, it is called the four P's:

1. *Purpose*: Explain why the change must be done
2. *Picture*: Explain what the situation will look like when the goal has been reached
3. *Plan*: Show a detailed plan of how the implementation process will be conducted
4. *Part*: Explain what each employee can do to aid the process of reaching the goal

- Bridges and Mitchell (2000)

Using the four P's is a very easy way of constantly keeping all employees and stakeholders informed of what is going on, and it will most certainly help ease the transition. Many issues commonly related to leadership, organizational development, or learning may very well-be symptoms of the transition state and these problems can thus be reduced drastically by applying the 4P strategy (Bridges and Mitchell, 2000).

Part I – Empirical Data

3 Introduction: Part I

In this part of the thesis all empirical data will be gathered and discusses. This will provide the foundation for the following parts of this thesis. It will be done by a combination of different methods and will be performed both internally at Wellspect and externally at other organizations.

4 Method: Part I

The methods used in this master's thesis are chosen so that the research questions can be answered as comprehensively and thoroughly as possible. This chapter explains how data was collected through interviews, going to gemba and benchmarking as well as how the pilot project was developed and conducted. It also contains a discussion regarding the validity of the results and analyses in the report.

4.1 Research strategy and research design

The strategy of the research conducted in this thesis is of a qualitative nature as it mainly is based on interviews and observations instead of hard measurements. Qualitative studies are based on the relationship between data collection, analysis and theory and the notion that theory is generated through iterative data collection and analysis; meaning that the theory generation is inductive (Bryman and Bell, 2011). Qualitative research was found to be a suitable strategy for this study as it according to Bryman and Bell (2011) is the most common and suitable form for conducting organizational research and since it is hard to measure the results of enabling standardization and implementation in numbers.

As for the design of the study it was conducted as a case study due to the complexity of the case at hand. Part of the purpose of this thesis is to analyze the current state and to create a methodology of improving it, thus it must include a detailed and intensive analysis of this single case. This is what Bryman and Bell (2011) describe as a case study. In addition to the case study design, this thesis also takes on the design of action research. Action research implies that the researchers work closely together with the employees in the case company and through that knowledge is generated (Bradbury-Huang, 2010). This corresponds well to the fact that the researchers throughout the master's thesis work have been situated at the Lean Support office at Wellspect and that the employees of said department has aided the researchers in their work. The researchers were included in the daily routines of Lean Support and attended weekly meetings and project presentations, this inclusion helped the researchers to better understand the culture of Wellspect.

4.2 Literature study

Initially, a literature study was conducted in the area of standardized working processes. This was done to obtain a deeper understanding of the dynamics of the area and what possible improvements could be expected. Another important aspect of this was to avoid potential pitfalls and better understand the possible dangers. Also, a large emphasis was put on the implementation of said methodology in order to perform this as correctly as possible.

Research was also conducted on the area of organizational structures in order to gain knowledge of the different structures of organizations and the implications of these. This was especially important

for the current situation analysis so that relevant conclusions could be drawn and suitable recommendations could be made. The knowledge of organizational structures and their strengths and weaknesses was also valuable when developing the new methodology and the organizational structure surrounding it.

Furthermore the area of Change management was also part of the literature study as it is vital to not only develop a suitable solution for the problem at hand but also to design the implementation process correctly. This area covered how an implementation process should be conducted in order to get the involved employees to accept and embrace the change and to reduce the resistance for change, this was considered crucial for the outcome of the thesis work.

4.3 Current situation analysis

One of the main goals that were required by Wellspect of this thesis was a current situation analysis. This analysis was important not only for the company to understand how the current state really was but also for the researchers to deepen their knowledge about the problem in order to know what to change, why it should be changed and how it could be achieved. In order to conduct this analysis data needed to be gathered and this is accounted for in the following chapters.

4.3.1 Go to Gemba

In order to get to know relevant people of all levels in the organization and to get a feeling of how things work at Wellspect much time was spent during the initial weeks on guided tours in the different departments. A half-day each was also spent following three different Team Coordinators in their daily work at the production line. These guided tours and work studies provided a lot of useful information that would have been very hard to obtain through interviews or other formal lines of communication (Bryman and Bell, 2011). Working like this is called “Going to gemba” and it means going where the value is found (Suárez-Barraza et al., 2012). Suárez-Barraza et al. (2012) state in their article that going to gemba is useful when trying to define how and why something is done in a certain way and that it therefore is suitable for research on operational management, thus it was used to gather data on how the instructions really were used in production. This is much like how managers use it to identify quality issues or waste that is obvious at the floor but which does not show in the production data (Suárez-Barraza et al., 2012).

The idea of going to gemba is to understand the current situation by watching the everyday workflow with the intention of improving it (Suárez-Barraza et al., 2012). Going to gemba was considered a very useful tool when mapping the current state usage of instructions at Wellspect.

4.3.2 Interviews

A number of interviews were conducted during the initial weeks, both to get a deeper understanding of the organization and its processes and also to conduct research for the current situation analysis. The interviews that were conducted were both unstructured and semi-structured interviews. The first is when the interview is initiated by one or a few questions to the interviewee which is followed by an open discussion or conversation between the attendants, the second is more considered a guide where the researchers have prepared a list of questions to follow, but for each question the interviewee is free to elaborate and discuss freely and follow-up questions might arise (Bryman and Bell, 2011). The interviewees were selected together with the supervisor from Wellspect in order to meet persons with appropriate knowledge.

The unstructured interview method was used when having meetings with people from different parts of the organization to gain an understanding of the different views and perceptions of the current situation. This is according to Bryman and Bell (2011) the most suitable technique when investigating objective views of people and it gave a lot of insight for the current state analysis. These interviews were often performed in connection to a guided tour of some process where the interviewee described and additional questions were asked. As the picture of the situation became clearer the methodology changed to semi-structured interviews with key employees to obtain facts of the current situation and to confirm observations that had been made. This method was chosen as it gives better control over the interview and because it was known how the sought data would be analyzed (Bryman and Bell, 2011). The interviews conducted within Wellspect's organization were documented by taking notes. The interviews were not recorded due to multiple reasons: firstly it was not always practically suitable to record, e.g. in the production area, secondly it was desired to keep a low formality level to avoid the interviewee feeling interrogated, and finally it was always possible to return with further question and clarifications.

The semi-structured interview technique was also used when the researchers had a video conference interview with a specialist in the area of standardized working processes. This interview was conducted to validate the knowledge gained through the theoretical framework and to gain in-depth knowledge of how Standardized Work should be used in this specific project for the best possible outcome. This interview was also recorded, with the interviewee's consent, so that no details would be missed and so that the researchers could focus on the interviewee (Bryman and Bell, 2011). The recorded interviews were not transcribed literally but worked as a backup and a source for validation of the taken notes.

4.3.3 Stakeholder Analysis

A stakeholder is defined by Maylor (1996) as any person or group that has interest in the outcome or the process of the project. The stakeholders of a project can be a great deal of different people both within and outside the organization and the different parties here often have conflicting requirements of the outcome (Maylor, 1996). In order for this thesis to be successful a mapping of the most important stakeholders was considered important so that these could be kept informed of the progress as well as used as a source of information for the project. This gives both valuable input from all different aspects of the problem and also ensures that no one is neglected.

To identify the stakeholders of this project the supervisor at Wellspect helped the researchers to get in touch with many of the different managers and operators that would be affected. In addition to this, and in order to further identify stakeholders that the supervisor might not had considered, the researchers themselves spoke to and identified many stakeholders during the work studies that were conducted at all the different production departments of Wellspect.

4.4 Benchmarking

To gain insight into how delicate and strictly regulated documents like the instructions at Wellspect could be handled, and to investigate possible solutions to the problems at hand, a number of benchmarking visits were made to different companies. These visits were made to see how other companies had organized their working instructions to fulfill their regulatory demands and to see how they worked with standardization of working processes and efficiency in production.

The selection of companies was due to a number of factors such as; the market they operated in, the level of standardization they had achieved, geographical placement, willingness to share information, and if there already were an available contact at the company. Most of the companies that were observed operated under similar conditions as Wellspect regarding high regulatory control, thus the focus of these visits was mainly how the quality compliance was controlled and how regulations were followed. For the aspect of how the instructions could be used to strictly increase efficiency a company in the engine and powertrain industry was also included. Here the focus was to understand how the instructions should be developed in order to make them easy to understand, use and constantly improve.

Before each of the benchmarking visits the researchers prepared a set of questions relevant for the specific company and then had a short meeting with the supervisor at Wellspect so that nothing was left out or forgotten. The structure of the benchmarking visits was mainly a semi-structured interview, followed by a guided tour of the production site to see how the instructions were used. The semi-structured interviews were recorded with the interviewees' consent while the information gathered during the tours was noted. One relevant person from each company was interviewed and the interviewee was chosen by the benchmarked company based on the topic of this study.

To summarize all the data gathered from the different companies in a comprehensive way the most useful data was put in a result matrix. This way it was easy to compare how the different companies worked with their instructions and improvement work. After the matrix was finished each company representative that had been interviewed was shown the compilation of their interview so that they could verify that the information gathered was correct.

4.5 Data analysis

The data collected from the different chosen methods then had to be analyzed and depending on the kind of information and the goal of the information, different methods of analysis were used. Data from interviews conducted within Wellspect's organization was qualitatively analyzed as specific information was sought and the data gathered had to be combined together with data from other interviews to form a holistic view of the big picture. The different opinions and statements were analyzed and verified if needed and then placed as a brick in the puzzle. This was also enhanced and complemented by the information generated from the gemba-visits.

For the benchmarking, the same questions were more strictly followed and the information gathered was written down immediately and recorded for follow-up. The interviewees' answers were compiled and compared to each other, Wellspect's case, and to the literature. This allowed a comprehensive comparison with the ability to take external environmental factors into consideration.

4.6 Validity

For the thesis to have effect and become successful, validity of the results was very important. The researchers thus identified two main types of validity that were crucial, the internal and external validity. The first is whether the theories and conclusions that are drawn from the observations and data gathered is credible and causality can be confirmed, while the second is whether the results found in the thesis can be generalized and applied elsewhere (Bryman and Bell, 2011). As the study was conducted mainly at the Urology Department of Wellspect it might limit the applicability of the results at other parts in the company, thus it was an issue of external validity. The researchers argued

though that if success could be achieved at the Urology Department, which is the single largest part of Wellspect's production, then it could easily be applied at the other production units as well.

As the data gathered in the current situation analysis came from people on all levels and from all departments of Wellspect it was argued by the researchers that internal validity was achieved as the conclusions were made on a multifaceted, holistic ground.

4.7 Credibility

To ensure high credibility of the results was naturally very important. High credibility means that it can be assured that good practice has been applied and that the subjects of the research approves of the conclusions that have been drawn (Bryman and Bell, 2011). To reach high credibility the researchers used a technique called triangulation. Triangulation is used to cross-reference different sources of data to make sure that the conclusions that are drawn are correct (Bryman and Bell, 2011). For this thesis the researchers combined the interview data and the working observations with the knowledge gained from the theoretical study to achieve triangulation and credibility.

Regarding the benchmarking investigation all interviewees were shown the result of their interviews so that they could give their consent, this is called respondent validation and is a practice that can be used to increase credibility (Bryman and Bell, 2011). Triangulation and respondent validation are the two main tools that are proposed by Bryman and Bell (2011) when striving for credibility in a research project.

Furthermore, the use of a stakeholder analysis like the one in this project increases the credibility as it is more likely that all parties that are affected of, or interested in, the project are notified and informed sufficiently and thus have an opportunity to come with input or critique. This has further been achieved through the continuous involvement of, and conversations with, different employees throughout the organization as the thesis work has been conducted.

5 Results: Part I

In this part of the report all results from the data gathering, the benchmarking and the pilot is presented. To begin with all findings regarding Wellspect's organizational structure and document structure are presented in detail followed by a section on how the instructions are designed and handled today. The general improvement work findings then follow before the interview results from the Quality Department and the standardization specialist end the data gathering part. The benchmark findings are then presented.

5.1 Empirical Data Wellspect

5.1.1 Organizational structure

The organizational structure of Wellspect is quite formal and centralized in its decision-making. The Operations Department from the top down to the production is as follows: at top is the Vice President Operations, second level the Director Manufacturing, below that is the Head of Production of the different production areas, the Productions Supervisors of the different lines, Team Coordinators, and Operators.

The production is circulating on up to five shifts, which makes it possible to have the production running 24 hours a day, seven days a week. Each shift has a Production Shift Supervisor who is responsible for the shift's production and work directly underneath the Head of Production. The

Team Coordinators and Production Supervisors work daytime, while the Operators and Production Shift Supervisors work shift time, which follows a special rotating schedule. Between each shift there is a five minute overlap where the ending shift team can hand over information to the next team. This exchange of information is mainly done between the Production Shift Supervisors from each team who then passed on the relevant information to the affected personnel. This information exchange is currently kept to a bare minimum consisting of performance data and present status of the production. Otherwise, the shift teams stay within their own circle and one Team Coordinator implied that they tend to keep much knowledge inside the team. The Team Coordinator said that he sometimes refer to the five different shift teams as the "five sects" due to this phenomena.

The Operators are the generally called productions workers. The Team Coordinators are noticeably experienced Operators who has advanced to a more administrative duty. There is one per line and a major part in their work description is to perform improvement work, handle educational task and perform help with quality compliance. The Team Coordinator is also responsible for updating the instructions and verifying that the ones available in the production are of the correct version. They may also help in the production when other operators are on education or absent because of other causes. The Production Supervisor is responsible for the production outcome of the line and is dealing with things such as production numbers and bigger problems that the Operators and Team Coordinator cannot solve themselves or need to forward further in the organization.

The production in the Urology Department is highly standardized and automated with little manual work and the biggest factors behind down time in production are the manual exchanges of materials and tools when changing product to produce.

5.1.2 Stakeholder analysis

As data was gathered for the current situation analysis an extensive mapping of the company was conducted by observing and talking to the employees. During this process many levels of managers and employees were identified as stakeholders of this thesis work, most with different interests in the project outcome and different viewpoints of the problem at hand.

A stakeholder analysis was conducted to make sure that all possible stakeholders were kept informed and they were also used as sources of information and input for the thesis. The analysis aimed at first identifying all stakeholders so that no one was neglected or forgotten. The result was then used as support throughout the entire thesis work to make sure that all the right stakeholders were informed of the progress that was being made and to enable gathering of input and feedback from the same. The identified stakeholders are as follows in the list below, starting with the ones closest to the instructions and moving up in the hierarchy of the organization. This is also illustrated in Figure 3.

- *Operator*; the operators are the first in line to use the outcome of the thesis. As the outcome is intended to enhance the efficiency focus and shall be used on a daily basis it is important that the operators are satisfied and feel secure with the new way of working. Further, as a step to achieve satisfaction, the instructions should be developed in collaboration with the operators themselves, and enable continuous agile improvements of the instructions by the operators, the operators are important stakeholder that needs to be involved in an early stage.

- *Team Coordinator*; the Team Coordinator is the person who works with the continuous updating of the instructions. Hence it is very important that the outcome facilitates the ease of use as much as possible for the Team Coordinator. The Team Coordinator should preferably be a central part of the development of any new instructions or methods from an early stage and their input should be carefully taken into consideration.
- *Production Supervisor*; the Production Supervisor holds the responsibility for the production and is therefore largely involved in the efficiency and the overall situation at the production. It is also important to gain good support from the Production Supervisor as well as root any changes with him/her in order to reach a successful implementation and change. Also, in today's situation it is the Production Supervisor who owns the production instructions and thereby has to approve changes made to them, although it is the Team Coordinator who works with them on a daily basis.
- *Production Shift Supervisor*; the Production Shift Supervisor share many of the same stakeholder aspects as the Production Supervisor does. However, the Production Shift Supervisor is more concerned over the entire shifts production and is more closely related to their shift and not to any particular lines. This means that they rarely have the same concern for the specific process.
- *Head of Production*; there are five main areas within the production of Wellspect and each of these has a responsible manager, these are called Head of Production. They are responsible for the entire process and report to the Director Manufacturing. As the outcome is intended to improve the efficiency this affects the Head of Operation directly.
- *Director Manufacturing*; has an overall interest of everything in the production, and thereby an interest for changes in instructions and working processes. While not directly involved in the development and improvements of the instructions, the Director Manufacturing has the ultimate responsibility over the production and hence need to be satisfied with the changes made, especially changes of larger magnitude.
- *Vice President Operations*; the Vice President Operations do not have a significantly great interest in such a rather detailed question as the instruction, as long as they do not interfere with the regulatory demands and that the Director Manufacturing is satisfied. However, as the outcome is to lay the foundation for increased efficiency improvement work, the bigger picture is of interest and a good delivery is of course desired.
- *Document Coordinator*; as they handle the routing of the document, the Document Coordinators need to be informed of any changes made and is a valuable source of information and input regarding the current updating process and possible future development of the outcome. Currently they are dealing with the administrative task concerning the instructions and act as the coordinator of the process and hence have a major part in any possible changes of a future method.
- *Process Manager*; the Process Manager has the highest responsibility over the process and is a part of the Production Support Department. In case of a revision of the production the Process Manager is the ultimately responsible if the processes are insufficient. Hence the Process Manager has a big impact on judging process affecting changes and as standardized work in some cases can be considered as process affecting, the Process Manager need to be informed of changes to the current way of working in order to give consent. The Process Manager is always assigned change admin in a formal change request that is considered process affecting.
- *Quality Department*; the Quality Department holds the responsibility that the changes made to an instruction will not risk the quality of the product. This is probably the most important aspect of everything concerning the production as of the possible catastrophic consequences

in case of a major quality failure. The Quality Department is a crucial part of the system that Wellspect uses, and this will not be changed, hence the need of approval from their side cannot be stressed enough. In case of a product affection change the Quality Department becomes the responsible change admin of the change request.

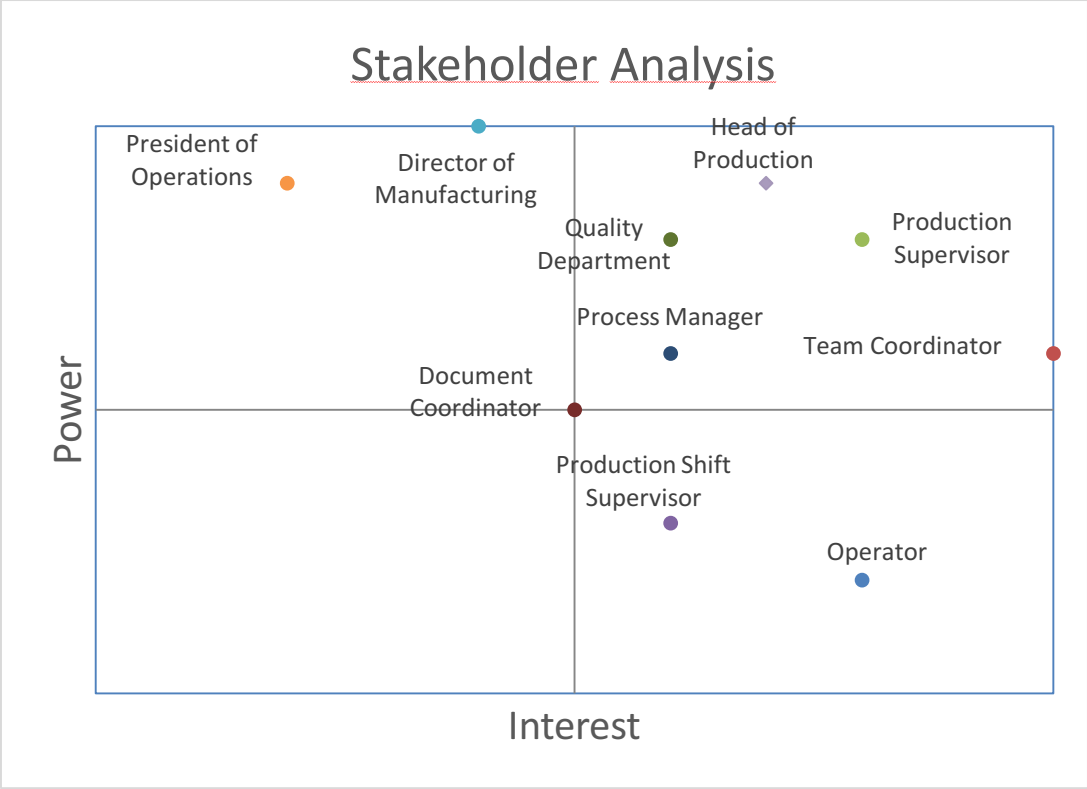

Figure 3: Stakeholder analysis.

5.1.3 The two different document systems: WIP and PDMLink

Currently Wellspect uses two different kinds of systems for managing documents. The first and most general is WIP, which acts as a system for managing regulatory and controlled documents within Wellspect. The second system is PDMLink, which is specific for product data. At the production, the Team Coordinator has to oversee documents in both systems since they may hold different document that are both needed for the production at the specific line.

5.1.3.1 Web Information Platform (WIP)

Web Information Platform is the web-based online platform that is used for many IT-related tasks across the entire organization. The platform is divided into different functions that separately handle general documents, laboratorial notes, equipment calibration systems, among other. For the scope of this research the relevant system is the general document managing system formally known as "WIP Document". Further on "WIP" will imply on "WIP Document", if nothing else is stated. WIP contains documents related to quality, safety, health and environment systems, but also occasionally other business areas. All employees have access to WIP since it acts as the central document storage of many organization-wide documents, but different permissions can be assigned. It also handles document versioning with predefined periodic reviews in order to assure that documents are up-to-date and stays relevant.

WIP works close with the current way of dealing with instructions in the production, where all documents targeted at a process are collected in a binder that is placed close to the station. When a Team Coordinator shall review the documents in the binders they get an automatically generated table of content from the Document Coordinator and compare that to the binder so that it includes every document the table of content mentions, with the right version number. If there is a deviation they must address it.

5.1.3.2 PDMLink

PDMLink was introduced more recently than WIP and is used for storing, managing and approving all product related documents. More specific, PDMLink shall contain information about the complete product life cycle, change processes, and all product and manufacturing specifications. Each product's documentation are to be approved together with its components and specifying documents. PDMLink uses a slightly different structural approach compared to WIP. While WIP is simply a place for storing different documents in different places, like a regular folder structure on a computer, PDMLink works more as islands for each product where every informational document connected to that product is collected.

The intention is that in the future PDMLink shall handle all information about the products and WIP should stop being used. Although, there is currently no time plan for this and WIP will never be fully removed since it contains a big amount of old and important documents.

There are some noticeable differences between PDMLink and WIP that affects the way documents need to be processed. Firstly, PDMLink does not have the same compatibility with the binder-based document handling system used in the production. This is due to its product oriented approach that has to be adapted to the more function-process oriented approach in the binder system, leading to customizations and additional manual work is done in order to achieve this. For example, instead of just printing the supposed table of content with correct documents and versions, the Document Coordinator must extract all available documents associated with the product to Microsoft Excel to filter and remove all unwanted documents, before sending the list to the Team Coordinator in the production. Secondly, expired documents do not automatically disappear in PDMLink like they do in WIP. Thirdly, due to the high license price on PDMLink, not every employee has access to PDMLink. Lastly, PDMLink does not have a function that supports periodical review notifications that WIP has.

5.1.4 Instructions in the production

The current way of handling instruction documents in the productions is to store all instructions for one process in binders that are placed nearby the process. The binders cover topics such as what is to be done at the process' different steps, cleaning instructions, and different settings and calibrations for the machine that are associated with different types of catheters. The instructions themselves are written in accordance to a standardized template that includes a number of topics that needs to be covered. The level of detail varies a lot between different activities and due to its large amount of formalities, even a rather short instruction generate multiple papers.

The production instructions' main function is to describe what needs to be done at the lines in order to reach quality compliance, and by that the regulatory demands. The production instructions are very thorough with much information that need to be followed, but at the same time they are vague in how to do it since if it is stated in the instructions how a particular task should be done, the company must be able to prove that it has been done in that way, in case of a revision. For example,

it can be stated that a component shall be placed in the package in the stated direction, but it will not state how one shall do in order to obtain the right placement. The binders do not have to be located at the production at all; they just need to exist somewhere. However, in case of revision, the production employees need to be able to prove why they are doing as they are and therefore the binders are easy to have available to refer to.

The current general perception regarding the instructions is that they are nested in a complex situation where an update is quite a hassle. The process is seen as slow due to the many steps it has to pass and confusing due to the non-obvious restraints on changes. The auditing process performed by the Quality Department and other concerned people is often mentioned as the bottleneck, and further the reviewers often comes with objections on the changes.

5.1.5 Current document update approval process

Today the process of updating an instruction used in the production is a long and slow process that needs to pass through a number of instances for approval. Which instances that are being included in the approval process depends on the level and kind of product impact the change will cause. Below a common scenario of a production instruction update process is described:

The Team Coordinator finds a gap in the instruction document that need to be revised. He or she makes the necessary changes in the instruction and sends the document further to the Document Coordinator.

1. The Document Coordinator who handles the routing of the document receives the new version.
2. The Document Coordinator first sends the new version to the Production Supervisor who has to review it and formally start an issue for updating the instruction.
3. Then the Document Coordinator starts the review process and sends the document to all instances that need to review it. These instances are “people with relevant knowledge”, usually functions that could possibly be affected by the change or have a saying in the matter.
4. All involved reviewers must approve the changes before entering the next stage.
5. Finally, the Document Coordinator receives the newly approved instruction and locks the document routing, prints the instruction and distributes it to the Team Coordinator for implementation in the production and insertion in the binder.

5.1.6 Improvement work today

There is currently some improvement work performed continuously in the production. These efforts are currently fairly limited and have according to the Team Coordinators decreased in frequency as problems in the production have increased. Most visible of the improvement work is the improvement boards located at the production. The function of the boards is that a shift team can propose an improvement by writing it in their area of the boards. Then each shift team can give their comments and point of view about the improvement proposal. The boards are used to varying degrees on the different lines, much dependent on how many emergent problems there are and on the degree of emphasis the Production Supervisor puts on this work. For example, at one line the work with the improvement board has not been started as they have been forced to deal with the many emergent production breaks instead.

A couple of years ago Wellspect tried to increase the outcome of their improvement work by initiating a program to reward suggestions for improvement that led to an implementation. This reward was totally based on financial incentive as the production workers gain an additional cut in that month's salary. The program initially led to an increased amount of improvement suggestions but a after a while the quality of the suggestion declined and some used it solely for the increased salary and not for the improvement itself. The program was later canceled as a change of direction to the current state where work with improvements is considered as a part of the ordinary working tasks. This cancellation lead to a decreased number of improvement suggestions and some workers refer to the old situation as back then one at least got rewarded for making improvement suggestions.

There is no clarity today in who actually is responsible for driving the improvement work. On some lines the Production Supervisor drive this work, but this is mainly because they have a personal wish to improve and take responsibility. On other lines this work is not so eagerly done, which has led to a large diversity in how the different lines work with improvements and also in how much they do it.

At Wellspect there is currently dedicated software available for evaluating processes named AVIX. The core function centers on video recording the process and then analyzing the different steps. The purpose of this is to get a comprehensive picture of the current way of doing it to be able to provide possible improvements or changes. The software is successfully used at Wellspect's Surgical Department but at the department this study is conducted at the usage is far less widespread. It has been used successfully in some events but the everyday usage and the normalization of using the tool is not accomplished.

5.1.7 Alternative solution of the Surgical Department

The problem with lengthy and complicated document reviews and updates has been identified at the Surgical Department of Wellspect as well, and here the Production Supervisor and the internal improvement teams have come up with a solution that fits their situation. This solution builds on the creation of a lazybone-instruction that can be tested in production for a period of time without changing the real instructions and thus avoiding the reviewing process that otherwise would be needed. The creation and management of these lazybones are done by the improvement groups that are in charge of the different areas of the production and who meet every third week. As every operator of the department is involved in at least one improvement group, and as there only is one shift working at the Surgical Department, all employees are kept informed of the changes that are on trial and of the lazybone content and purpose. Every third week, at the improvement group meetings, the outcome of a lazybone is discussed and if more time is needed for evaluation then the trial period is extended for another three weeks. If there is a result of the lazybone trial at hand then the improvement group decide whether the change was something that is desired to keep or if it should be discarded. If it is decided to be kept then the change is written into the production instructions and sent for review in the formal change process.

Another use of the lazybones that has been utilized at the Surgical Department is to write instructions that are not affecting the process or the product, e.g. how to arrange all material at the station before starting the assembly. The purpose of these lazybones is to make sure that all stations always look the same with the correct material at hand so that the operators are familiar with the set-up when they rotate to a new station, all to improve efficiency.

5.1.8 Potential for changes

As previously mentioned all work at Wellspect is conducted strictly according to the rules and regulations that are present. The Quality Department is responsible of making sure that the rules, regulations and quality measurements are met. Hence it is demanded that any change to the working procedures are accepted as within the boundaries by the Quality Department.

The reasons for the rigorous audits that are performed are that in order to sell the medical technology products that Wellspect produce, certain quality requirements need to be fulfilled. In Europe there is a document called ISO13485 that when fulfilled gives the products a CE-mark which shows that all products are produced according to the quality regulations that are at hand. Regarding the business in USA the Food and Drug Administration (FDA) demand that a quality document called QSR820 is fulfilled, if not they can withdraw the permission to sell the products in USA immediately. Failure to fulfill the ISO-document would result in a similar situation in Europe, thus fulfilling these requirements are essential for the entire company. This has led to all documents being strictly controlled and all changes have to go through the Quality Department's audit process, thus the change process of instructions in the production of Wellspect is seen as slow and inefficient.

The actual rules that are in the ISO and QSR documents are quite few and vague, the regulations that are made to follow these rules are created by the Quality Department in order to keep the production within the boundaries. Thus there are big possibilities to improve the processes of the document handling system as it is the regulations that are the limiting factors and these can be changed.

The most important aspect that is controlled in a revision by FDA or BSI (for the European market) is "Document Control", which means that it can be proven that everything that is said to be done has been performed accordingly – for the last five years. Each operator that works in the production must always sign that they have followed the exact instructions in a computer system called PING after each shift, and this is the only way of controlling it. This system is also important for the traceability of each product in case of a faulty product.

It would be possible to add efficiency instructions to the existing instructions. For example, adding a page to the production instructions containing only information of how to execute the steps for highest possible efficiency is doable, however it would require a change in the document controlling what can be in the instructions. The updating-process of the instruction including at what level a change need to be approved is also a creation of the Quality Department and can therefore be adjusted accordingly. However, the instructions that are affecting the quality or physical outcome of the product cannot be adjusted.

In order to let, for instance, the department manager of a production line approve a non-product-affecting change to the instructions it must be certain that this is the case. This creates an issue of moving the responsibility down to the Team Coordinator who is the one writing the change and thus have to be the one who determines whether the change need a Quality Department approval or not. The biggest difficulty is to decide what is product-affecting or not. It would be possible to print and distribute separate instruction that only contains the steps to be performed to all working stations of the production line. If done, it must then be incorporated in the working description of the Team Coordinator that when an update of instructions is conducted, the separate instructions at the working stations must also be updated and changed.

5.2 Interview with a standardization expert

In order to gain valuable insights and to validate the findings made, an expert on standardized work was interviewed through a video conference. The interviewee has over 20 years of working experience within the production industry and five years of experience from the medical technology sector. Four years ago he started his own company through which he hold educations, work as a consultant and he has also written a best practice book on 5S. He is currently writing a book about Standardized Work as he found the available literature scarce and too focused on the vehicle industry, thus he was found to be a reliable source and a valuable asset for this thesis.

The general wins that can be made through standardization is according to the interviewee that it enables improvement work that otherwise might be hard to achieve. Moving the ownership of the instructions down to the operators create a natural cycle of improvement as they are in charge of updating the instructions that control how they work. When asked about the biggest challenge in implementing standardized work he answered that it is to make the managers let go of the control over the instructions and let the operators and their nearest supervisor handle ownership instead.

The most common mistake made when attempting to create standardized work is according to the interviewee when leaders and management do not recognize their new role; that they need to work closer to the operators and train them in the new ways. They need to take a big responsibility and all levels in the hierarchy need to be educated in the new methodology to make the change sustainable.

When asked about the situation of this thesis he said that it is important not to create more instructions when standardizing the process as this would lead to more parameters that need to be controlled regulatory. This is hard to achieve but it is important to bear in mind. As the document updating system is rather time consuming at Wellspect today, it might be necessary to change this in order for standardized work to be successful as it builds on continuous updates of the instructions. One way of achieving this might be to adjust the level of audit for different types of instructions, for instance those that do not affect the outcome of the product might not need an audit by the Quality Department. Moving the audit responsibility down to people working closer to the operators also increase the sense of ownership over the documents, which further boost the eagerness of improvement work.

The current situation with all instructions gathered in a binder is a necessity according to the interviewee, but he also emphasized the need of visualizing the instructions at each station for the changes to have any effect. Having for instance a computer screen at each station showing the instructions color-coded would visualize both the instructions and the changes that has been made in a very efficient way.

As most of the production at Wellspect is automated, the manual processes are most likely less controlled by regulations according to the interviewee, thus large gains can here be achieved through a standardization of the working process. If time measurements are needed then the operators themselves should record each other in order to de-dramatize the experience.

In order for the outcome of this thesis to be accepted in all levels of the hierarchy the researchers must begin by creating a concept that they believe in and then they must anchor this among the top management, this is key according to the interviewee. This should be followed by an introductory education for all employees and managers who then also participate in workshops or pilot projects.

The interviewee ends these recommendations by emphasizing the need of not only training all personnel in the new methods but also in the new standards.

When asked about the differences in standardized work between the vehicle industry and the medical technology industry the main differences according to him was that the processes are harder to change in the latter as the regulatory constraints are higher. Though, the fact that the vehicle industry is more efficient in developing and applying standardized work might also be due to the fact that the competition in that market has been higher and the market demand more volatile, thus it has spurred the development of standardized work. The expert does not see any barriers in applying the same tools and methods in the medical technology sector as in the vehicle sector but rather that the biggest challenge lies in having a Quality Department manager that is willing to think new regarding quick changes and moving responsibility down in the hierarchy.

To conclude it all, the interviewee emphasizes once again that the key for success in implementing standardized work is to give ownership over the instructions to the operators and their closest manager. The people working by the instructions must feel that it is their instructions and thus it is their responsibility to improve them. Standardization led from the top decreases commitment and gives a feeling of being controlled rather than improving something.

5.3 Benchmarking

The first company that was visited is a global medical technology company located in the Gothenburg area. The company is world leading in their area and operates under similar circumstances as Wellspect regarding clean room production and strict regulatory control. The production at this site was run on day shift only and the company is called Company A in the result matrix presented below in Figure 4.

	Company A	Company B	Company C
How large is the production at this site? (employees/shifts/volumes)	~10 operators per productions line, three lines, only dayshift	One 8h shift with two different lines. 20.000 devices per year are produced.	~140 operators managing two lines, day-shift only. 30 engines per day are produced.
Do you have a vision/model for improvement work?	Large focus on Lean through management educations and lean workshops for operators. Vision is well anchored at top management with a purpose of improving while things go well instead of when things go bad and you are forced to. A lot of effort is put in giving the improvement work a positive feeling, to emphasize that becoming more efficient is so the operators get a better position, not to cut down on employees.	There is a project model that everyone is supposed to follow but there is no system for continuous improvement within the product development. No clear improvement vision. The focus of Company B is to produce mature products directly instead of improving as it goes, this as their business model builds on launching new products to the market often.	It is very clear that they must improve to survive. To inform all employees they shut down the production one day and held a Kick-off. At this kick-off the top management presented a three year plan of concrete goals and how to get there, two weeks later each department had a follow-up meeting discussing departmental goals. Every team has a daily meeting going through the results of the day before for follow-up.
What is the largest problem/obstacle in the improvement work?	Getting everyone aboard! It is easy to go too fast and thus not getting all the employees with you on the change.	70% of all production stops are due to material failure. Despite this, many project leaders think that DFA is time consuming and unnecessary, the interviewee argues that he *gives* time due to reduced amount of failures but this is hard to get through. At the Gothenburg site DFA has become an integrated part of the product development process, although it is not yet a part of the international standard way of the company.	The hardest part of the improvement work is to get everyone to join the movement, it is easy to agree on changes to be made but it is harder to get everyone to actually act accordingly. This is especially true for standardized work.
How is the update process for instructions?	The production manager and 1-2 operators per team are authorized to initiate a change of a document. The document is then unlocked and the change is written, an explanation of why it was needed and what was changed is recorded. The document version is updated automatically and the document is signed before it is sent for approval. The quality department and the affected department manager are the ones who must approve the change, if it is not approved then the process iterates until approval. All printed instructions at work stations are stamped and recorded in the system so when a change is done the systems notifies how many copies must be replaced. After the change is approved it is up to the production leader to inform the operators.	The one responsible for the daily updates and controls of the instructions (mostly a production technician) gather opinions from the operators, then the change is made. All operators have to look through the document when a change is made, study the change and then sign that they have noted the change. The standard operating procedure is for all operators to look through the binder with instructions every time the sit down to start working, if there is a change they then sign that they have noticed and understood.	When the team agrees on a change they can write it by hand on the instruction document and then this change applies for all operators until a new version with the change is printed. This works as all employees of the team has to agree on the change before it is written on the instruction, this is handled at the morning meeting of each day. Then, the resposibility for the doucments are splitted between the production manager and the technician form Production Technology. The technician is responsible of having correct and updated instruction available, while the production manager holds the responsibility that correct and updated instructions are available at each working station.
How many people are involved in the process?	The department manager and a person from the quality department are always required to approve of a change, but if it is a large change that affects others then these would be contacted as well, there is however no real structure of these issues.	The process owner and the team leader. Quality department can be involved if it is a big change affecting the design or the assembly.	The team members discuss and make changes, the Production Technology technician is in charge of printing new instructions and keeping them up to date and the production manager ensures that the latest version is available at the working stations.
How often are changes scheduled?	Once a year every instruction must be updated.	They are checked about once a month initially but the intervals get longer as time goes by. There are no set intervals for updates of instructions.	No decided interval, but in reality a check-up is made every 1,5-2 years.
Who owns the instructions?	Each document is owned by a specific person that is in charge of the status of the document.	Production support department owns all instructions and it is also them who conducts all the changes.	Each team owns their documents and is responsible for the changes of how something should be done or the order of which the steps should be performed. The Production Technology department owns the step times, the properties and the document codes (WES-numbers) etc.
How are the documents structured?	Clear instructions, step by step. Three columns: *Step*, *Info* and *Important aspects*. Four types of important aspects: Q = quality control, K = critical aspect, V = variant specific and ! = safety. All personnel sign that all steps have been performed in a correct way, important parameters are signed individually while more simple steps can be signed as a group. The instructions are printed and put up on the wall at each station. In the instructions there can be references to larger and more detailed documents regarding machine parameters etc. In the information column takt time and step times are shown.	It is desired to have a *why* something is done in the instructions but it is hard to fit in for all steps, so it is mainly a *what* and *how* said steps are done. It would be preferable to have a clear description of why everything is done the way it is in an educational instruction. The interviewee would like to decrease takt time of the production in order to divide the work into more stations with less instructions at each station, that way the work can more easily be standardized and thus the quality outcome is easier to control (standardized instructions, predictable work flow, pull not push etc).	Each station has an OIS-instruction (SOP) that says which steps are to be performed, which order to perform them in and what time each step takes. Each step has its own code which is tied to a more detailed instruction of that precise step, a WES-instruction (work element sheet) which describes how and why each part of the step is performed. The WES-instruction is structured as *Activity - How - Why* and always has a picture of the step, these instructions are used as education when someone is new and also if there is a problem with quality compliance.
What is the general opinion of the document system today?	Very good! An instruction that earlier was ~14 pages of text now can be around 2-3 pages step-by-step instructions. Also, the current system has fewer steps to sign which also is positive.	No problem at all among the operators as they do not see the system, only the changes that occur.	As the operators themselves handle the updates and the update process within the teams they cannot complain.
How visible and accessible are the instructions?	Printed and posted at each station!	They are kept in a binder at the station, as there are four or five different products being produced at the same station there are instructions for all of them in the binder.	At one line the instructions are printed and posted at each station while the other line have digital instructions on touch screens. The digital instructions need to be cleared before the product can continue to the next station.
What is the average lead time of a document change?	Hard to say, if it is an important change then you can follow the document in all steps and push the process between each agent. This way it goes vastly faster than otherwise.	It is quite short as the ones conducting the change are close to the ones reviewing it in the organization, they are both part of Production Support.	From one day to two weeks, depends on the technician (Production Technology) in charge of the change. Faster if they are not involved, then the operators just do the change manually and inform the production manager so a new document can be printed.
How much are the instructions used?	The operators have been part of developing the instructions and they know where they are, but they do not look at them regularly while working.	The operators know the instructions by heart and do not look at them regularly while working. Look through the instructions to see if any changes has been made when the shift starts.	The ones working at the line with touch screen instructions must check each step that it has been performed. The other operators have helped develop the instructions and know them by heart so they do not look at them regularly while working.
What incentives are there for improvement work?	Nothing concrete, focus is on explaining the benefits of improving and how it will affect their working environment positively.	Earlier there would be an improvement meeting if an employee came up with an idea so that it could be discussed, this is not done today. The production leader and the team leader are not that engaged, they have more of a "Do things right" mentality. It is up to personal interest to drive a change. Head of Operations has identified changes as costly, so there is a resistance towards too many changes from above. No improvement meetings are held regularly where input is gathered.	To reach one's goals everyone must strive to become better. This is important especially considering the current situation for the company. If it is made visible how everyone is performing everyone will work harder to become better.
Is it controlled how much the instructions are followed in the daily work?	It is not controlled today. It would be preferable to do it but it is the case today. "*Should be checked more often by the work leader both to see if someone has developed a better way of performing a step and to see if the instructions are followed at all.*"	There is a controller in production who observes so that everyone follows the instructions and also take measurements of the machines so that they are accurate enough. This person is part of the production team and focuses solely on the quality aspects.	During training of a new employee the coach is responsible for steps being conducted correctly but after the employee has been trained properly the responsibility is on the individual. At this stage there is no follow-up control unless it is needed out of quality concern.
How is quality compliance ensured in production?	Every operator signs the steps that are performed to ensure that everything has been done according to plan.	Each station has a touch screen with the most important quality aspects of an operation, these aspects must be checked before the part is sent to the next station otherwise the next station cannot continue working on the product. The production of Company B is not as thoroughly controlled quality wise as Wellspect as it instead has a 100% control of all finished products. This means that all steps of the production does not need to be validated, instead the control process of the end product is a validated system. This also shows by looking at the takt time vs. quality control time, every 4.5 minutes a new product is finished but the quality control of that product takes 10 minutes. To cope, four quality control stations operated by one operator are running simultaneously.	After a certain amount of steps each operator must sign that they have been performed, it is also signed if there is a change of operator. These signatures are used for follow-ups if needed and are vital to investigate if a quality problem is due to the process or the individual. The most important processes of a certain department are controlled within the team once a month by a member of the team (by a rotating schedule), once a week by the team leader and within 3-4 months by the production leader and other managers.

Figure 4: Benchmarking result matrix.

The second company, called Company B in Figure 4, that was studied is also a medical technology company located in the Gothenburg area but it is part of a global world leading consortium. This production site differed a bit from Wellspect regarding clean room in production but the regulatory demands were similar. The control process of the end products at this site was very extensive.

The third and last company, Company C in Figure 4, is a world leading manufacturer of engines and powertrain solutions. This company has less regulatory control from external authorities compared to Wellspect but the purpose of this benchmarking visit was to see how they have worked with efficiency optimization within production. This company is currently in a situation where they must improve significantly each year to keep production at the current site, thus there have been extensive developments of the instructions in order to optimize the outcome as much as possible.

The results from the three benchmarking visits are presented in the result matrix (Figure 4) below, here the most important questions and rewarding answers have been gathered to show the most significant findings and compare these to the other companies. The complete answers to all questions can be found in Appendix A-C.

After the result matrix was compiled each interviewee was sent the column containing the information gathered from them to let them validate the information, all interviewees have thus given their approval that the data presented is valid.

6 Analysis: Part I

6.1 Current Situation Analysis

This section aims at using the knowledge gained from the theoretical study to help analyze and understand the results of the empirically collected data. Current methods and systems of Wellspect will be analyzed based on their benefits and drawbacks to further evaluate improvement areas and existing success factors.

A general analysis of the organization as a whole will start this section followed by an in-depth study of the organizational structure and the document handling system of today. Drawbacks and problems that have been observed are then presented and a SWOT-analysis ends this section as it sums up the situation (SWOT stands for Strengths, Weaknesses, Opportunities and Threats).

6.1.1 Organizational structure

To understand today's situation and how it can be improved the organizational structure at Wellspect was studied. As was described in the theoretical study there are different structures that are suitable for different business situations. One that stood out as the most suitable for the situation at Wellspect after looking at the results of the data collection was the one called Machine Bureaucracy. It builds on a business that is very formalized and standardized in its production and has large units in the operating core performing routine tasks (Mintzberg, 1980). This is very much the case at Wellspect as the rigid regulatory control requires a stable environment resulting in a very standardized production. Mintzberg (1980) state that Machine Bureaucracy often is found in mass production companies where a high level of standardization is applied and where line and staff are separated. Much of the power in organizations like these also lie in the technostructure where the analysts are found, that is because of the extensive rules and regulations that are constraining the decision-making process (Mintzberg, 1980). Again, this corresponds well to the situation of Wellspect

where the analysts are represented by the Quality Department which are responsible for quality compliance and thus have the last saying in these issues.

Machine Bureaucracies are often found in environments that are stable and simple so that the production can be standardized and more easily predicted, furthermore to obtain this stability large resources are also often put in the support services to ensure autonomy (Mintzberg, 1980). The situation at Wellspect can be considered both stable and simple as it is a mature company with much experience and an established position in the world market, while the production process at the Urology Department mainly consist of simple assembly lines. Another aspect that Mintzberg (1980) said characterizes a Machine Bureaucracy is that high external control drives the organization towards a centralized and formal structure. At Wellspect this is true regarding the structure and it might be due to the fact that Wellspect always has been owned by another larger company. In general, Mintzberg (1980) says that companies associated with Machine Bureaucracy tend to be mass producing firms with high demands on security and safety, which is exactly the case at Wellspect. The quality control has historically proven to be very high throughout the revisions performed by different authorities such as FDA and this is largely due to the organizational structure with much power in the Quality Department.

All in all, it can be argued that the organizational structure of Wellspect corresponds very well to that of a typical Machine Bureaucracy. All from standardized working procedures in the production to analysts having much power due to regulations, from a centralized and formal structure to a stable and predictable process, it all fits the organizational structure described by Mintzberg (1980). The conclusion that can be drawn here is that Wellspect has a most suitable and fitting organizational structure for the business and the situation that the company operates in. This implies that the difficulties in handling the working instructions and the inertia surrounding the change procedures cannot be blamed on the organizational structure. Thereby, the strengths in the organizational structure should not be considered for change but instead be used for the benefits it provides.

6.1.2 Document handling system

The process of updating the instructions today is quite extensive and it makes no difference which kind of update or change that is being made. As was earlier described in the result section, the instruction need to go through several steps and thus it must be sent back and forth between different instances several times before it can be updated in the binder in production. This procedure gets an unnecessarily long lead time as it consists of several deliveries being made between several people. The more people that need to take part and be involved, the less disturbance is needed for the total lead time to become noticeably longer. Here is a large possibility of improvement in the future. If a change in instructions affects the quality or the outcome of the process then it is important that this rigid quality control process is applied, but if the changes are due to e.g. ergonomics or efficiency then the change could be revised and approved within the department to reduce lead time. This was identified as an area of improvement and it is also something that the Head of the Quality Department verified as being possible to change.

In addition to a reduced lead time for efficiency changes, a second hand effect would most likely be that the total number of change issues sent for revision in the organization would be reduced. This could lead to a reduced lead time for the revision of product or process affecting changes as well.

A further topic regarding the process of the instructions is the question of ownership. Today the instructions of each production line are owned by the Production Supervisors, but all changes made to the instructions are done by the Team Coordinators who handle all the work with the instructions. The Production Supervisors never really use the instructions or hear what the operators think of them, the Team Coordinators are the ones closest to the line and thus the ones who get all the direct knowledge of how the functionality of the instructions are. This can be an obstacle in the improvement work that builds inertia and causes delay. According to the standardization expert that was interviewed for this thesis, an important part of enabling standardized work with continuous improvements is to give ownership of the instructions to the operators and their nearest managers - the Team Coordinators. Doing this would most likely lead to an increased eagerness to participate in the improvement work from the employees due to increased responsibility. Thereby, a change of ownership of the instructions is something that could make the process more agile.

Today all instructions for a production line are gathered in different binders which covers the specific process. They are separated according to which type of documents they are and the binders are all gathered at a specific place in the vicinity of the production line. This system builds on the idea of having total control of all instructions so that they always are up to date and correct. Another observation that was made regarding the instructions was that they often were vague in their descriptions. This is due to the need of being able to prove that all details in the instructions have been followed in case of a revision, thus most details are left out and instead they refer to some other document containing all data. The instructions mostly contain just enough information of what needs to be done but not how they should be performed for best possible outcome. The backside of this configuration is that there are no instructions at the specific working stations and that the operators therefore seldom use the instructions as they are both far away and also rather vague. This lack of detailed information in the instructions also means that there is no knowledge of the process time and the exact steps of a process; this is information that for example could be used to measure the efficiency of an improvement but which is not available at the moment.

6.1.3 Alternative solution of the Surgical Department

At the Surgical Department an alternative solution to the reviewing process was developed. It consisted both of a trial period of improvement suggestions before changing the production instructions and the use of the lazybones to set working standards that do not affect the product or process. This was looked at to see if a similar solution would be possible to use at the Urology Department. A big issue that was identified early was that the system with improvement group meetings every third week is not practiced at the Urology Department as the organization there is much more complex. In the production of the Urology Department there are up to five shifts rotating to keep production up at all times, therefore it is impossible to have operators from each team in a common improvement group. Using this structure would then mean testing changes without the possibility of making sure that all operators are informed and involved in the process, which could become a problem.

In addition to this, one of the main purposes of this thesis was to create a method for standardized working processes, and a big part of that is to constantly evaluate the processes, find the best way and make that the new standard. This builds on incremental improvements that are conducted continuously. Thus, one of the biggest obstacles that needed to be handled was that of the long and complicated reviewing process that each change needed to go through. The use of lazybone-

instructions to test and refine a change in an instruction before starting the reviewing process does produce better and more thought through changes but it does not reduce the lead-time of getting it approved and conducted.

6.1.4 Drawbacks and difficulties of today

The organizational structure of Wellspect combined with the strict focus on quality compliance has led to the production lacking an efficiency mindset that is vital. Today all focus lies on creating products with the highest safety possible and having processes that are controlled strictly enough so that they pass a revision, little focus is on being as efficient as possible. This is contra productive as increased efficiency can be achieved while quality compliance is maintained, therefore it is something that should be part of the improvement work mindset of all employees. Also, some interviewees implied that it is easy to lean back and blame the strong regulatory demands for the low efficiency mindset while it may instead be that people are afraid of stepping outside of the comfort zone. A solid efficiency mindset is the foundation for continuous self-initiated improvement work and is important in order to get the routine rooted in the organization.

The lack of efficiency mindset in the improvement work and the low focus on efficiency over all is further indicated by the fact that the AVIX system is rarely used. This tool is a very good way of analyzing a process to see whether it is performed in a time efficient manner or not, and it can also be used to identify the best way of performing the steps of the process. The tool has been proven successful in the Surgical Department of Wellspect where the usage is more extensive. AVIX is a great asset and using it could be a big opportunity to better understand the process and which efficiency wins that could be made.

During the work studies and guided tours it was observed that the main factors behind production down time were the material changes when something ran out or when the materials and tools needed to be changed as the production switched from one product to another. These factors are manually handled and can benefit greatly from a standardized way of performing them; this is seen as a big opportunity to contribute to the efficiency of the production by reducing down time.

Today there is no clear distinction on whose role it is to drive the improvement work in the production. Even though it can be argued that the current system actually produces improvement suggestions regularly and that it has worked for many years, it is important to determine whose role it is to see to that it is done. The system of today builds on the personal initiative and drive of individual Team Coordinators or Production Supervisors, but in case of them being overrun by work or distracted by other things the improvement work may be forgotten or pushed aside. It should be clearly stated whose responsibility it is to drive the improvement work of the production line and how this should be followed up, otherwise possible improvements might fail due to no one taking responsibility for the job. This is very important to address in order to achieve a sustainable long-term solution that will lead to a successful outcome.

From visiting the production and talking to Team Coordinators a knowledge gap concerning WIP and PDMLink was identified. To some it was unclear why two different systems are needed and the perception was that PDMLink is not as handy due to the limitations in permission for operators. From the interview with a Document Coordinator the differences and underlying reasons for them were described clearly but it is inappropriate that the reasons for such a change of system is not

communicated clearly enough. The shift of system itself is motivated but the shortcomings in communication create unnecessary confusion about topics that should not be an obstacle.

Finally, as the previous way of encouraging improvement suggestions with financial rewards led to a skewed motive for working with improvements, the suggestions became a way to increase the salary instead of a way to improve the production. The reversion of this approach led to a decline of improvement suggestions that is not yet recovered. While the change of direction was necessary the inevitable downsides should be considered as a lesson learned. The incentives driving continuous improvement work should be the benefit of improved learning, safety and self-development that will be achieved by improving the working methods and the environment (Adler, 1993).

6.1.5 SWOT-analysis

To summarize the current situation analysis all found topics and conclusions were put in a SWOT-analysis. This tool helps visualize what aspects are the strengths of the current situation, what are the weaknesses, what opportunities can be found and what threats should be avoided. The resulting analysis is displayed in Figure 5 below.

Strenths

- High quality control
- Suitable organizational structure
- Proven valid in case of revision

Weaknesses

- Instructions not looked at/used
- All instruction placed away from stations
- Unknown process time and exact steps
- Lack of efficiency orientation
- Low detailed instructions on how to do tasks
- AVIX available but not used

Opportunities

- Create efficiency instructions that can be updated within the department
- Increase participation in updating the instructions
- Fewer document changes needing review → remaining changes handled faster
- Anchoring of efficiency mindset and making changes easier lay the foundation for standardized work and continuous improvement
- Majority of downtime on manual tasks → improvement potential
- Start measuring time of steps and processes to increase efficiency and knowledge of the process

Threats

- Slow update process
- Conservative quality stance
- Insufficient document ownership
- Confusion concerning the two document systems
- Common attitude that Q department is rigid
- Quality assurance overweighs efficiency
- No assigned responsibility of driving improvement work

Figure 5: SWOT analyze of the current situation.

6.2 Benchmarking

To gain insight and inspiration in how to tackle the problems of this thesis a number of benchmarking visits were made. Two of these visits were to companies in similar situations as Wellspect regarding

production, regulations and market situation and the third was to a company under high pressure using standardized work as their key concept for improvements in order to survive. The interview answers from the benchmarking visits are presented in the matrix in the Result-chapter (see Figure 4) and the analysis for this thesis is as follows.

Whether having similar or non-similar market situations, all of the benchmarked companies were only using day-shift for their production and they all had lower volumes of produced products yearly than Wellspect. This is important to remember when considering their methods and procedures as this means that the organization is significantly smaller and thus information is more easily disseminated.

When asked about a vision/model of improvement work companies B and C had no clear outspoken idea of how it was to be conducted. Although, as company C operates under very clear conditions that if they do not improve they will not survive, they have launched a big scale improvement effort involving all employees over a three-year plan, but this is not considered as a vision/model. The interviewee of company A said that there was a big focus on continuous improvements and Lean through management educations initially, and that the vision is well anchored among the top management with the purpose of improving while the business still was going strong. The conclusions that can be drawn of these answers is that in order to avoid the situation that company C is in, where improvements are forced in order to survive, the strategy applied by company A is desirable.

Looking at the answers of what the largest obstacle is, it is clear that participation and commitment is the biggest issue. Both company A and C stated that getting all the employees to join in on the movement is the hardest part, whereas the interviewee of company B talked mostly of the misunderstanding that early conducted improvement analyses was time consuming when it really meant less time fixing the processes later. The conclusion here is that the biggest obstacles mostly are resistance of change and poor communication. This corresponds well to the theoretical framework where it is stated that in order for a change process to be embraced by the people four parts are central, one of which is to create a collective identity so that all individuals feel part of something bigger (Garrow, 2012). Achieving that means everyone becomes committed and clear communication is a way of getting there.

All of the three companies that were visited had different methods for updating their instructions and they differed a lot. Company A had a method similar to the one that Wellspect applies today while the process at company B was handled entirely by the production technicians. In company C the production team agreed upon a change when it was found necessary and then this change was written by hand on the existing instructions. The conclusion that can be drawn here is that no best practice seems to have been identified so far. The same can be said about set intervals between updates, company A updated all documents each year while company B checked the instructions much more frequently at first but with a decreasing frequency as time went by. Company C stated that they had no set interval but in reality each instruction was updated every 1.5-2 years. It is hard to derive a best interval from these answers but it can be concluded that a normal interval for updates is 1-2 years.

Regarding the structure of the documents in production, company A and C showed to have really elaborate and easy to follow instructions that still maintained a high level of quality assurance and

safety. Company A utilized step by step instructions where each step was divided into *step*, *info* and *important aspects*. In the important aspects column each step could be labeled "V" (variant specific), "Q" (quality control), "K" (critical aspect) or "!" (safety), all so that the operator would get a heads up when conducting said step. According to the interviewee the general opinion of the document system improved significantly in company A when the step by step instructions were implemented, earlier the instructions were more like the production instructions at Wellspect which were long and more complicated to read.

Company C had a system with step by step instructions at each station as well. The biggest difference here was that each step of those instructions had an individual instruction tied to it explaining said step in detail with pictures and time-measurements. These step-instructions are mainly used when training a new employee or if there are quality issues. Company B had a system with a binder filled with step by step instructions for all their different models at each station, but the interviewee wanted a why part in their instructions, in addition to the what and how of each step that is present. Looking at these three document structures in comparison to the current structure at Wellspect gives a lot of good ideas for improvement. Especially the structure of simple step by step instructions with important aspects as a complement to the more elaborate production instructions. Also, as all the three companies agreed on the need of room for an explanation of why the steps are necessary this is something to consider for the new instructions of Wellspect.

All of the observed companies had a very high level of accessibility and visibility of their instructions, in all of the three cases were the instructions printed and posted at each station. Company C had even implemented digital screens showing the steps at one of their two lines, the operator then had to check each step on the screen before moving on to the next set of steps.

Another question that was asked is how much the instructions are used at the three companies. All of the companies answered the same, that the operators know the instructions by heart thus they do not look at them while working. The only exception was the line with digital instructions at company C as they have to tick off each step on the screen. This corresponds well to the situation at Wellspect where the operators seldom look at the instructions in the current system. This is a natural development as the operators repeat the steps multiple times each day, therefore it is all the more important to focus on follow-up audits after changes has been implemented to make sure that the old habits do not linger.

None of the visited companies had any clear incentives for improvement work, but they all had different views on the subject. Company A said that focus is on explaining the benefits of improvements and how it would affect the operators' working environment positively whereas company B had a more "do things right" mentality instead of finding better ways. The interviewee also said that the head of operations had identified changes as costly, which further send signals that change is not desired. For company C who is in a dire situation and must improve, the incentive is to survive. Here it has been made clear that all must participate and strive to reach one's goals to improve. Considering these three answers it is hard to derive a model for improvement work incentives.

When asked of how the three companies worked to ensure quality compliance in their production they all had the same system, the operators must sign that all critical steps have been performed correctly and that everything has gone well. At company B this is done digitally at the stations before

a product can go on to the next station, and at the line of company C with digital screens it is the same. The signatures are important for follow-up revisions and traceability, e.g. if a quality issue is continuously appearing it can be used to see if it is due to the process or if it is due to a single operator. At company B the production is not as thoroughly controlled as the others, instead they have an extensive final control of all products to ensure quality. Company C has a schedule for revising their most important processes regularly, these are conducted by team members, team leaders, production leaders and other managers. Standardized work in production is one of the revised processes.

7 Discussion: Part I

Starting with the stakeholder analysis that was conducted it early showed that this thesis would affect a great deal of people. This is not surprising as in order for the outcome to fix all the identified problems it must operate in a grey-zone between many different departments. For instance, in order for decisions regarding the instructions to be taken within the concerned department responsibility would need to be lifted from the shoulders of e.g. the Process Manager and the responsible person of the Quality Department. This would most likely instead be put on the Production Supervisor and the Head of Production of the certain area. This shifts the power balance within the organization and that concerns a lot of people. In addition to this, the Document Coordinator would possibly be affected by an increase of workload if changes suddenly are approved and conducted more frequently. These are delicate issues that must be taken seriously before the any new methodology is implemented; otherwise there is a risk for resistance within the organization if someone for instance feels that their power is being given to somebody else.

As is stated in the current situation analysis, the organizational structure of Wellspect is well suited for the business they operate within and the market situation that applies. Wellspect has a quite central and formalized structure and the technostructure, consisting mainly of analysts from the Quality Department and the production support, is strong. This is common in companies that work with high quality standards in mass production. As the theoretical framework showed that this structure is the most suitable for a company like Wellspect, it is important that the new methodology is built accordingly. Having a strong technostructure like Wellspect has in the Quality Department and the Production Support Department is vital, thus any new methodology that is created cannot simply rule out these functions to make the process more agile. Instead it must be created with the purpose to isolate which changes the Quality Department and the Production Support Department do not need to be part of so that these can be handled separately, in a more agile and fast process, while the larger changes still go through the more rigorous process that the technostructure are a vital part of.

Considering the document handling system of updates or changes in documents this is where the biggest change is possible. As the system today need to go through multiple steps back and forth in order for a change to be reviewed by all relevant personnel and finally be approved, it is very time consuming and frankly quite unnecessary in many cases. The new methodology need to take advantage of the possibility stated by the Head of the Quality Department that it is possible for minor changes to be reviewed, approved and updated within the department. This would increase the efficiency and move ownership of the instructions down in the organization to the people who actually are affected by and work according to the instructions.

The instructions system in production today, which builds on binders containing all instructions for a certain area, is also something that was identified as a problem. It is good of course for the purpose of having control over all printed documents so that no faulty instructions exists, but it is negative in terms of making people follow the instructions or look at them when in need of information. Also, the instructions that are available today mostly contain information of what need to be done, not how. Here the benchmarked companies had taken a different path. All of the three visited companies had simple, step by step instructions as a complement to the more detailed and complex instructions that cover the entire process. These instructions were also placed at the station where they were used, so that the operator always could access the correct instruction. These were identified as good solutions that could enhance the situation at the production in Wellspect significantly regarding standardization and efficiency. The new methodology should thus result in instructions that are available at the station and are easy to follow to increase the usage and thus the standardization of the processes. They should also be more precise in how to execute the steps so that the currently known best way can be described.

Regarding the solution developed at the Surgical Department it was early identified as troublesome to adjust for usage in the Urology Department, or any of the other departments for that matter, due to the non-existing improvement group meetings and several shifts rotating. Using that system would in other words become very complex and difficult to handle information-wise, while not really solving the problem of enabling standardized work in the production.

The culture within production in Wellspect is also something that needs to be changed. There is no real general interest in improving or changing the current processes. Creating an efficiency-mindset and spreading that among the employees is vital in order for the standardization of the production to prosper, thus the operators and managers alike must first be forced to enter the “neutral zone” which was described in the theoretical framework. Success can be accomplished by embracing the four parts of a social change mapped by Garrow (2012). The first part of that is to formulate a common description or message of why the change is needed, this is then followed by creating a collective identity where all involved feel part of the movement. Finally the change should be mobilized through a guiding coalition leading the way and then it need to be visualized and anchored through short term wins and long term goals. The notion that the biggest obstacle for implementing change is to get the employees committed is backed up further by the benchmark analysis where two of the three companies clearly stated this as their main issue. These are aspects to bear in mind when developing a new methodology for the production of Wellspect; not to rush the process and to plan it carefully.

The question of leadership and responsibilities is crucial for the ongoing development and continuous improvement that is strived for. In the Current Situation Analysis it was identified that most improvement efforts conducted today arose from personal drive or interests and that there seldom were any demands from above regarding improvement work. In order for a change towards standardized working processes to become successful it must be supported from above and managers of all levels need to start pushing for progress. A clear hierarchy of responsibilities over reviews, approvals, implementations and audits need to be mapped so that there always is a receiver of all steps and outcomes. The methodology which is to be created must also have an owner so that the responsibility of working with it is clear after the thesis is finished and the researchers are gone.

Part II – The New Methodology

8 Introduction: Part II

In this second part of the thesis a new methodology for working with standardized working processes will be developed, tested and analyzed. The methodology will build upon the knowledge gathered in the first part and will result in the end product for delivery to Wellspect. This part will describe three phases; the creation of the new methodology, a small-scale pilot test, and the final outcome and delivery of this study.

9 Method: Part II

9.1 Creating the new methodology

In order to create documents that both fulfill the purpose of the thesis and that are ready to be delivered to the organization a thorough process has been carried out. The process started with gathering the knowledge and information from the theory, current situation analysis and the benchmarking from the first part. This since the theoretical best practice together with real-work experiences has to be tailored to the environment and circumstances that Wellspect's production operates in to result in a sustainable solution to the problem. Once the decision is taken on how the future way of working with standardized working instructions should look like it is time to create the tools and methods that are required for the outcome to be approved from a safety and quality perspective, e.g. what the change will and will not affect.

A meeting with a person highly knowledgeable in the approval routing process was held to unravel what documents needed to be created and what changes were needed in already existing documents. Further, help with mapping out all necessary steps needed for the method to be approved was provided and relevant people to inform and involve in the process was chosen from the stakeholder analysis. Drafts of the new documents and changes to already existing documents were created and continuously sent to relevant people for feedback. Once the documents were ready for routing in the system they were introduced to the relevant people for a final reconciliation so that no one felt that something was done behind their back or that anything had been left out.

9.2 The Pilot

When the documents had been routed and approved in the document approval process the next step was to try the new methodology in a small scale pilot. The pilot was decided to be on a part of one production line that manually places the catheter into the plastic package. This line was chosen for several reasons. The Production Supervisor responsible for this line was interested in introducing a more standardized work and it aligned well with this year's goal he had set for the line. Further, a so called Rapid Event (a two-day change project) was performed about two years ago on this exact station where steps for a more standardized work were developed. However, this work fell between the chairs as there was no structure that could support the outcome to make the change sustainable. Thus there was no need to develop new content for the instruction steps but instead the Rapid Event instructions could be refined into the new method's instruction template. The line also has a much more automated sister line that ramped up its' production prior to the pilot which decreased the pressure on the pilot line and made more resources available for working with the pilot. Even though the Production Supervisor of the chosen pilot line was unable to participate in the pilot continuous

correspondence ensured that relevant feedback was gained and that the Production Supervisor always was informed.

The pilot was initiated by a startup meeting with the Team Coordinator and an operator. This was done in order to introduce the final concept, provide one last possibility to give feedback before testing it and to educate everyone in the different responsibilities that were introduced. Directly afterwards the Team Coordinator and the operator sat down to, with help from the researchers, translate the already existing production instruction together with the Rapid Event instructions into fitting the created template. The instructions were then added to the document system and approved for usage in the production. The wider introduction to the personnel working at the production line was handled by the Team Coordinator as well as the education in the new methodology with the different shifts. The Production Supervisor is the one in charge of driving the improvement work but most of it is delegated to the Team Coordinator as that is the one in charge of all practical work with the instructions and educations. The Team Coordinator was also deemed more suitable for implementing the new methodology as the operators and the Team Coordinator work more closely in production and thus has a natural working relationship. This is beneficial to reduce the feeling of management pushing down efficiency changes from above which could result in resistance of change. It will also make it easier to explain that the changes are a help for the operators that can improve their working environment and not a threat. The pilot lasted for seven days.

9.3 Analysis of the outcome

The main purpose of the pilot was to test the document creation process of the Method for Standardized Work to see if the created methodology was viable, easy to understand and easy to use. To analyze this the initial meeting and document creation session was used to ask questions regarding the method and the processes. After the pilot was conducted the Team Coordinator was interviewed once more but this time focus lay more on how the implementation process had gone and how it had been received in production, the questions for the interview can be found in Appendix D: Interview Team Coordinator - Evaluation of pilot. This interview was together with ongoing observations the main data sources of the qualitative analysis that was conducted on the method.

The created instructions were mainly analyzed on qualitative aspects since the operators already worked mostly according to the pilot-instructions. This was due to them being based on the already generated best practice instructions from an old Rapid Event and therefore it did not bring any measurable time improvements on the line either. The test on the line was instead focused on increased usability, accessibility and whether the instructions enabled a change in culture regarding improvement work. The qualitative analyze was conducted through interviews and observations with operators, the Team Coordinator and the Production Supervisor.

The template for self-audit was also used as a tool in evaluating the pilot and in doing this the template itself was tested as well, the results of these audits were used to evaluate how well the instructions were followed.

10 Result: Part II

10.1 Methodology of working with the new instructions

The new documents were created to enable standardized working processes in the production of Wellspect. To achieve this the current situation analysis and the benchmark analysis along with the current instructions, rules and regulations were studied to identify what holes needed to be filled and which instructions needed to be changed. The result of this was an instruction called *Method for Standardized Working Processes*. In this instruction it is described how the simultaneously created *Instruction for Standardized Working Processes* template is used, what it may contain, how it is created, how it is updated and who holds the responsibilities of the different tasks connected to it.

The meaning of these new *Instructions for Standardized Working Processes* that the methodology results in is to map out the current best practice in a step by step instruction, containing important aspects and time measurements. These instructions will focus on improving the efficiency of production and to get all employees to work according to the known best practice. Another important change that this methodology will bring is that the instructions created can be updated and approved within the department so that changes can be applied swiftly and the instructions are continuously improved. By making it easier to update the instructions the operators will experience an increased ownership over their working situation and the instructions, this will result in knowledge being documented that otherwise could be lost. The step by step instructions will also be placed out on the stations in production so that all operators always can stay updated if a change is made and so that new employees more easily learn the correct way of working. Visualizing the instructions will also lead to a more standardized production where everyone works according to the best practice.

The instruction is defined to apply for the production of the entire Wellspect organization, although it clearly states that it does not apply for changes in documents that include quality controls, product or quality requirements or production instructions. The methodology described in the instruction is neither applicable for changes that are considered Major nor in need of a formal Change Request. Major changes are those who are calculated to require more than 100 working hours or cost more than 100.000 SEK, and a Change Request is always needed if the proposed change affects the product or process directly.

The biggest difference between the methodology developed in this thesis and the one used at the Surgical Department is that this new kind of instruction is utilized to increase efficiency through incremental, continuous improvements. At the Surgical Department the work-around that is used enables the trial of a proposed change for three weeks without changing the instructions. The change can then be evaluated and a choice can be made if the production instructions should be changed. This system does not reduce the lead time to implement changes, which is a lengthy process, thus it does not promote standardized working processes with living documents that are constantly evaluated and improved. The system used at the Surgical Department is possible due to the production only running on one shift, information can then easily be spread via their improvement meetings. In the rest of Wellspect's production as much as five shifts rotate, which gives a more complicated situation, therefore it is important to have real instructions that are regulatory controlled instead of lazybones on trial.

10.2 Instruction for Standardized Working Processes template

To complement the *Method for Standardized Working Processes* a template for the Instructions for Standardized Working Processes was developed. In this template the existing production instructions are translated into a step by step instruction stating all actions performed at a station, what is important to consider for each step and ultimately the required time for each step. It is also possible to add pictures of certain critical aspects or steps to further clarify something. At the bottom of the instruction there is also room for specifying a rotation schedule between the stations. All of this can be seen in Figure 6 below.

INSTRUCTION FOR STANDARDIZED WORKING PROCESSES

Station:	Step	Important!	Time				
			Man (s)	Auto (s)	Walk (s)	Units	
1							
2							
3							
4							
5							
6							
7							
8							
		Total:					
Use "!" (safety aspect), "K" (critical operation) or "V" (variant specific) to highlight important steps in *Important!*							

Station:	Step	Important!	Time				
			Man (s)	Auto (s)	Walk (s)	Units	
1							
2							
3							
4							
5							
6							
7							
8							
		Total:					
Use "!" (safety aspect), "K" (critical operation) or "V" (variant specific) to highlight important steps in *Important!*							

Rotation schedule:	

Figure 6: Instruction for Standardized Working Processes. Pilot edition.

These instructions are designed to increase accessibility and visibility of the instructions for the operators. As the instructions are placed at the working station, instead of in a common binder for the entire line, all operators can view the instructions as they are working, ensuring that all work according to the instructions and thus creating a standard for the outcome. As it is not controlled today how a certain step is performed many of the operators may have their own way of performing it. This is not only a potential quality issue but also a potential loss of vital information that should be shared with all other operators.

10.3 Self-audit template

The template for self-audit was created as a tool to help utilize the standardized working processes as much as possible. To reach a state where the standardized work instructions become living documents and are continuously challenged and improved it is important to see whether the instructions are followed or not. The outcome of the self-audit has two main purposes: ensure that the operator follows the chosen best practice, and to explore possible improvements of the existing

method. If there is a deviation from the best practice it is important to communicate it to the person who deviates and find out the reason why the instruction is not followed. If the deviation is unjustified the operator must adapt to the instructions but if there are recurring deviations on the same step or station it should raise questions whether the current instruction really is the currently known best practice or if change is needed.

There are no written requirements that self-audits have to be performed nor that this template strictly has to be used. Therefore no explicit responsibility for dealing with the self-audit is delegated in the *Method for Standardized Working Processes*. However, it is stated that the Team Coordinator should perform self-audits on a regular basis and report it to the Production Supervisor, and that it is appropriate to use this provided template. Since the template works solely as a supporting tool for the person performing the self-audit there is no requirement that the report is archived, but it is stated that the results should be communicated to the Production Supervisor. The same template can be used multiple times for up to 20 self-audits for the matter of convenience and to visualize patterns in the deviations. The template can be seen in Figure 7 below.

Year/Month:					**Self-audit Standardized Working Processes**										Line/Area:					
					Occasion of Self-audit															
Station	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Signature																				
Date																				

Occasion	Date	Station	Description

Instruction			
Green marking:	Do nothing.		Performed accordingly to the instruction
Yellow marking:	Write a description of what deviated from the instruction		Minor deviation from the instruction
Red marking (and if any yellow):	Write a description of the larger deviation from instruction		Larger deviation from the instruction
Add date and sign after completed self-audit.			

Wellspect HEALTHCARE

Figure 7: Self -audit Template.

10.4 Approval process of the created documents

After the three documents described above had been created, they needed to be approved and uploaded into the document handling system WIP. Even though there had been extensive communication between the researchers and relevant people from the pilot line, the Quality Department, the Document Coordinator and concerned managers throughout the document development process there still remained several more people who were interested in the work. This

became very clear when the routing-list was determined for the audit of the documents before being approved in the system. On this list were the Head of Operations, Director Manufacturing, Head of Lean Support, Head of Quality Assurances and Regulatory Affairs, Process Manager, Production Supervisor, Document Coordinator, Quality System Engineer and Safety-Health-Environment (SHE) Engineer.

As more people were introduced into the audit process than had been involved in the development process, some issues were raised immediately. For instance, the SHE-engineer identified that the Safety Representative, who is responsible for the working environment together with the Production Supervisor at each line, was not necessarily included in the decision making process of the *Method for Standardized Working Processes* and requested that this was changed. Another issue that was raised was concerning the Time-column in the *Instruction for Standardized Working Processes*. Here concerns regarding how the operators would feel about being measured by their supervisors were raised and the Production Supervisor also said that it could become a union issue.

Some issues, like the one raised by the SHE-Engineer, were promised to be adjusted for the final update with a temporary exception for the pilot. Other issues that were more of a matter of opinion regarding design and content were gathered as input to be taken into consideration for the final proposition of the documents after the pilot had been conducted.

From when the document were sent for review until the new instructions were ready to be implemented in production, three entire weeks had passed. This was due to problems on the sister line resulting in resources being allocated there, but also due to resistance within the organization during the routing process. Many people were still a bit suspicious and did not immediately accept this new kind of instruction being applied from outside.

10.5 Pilot

A small scale pilot was conducted for one of the lines as a way to ensure that the methodology would work in the real-life environment. It also worked as a practical evaluation where feedback was provided from the people that are going to work with it on a daily basis and not only reviewed it in a formal process. As the result of the pilot was unlikely to directly affect the efficiency of the production the evaluation was made on qualitative aspects such as usability, accessibility and culture of change.

To initiate the pilot a start-up meeting was held so that the researchers could explain the background of the thesis and why it was necessary. During this meeting a short education in how the methodology is to be used was held so that the Team Coordinator could implement the method correctly at the production line, the material used for this education was thus also tested which is beneficial as it is part of the end product package that this thesis produces for Wellspect and is vital for the future implementations of the method after the researchers are gone. The start-up meeting was attended by the Team Coordinator and an operator and after the introduction of the thesis was finished the different documents and how they are used was thoroughly explained. The operator and the Team Coordinator had the possibility of asking questions and convey their point of view continuously during the meeting which resulted in several interesting discussions and good direct feedback. The Team Coordinator e.g. stated immediately after the presentation of the method that:

"The best part of this method is that it really is operator friendly, there has not been any operator friendly projects here for ages!"

When the presentation of the project and the introduction of the documents were over, it was time to start working with the actual instructions for the pilot. The Team Coordinator and the operator then were handed the current production instructions of the line as well as the instructions from the Rapid Event on standardization of the work at the station. The template for *Instruction for Standardized Working Processes* was then filled with the steps that were deemed best practice and thus the new instructions were created. When it was all finished it had resulted in three instructions containing only the necessary steps and vital information for the three positions of the station, when looking at the finished product the operator stated:

"God, it would have been so nice to have had these instructions the last few weeks! We have had so many new operators being transferred to us from another production line and I have heard my name being called from all over the place constantly. It would have been so convenient to just refer to these instructions when people asked me how to do things all the time."

The filled in templates were then sent into PDMLink for approval by the Production Supervisor and the Head of Production before the Team Coordinator could implement the new instructions in production and educate all operators in how the new methodology works and what is required of them.

It took a whole week for the instructions to be handled in PDMLink and printed for production. The reason for this was that the templates were not available in PDMLink but needed to be transferred from WIP, a miss in communication between the researchers and the people responsible for the document handling systems. After the instructions had been printed the Team Coordinator held the education of the method and the instructions for the operators at the following Monday's shift meetings. After the education, when the pilot had been running for a week, the researchers went down to interview the Team Coordinator, the operator who was part of the creation of the instructions and a few operators who had worked with the instructions. The researchers also intended to perform a self-audit at this visit to try out the template and to evaluate the process. Here a problem arose, the instructions had not yet been put up on the station so even though the operators had been educated and informed there was nothing to evaluate of the late stages of the method. The Team Coordinator said that the problem was to find a good place to put up the instructions and that it had not yet been fixed. This was troublesome as the time put aside for the pilot was out, much due to the three weeks of initial delay of creating the instructions.

As the instructions had not yet reached the production floor when the pilot was ended it changed the way of how to evaluate the pilot a bit. Since no operators had worked with the instructions there was no purpose in interviewing them on the topic, and as the instructions had not been used no self-audits had been performed so these could not either be analyzed. Instead a wrap-up meeting was held with the Team Coordinator where the interview questions of Appendix D: Interview Team Coordinator - Evaluation of pilot were used to evaluate the different stages and steps of the pilot implementation and how it had gone. The Team Coordinator said here that the method of informing all operators and to educate them functioned very well. Furthermore the design and functionality was deemed very positive as it is so perspicuous and provides good support both for experienced

operators as well as newcomers. This is particularly valuable when bringing in extra personnel to cope with high volume demands, said the Team Coordinator. When asked about the will of improving the processes among the operators and whether this had changed, the Team Coordinator said that immediately after the instructions were introduced one of the operators brought up an improvement proposal. This was according to the Team Coordinator thanks to the clear and easy to understand design which made the operators really get into the details of the instruction. Earlier when a production instruction was updated it was so much text and details that few really bothered to read it all. The Team Coordinator further said that it now was important to update the instructions to include the change fast so that the other employees would see that change comes fast if the issue is raised. The issue of the self-audit not being tested was not seen as a problem by the Team Coordinator as similar methods have been used earlier and that by letting the operators perform some of the audits themselves it would not be any objections. The Team Coordinator also underlined what good support the self-audits will be in the future improvement work. The final comment by the Team Coordinator was that the new updating process that the *Method for Standardized Working Processes* brings is extremely welcome as the old process has been a bottleneck and an issue for years. Too much time has been spent on the wrong things which only brought reluctance to the change process.

The Production Supervisor was also contacted for feedback and thoughts of the methodology in general and the pilot in particular. The feedback was only positive and no complaints were brought up. The Production Supervisor has the same ambition as the Team Coordinator in continuing using the *Method for Standardized Working Processes*, which is seen as a great result.

The template for *Instructions for Standardized Working Processes* was used for a Rapid Event simultaneously as the pilot was supposed to be running. In this Rapid Event it was used to document the steps of a tool exchange so that this new best practice would be easier to apply when performing the exchange in the future and so that all personnel would do it the same way. The template was considered extra useful for this purpose as a tool exchange is not performed very often and thus it is hard to standardize. This extra test of the template showed that this kind of instruction is something that was needed and it also provided useful input. The Team Coordinator involved in the original pilot was also involved in filling the template for the Rapid Event, thereby the feedback that was provided was well grounded. The only critical feedback of the template that came out of the Rapid Event was a combined experience from it and the pilot, and it was that it would be much better if the template was converted to Microsoft Word-format instead of Microsoft Excel-format. This was mainly so that it would be easier for people with little computer skill to fill in the template.

10.6 Final proposition

For the final propositions of the documents that this thesis has resulted in all feedback was gathered and analyzed together with the results from the pilot testing period. Many of the stakeholders who were involved in reviewing and approving the documents when they went live in the document handling system of Wellspect had opinions that were taken into consideration and this resulted in a number of small changes to the documents. The final propositions of the three documents are presented below together with a description of how they are used.

10.6.1 Method for Standardized Working Processes

The day-to-day work with the new methodology builds on the current improvement system where operators can write improvement suggestions on an improvement board. The Team Coordinator then lifts the suggestions to the Production Supervisor who together with the Head of Production decide whether the change is major, if a change request is needed or if it is possible to change within the boundaries of the new methodology. If the change is to be made through the new methodology then the Team Coordinator writes a draft of the changed instruction. The Production Supervisor and the Safety Representative of that area take a decision whether a formal risk evaluation is needed or not based on the draft, this is one of the things that was updated for the final proposition. When the evaluation, if deemed necessary, has been conducted the outcome is used by the Team Coordinator to adjust the draft so that it reaches the safety precautions. The new draft is then presented to the Production Supervisor and the Head of Production who approves or rejects the proposal. When the change is approved the Production Supervisor initiates a document update in PDMLink and when that is done the Team Coordinator updates the paper copies out in production. The Production Supervisor announces the change in instructions by placing the updated instruction on the information board together with a form which the operators must sign when they have observed and taken part of the change, by doing this it can be controlled that all operators have been notified of the change. A process map of the updating process can be seen below in Figure 8.

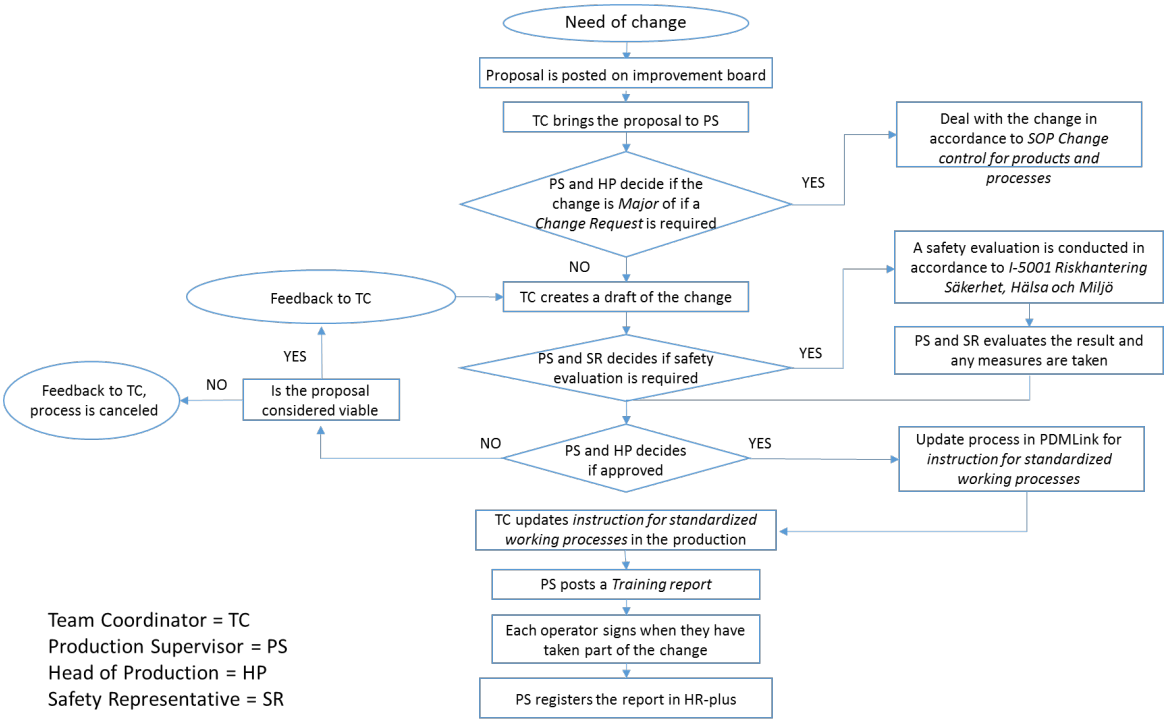

Figure 8: Process map for instruction updates.

When creating the first instructions for standardized working processes at a line a similar process is conducted, although it is a bit shorter. As the instructions are derived from the existing production instructions there is no question of changes being major or if a change request is needed, but the Production Supervisor and the Head of Production must still approve the new instructions before they can be implemented. Otherwise the process is mainly the same, a process map of the creation process can be seen below in Figure 9.

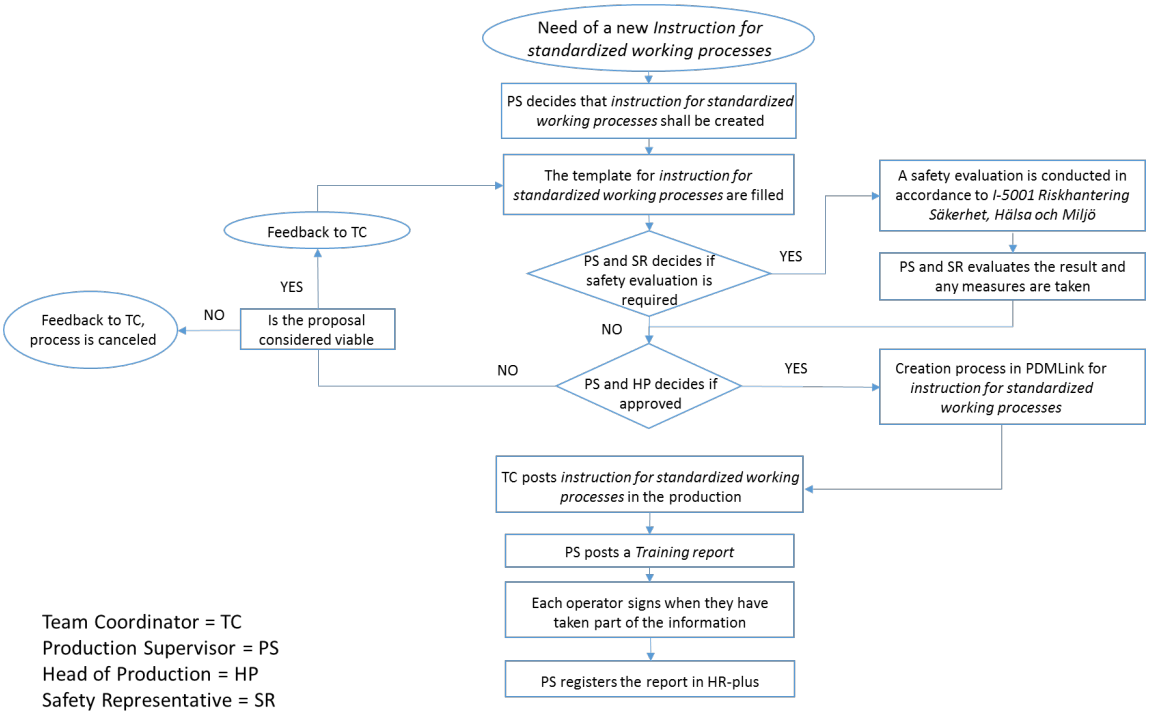

Figure 9: Process map for creating new instructions.

10.6.2 Instruction for Standardized Working Processes

The instructions are created by breaking down the processes of a station into short steps which are numbered, this could for instance be to grab a certain number of catheters. Next to the column with steps is a column for important aspects to consider, if there are any for that certain step. These important aspects could either be marked "!" (safety), "K" (critical operation) or "V" (variant specific), there were previously also a mark for "quality parameters" but this was removed for the final proposition as it gave rise to misunderstandings since vital quality settings must not be handled through this method. A safety aspect ("!") could for instance be if there is a hot surface to avoid, a critical operation ("K") could be placing the catheter in its package where a faulty placement results in a faulty product and finally a variant specific aspect ("V") is simply if there are different things to consider for different variants of catheters that are produced at the station. The next column of the instruction is where the required time for each step is noted to calculate the required time for completing the steps of the station. The time column is itself divided into four different columns explaining the nature of the measurement; manual (Man(s)), automatic (Auto(s)), walking (Walk(s)) and time required for a certain number of units (Units). The actions of each step should be measured and then noted in the appropriate column, e.g. if placing the catheters in the package takes six seconds then the number 6 should be noted in the column "Man(s)". If on the other hand a step is producing a batch of 50 sachets for the next step, and the automated process takes 30 seconds, then the number 30 should be noted in "Auto(s)" and the number 50 should be noted in "Units", the time per sachet is thus 30/50=0.6 seconds. The times measured for each step at the station is then summarized at the bottom in the field "Total time process", this is the total time required for the station. The time per produced unit is summarized in "Total time unit" where the time per unit is used instead of the time for the process step (e.g. in the example above where 0.6 seconds would be used instead of 30 seconds). The field for "Total time unit" was added for the final proposition and the previous field "Total" was renamed "Total time process", this since the column "Units" otherwise

would be irrelevant for the measurements. Another large improvement that was made to the template was that the researchers filled in the template with an example, showing in detail how it should be filled in and how to use the time measurements. This example of the filled in template can be seen in Appendix E: Final proposition – Instruction for Standardized Working Processes.

Even though time measurements are not frequently used in the production of Wellspect today, it should be utilized further in the future as it gives clear evidence if a change has resulted in a more efficient process or not. If a certain schedule is set for rotation between stations then this can be noted at the bottom of the instruction in the field "Rotation schedule". Here it could for instance be written if station 1 and station 2 should switch positions every 30 minutes. The purpose of this field is to have the same rotation schedules in all shifts as this varies today.

10.6.3 Self-audit Template

The template consists of two fields for identification of the year and month span the performed self-audits are performed within and what production line that it covers, as can be seen in Appendix F: Example of filled in Self-audit. These fields are manually filled by the issuer of the self-audit to make the template viable for all different lines/stations. On the top section of the template there is an area dedicated for the notation of deviations. Every station has one row in the matrix and the vertical columns correspond for the specific self-audit occasion, numbered up to 20. The result from the audit is filled in the cell corresponding for the specific station and occasion. The result has a simple color coding for ease of use; green for no deviation, yellow for minor deviation from the standardized work instruction, and red for a larger deviation. For example, the yellow marking is to be used when the deviation is so small that it does not affect the outcome of the process, e.g. perform an operation in a different order than stated. A red notation is for deviations that could affect the procedure, e.g. that take longer time and will result in missed production goals. After each audit occasion the one performing it signs the audit sheet and fills in the date of the audit.

In the second section of the template is the place where notes are written. Any yellow or red deviation marks should be followed by a note describing what was deviating, on what station, and on what occasion. This is to make the self-audit more qualitative so that it actually is useful for evaluating the standardized working processes. For example, if the same procedure is marked yellow multiple times it is a sign that it may not be the best currently known way of doing it and should be considered for revision. For an example of a filled in self-audit see Appendix F: Example of filled in Self-audit.

11 Analysis: Part II

Based on the current situation analysis and the benchmarking visits a number of conclusions of how the new methodology could improve the situation were drawn. For instance was the current organizational structure deemed most suitable for the market situation and processes that Wellspect operate in, thus the new methodology should be constructed to fit it. This has been achieved by using the current document system and structure as a base for the development of the new method and its documents, with some significant differences that enable the continuously improved, living, standardized working processes that was the aim of the thesis.

11.1 Documents

To make sure that the documents created for the new methodology followed regulations and were safe an extensive reviewing process was conducted involving managers and key employees of most levels and departments in Wellspect. This did not only make sure that the documents were safe, but it also made sure that everyone who might had opposed the change in a later stage got involved and incorporated in the process. This way, relevant input from all levels was retrieved and also information about the method was spread, helping to anchor the new methodology in the organization.

11.1.1 Method for Standardized Working Processes

As the document handling process in general, and the updating process in particular, early was identified as one of the biggest obstacles for this thesis it was naturally something that needed to be changed. To keep the updating process within the concerned department was something that not only would eliminate many steps in the updating process and thus make it faster, but it would also move the ownership of improving the processes down in the organization to the people who actually work in that environment. This was achieved by limiting the *Method for Standardized Working Processes* to changes that are minor and which do not need a formal Change Request, that way it was agreed that the Production Supervisor and Head of Production could make the decision whether the change was approved or not. This is not seen as a problem as the changes that are needed to continuously improve the standard and increase the efficiency mostly are small, subtle, incremental changes that rely on fast implementation and evaluation. Making it easy to update the instructions with tips and tricks of how to improve the working environment will also make it easier to capture knowledge that experienced operators have gained and that otherwise could have been lost if that operator retired or quit.

Another large obstacle for standardized working processes was that all instructions were kept in a common binder for the concerned production area. This led to the operators asking each other if questions arose and the instructions were never used. This is no safe system as faulty instructions might be passed on and thus become the current standard, therefore the accessibility of the instructions were identified as the next issue to attack. This was solved by creating a system where the produced Instructions for Standardized Working Processes are tied to the station which they are written for, and then they are placed visibly at that station. Similar solutions were applied at all three of the benchmarked companies.

Another issue that was identified in the current situation analysis was that there were no clear roles of who is responsible for driving the improvement work at the different areas and for whom it should be presented. Currently this varies a lot and it is mostly up to committed individuals to take things into their own hands when they want to change something. In the *Method for Standardized Working Processes* it is clearly stated, the entire chain from operator to Director Manufacturing, who is responsible for driving change initiatives, approving them, implementing them, evaluating them and to whom the result should be reported. This will lead to an increased awareness and commitment to the very necessary process of continuous improvement and will in time contribute to a change in the culture of Wellspect regarding changes in general.

11.1.2 Instruction for Standardized Working Processes

As usability also was raised as an issue of the current instruction in production this was something that needed tending to. The current documents are long with extensive instructions of all processes in the area; they are rich in text and are hard to get a quick overview of. This is another reason for the operators not using the instructions and instead just asking each other, as described regarding the accessibility above. It is undeniable that the production instructions must be as comprehensive as they are, but the instructions regarding working process and course of action at a certain station must be made visible in a simple and user friendly way. This is also something that was confirmed during the benchmarking visits that were conducted; all of the visited companies had step by step instructions over the specific process at a station. Therefore the *Instruction for Standardized Working Processes* consists of step by step instructions of the required steps of a station. This way it is easy for all operators, old and new alike, to follow the standard in a correct manner.

The mindset and culture of Wellspect was identified as solely focused on quality and safety in the current situation analysis, which of course is a positive thing, but there must also be a desire to improve efficiency to prevail in the long run. One step in the right direction of increasing the efficiency mindset of Wellspect is to start making it visible how the processes perform so that they can be measured and improved, and the way of achieving this is to start measuring the time required for each step. The literature study on standardized work clearly stated that it is vital to measure time, and all three of the benchmarked companies measured time for each step to increase efficiency as well. The *Instruction for Standardized Working Processes* therefore have a section for time measurements for each step, for the process in total and for the total time per produced unit.

During the work studies and observations in the production of Wellspect it was identified that the largest contributing factor to the downtime of the production was all the manual work during material or tool changes. This is a very clear area where standardization of the working processes can improve the efficiency and reduce the downtime significantly. In the current instruction system there is no place to put simple and clear instructions of how to perform e.g. a tool change, therefore the time required for these operations vary a lot. The *Instruction for Standardized Working Processes* can here contribute greatly to an increase in efficiency through standardization of the manual tool and material changes, simply by providing a template for step by step instructions that can be filled in and then used when performing the operation. The fact that as soon as the instruction template was approved in the document system it was used to document the outcome of a SMED (Single Minute Exchange of Die) focused Rapid Event can be regarded as proof of this.

11.1.3 Self-audit Template

The purpose of the self-audit template is twofold as it both should serve as a tool for evaluation and follow-up of changes in the Instructions for Standardized Working Processes and also be used to continuously monitor whether a new, better way of performing an action has emerged. To begin with it is very important that there is a way of making sure that the operators are following the created instructions, otherwise the standardization of the working process has failed. Therefore this template is an easy way for the Team Coordinator, the Production Supervisor or even other operators to check whether the instructions are followed or not. If there are too many deviations in a certain step then perhaps the instructions have been faulty constructed and need to be edited, if the pattern instead show that it is a single operator who is behind the deviations then this operator need to be informed of right way. The use of this template for self-audits will thus further boost the

improvement process by helping identify potential areas of change as well as help standardize the working processes.

Furthermore should the Self-audit Template, as the *Method for Standardized Working Processes* suggests, be used as a way for the Production Supervisor to regularly get status reports of the performed changes to stay updated on how the improvement work at the department is going. This is important to further clarify the different roles within the department and their responsibilities regarding the improvement work and to keep the ownership of the improvement work within the department.

11.2 Approval process of the created documents

Another area of interest is the approval process that needed to be carried out in order to be able to use the new methodology in the day-to-day practice. From the current situation analysis it was concluded that the general perception was that the change approval process was slow, rigid and considered an obstacle for the improvement work. This view was broadly agreed upon among the employees and the process of getting the new methodology accepted functioned as a evaluation of this. The approval process started with about five people on the routing list but it quickly increased to over ten as reviewers mentioned other people who might have a relevant opinion or might be affected by it. It came up new persons who needed to be introduced to the case and who came with new input that had to be dealt with. This process sent signals that no one really wanted to be responsible for reviewing the method and instead they wanted more people involved who would share the burden. This is one of the identified reasons for the change process being perceived as slow and rigid.

Other persons who had already been introduced and was mutually on-board now found details that could lead to misinterpretations or were not clear enough, even though they had been asked to review the methodology prior to this and at the time had given their consent. A lot of formalities was also highlighted, such as in what binder each document should be in, titles and terms used, and different regulatory document that may be concerned or required. These formalities are of course important to get right, but another identified problem that lies outside the delimitations of this thesis is that many of the reviewers did not know that they could approve a document and attach comments containing opinions in the system, instead they would then reject the document which results in an increased lead time.

A general dilemma was that the involved people had already fully booked schedules and therefore did not prioritize the task of reviewing the new method. When they finally reviewed it, new objections were brought up. Constantly people had to be reminded and asked to hurry up with the review and sometimes situations occurred where one person refused to approve before another person had approved. To get the new method approved for testing in the pilot promises had to be made that the objections should be rectified for the updated versions that were to be published after the pilot.

To sum up the document approval process the conclusion is that what was said in the current situation analysis corresponds quite well to what was experienced. The process is slow and the documents have to go through a lot of different steps and different people before being approved. It must though be stated here that the extensive reviewing process is a positive thing when it comes to

critical changes, but this also adds to the notion that the *Method for Standardized Working Processes* is needed at Wellspect to enable small changes in production that can be implemented fast.

As mentioned in the result, it took three weeks for the documents to be approved in the routing process. The reason for this was partly due to machine failures, which could not have been foreseen, but also due to resistance within the organization that resulted in longer lead times in the document creation and approval process. This is however not considered a threat for the methodology in the future as the doubts that some people had were due to the documents being tested for the first time and that the changes were pushed in from the outside by the researchers. When creating the pilot instructions for the production floor the process only took one week, and that time included a few days lead time for transferring the document templates from WIP to PDMLink. That is a good result and it is fair to assume that the creation/change of Instructions for Standardized Working Processes will require far less time after the pilot has been conducted. When, in the future, more departments and production lines want to implement Instructions for Standardized Working Processes the process will be driven by the concerned Production Supervisor and it will only need to be approved by the head of that production area. Therefore it is safe to assume that there will be no similar objections or questions to hinder the process then as it is both driven from inside and the methodology already has been tested.

11.3 Pilot

Before the pilot could be initiated a number of preparations had to be made. For instance was a How To-document created to explain why the new method is needed, explain the different parts and documents that are part of it and to explain what important steps must be performed and how. This document was not only necessary for the success of the pilot but also for the future usage of the *Method for Standardized Working Processes* after the researchers are gone. This document was used at the start-up meeting for the pilot to make sure that the operator and the Team Coordinator were mutually informed of the project and what is needed for the pilot. The presentation was used to break the ice and to spread a positive feeling and a sense of urgency of the changes that the pilot would bring, which is important from a Change Management perspective. The purpose of the start-up meeting was very much centered around building a guiding coalition that would lead the change work in production making sure that more people jump on the train. This was achieved as both the operator and the Team Coordinator were extremely positive and looking forward for the implementation of the Instructions for Standardized Working Processes.

The start-up meeting was also used as a chance of providing input for the documents before the pilot was initiated, which is important both to get input bottom-up in the organization and to give ownership to the people who actually are going to work with the documents. These are important aspects to make sure that the people in production feel that they have been part of the development of the methodology and that it is not just pushed down from above. This leads to a reduced resistance of change and a higher probability of the methodology being accepted among the employees.

When creating the new Instructions for Standardized Working Processes of the pilot line the operator and Team Coordinator from the start-up meeting were the ones conducting all the work, the researchers were mainly involved as support. Letting the people who are affected by the new instructions create them is a way of further increasing the involvement and sense of ownership of

the methodology, this is very good for the acceptance in production as it is the operators themselves who have created them.

The pilot started off good when the documents finally were approved. The instructions were written and printed and the Team Coordinator held the education for the shift teams. Then it stopped. The problem was that the Team Coordinator found no good place for the instructions to be placed at the concerned station, so therefore the instructions never came out in the production area. This meant that no final evaluation of the method could be conducted as no self-audits had been made and no operators could be interviewed after working with the instructions. The analysis of this pilot was instead focused on the early stages of the method; the instruction creation, approval and education processes. After the interview with the Team Coordinator these were found to be satisfactory and are expected to go even smoother in the future now that they have been tested. The fact that an improvement suggestion was brought up immediately as the instructions were introduced is a very good result on the layout and design of the *Instruction for Standardized Working Processes*. It also gives a good indication that the *Method for Standardized Working Processes* will bring a change of culture regarding efficiency mindset and continuous improvement work in the production of Wellspect in the future. Even though the time for the pilot ran out, the initiated process in production continued. This is seen as very positive and as a sign that the responsible people of the department want to work according to the *Method for Standardized Working Processes*. Just days after the pilot was ended were the instructions put up in production and so the Team Coordinator carried on the evaluating the method. The obstacles that were encountered during the pilot were mostly due to the method being tried for the first time and are not expected to occur again.

12 Discussion: Part II

The new method that this thesis work has resulted in has in many ways been a mapping of already existing possibilities within the current regulations and much of the work was on connecting all the dots, tying the loose ends and creating a new culture.

12.1 The New Methodology

This method enables a shorter lead time for changes that are purely concerning the working processes. Rapid changes are crucial for the will to continuously update and work with standardized working processes, which leads to better performance in the production. The created method achieves this by letting the concerned department handle changes within their area. There are possible other ways to speed up the change process, most notably to make the already existing process more agile instead of adding another route. In that case a number of changes would be necessary to introduce. The number of people involved in the review process should preferably be kept to the bare minimum so that only the people with the right power and knowledge should be included. These people should also need more dedicated time to deal with the change requests as the process would choke otherwise. This of course requires that fewer people need more knowledge, take more responsibility and hold more power.

This approach holds the advantages over the *Method for Standardized Working Processes* that it does not require any clearly defined boundaries of what is or what is not allowed to deal with locally as everything passes the same change request process. Further, as the *Method for Standardized Working Processes* approach still requires supporting functions and expert knowledge in areas that are above their jurisdiction, this could all be handled by the "right" people directly by tweaking the

current process. However, this would lead to an increased distance between the decision takers and the affected employees, even for smaller working process related changes, which would not improve the change culture in the desired way. It would not enable the local more independent changes of the standardized working processes that are desired which would make the purpose of this thesis unresolved.

12.2 The Templates

The templates for *Instructions for Standardized Working Processes* and the Self-audit created in this thesis were designed to fulfill the purpose of the thesis and thus to enable standardized working processes. There might be flaws in their design which will be identified as they are used more and more, but they are satisfactory for this thesis and for the outlines of this project. It was clearly stated from the beginning that Wellspect needed methods and documents that were "good enough" so that they could start using them immediately and rather tweak them as time went by. This has been accomplished and proven true through the pilot, the Rapid Event and oral feedback. It is now up to the owner of the methodology within Wellspect to further enhance the templates for their specific purposes.

The only concerned that has been raised regarding the created documents was the time column in the *Instruction for Standardized Working Processes*. This has been taken up for discussion and the conclusion was that measuring time is a fundamental part of standardized working processes and that removing it from the methodology would be leaving it half-baked.

As the pilot was ended prematurely the template for the Self-audit was actually never tested. This is of course unfortunate but it is very much alike a self-audit that was used in a Rapid Event a few years ago thus it is not considered a major issue. The Team Coordinator and the Production Supervisor have both given their point of view on the matter and are both satisfied with the template, thus it is deemed sufficient.

12.3 Document approval process

As the new method should be approved in the document system many of the communicated difficulties were confirmed. The process really was slow and comprehensive and the energy required to get it through was substantial, especially if one tries to speed up the process. Most of this is for understandable reasons; the thoroughness and breadth of the review. The quality assurance is really the number one priority and nothing is left to chance. In many cases common sense would be enough to understand that some changes are not appropriate but that is something that cannot be formally defined or regulatory proven in case of a revision. Therefore, every nitty gritty detail needs to be correct and people from across the entire organization, on all levels, need to approve the new documents.

There is a delicate balance between being specific enough to accurately describe the boundaries of the method and to be vague enough to not get trapped by it. Naturally, the sweet spot of this balance depends largely on who reads it. People dealing with quality tend to dislike descriptions that are not crystal clear and therefore if the person was not personally introduced to the case they reject the new method. It somewhat seems like by using a conveniently vague description the people who has not been involved in the development cannot get an overall picture and thereby refuses it.

Furthermore, an observation that was made during the document approval process was that some people within the organization used the reviewing process as an information channel rather than a vital process for creating safe and correct documents. This is of course troublesome as one of the biggest obstacles that initially were identified for this thesis was the long and complicated process of changing documents. More discipline need to be applied in this process if efficiency in the change process is wanted so that only the relevant people who actually are concerned are added to the routing list. If someone is identified as possibly interested in the change then this person need to be informed in another way than being added to the routing list, otherwise processes like the *Method for Standardized Working Processes* must be applied to ensure that only the most vital people are engaged in the change process. There is of course an underlying difficulty that has led to this situation. As can be seen in the Stakeholder analysis a large number of people from different areas needed to be involved for this thesis to be conducted, and when the documents were sent for routing even more people were added. The structure of evaluating large changes is complex and it naturally involves people from different departments and areas as few changes can be considered having no effect outside a specific area. This situation is troublesome, and it might be hard to eliminate entirely, but by separating the changes based on e.g. magnitude or specific processes large efficiency improvements can be made.

If the documents are to be reviewed rapidly the people needed for the review must also have time to spare for the task. During the process of this thesis most people has generally had tight schedules, which led to that when the document review was just initiated the task was placed far down on the todo-lists as nothing could change before it was reviewed and then the reviewer would wait until having enough free time to thoroughly review it. One can spend a lot of time reminding people or asking them to hurry up, or set an eligible deadline which, although no practical meaning, can at least get most people to put off time for the review. Naturally, the late reviewers might also find possible needed changes that would lead to additional lead time.

12.4 Pilot

Clearly the pilot of the method did not turn out as anticipated. The many different steps that were needed before using it in the daily routine had longer lead time than expected. Things that were thought to have a minor impact took over a week and it became clear that when the researchers stopped pushing the pace slowed down. The lack of push in this phase was deliberately done to see how it would actually work in a real situation. The pilot should be owned and driven by the production itself, which led to this situation with the time running out. This could be seen as a sign of the very limited involvement in improvement work. Even if there probably were several factors behind the delays it is clear that there are either too many severe tasks to deal with or that the improvement work is of very low priority, or both.

While many of the positive aspect of the method could still be valid it is an important step to gather precise feedback from the employees mostly affected by the change, even though it was on a limited production area on a limited time. Teething problems might still be discovered after the pilot but this thesis has still completed the major part of the work and considering all the people who have been involved in the creation and evaluation, only minor modifications are to be expected.

Conclusions and Recommendations

13 Conclusions

This thesis searched to analyze how Wellspect could form a methodology for standardized working processes without risking the high level of quality assurance. Further it sought to answer the question of how the balance between flexible efficiency and quality assurance could be handled. Below the findings concerning these topics will be concluded with the experience of this study as the base.

The previous approach to dealing with working instructions at Wellspect was a two sided story with very bureaucratic working instruction which instead did not describe in detail how to perform certain tasks in the production. The production instructions were updated as little as possible due to the long and slow updating process and at the same time there were barely anyone looking at them since they were stored in binders far away from where the actual work was conducted. This led to information and tips being mostly transferred orally, which leaves an unpleasant possibility of losing information and a difficulty to improve the processes.

By starting to use standardized working processes among all employees in the production several benefits are expected. First of all by only trying to map the processes increased knowledge and awareness will be achieved. The lowest level of performance from the employees will increase since everyone follows the currently known best practice. The goal is to make the *Instruction for Standardized Working Processes* a living document where many small incremental changes create an improved production. In order to achieve this and to promote improvement work the power and ownership of the standardized working instructions need to be moved down to where they are used. This will also further improve the working situation of the production employees. Another important aspect is the visibility and usability of the *Instruction for Standardized Working Processes* that will make it easier for the employees, especially for newcomers.

The created methodology for standardized working processes will assure that the required quality demands are met by clearly describing what is allowed to be changed with this methodology and what must not be changed. This does not affect the quality outcome as all limitation is based on already existing and approved regulatory documents. With the new methodology not only all the necessary structures are provided but also a distinct written path to follow that ensures that no necessary evaluations are missed. This presupposes that a certain level of knowledge is available among the affected people.

By using the newly created methodology small incremental changes can be controlled from within the concerned department in the production. This means that small efficiency related changes that are not affecting the product or process will be implemented in a much faster pace. Further, by actually documenting the processes in detail will place the first building block in working with continuous improvements and even if there today is no work with time per operation measurements the *Instruction for Standardized Working Processes* enable and promote it. However, this method will not improve the production on its own, the management on all levels must continuously push the work with the method to improve through iterations. Simply creating a standardized working

instruction and then never changing it will improve the accessibility and visibility, and create a standard, but it will not lead to standardized working processes in its full sense.

As of the balance between strict quality assurance and flexible changes in the production it all comes down to the complexity of the change evaluation process. The research that has been conducted in this thesis show that there are two possible paths to go in managing the balance. The first is a centralized decision-making structure where a focus group consisting of experts from the different areas make all the decisions. The second is a decentralized structure where all different departments can manage their own change initiatives to an as far extent as possible, off course with clear jurisdiction over what is allowed and what not. In the latter case only the most complicated and severe change proposals will be handled centrally in the organization, thus a relieve in workload will be experienced which in turn will lead to a faster and more agile process there as well. Within the concerned departments all remaining change initiatives will be evaluated and implemented internally, leading to an increased ownership over the situation which increases the willingness to drive change. This will in the long run lead to a culture of continuous improvement. The process of evaluating and implementing change will naturally also be must faster as it is all handled within the department.

In larger organization that has recently seen a large growth, the way to handle change processes tend to lag in development. When the organizations were smaller a more centralized change review process was possible but as the organizations grew the knowledgeable employees handle much more in their day-to-day activities and the number of changes becomes too large to maintain a desired pace of approval. The tasks need to be divided into different kinds of changes to be handled efficiently. The different kinds of changes need to be clearly defined with boundaries on the different levels of approval needed. If done correctly this will still ensure that potentially severe changes will require the appropriate level of authority while non-harmful changes can be reviewed by people working more closely to the affected area. This will increase the amount of responsibility for the employees working in the production and will enhance their possibilities to affect their working situation.

There is also a more general mindset or cultural aspect to the efficiency of the change process. If a company knows that they are operating under high regulatory demands this should not be considered an excuse for slow change review processes. Instead it should be a spark to constantly improve and refine the reviewing process. To constantly question the processes and streamline them should be the goal instead of adding additional reviewers just in case or to use the review process as a tool for sharing information across the organization.

14 Recommendations

As the result of this thesis work has led to an increase of responsibilities for the concerned Production Supervisors and their respective Head of Production, and to encourage them to embrace this responsibility and start taking action, a deeper education on Major changes and Change Requests might be needed. Not only because they must be confident in deciding whether a change is major or if a change request is needed but also so that the people who lost said responsibilities feel secure and support this change of power. The purpose of this thesis was partly to enable standardized working processes which builds on continuously searching for the better way to perform, therefore the concerned people must start working actively and feel comfortable enough to

take the decisions needed. For the process to be agile and fast, the Production Supervisor and the Head of Production must be able to decide on their own when a change can be handled through the *Method for Standardized Working Processes* or not.

Another issue was identified of the same nature, but it is even trickier to overcome. It is regarding the definition of what changes affect the products or the processes and where to draw the line. In some way, all changes in production affect both the products and the processes, it all depends on how far back you search for causation. This is not an easy thing to define, but it would be extremely beneficial for all concerned if progress could be made. It would also help the Production Supervisors and their respective Head of Production in their decision making regarding approving changes in Instructions for Standardized Working Processes.

When going through the routing process to get all document templates and the method document approved it was identified that the document approval process is used somewhat as an information channel. As the current system of who needs to review a document change mostly are "People with relevant knowledge", many involved in the reviewing process add more people to the routing list just in case and to inform them of what is going on. This is a contributing factor to the process taking much longer than intended for the thesis documents to be approved and it is might very well be a contributing factor to why people within the organization feel that the document reviewing process is slow. A choice of strategy ought to be made here, is it okay to involve interested parties to inform them or should a stricter discipline be applied? The researchers recommend the latter. If only the most significant people are involved, they are much more likely to make the right decision without unnecessary time loss.

The transition to using both PDMLink and WIP has its advantages, it is clear, but it has also given rise to a lot of confusion within Wellspect when some people do not know where to find certain documents, why they have been moved from one system to another or even why both systems co-exist. This is something that should be made more clear and it need to be communicated better in the organization so that all concerned people are informed. A comprehensive plan over the implementation of PDMLink and the out-phasing of WIP should also be made so everyone knows what is going on and what is planned for the future.

A big issue that was identified early during the thesis work and which is of vital importance for the future success of the sought after standardization of the working processes is to measure time. All of the benchmarked companies that were visited had time measurements of how long their processes were, and Wellspect should start measuring this as well. If there are no measurements, no improvements of efficiency can be made as you cannot know whether a change is an improvement or not. The AVIX system is already used occasionally for analysis of processes, time is then measured for the processes to evaluate them, but is then disregarded. These measurements should be utilized and used for an even more efficient production. Measuring time and using it as the base for improvement is one of the corner-stones of standardized working processes and almost a prerequisite for the concept to work at all. Therefore it is strongly recommended to start measuring time and to use the columns dedicated for this on the *Instructions for Standardized Working Processes*.

Regarding the *Instructions for Standardized Working Processes* template there is more than one area where it can be utilized. Apart from the current usage of helping standardize the working processes

in production they should also be used to document processes like tool changes or material changes that are not conducted as regularly. This is both due to that these manual handling processes are very likely to benefit from a standardized working process and also due to these processes not being performed very often and thus a step by step instruction would be handy to look at. During the pilot of this thesis work the template was also tried in a Rapid Event on a tool change to document the steps of that process and the outcome was very good. Thus it is recommended that this template is used in the future for these kinds of processes as well.

Considering the conducted pilot it was done on a rather small area of the Urology Department and for a short period of time, due to the time delimitation of the thesis work. Not all phases were completed due to unexpected delays and therefore it would be wise for Wellspect to continue the evaluation process of the method. Wellspect could also try the documents in another area with a few document changes so that the methods are thoroughly tested for all environments, for instance at the Surgical Department.

The *Method for Standardized Working Processes* should also be encouraged to be used in all production departments of Wellspect, this as it would lead to a more standardized production that will continuously improve efficiency with a preserved level of quality. A natural next step after this would be to digitalize the instructions and implement monitors at each station for even faster updates and more secure document handling.

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Appendix A: Summary of Benchmark Interview Company A

Q: How large is your business/production here at this site?

A: Three departments, ~10 people working in each department, only day shift. 100% manual inspection of all produced items. Two of the departments have robots that can produce material for assembly 24/7 but the assembly is manual in day time. The third department produces liquids and has the highest level of cleanroom regulatory demands. There are 35 different cleanrooms in production in total.

Q: How many shifts do you have in production?

A: One, only day shift.

Q: How many different assembly lines do you have?

A: Three different departments producing different products, no real lines.

Q: How large volumes do you produce?

A: Differs between products but for the needles the capacity is about 5000-6000 per week.

Q: Do you have a clear vision/model for your improvement work?

A: Starting in 2010 it has been a large focus on Lean through management education and workshops with all employees. It is easy to just focus on lean and improvements in the production and not the entire organization, but the work that is conducted now is well anchored in top management with a vision of improving and getting more efficient while everything still is going well instead of when things go worse. A lot of effort is put in trying to make it a positive thing with improvements, to emphasize that the purpose is to be more efficient and not to cut down on employees.

Q: What has your journey been like up until today?

A: For instance, the liquid chemical department was earlier selling the components in bulk and it was the different clinics who mixed it to the right proportions. Nowadays all mixing of chemicals is handled in-house and sold in small vials. Very important with good standardized instructions for this!
Regarding the instructions they used to be very long with a lot of complicated sections of text, this was changed to more simple instructions with separate documents for signing to ensure that the tasks had been performed correctly. Nowadays when change is on its way opinions are gathered from all workers, but in a perfect world they would write the instructions themselves.

Q: What are the largest problems/obstacles?

A: To get all the personnel with you. It is easy to go to fast and thus not having everyone aboard, it is better to take it a bit slower and to get everyone with you on the change. When the production manager initially wanted the improvement work to get started she personally drove a number of changes that later proved to be pure process improvements that it would have been preferred if the operators themselves had performed.

Q: How are new instructions developed?

A: The production leader initiates the process and creates a proposition that is shown to the workers who then can come with input. The changes/instructions are then approved by the department manager and the quality department.

Rules and structure

Q: How clear are the rules regarding document changes?

A: Department manager and Quality Assurance must approve and sign every change that is made.

Q: How are the documents structured?

A: Clear instructions, step by step. Three columns: *Step*, *Info*, *Important aspects*. There are four different types of important aspects that signal different things: Q = quality control, K = critical aspect, V = variant specific and ! = safety.
All personnel sign that all steps have been performed in a correct way and some important parameters are signed individually while more simple steps can be signed as a group.
The instructions are printed and put up on the wall at each station, and in the instructions there can be references in the instructions to larger and more detailed instructions regarding for instance machine parameters etc.

In the information column there are columns with takt time and how long each step should take. Measuring time is important to know max capacity of production and to plan the production quantities. It is also important to know how the productivity is to see if a change is an improvement or not. Each morning there is a work team meeting where the working leader goes through the numbers from the day before. **Measuring time is vital!**

When calculating the takt time and measuring the steps the personnel did this themselves, very important! Would spread discomfort if management came down to measure the work. Very important to emphasize that it is not about being as fast as possible but to determine the normal pace so it can be used correctly. Good if the closest manager handles the introduction so that this can be explained properly.

A company that interviewee had benchmarked had developed "educational instructions" that were used when someone was new in production. They contained the same instructions as the regular documents but were complemented with pictures and more detailed information so that the employee really understood *why* the steps were carried out as well as how.

Using of instructions

Q: What is the general opinion of the document system of today?

A: Very good! As the instructions formerly sometimes were about 14 pages long containing mostly text, the instructions today of 2-3 pages with step by step instructions are seen as very positive. Less steps to sign as well, which also is a positive thing.

Q: How much are the instructions used?

A: The staff know that they exist as they have been part of the development, but it is not something that they look at daily. This is something that the work leader should test regularly, both to see if there are new better ways of performing a step but also to check that the instructions are followed.

Q: How visible are the instructions?

A: Printed and posted at each station!

Q: How is the accessibility of the instructions?

A: Printed and posted at each station!

Q: Is it controlled how much the instructions are followed in the daily work?

A: Time measurements are not controlled entirely.

Q: What incentives are there for improvement work?

A: Nothing concrete, try to get all employees in on the process by explaining the benefits and how their situation will improve.

Update process

Q: How is Q perceived?

A: Both good and bad, they have their specific knowledge and they come with good input even though you sometimes disagree. If they oppose then they need to state why and which document it is that limits the change.

Q: Ownership and change responsibility?

A: Each document is owned by a specific person, once a year they must be updated. The owner of the document is responsible for the change to happen.

Department manager and QA must always approve a change before it is implemented.

Q: Who initiates the change process of an instruction? (top/down vs bottom/up)

A: This varies, the production leader together with the staff comes with the ideas and drives the change, then QA is involved to see how the change can be conducted.

Q: What is the average lead time for a change of a document?

A: Depends on the change and who is driving it, if it is really important then the person driving the change can push the process in each step making it very fast.

Q: How is the updating process?

Not all personnel but 1-2 operators can initiate a change issue on a document. They then unlock the document, write the change, write an explanation of why the change was needed and also what has been changed. The version of the document is automatically updated and it is signed by the person

writing the change. The document is then sent to QA and department manager for approval, and this part of the process then iterates until all parties are satisfied.
All printed instructions at working stations are stamped in the system so it is known how many are around. When an update is conducted that affects the printed documents then the operator knows how many printed pages that also need to be updated by the stations.
There are different levels of documents: Department routines, specifications, instructions and blankets etc. If it is a large change or in a large and important document then a change issue is started so that all concerned can take part in the change.
When a change is conducted it is up to the production leaders to spread the word.

Q: How many are involved in the process?

A: The department manager and QA are the ones responsible for approving the change, but if the document affects others then there is no real structure for how to handle who to contact and not.

Q: How often is a change conducted?

A: Update of each instruction is schedules for every year!

Appendix B: Summary of Benchmark Interview Company B

Q: Would you like to introduce yourself?

A: Markus Hjärtstam, working in the department *New Product Industrialization*. Started working here in 2000, just after the company was started (1999). Started in production then climbed within process development and maintenance, today works with DFA and risk analysis.

Q: How large is the production? (volume/shifts/lines)

A: 20.000 devices per year! It used to be two 6h shifts but has now gone over to only having one 8h shift. There are two different lines and the work here is mainly manually, the actuator is pre-assembled but the rest is put together on the lines.

Q: Do you have a clear vision/model for your improvement work?

A: There is a project model that everyone is supposed to work according but there is no system for continuous improvement within the product development. No clear improvement vision. Much focus of Company B is to produce mature products from the start instead of improving as it goes, this is due to the fact that their business relies on launching new products to the market often.

Q: What has your journey been like up until today?

A: The company grew 100% each year and in 2005 it was bought as a complete concept with its own R&D, product development, logistics etc. Was about 20 employees when it started and is now about 290 here in Gothenburg, which is run as an own company even though it is owned by another company. The site is described as flexible and self-administered and it mainly makes its money on bringing new products to the market frequently.

Q: What are the largest problems/obstacles?

A: 70% of all production stops are due to material failure. Despite this, many project leaders think that DFA is time consuming and unnecessary, Markus argues though that he *gives* time due to reduced amount of failures but this is hard to get through. At the Gothenburg site DFA has become a part of the product development process, although it is not yet a part of the standard way of Company B.

Rules and Structure

Q: How clear rules are there surrounding the documents?

A: FDA has demands on quality assuring documents, ISO13485 and QSR820 are used as guidelines. There are firm rules of how instructions are created and controlled.

Q: How are the documents structured?

A: Working instructions: Desired to have a *why* something is done in the instructions but it is hard to fit in for all steps, so it is mainly a *what* and *how* said steps are done. Markus says that it would be preferable to have a clear description of why everything is done the way it is in an educational instruction. Markus would like to increase takt time of the production in order to divide the work into more stations with less instructions at each station, that way the work can more easily be standardized and thus the quality outcome is easier to control (via standardized instructions, predictable work flow, better balancing of production, pull not push etc).

Q: How is quality compliance ensured in production?

A: Each station has a touch screen in which the most important quality aspects of an operation are presented, that way the operator can check the boxes at each aspect before the part is sent to the next station. If all boxes are not checked then the next station cannot continue working on that product.

The production of Company B is though not as thoroughly controlled quality wise as Wellspect as it instead has a 100% control of all finished products. This end control means that all important steps of the production does not have to be validated, instead the control process of the end product is a validated system. This also shows by looking at the takt time vs. quality control time, every 4.5 minutes a new product is finished but the quality control of that product takes 10 minutes. To cope Company B has four quality control stations operated by one person running simultaneously.

Q: How are new instructions developed?

A: At the testing stage of the product operator input is extremely valuable and is taken into account when writing instructions.

Usage of instructions

Q: What is the common opinion of the current document system?

A: No problem at all among the operators as they do not see the system, only the changes that occur.

Q: How visible and available are the instructions?

A: They are kept in a binder at the station, as there are four or five different products being produced on and off at the same station there are instructions for all of them in the binder.

Q: Is it controlled how much the instructions are followed in the daily work?

A: There is a controller in production who observes so that everyone follows the instructions and also take measurements of the machines so that they are accurate enough. This person is part of the production team and focuses solely on the quality aspects.

Q: How is improvement work of instructions encouraged?

A: Head of Operations has identified changes as costly, so there is a resistance towards to many changes from above. Otherwise so far it has been hanging on the individuals, no improvement meetings are held regularly where input is gathered.

Q: What incentives are there for improvement work?

A: Earlier in the production there would be an improvement meeting if an employee came up with an idea so that it could be discussed, this is not done today. The production leader and the team leader are not that engaged in it today, they have more of a "Do things right" mentality. Up to the personal interest to drive a change.

Update process

Q: How is the update process?

A: The one responsible (mostly production technician) for the daily updates and controls of the instructions ask the operators what their opinions are, then the change is made. All operators have to look through the document when a change is made, study the change and then sign that they have noted the change. The standard operating procedure is for all operators to look through the binder with instructions every time the sit down to start working, if there is a change they then sign that they have noticed and understood.

Q: Ownership and change responsibility?

A: Production support department owns all instructions and it is also them who conducts all the changes.

Q: Do most changes come top-down or bottom-up?

A: If Production Support is counted as top-down, then it is roughly speaking 75/25.

Q: What is the average lead time for a change in documents?

A: It is quite short as the ones conducting the change are close to the ones reviewing it in the organization, they are both part of Production Support.

Q: Is time measured as follow-up of instructions?

A: Would like to use AVIX per station but is not there yet. The problem is to control the takt time rather than measuring a step and then stating a certain time that all should follow.

Q: How many are involved in the update process?

A: Process owner and the team leader. Quality department can be involved if it is a big change affecting the design or the assembly.

Q: How often are the documents updated?

A: They are checked about once a month initially, but this is decreasing as time goes by. There are no set intervals for updates of instructions.

Appendix C: Summary of Benchmark Interview Company C

Q: Would you like to introduce yourself?

A: The interviewee, worked for 24 years at SAAB as lean coordinator and production technician before coming to Company C. The initial three years at the company was spent at the production technology department before become line coordinator which is the current employment.

Q: How large is the production (volume/shifts/lines)?

A: Only one shift, day-time, and two different lines. Each day 30 engines are produced. 175 employees and of those all but 32 are operators.

Q: Do you have a clear vision/model for your improvement work?

A: There is a very clear situation today that if they do not improve they will not survive. To really get this through they had a kick-off where the entire production was shut down so all employees could attend. At this kick-off the top management presented a three year plan of concrete goals and how to get there, two weeks later each department had their own meeting discussing more departmental goals.

Each day there is a meeting going through the results of the day before, to keep everyone updated of how things are going and to gather information of the current situation.

Q: How clear rules are there surrounding the documents?

A: They are ISO-certified. The documents that are in the production system are the ones who are supposed to be out on the stations, if a change is made it is shown on a board where each operator must sign that they have been informed and that they understand.

Q: How are the documents structured?

A: Each station has an OIS-instruction (SOP) that says which steps are to be performed, which order to perform them and what time each step takes. Each step has its own code which is tied to a more detailed instruction of that precise step, a WES-instruction (work element sheet) which describes how and why each part of the step is performed. The WES-instruction is structured as Activity - How - Why and always has a picture of the step, these instructions are used as education when someone is new and also if there is a problem with quality compliance.

Q: How is quality compliance ensured in production?

A: After a certain amount of steps each operator must sign that they have been performed so this can be used for follow-up if needed later. It is also signed if there is a change of operator so that this can be seen in the follow-up. These signatures are important to know if a quality problem is due to the process or the individual.

The most important processes of a certain department are controlled within the team once a month by a member of the team (by a rotating schedule), once a week by the team leader and on various other frequencies by higher levels of managers, one part of these evaluations is standardized work.

Q: How are new instructions developed?

A: The technicians from Production Technology first develop instructions according to their experiences and their knowledge, then these are developed in time as the operators come with their input of how the instructions should be. The technicians and the operators together update the instructions.

Usage of instructions

Q: What is the common opinion of the current document system?

A: As the operators themselves handle the updates and the update process within the teams they cannot complain.

Q: How visible and available are the instructions?

A: The instructions are printed and available at each station of one line, the other line have digital instructions on touch screens which need to be cleared before the product can continue to the next station.

Q: Is it controlled how much the instructions are followed in the daily work?

A: During training of a new employee it is the coach who is responsible for things being handled correctly but after the employee has been trained properly the responsibility is on the individual. At this stage there is no follow-up control unless it is needed out of quality concern.

Q: How is improvement work encouraged?

A: To reach one's goals everyone must strive to become better. If it is made visible how everyone is performing everyone will work harder to become better.

Update process

Q: Ownership and change responsibility?

A: Each team owns their documents and are the ones responsible for the changes of how something should be done or the order of which the steps should be performed. The Production Technology department owns the step times, the properties and the document codes (WES-numbers) etc though. If the team agrees on a change they can write it by hand on the instruction document and then this change applies for all operators until a new version with the change is printed. The line manager is in charge of printing documents and keeping the instructions up to date. The Production Technology department should be part of the process more but they do not have time. The instructions written by the production technology department describes what has to be done and what critical aspects there are, how it should be done is up to the production teams.

Q: What is the average lead time of an instruction change?

A: From a day to two weeks, depends on the technician (Production Technology) in charge of the change. Mostly faster if they are not involved, then just write a change and inform the line manager so a new document can be printed.

Q: Is time measured as follow-up of instructions?

A: The line with digital instruction screen warn if the operator runs out of time, but on the other line the time of each step is not measured.

Q: Who handles the time-measurements?

A: Production Technology department handles all time measurements, no one else, it is only their responsibility.

Q: How often are the documents updated?

A: No decided interval, but in reality a check-up is made each 1,5-2 years.

Appendix D: Interview Team Coordinator - Evaluation of pilot

1. Spreading of information
    a. Have all of the operators been informed?
    b. Does the system with notes on the improvement board to announce changes work?
2. Current state: Does it work well to raise improvement issues?
    a. How is it done?
3. General feeling: good/bad?
    a. Do the operators feel support/comfort in having the instructions visible on the station?
    b. For a newcomer, would the instructions help learning the process?
4. The will to improve the processes, has it changed?
    a. Has the instructions brought any will to change/improve anything?
    b. Has more discussions come up on how things could change for the better?
5. Self-audit process
    a. How was the functionality of the template?

General impressions from the Team Coordinator:

Appendix E: Final proposition – Instruction for Standardized Working Processes

INSTRUCTION FOR STANDARDIZED WORKING PROCESSES

Station:	Example: Switch the tires at a do-it-yourself facility with a car lift.		Time			
	Step	**Important!**	**Man (s)**	**Auto (s)**	**Walk (s)**	**Units (pcs)**
1	Put in the first or reverse gear, apply the parking brake	**!** - To hinder the car from moving	5			
2	Get the wrench and the new tires	Place each tire at its' place			240	4
3	Loosen the nuts, don't take them all the way off		720			4
4	Lift the car so that the wheels leave the ground			30		
5	Remove the nuts the rest of the way		60			
6	Remove the tire		10			
7	Place the new tire on the hub		10			
8	Tighten the upper nut (nut 1) by hand		15			
9	Add the rest of the nuts	Use hand power only	40			
10	Tighten the nuts with the wrench, but not fully	**K** - Tighten in a star pattern	30			
	Repeat step 5-10 for the remaining tires	Time = sum of step 5-10	495			3
11	Lower the car fully to the ground			30		
12	Fully tighten nut 1 with the wrench	Tighten firmly	10			
13	Fully tighten the remaining nuts	See picture for pattern!	40			
14	Ensure that all nuts are fully tightened	**!** - To avoid a schewed wheel	30			
	Repeat step 12-14 for the remaining tires	Time = sum of step 12-14	240			3
15	Return the wrench and the old tires to their location				240	4
		Process total time:	2245			
		Total time per unit:	561			

Use "!" (safety aspect), "K" (critical operation) or "V" (variant specific) to highlight important steps in *Important!*

Rotation schedule: N/A

The blue example text is intended as information/help and shall be removed/replaced before being published. The final text shall be in black. If the rotation schedule is not applicable mark it with Not Applicable (N/A). If possible place adjacent stations' instructions on the same page. At "Important!", especially important steps can be highlighted with "**!**" (safety aspect), "**K**" (critical aspect) or "**V**" (variant specific). **!** can be used if for example a surface is hot, **K** can be used if e.g. the placement of a product is critical for the process and **V** can be used when different variants of products require different measures. The time required per step is noted at "Time": manual work at "Man(s)", automated actions at "Auto(s)", movements at "Walk(s)" and if the time is for a determined number of products it is noted at "Each(st)". "Total time per unit" is calculated by dividing "Process total time" with the total number of units.

Appendix F: Example of filled in Self-audit

Year/Month:

Self-audit Standardized Working Processes

Line/Area:

	Occasion of Self-audit																			
Station	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
M1																				
M2																				
S1																				
S2																				
Ä1																				
Signature																				
Date	24/03	25/03																		

Occasion	Date	Station	Description
2	25/03	S2	Catheter placed badly in container
2	25/03	Ö1	Catheter batch running out
3	27/03	S3	Catheters placed in the wrong order
3	27/03	Ö1	Catheter batch is still running out

Instruction

Green marking: Do nothing. Performed accordingly to the instruction

Yellow marking: Write a description of what deviated from the instruction Minor deviation from the instruction

Red marking (and if any yellow): Write a description of the larger deviation from instruction Larger deviation from the instruction

Add date and sign after completed self-audit.

Wellspect HEALTHCARE