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Asare, Richard O. ***Utilizing Lean Process Improvement Methodology to Address Marker Band Shortage***

Abstract

This study examined how lean process improvement practices coupled with process assessment were utilized to address component or raw material shortage on a production assembly line. The used of lean process improvements tools, such as value stream map, fishbone diagram, scrap data collection sheet as well as process assessment forms, helped bring a tremendous improvement to the production assembly Line One of Company XYZ, which had been struggling to alleviate this problem for years. Chapter I contains the introduction, problem statement, the purpose of the study, assumptions, as well as the limitation to this study. Chapter II discusses the literature review of related subject, which gave added understanding to the topic. Chapter III discusses the methodology, followed by the results presented in Chapter IV. Finally, Chapter V provides a reflection on the whole research, conclusion and recommendation by the researcher.

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Chapter I: Introduction

Company XYZ (name withheld for privacy purposes) is a medical device manufacturing company in Minnesota, United States. It started from a humble beginning with some few employees and has thus grown into a multinational company that uses technology to transform the way enervating chronic diseases are treated, using less invasive medical devices. Today, XYZ's technologies are used to treat several chronic diseases affecting the human body. Company XYZ has a reputation for attracting and developing some of the brightest leaders in the medical technology industry. The company recognizes how vital leadership is to achieve their goals and, as such, have numerous career development programs at all levels.

XYZ partners with medical professionals to develop life-changing technologies that improve the treatment for chronic diseases. While most of XYZ work occurs at the business level, the company has several cross-business groups that help to leverage best practices, knowledge, and technologies. XYZ's best practices include quality and operation which relentlessly drive to continuous process improvement throughout the company to support the fundamental tenet of their mission: strategy as well as an innovation that coordinate research and development across the entire company, health policy, and regulations which provide a strategic approach to policy issues that affect the entire industry.

XYZ is passionate about improving the health of people and communities throughout the world, and their philanthropy reflects that passion. Today, to maintain good citizenship as a company, as a global leader in medical technology, XYZ serves patients and partners with medical professionals in most countries across the globe.

The medical device industry is inundated with a wide array of devices, including balloon catheters. Balloon catheters are used in many minimally invasive diagnostic and therapeutic procedures, such as opening blockages in the artery, stent delivery and a lot more. Building the balloon catheter is as essential as its delivery; for this reason, factors such as application, performance, type of catheter as well as type of balloon must all be considered. XYZ balloon catheters are used in different applications, such as balloon angioplasty, stent delivery, drug delivery, balloon occlusion as well as esophageal dilation. XYZ Company has several types of balloon catheters, such as the Maverick-over-the-wire that has a guide-wire tracking along the full length of the catheter as well as the rapid exchange balloon catheters, which have a guidewire along a short section that saves time compared with advancing a guidewire through the full length of the catheter. The fixed-wire balloon catheters have a wire core built inside the catheter, thus eliminating the need for a guidewire to advance the catheter to the treatment site.

Company XYZ manufactures several different types of balloon catheters; notable amongst them are urinary catheters and hearts catheters, just to mention a few. These catheters are manufactured using different components and thus have different parts; every part of the balloon catheters must play a specific role during insertion or delivery. There are three main parts of the balloon catheters: the guide, the marker band, and the balloon. Each part plays a vital role during surgery. Marker bands, located at the neck of a balloon catheter, show physicians the position of the balloon catheter when inserted into the artery during surgery.

Because marker bands play such an essential role, company XYZ relies heavily on it in manufacturing of balloons catheters. The company orders marker bands, a critical component of the balloon catheter. After going through shipping and receiving, the marker bands are delivered directly to the production floor, where they are used by product builders. Due to their precise nature, marker bands usually come with a certificate of conformance. Despite their availability on the production floor all the time, there are always shortages of this component at the workstation during production. The company will order a batch of 5000 marker bands, but that order does not always produce 5000 catheters but will run 300 to 500 short. The company is uncertain whether the vendor is not giving the company the right number of maker bands or if the product builders are scrapping them without recording them.

Statement of the Problem

Company XYZ was experiencing a shortage in the number of palladium rings (marker bands) used in manufacturing balloon catheters. The quantity stated on the Kanban label from shipping and receiving is not consistent with the quantity of product that is produced. It was against this backdrop that there was the need to investigate the production and process, using Lean manufacturing process improvement tools, to find out the root causes of the shortage and address it accordingly.

Purpose of the Study

The purpose of the research was to investigate the root cause of why one Kanban batch of 5000 marker bands intended to produce approximately 16 to 17 batches of 300 parts can only produce about 15 to 16 batches on the production floor, and then provide direction on how to mitigate this problem using lean manufacturing tools.

Assumptions of the Study

The following section discusses the assumptions made with regards to the success of the projects. Firstly, the number of marker bands received from the vendor was less than the quantity listed on the label. In addition to this, shipping and receiving checked the quantity of the Kanban before sending to the production floor. Product builders must verify the quantity of Kanban received from the warehouse by manually counting them to ensure the number corresponds with the quantity on the acceptance label and that scraps made during production are recorded as prescribed in the work instruction. Moreover, any marker band that falls off the workstation or falls on the floor must be accounted for at the end of the batch; finally, product builders must perform auditing on their SFP (Shop Floor Paperwork) before parts are moved from the assembly line to the next station.

Definition of Terms

The following were the definitions of terms used throughout this paper that may not be familiar to readers.

Certificate of conformance. This is a certified document that gives indication that a product or service meets specification or standard and is thus issued by a competent authority. In other words, it ensures that a process was followed and not overlooked during production. (Cox, 2007).

Corrective action and preventive action (C.A.P.A). This is an action taken to remove the causes of an existing nonconformity, defect or other undesirable situation to prevent recurrence (Powerway Suite, 2009).

Ishikawa (Fishbone Diagram). A lean tool that is used to find a potential cause of a problem to detect the causes. It shows the relationship between qualitative attributes and their related factors, that is, the problem is shown on the main bone and the causes of the problem are indicated on its four main branches respectively. (Amir-Abas et al., 2012)

Kanban. A visible record that communicates information, often in the form of a card (Esparrago, 1988)

Lean Manufacturing. This is an operating system that relentlessly pursues the elimination of waste. In other words, “It is a business improvement strategy based on the Toyota

Production system, designed to eliminate waste and improve effectiveness in a process" (Eaton, 2013, p. 302)

Marker bands. This is a small metallic ring made from palladium or platinum that is found at the neck of a balloon catheter that tells physicians the position of the balloon catheter when it is inserted into the artery during surgery.

Over-processing. Occurs when product parts or product are processed but are not needed or when product or services are in excess. (Womack et al., 1996).

Process improvement. It is the act of identifying, analyzing, and improving business processes. It involves quality improvement, eliminating wastes, as well as maintaining the improvements achieved. (Aqlan, & Al-Fandi, 2018)

Temporary change request. This is order from an internal department to change information previously submitted on a product specification (Powerway Suite, 2009).

Waste. This is defined as anything that does not add value to a product or services. "Any human activity which absorbs resources but creates no value" (Womack et al., 1996).

Work in process. This "work that has started production but not yet completed" (Eaton, 2013, p. 302).

Limitations of the Study

The following were the limitations of this study. The company did not keep track of the exact amount of the marker band shortage and as such did not have adequate historical data to work with during the research. In addition to this limitation, product builders were reluctant to co-operate with the researcher. They were afraid to give information as far as the marker bands that fall on the floor are concerned for fear of being reprimanded or fired. Moreover, Line One is a new line that was set up recently and as such there was not ample space for the researcher to spend more time to observe the product builders while they were working on the line. Finally, the research had a high potential for addressing the issue of marker band shortage on Line One, but management hesitated to address it.

Methodology

After a review of the problem coupled with the Lean process improvement tools available, the researcher and the team went to the production floor to observe production and how product builders discharge their duties. The production line was given a critical look and the various stages of production were observed. Upon an observation of assembly Line One, the team, comprised of the researcher, two production supervisors, a manufacturing engineer, and a quality engineer, chose a value stream map as well as Ishikawa, also known as Fishbone diagram, for the project. The reason for choosing the value stream map was to fully understand the flow of the marker band in the manufacturing of the catheters. In other words, value stream mapping was chosen in order to understand the various stages or steps the marker bands go through beginning with shipping and receiving to the final station where marker bands are attached to the catheters.

After designing the current state value stream map for Line One, the team did an initial assessment of the assembly line in detail to identify the flaws and loopholes or the areas of the current process that needed to be improved upon.

Having identified the loopholes in the process, the team drew a cause and effect diagram to find out the primary cause of the marker band shortage. The fish bone diagram gave the main causes of the problem as well as the reasons behind the main causes. During this period of brainstorming, the most likely cause of the shortage was identified. Since there was no historical data available, the project team observed the manufacturing line for a week to gather data. The purpose was to investigate the number of marker bands processed per day, the number of marker bands that are scrap and the entry of scraps per batch, and finally to audit the start quantity of marker band and the number of catheters produced.

A new value stream map was designed after analyzing the current state value stream map. The new value stream map gave the team a graphical view of how the line should be in other to alleviate the marker band shortage. A temporary change request was initiated to pave the way for the testing of the new values stream map for a week to check its efficiency. A second process assessment was made to test the new measures put in place to address the shortage. The engineering team determined that, since the project did not affect the machine settings, components, or the assembly line, there was no need for a corrective and preventative action (CAPA) to be initiated; however, it was determined that product builders be retrained on the new additions to the assembly line as well as training on other minor tooling that were added to their line to make their work easier.

Summary

Medical device manufacturing companies are constantly looking for ways to produce ample, less invasive medical devices that will meet the ever-increasing needs of medical practitioners as well as patients. In other words, companies must supply medical devices to their potential customers in a timely manner. To achieve this, all the waste in their value stream must be eliminated in other to improve upon their yields. Company XYZ's catheter manufacturing Line One was not producing as much as it should be, given the number of components they receive from their vendors, hence the need to address the situation to ensure that the company's yield improves and customers are satisfied.

Chapter II covers the literature review of the topics relevant to this study.

Chapter II: Literature Review

Company XYZ was experiencing a shortage in the number of palladium rings, also known as marker bands, used in manufacturing balloon catheters. The quantity stated on the Kanban label from shipping and receiving was not consistent with the amount of product produced. It was against this backdrop that there was the need to investigate the production and process, using lean manufacturing process improvement tools, to find out the root causes of the shortage and address them accordingly. The literature review examined what lean manufacturing is and what it seeks to address on the production floor. Not only did it discuss lean manufacturing, but it also defined waste and the seven forms of waste that lean manufacturing seeks to eliminate. It also addressed the various lean manufacturing tools that were used in this research. In addition to all the above-mentioned topics that the literature review examined, it also explained value stream mapping as well as the merits and demerits of value stream mapping. The literature review also addressed the fishbone diagram, including its advantages and disadvantages, and finally, process improvement assessment and how it is beneficial to use during the process improvement projects.

Lean Manufacturing

Lean manufacturing was introduced in Japan, and Toyota Motor Corporation was the first organization to implement lean tools. Today, lean manufacturing methodologies continue to be used amongst various industries. According to Womack and Jones (1996), lean is defined as a process that includes defining customer value, defining the value stream, creating flow, establishing the pull system and striving for excellence.

Wong (2009) stated that lean manufacturing could be characterized by a collective set of critical factors or critical areas. These key factors when implemented can help companies create value for end customers, increasing productivity through quality and efficient use of resources to boost customer confidence. Lean, an operating system that relentlessly pursues the elimination of waste, has five principles: identify customer value for a product, identify value stream to make products to flow, establish a pull, and strive for excellence (Womack & Jones., 1996). Lean manufacturing is made up of methods and tools used to address most of the challenges that manufacturers, as well as the service industry, faces during their day-to-day activities. Notable amongst the lean tools are Kaizen, known as Continuous Improvement, the Kanban system, value stream mapping, A3 report, 5S, and Six Sigma, to mention a few.

What is Muda

The word Muda is a Japanese word which means waste. Waste is anything that does not add value to a product or services but takes away time and resources, such as money, raw material inventory, and labor. According to Womack and Jones (1996), any human activity which absorbs resources but creates no value is considered a waste. Waste comes in many forms, such as unused space, redundant equipment, excess inventory and many more (Womack et al., 1996).

Lean manufacturing identifies seven forms of waste: movement, inventory, transportation, waiting, overproduction, over-processing and defects. Dennis (2007) indicated that Taiich Ohno, a former executive at Toyota Motor Corporation, identified the seven different types of wastes in a manufacturing process.

Ohno (1988) identified movement as either an excessive motion or needless movement of employees, materials, products, and machinery that does not add value to the business process. Employees commonly make unnecessary movements on a shop floor either looking for a tool or moving around unneeded equipment in their work process. This is one of the primary sources of waste in a company and can be eliminated or reduced to increase production process efficiency and minimize unnecessary movements in a work cell (Ohno & Mito, 1998).

Alvord (2010) mentioned that excess inventory, which is a type of waste, takes up shop floor space, creates longer lead times, delays the traceability of defects and creates bottleneck issues that do not add value to a manufacturing process. Too much inventory consumes an organization's budget and reduces the return on investment on goods sold.

Transportation waste as stated by Alvord (2010) occurs when machinery, people and products move for longer distances than required. Some shop floors do not have work processes next to each other; they might be far from one another, requiring the use of equipment such as forklifts and conveyors to move materials to the next operation. This unnecessary transportation of materials in a work process does not add value to what the customer is paying.

Waiting, as per Alvord (2010), is when materials are not readily available when they are required in a process. When this occurs, operations, people, and or work-in-process inventory have to wait in line for the next process. Some factors such as poor design layout, less communication, and inaccurate inventory information form a bottleneck with a manufacturing process, which cost organizations time and money. Reducing waiting in a business process is crucial as it decreases lead time, increases machine utilization and reduces work-in-process inventory.

According to Liker (2004), overproduction occurs when products are manufactured before they are required. This type of waste increases storage, labor and material handling cost due to the excess inventory being produced when not needed. According to Rawabdeh (2005), when employees are providing more than required, the quality of the product decreases, thereby creating unnecessary bottleneck problems in the manufacturing process.

According to Liker (2004), over processing is a type of waste that occurs when a production process is done more than it is required to do so; doing more than what the customer needs increases cost and additional activity.

The other form of waste is a defect, also known as rejects and rework on defective products. This type of waste occurs when there is the absence of a preventive technology or a built-in system to notify defects in a process (Carreira, 2005). The method of remanufacturing, re-assembling or repairing a product adds extra cost to the final product and does not add value to a company's customer.

Many organizations have widely accepted the relevance of lean manufacturing in their day-to-day operations as a way of reducing waste and eliminating non-value added activities (Womack, 2007). The essential objective of the lean system is to create and to maintain value for the customer by eliminating waste through continuous improvement efforts. Production time, flow and cost are reduced, and overall profitability and quality of a business process will be improved within an organization (Dennis, 2007).

Value Stream Mapping

Value stream mapping cannot be discussed without knowing what value stream is. According to Rother and Shook (2003), value stream is about all the actions needed to bring a product through the main flow essentials to every product by "(1) the production flow from raw material into the arms of the customer and (2) the design flow from concept to launch" (p. 3). Having defined what value stream is, Rother and Shook (2003) went on to describe value stream mapping as a pencil and paper tool that helps users see and comprehend the flow of material and information as a product makes its way through the value stream (Rother & Shook, 2003). In other words, value stream map follows a product's production path from customer to supplier and carefully draws a visual representation of every process in the material and information flow, then asks a set of key questions and draws a future state map of how the value should flow (Rother & Shook, 2003).

Lasa, Laburu, and de Castro Vila (2008) posited that value stream mapping (VSM) is a tool fashioned by the crusaders of lean manufacturing for redesigning the productive systems. Since VSM was developed, some cases have been published where the tools have been used; however, there is a need to see how it is put into work, that is to analyze the level in which theory is able to adapt to real practice, the strengths, weaknesses, and the key aspects to be taken into account by the applicant teams to obtain the highest performance of the VSM. In addition to the definitions above, Shararah (2013) indicated that value stream mapping is an integral part of lean manufacturing that recognizes the activities that add value. It highlights which activities the customer is willing to pay for and which ones they will not. It is a powerful tool used mainly for visualizing a system, whether this system produces a product or supplies a service.

Value stream mapping is the tracking of the flow of raw material from the supplier to the end user throughout the organization. This process investigates the current and possible future state which products or services go through from the beginning to the end, to the point where customers' expectations are met or satisfied. VSM uses symbols to show the various activities in production or services as well as the flow of information. VSM helped the researcher to identify the stages marker bands go through beginning with the supplier and ending with the physicians. One exciting benefit of value stream mapping is that it gives a vivid overall picture of the whole process. In addition to this benefit, VSM provides insight into the problem as well as identifying a bottleneck in the process that is seldom seen. In addition to the aforementioned fact about

VSM, it also helps to identify waste in the production process and makes it easy to make improvements to the process.

Benefit of value stream mapping. VSM has a lot of benefits. Notable amongst them is the fact that, by virtue of its unique features, VSM maps both the flow of product or services and the flow of information that triggers the flow of product or services (Shararah, 2013). Shararah also professed that how information flow and material flow are linked together helps industrial engineers visualize how a production system works from when a customer initiates the order until the order is fulfilled by delivery (Shararah, 2013). Furthermore, value stream mapping focuses on issues of adding value and highlights a timeline, identifying whether activities add value; finally, the map is an indicator of how long a product stays in inventory and the time needed to replace them (Shararah, 2013).

Drawbacks of value stream mapping. In as much as value stream mapping gives users a lot of benefit, it also has some drawbacks. According to Aziz (2017), VSM cannot provide hard facts for decision making and merely points towards a direction as well as the lack of the ability to forecast the effects on future performance of a system analytically. Hence the need for simulation arises to experiment and evaluate the future behavior of a scheme (Aziz, 2017). In furtherance to what has been said above, Shararah (2013) also elucidated on Aziz's assertion by saying, “The problem with value stream maps is that they are static representations and capture the state of a system at the single moment when the map was drawn, and they completely neglect time and its effect" (Shararah, 2013, p. 48). Lian and Landeghem (2007) also posited that, upon all the good things said about value stream mapping, it is time consuming. In as much as value stream mapping may have this problem, however, for the very fact that the merit of value stream mapping outweighs its demerits, it is prudent for organizations to utilize it.

Fishbone Diagram

A fishbone diagram is a lean tool that is used to find a potential cause of a problem and its effect. It shows the relationship between qualitative attributes and their related factors; that is, the problem is shown on the main bone and the causes of the problem are indicated on its four main branches respectively (Amir-Abas & Tavakkoli., 2012). A cause and effect diagram, also known as Ishikawa or fishbone diagram, is a tool used for thinking through and displaying the relationship between a given effect and its potential causes (Park, Nam, & Choi, 2011). Park et al. (2011) posited that the likely reasons are organized into major groups and subgroups in the diagram. The diagram begins by defining the effect, which is the uncertainty of output value for the application of uncertainty assessment. The second group is to determine the major categories of possible causes, which are also the uncertainties of the input value. Amir and Tavakkoli (2012) indicated that the cause and effect diagram was introduced by Ishi Kava from Tokyo University during a teaching section with some engineers on an analysis method of different factors and their relationship with each other. In other words, the cause and effect diagram show the relationship between qualitative attributes and their related factors. The main bone depicts the problem whereas the four main branches show the causes.

Merits of using a fishbone diagram. A cause and effect diagram provides numerous benefits during brainstorming and problem-solving. It allows problem-solving teams to organize their thoughts, ideas, and discussions and to consider conclusions. Secondly, it provides an overview of the problem a company faces in a much broader picture. Finally, it gives a graphical representation of the causes and effect of the symptoms (Loredana, 2017). According to Andrews & Ridley (2002), the advantages of the cause and effect diagram are that the picture can be created directly from the system description. Secondly, dependencies in the system can be fused in the analysis, and finally the system is modularized to increase efficiency (Andrew & Ridley, 2002).

Manufacturing Process Assessment

According to Shevtshenko and Mahmood (2015) manufacturing companies are working hard in order to be successful and to remain in today's competitive market. Achieving this feat depends on several factors such as reliability and reliable manufacturing process. For a process to be considered reliable, that specific manufacturing process must be evaluated in order to identify what needs to be improved. Shevtshenko and Mahmood (2015) went further to say that, to be able to identify the improvement needs, two factors must be considered: Internal factors that deal with the identification and measurement of process risk and external factors that deal with what the customer asked for.

The benefit of manufacturing process assessment. Evaluating the manufacturing process leads to improvement in the product quality. This is due to the fact that improvements lead to error free process and good product are produced and sent to the customer (Shevtshenko & Mahmood, 2015). Secondly, process assessment also helps to detect potential production failures of a production process, costs of the failure and possible causes of the failure together with frequency of the failure. In addition to this, it also leads to determine risk level of the production process and setting up production controls. Finally, it reduces production losses and improves profit (Shevtshenko & Mahmood, 2015).

Summary

This chapter discussed lean manufacturing, defined waste and provided details on the seven types of wastes in lean manufacturing. It also examined value stream mapping and its benefits, fishbone diagram and its benefit, manufacturing process assessment and how it is beneficial to assess existing manufacturing processes as well as the benefits of process assessment. Chapter III examines the methodology in using lean process improvement tools that helped production assembly Line One to address its component shortage problem.

Chapter III: Methodology

Company XYZ was experiencing a shortage in the number of palladium rings, also known as marker bands, used in manufacturing balloon catheters. The quantity stated on the Kanban label from shipping and receiving was not consistent with the amount of product produced. It was against this backdrop that there was the need to investigate the production and process, using lean manufacturing process improvement tools, to find out the root causes of the shortage and address them accordingly.

The purpose of the research was to investigate the root cause of why one Kanban batch of 5000 marker bands intended to produce approximately 16 to 17 batches of 300 parts only produced about 15 to 16 batches on the production floor, and then provide direction on how to mitigate this problem using lean manufacturing process improvement tools. The intended result was elimination of marker band shortage, thereby reducing cost of stockroom scrap. The remainder of the chapter describes the methodology used to mitigate the marker band shortage on production assembly Line One. In addition to the aforementioned facts, the limitations of this study coupled with the summary of the chapter follows in order.

Data Collection

Due to the unavailability of historical data and the newness of the assembly line, the data analyzed was actual data of company XYZ collected by the research team through observation of production Line One. It was incumbent upon the research team to observe the production line for one week across all three shifts to gather data for the research. During the data gathering, the research team observed several steps and processes in the areas where marker bands are used during the production process, beginning from marker band crimping and swaging through final inspection. Data was collected in areas such the working environment where the lighting system, the work surface such as table, chairs as well as the availability of space where the product builders can easily move freely without any obstructions were looked into. Secondly, the materials, such as production mandrels and marker bands, were also looked at to ensure that the quantity of marker bands received from the warehouse and stated on the Kanban label corresponded with the physical count of the marker bands. Moreover, the crimping machine was also observed to see the number of times it malfunctioned; idle time as well as down time was looked at. Finally, product builders were also observed during this period. The research team observed how product builders handled the marker bands while discharging their duties on the production floor, specifically the difficulty and ease in performing the process. The team took a critical look into scraps and how they are recorded. The marker band scraps observed across all three shifts was entered into an Excel spread sheet similar to Table 1. The actual data was entered into a spreadsheet and the result included in Chapter IV.

Table 1

Example of Marker Band Scraps on Assembly Line One

Shift	1st Shift	2nd Shift	3rd Shift
Scraps			
Poor Crimp	#	#	#
Bad Marker Bands	#	#	#
Marker Bands Fell on the Floor	#	#	#
Marker Band Position	#	#	#
Equipment Failure	#	#	#
Total	#	#	#

Current State Value Stream Map

To fully understand the flow of the marker bands throughout the assembly Line One and to fully understand the causes of the marker band shortage as well as the production process of the assembly line, the research team constructed a value stream map. The value stream map tracked every stage of the marker bands throughout the production process. The flow of marker bands is as follows: marker bands begin with the supplier, are transported to the warehouse, and sent to the staging location on the production floor. The product builder then transports the marker bands to the crimping location, where bands are crimped to a mandrel before beginning the swaging process, where dies alter the marker bands to the required dimension. After swaging, the product builder performs final inspection and the inspected products are sent to the storage location in preparation for the next line to continue with the catheter production process. Figure 1 shows an example of a value stream map for a manufacturing process.

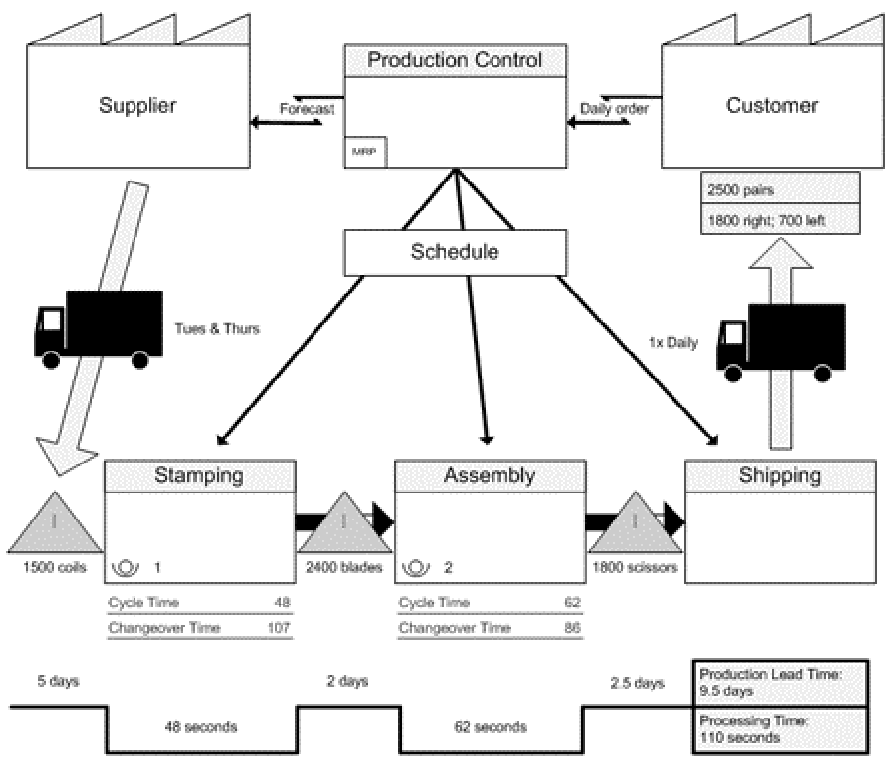

Figure 1. Example of a current state value stream map.

Data Analysis

The data analyzed focused on the one-week data collected by the research team on the production floor since there was no ample data available from the production assembly Line One that tracked marker band usage as well as marker band shortage. Two methods were used to analyze the data: a fishbone diagram, also known as cause and effect diagram, and a process assessment. A fishbone diagram is a lean tool that is used to find a potential cause of a problem to detect the causes. It shows the relationship between qualitative attributes and their related factors; that is, the problem is shown on the main bone, and the causes of the problem are indicated on its four main branches (Amir-Abas et al., 2012). The team also used process assessment, where the manufacturing process was examined against certain criteria to determine its potency or capability, to analyze the gathered data.

The main purpose of the cause and effect diagram was to summarize the causes of variation in the process and to begin the search for root causes. The team began by first identifying the main problem, marker band shortage. Having identified the problem, the team then identified the major factors that may be involved in the marker band shortage: environmental, material, machine or equipment, and human or people. The environmental factor is the condition within which production builder's work. The material factor includes determining whether the actual quantity matches the inventory and the quality is acceptable. The machine or equipment factor identifies machine malfunction or poor machine settings. The human or people factor includes inadequate training, inexperienced product builders, or workers not following process. Figure 2 shows an example of a cause and effect diagram. The actual data is entered into the diagram in Chapter IV.

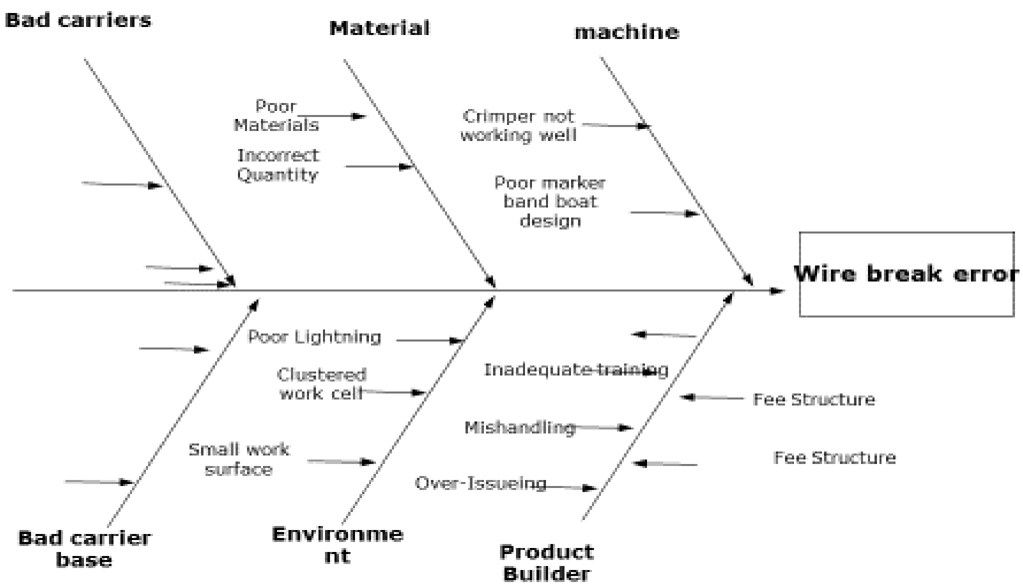

Figure 2. Example of cause and effect diagram.

Having identified some of the potential factors that may be part of the problem, and for each of the factors considered, the team brainstormed the possible causes of the problem that may come from these factors. As per the complexity of the problem, the team investigated the most likely causes further based on the team's one-week observation data, enabling the team to figure out which of the possible causes was contributing to the marker band shortage.

Process Assessment

The research team proceeded to do initial assessment of the production process to find out the loopholes in the production process that may have contributed to the marker band shortage. The assessment looked at issues like process description, technology and automation, technical issues, process status, measurement systems, process capability cost, and risk mitigation as well as overall risk assessment. Here, targets were set, gaps were recorded, key issues and risks were surfaced, and risk minimization plans were described. An example process assessment form is shown in Appendix A.

Future State Value Stream Map

The objective of the team was to address the marker band shortage on production assembly Line One. The research team, having identified the root cause of the marker band shortage, designed a new value stream map, based on the outcome of the fish bone diagram, current state value stream map as well as the assessment made. All the bottlenecks that were identified during the data analyses were considered. The team looked at the areas that needed modification or attention incorporated those needs into the new or future state value stream map. The new value stream map showed what the assembly line should look like in order to address the marker band shortage. Figure 3 shows an example of a future state value stream map for a manufacturing process.

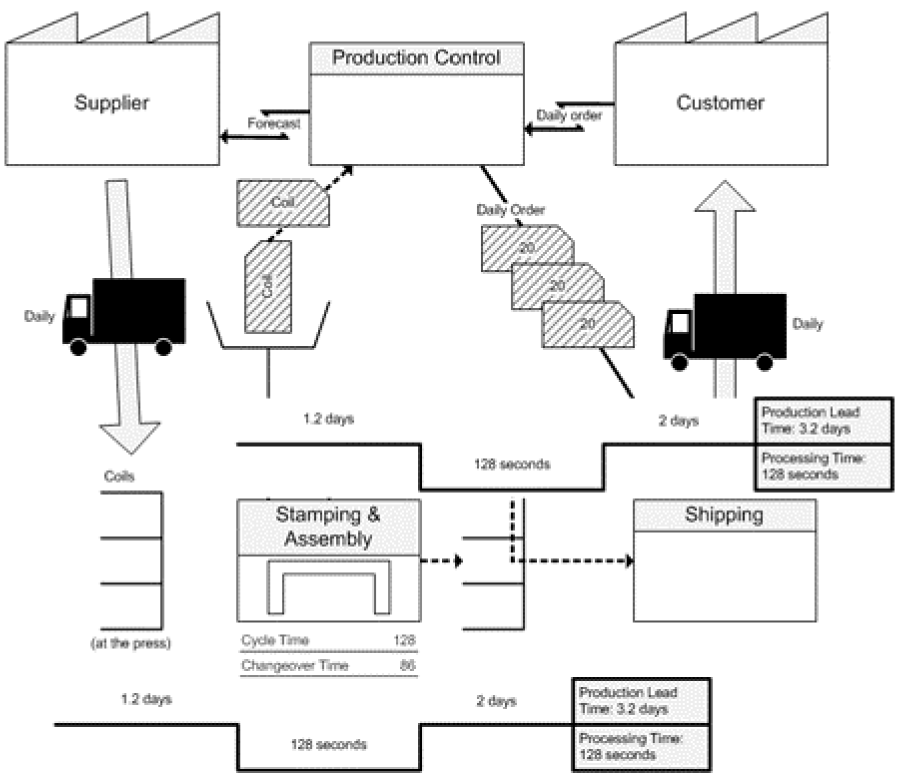

Figure 3. Example of a future state value stream map.

Limitations

The following were the limitations of this study. The company had not kept track of the exact amount of the marker band shortage and as such did not have adequate historical data to work with during the research. In addition to this limitation, product builders were reluctant to co-operate with the researcher. They were afraid to give information as far as the marker bands that fall on the floor are concerned for fear of being reprimanded or fired. Moreover, Line One is a new line that was set up recently and as such there was not ample space for the researcher to spend more time to observe the product builders while they were working on the line. Finally, the research had a high potential for addressing the issue of marker band shortage on Line One, but management hesitated to address it.

Summary

This chapter described the methodology used at Company XYZ assembly Line One. The team's goal was to find out the root cause of marker band shortage on production Line One and then, using lean process improvement tools, to find a lasting solution to it. Firstly, the chapter described the types of scraps recorded at marker band crimping, swaging and the final inspection.

Secondly, it described the current state value stream map which emphasized the various processes that marker bands go through during the production of balloon catheters. Thirdly, it elucidated on a fish bone diagram that was used to find out the root cause of the maker band shortage. Moreover, an initial assessment was made on the assembly Line One utilizing the current state value stream map.

In addition to what has been said, this chapter described the future state value stream map and illuminated the final process assessment of the new or future state value stream map in detail. The next chapter described the result of using lean process improvement tools to address the marker band shortage on assembly Line One. The actual data and findings of the study were presented.

Chapter IV: Results

Company XYZ was experiencing a shortage in the number of palladium rings, also known as marker bands, used in manufacturing balloon catheters. The quantity stated on the Kanban label from shipping and receiving was not consistent with the amount of product produced. It was against this backdrop that there was the need to investigate the production and process, using lean manufacturing process improvement tools, to find out the root causes of the shortage and address them accordingly.

The purpose of the research was to investigate the root cause of why one Kanban batch of 5000 marker bands intended to produce approximately 16 to 17 batches of 300 parts only produced about 15 to 16 batches on the production floor, and then provide direction on how to mitigate this problem using lean manufacturing process improvement tools. The intended result was elimination of marker band shortage, thereby reducing cost of stockroom scrap.

This chapter reviewed the results of, firstly, the value stream map, secondly, the fishbone diagram, thirdly, the future state value stream map; moreover, the analysis of the marker band crimping process was also discussed. This was followed by the summary of the whole chapter.

Scrap Data Sheet

The scrap recorded during crimping of marker band on the mandrels was recorded within a one-week period of observation by the research team. Table 2 shows the accrual scrap data recorded across all three shifts during the research. The data was used to determine which shift recorded the highest scrap.

Table 2

Marker Band Scraps on Assembly Line One per Shift

Shift	1st Shift	2nd Shift	3rd Shift
Scraps			
Poor Crimp	45	38	22
Bad Marker Bands	66	44	28
Marker Bands Fell on the Floor	125	160	21
Marker Band Position	41	52	12
Equipment Failure	63	91	15
Total	340	385	98

Current State Value Stream Map

Figure 4 represents the current state value stream map. The flow of production recorded by observing the production flow is represented in the value stream map. To fully identify where the shortage of marker band emanates from, the team looked at the operator working on the production process. It was observed that when the marker bands were delivered to the staging location by the warehouse attendance, product builders took the whole bag of about 5000 marker bands, which were in plastic bags, and emptied them into a marker band boat. During this process, no tool was used to scoop the marker bands from the bag. In this process, a lot of marker bands fell on the floor, and the product builder did not account for the marker bands that fell on the floor. Secondly, the product builder did not verify that the quantity on the acceptance label or Kanban label matched or corresponded to the physical marker bands on hand. Thirdly, the product builder worked on three major processes at a time. An operator works on marker band crimping, and then after crimping, the same operator then goes to the swaging table to perform marker band swaging and then proceeds to perform final inspection after swaging a hundred parts. Having one product builder performing these three steps had an adverse effect on the performance of the product builder, thus neglecting to record some of the scraps.

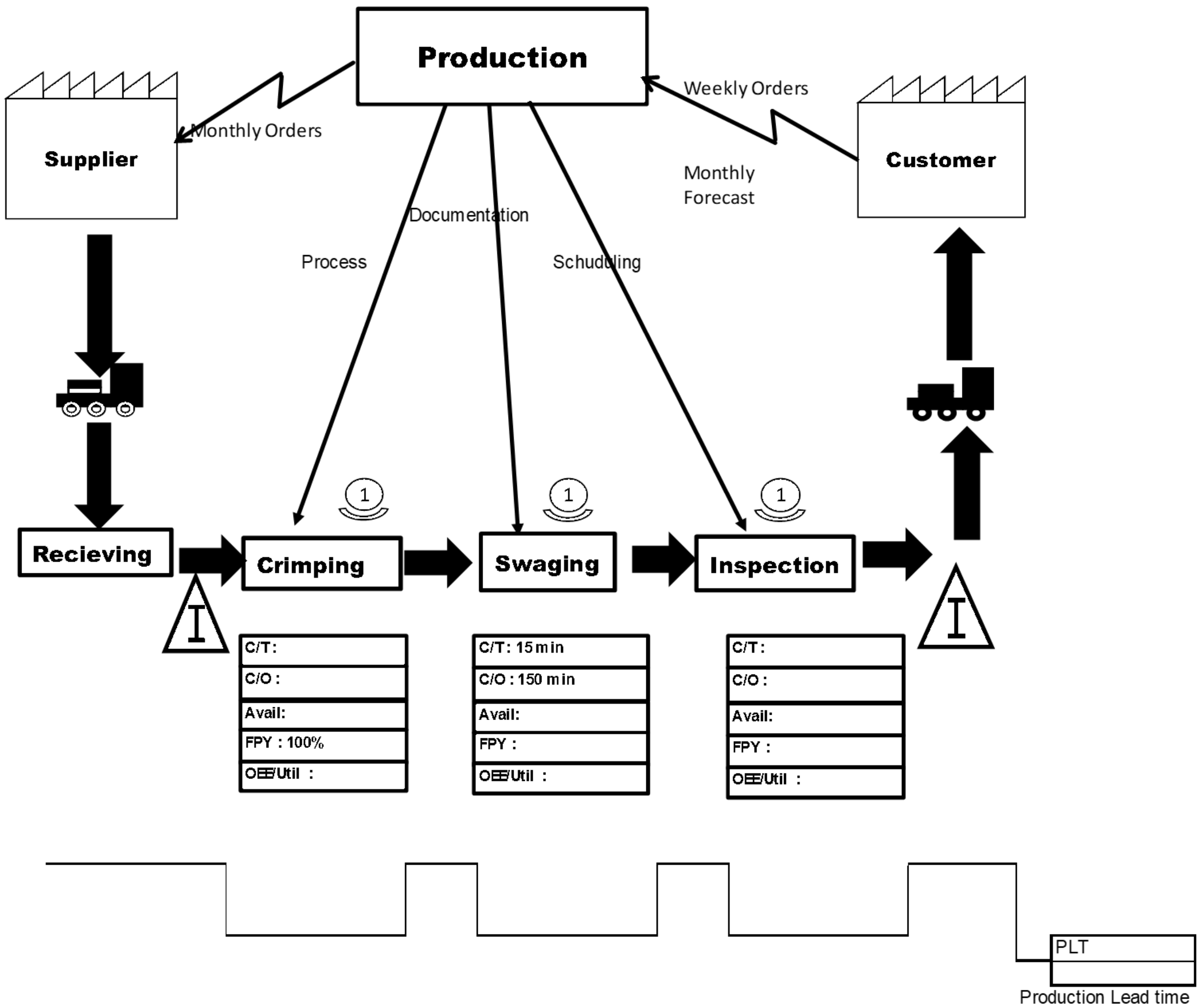

Figure 4. Current state value stream map.

Data Analysis

Figure 5 shows a fishbone diagram which identified the major factors for the marker band shortage on production Assembly Line One of XYZ Company. The fishbone diagram was created from the data gathered from the assembly Line One during the one-week period of observing the line.

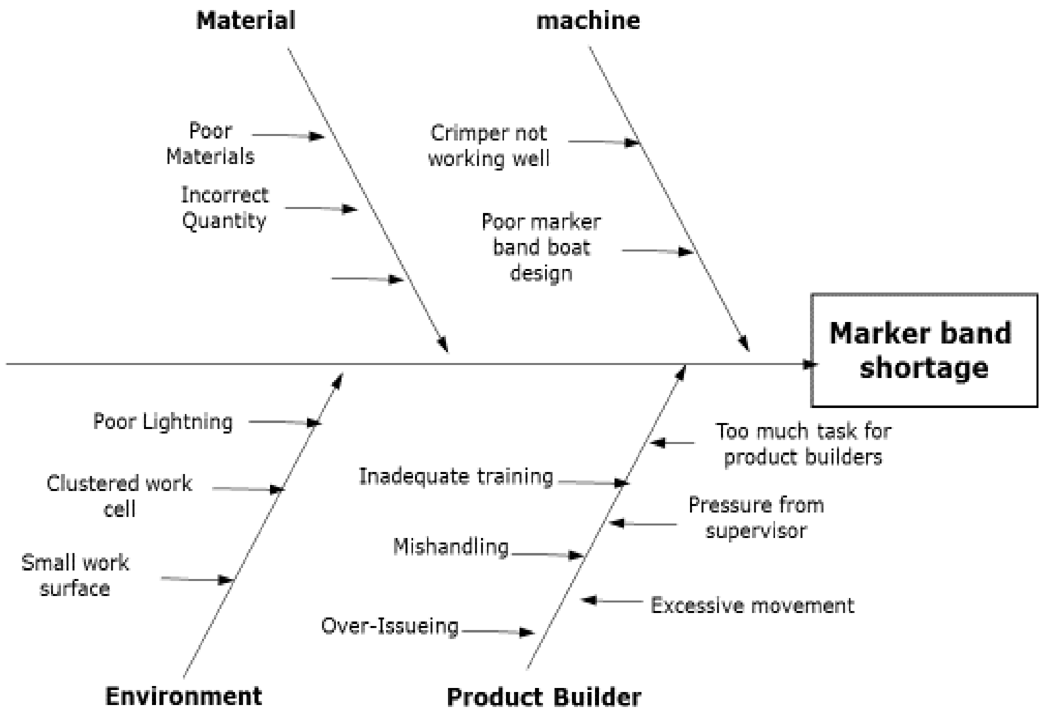

Figure 5. Cause and effect diagram.

As per the information gathered on production assembly Line One, coupled with the careful analysis of the various factors outline in the cause and effect diagram, the team noted four main triggers that were attributed to the marker band shortage on assembly Line One: machine, material, environment, and product builder or human factors. With respect to machines, the team looked at the scraps created by the crimper as well as the equipment such as the marker boat, a device that carries the marker bands when they are picked up from the staging location. The team also looked at the quality of the marker bands, ensuring that all marker bands used had a certificate of compliance; additionally, the team manually checked the quantity of marker bands received from the warehouse. The team also looked at the environment within which the product builders work, such the lighting system, chairs, tables and the space within the work cell. Apart from the above mentioned factors discussed, the team also looked at the human factors that had to do with the product builder. Having done this, the team then brainstormed possible causes of the problem that may be related to these factors.

During the brainstorming process, the team observed that the shortage of marker band on assembly Line One was related to human factors. In furtherance to this, it was observed that one operator performs three major processes, such as crimping, swaging and final inspection. In the process of performing these tasks coupled with the high expectations from supervisors, product builders tend to drop the marker bands on the floor without accounting for them. Secondly, mishandling of the marker band was another cause of the shortage. In addition to the before-mentioned facts, the pressure from supervisors for product builders to meet their goals also affected their output on the job. During the brainstorming, it was noted that some operators sometimes scrap marker bands without recording them. Finally, excessive movement by product builders coupled with the small work surface was also a reason. When parts fell off the marker band boats, instead of the work surface, they fell on the floor and as such were not scraped out as per the work instructions.

Process Assessment

The initial process assessment performed by the research team on the assembly Line One production process revealed that the production process itself was not flawed, meaning the process was working as it was intended to work. The process description, technology and automation, technical issues, process status, measurement systems, and process capability as well as cost were on track. All the targets set, gaps recorded, key issues, risks were addressed, and risk minimization plans described in detailed. An initial process assessment form is shown in Appendix B.

Future State Value Stream Map

The objective of the team was to address the marker band shortage on production assembly Line One. The research team, having identified the root cause of the marker band shortage, designed a new value stream map, based on the outcome of the fish bone diagram, current state value stream map as well as the assessment made. All the bottlenecks that were identified during the data analyses were considered. The team looked at the areas that needed modification or attention and incorporated those needs into the new or future state value stream map.

In the future state value stream map, two processes were merged into a single process. Crimping and swaging were amalgamated into one process that was performed by one product builder, and then final inspection was also performed by another product builder. With this update, when components were received from the warehouse, they went directly to the staging location. The product builder in crimping and swaging performs the task and, when completed, moved the product, which is a work in process, to the final inspection. The second product builder did the final inspection and then moved the inspected product to the staging location for the next assembly line. This development enabled product builders to relax in performing their task and ease the pressure on them. New work surface was provided so that marker bands that fell from the boat fell on the table rather than on the floor. In this way, these marker bands are picked up and put back to be used.

In addition to what has been discussed earlier, product builders were retrained on the handling of the marker band boat so that marker bands do not fall from the boats. A test performed on the future state value stream map showed a significant reduction in the marker band shortage on assembly Line One. It also improved on their yields and contributed to the team meeting it daily goals.

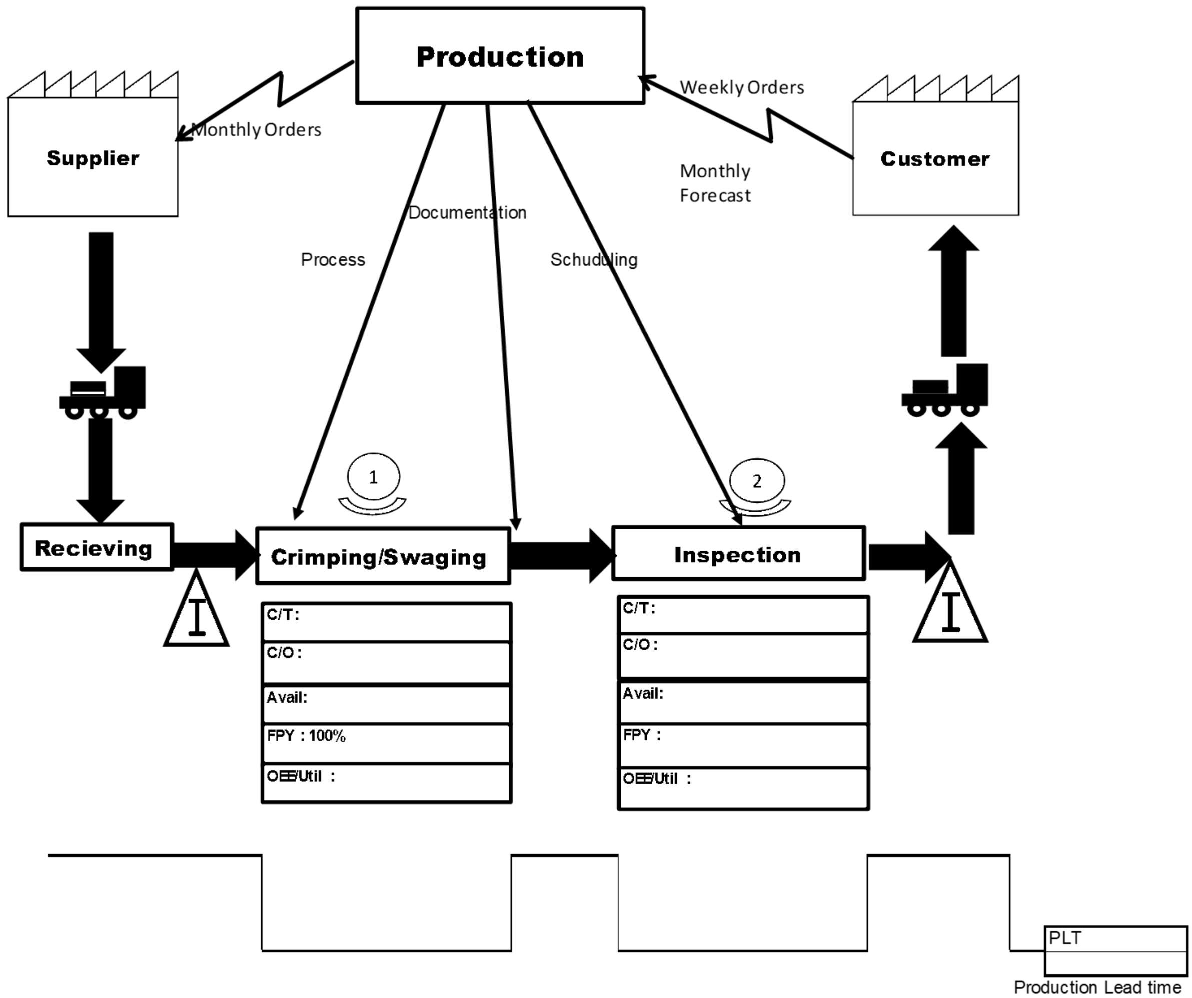

Figure 6. Future state value stream map.

Summary

After analyzing the one-week scrap data sheet as well as the entire flow of production, a current value stream map was created. Having created the current state value stream map, the team created a fish bone diagram to find out the root cause of the marker band shortage. The team brainstormed on the fishbone diagram to identify the factors that caused marker band shortage on production Line One. An initial process assessment was done on the assembly line.

The data gathered from the current state value stream map coupled with the fishbone diagram after brainstorming was used to draw a future state value stream map. The future state value stream map was implemented, and the result was tremendous.

Table 3

Marker Band Scrap on Assembly Line One per Shift After Improvements

Shift	1st Shift	2nd Shift	3rd Shift
Scraps			
Poor Crimp	16	21	4
Bad Marker Bands	66	44	28
Marker Bands Fell on the Floor	36	66	7
Marker Band Position	18	21	5
Equipment Failure	27	42	15
Total	163	194	59

There was a significant improvement in marker band shortage on assembly Line One as shown in Table 3. Prior to the implementation of the future state value stream map, the total scraps recorded across all three shifts was 823 parts; however, with the implementation of the new value stream map, the total scrap was reduced to 416 parts, representing a little over 50% reduction in scrap on production assemble Line One. With the improvement in marker band shortage, scraps were reduced, and production yield increased, thereby improving the team production goals.

The final chapter discusses the conclusion and recommendation for assembly Line One of XYZ Company.

Chapter V: Discussion, Conclusion and Recommendation

Company XYZ was experiencing a shortage in the number of palladium rings, also known as marker bands, used in manufacturing balloon catheters. The quantity stated on the Kanban label from shipping and receiving was not consistent with the amount of product produced. It was against this backdrop that there was the need to investigate the production and process, using lean manufacturing process improvement tools, to find out the root causes of the shortage and address them accordingly. The purpose of the research was to investigate the root cause of why one Kanban batch of 5000 marker bands intended to produce approximately 16 to 17 batches of 300 parts only produced about 15 to 16 batches on the production floor, and then provide direction on how to mitigate this problem using lean manufacturing process improvement tools. The intended result was elimination of marker band shortage, thereby reducing cost of stockroom scrap.

Chapter I presented an overview of Company XYZ, who they are, what they do and their history. It also defined the problem and its setting, purpose of the study, assumptions, definition of terms related to this project, limitation, methodology as well as a brief summary of the chapter. Chapter II examined literature from experts in the field while discussing what was already been implemented in the industry and what might apply to this project. The literature review asserted how a previous application of lean process improvement tools and process assessment has been successful with related projects aligned with expectations on the outcomes regarding this study. Chapter III detailed the methodology used in collecting and analyzing data, including sample data tables on scraps, current state value stream map, fishbone diagram, future ate value stream map as well as sample process assessment forms. It also explained how lean improvement tools worked in collaboration with other tools to develop viable solutions aligning to this project's achievement. Chapter IV presented the results of the lean process improvements tools application and methodology. Finally, Chapter V examines the project's limitations, conclusion and the researcher's recommendations for future advances.

Limitations

The results gathered in this study were limited to the one-week observation of production assembly Line One of Company XYZ. Since assembly Line One was a new line, the company did not keep track of the exact amount of the marker band shortage and as such did not have adequate historical data to work with during the research. In addition to this limitation, product builders were reluctant to co-operate with the researcher team. They were afraid to give information as far as the marker bands that fell on the floor are concerned for fear of being reprimanded or fired. Moreover, Line One was a new line that was set up recently and as such there was not ample space for the research team to spend more time to observe the line while product builders were working on the line. This development greatly affected the data gathered during the week-long observation. Finally, the research had a high potential in addressing the issue of marker band shortage on Line One, but management hesitated to address it due to the cost that the company may incur as well as the tendency of the research team to slow down assembly Line One.

The methodology examined during this research, the data collected, and the analysis done was unique and specific to the production assembly Line One. Due to time constraints, the research team did not put much effort in looking into other factors seen on the fishbone diagram that could have been potential causes of the marker band shortage. This research was limited to the problem addressed and did not utilize all the lean process improvement tools.

Conclusions

Due to the marker band shortage on assembly Line One, and the very fact that one product builder performs three main processes, such as marker band crimping, swaging and final inspection, the process improvement team at Company XYZ implemented lean process improvement methodologies in this study to successfully reduced the marker band storage on the assembly line that was discovered. The used of scrap data sheet, value stream map, fishbone bone diagram, coupled with process assessment methods, and implementation of the change by the team, helped a great deal in achieving the goals of this research. Company XYZ saw a significant reduction in their marker band shortage problem. The scrap data sheet that was used recorded about 824 scraps across all three shifts. This high volume of scraps and unrecordable marker bands recorded in the current state value stream map is partly due to labor, where one product builder was overloaded with three major tasks within a work cell. This resulted in the high volume scraps recorded. However, after implementing the future state value stream map, two processes, namely crimping and swaging, were combined, and one product builder was assigned that task. Final inspection was also assigned to another product builder. This development greatly reduced the load and pressure on the product builders, and, as such, scraps and unrecordable scraps were tremendously reduced. Scraps recorded after the implementation of the changes was 416. With this figure, it is evidently clear that the goal of the research was achieved with an approximated percentage scrap of 49.99%.

Recommendations

The goals for this study were to eliminate marker band shortage on production assembly Line One using lean process improvement tools and methodologies. The use of the process improvement tools to address the marker band shortage was focused primarily on production assembly Line One. Looking at the success rate and the fabulous improvements it brought on the line, these tools coupled with other applications should be applied to improve product builder’s efficiency and effectiveness in other lines as well as departments of Company XYZ and all its affiliates within the United State.

Secondly, Company XYZ should look at their labor and machine capacity and make adjustment when necessary. This way, undue pressure on product builders by their supervisors to make their daily goals will be eliminated and product builders can produce good product that meet quality requirements without having to rush for number.

Thirdly the research team did not deliberate on all the other factors found on the fishbone diagram. It is obvious that some of these factors contributed to the high volume of marker band shortage experienced by Company XYZ, on their assembly Line One; hence, the company should do further research into that and see how they contribute to the marker band shortage on their assembly line and then follow the same methodology to eliminate them.

In furtherance to the above mentioned fact, product builders retraining could also be a potential source in addressing the marker band shortage. As enshrined in the scrap data sheet in Chapter IV, some of the issues that recorded higher scraps were peculiar to certain shift. In looking at this further, it was discovered by the research team that these product builders were novice who had little experience on the job and as such, it was recommended that production trainers spend ample time with new hires during training and old product builders who underperform should also be retrained to help mitigate the problems mentioned earlier.

Summary

The marker band shortage on production assembly Line One was tremendously improved after utilizing lean process improvement tools as well as process assessment. It is envisaged that in the near future, the company will implement lean process improvement methodologies throughout the plant to address similar problems that may crop up in other assembly lines and other departments, thereby improving production yields, employee performance and productivity, reducing cycle time, improving lead time, increasing assembly line efficiency and ultimately meeting the ever-growing demand market. In this way, the company can get product to their customers in a timely manner to increase their market shares and maintain their supremacy in today's competitive balloon catheter market.

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Appendix A: Sample Process Assessment Form

Section A: Process / Technology Assessments

1.0 Purchased Components

Process Work instructions	
Process Description	
Technology and Automation status	
Technology and Automation Contingencies	
Technical Issues	
Process status	
Measurement System Status	
Process capability	
Expected yield	
Scrap Cost	
Process FMEA	
Process Cycle Time Data to Date	
Risk Mitigation Plan	
Process Risk	
Overall Risk Assessment	

2.0 Marker bands (Crimping)

Process Work instructions	
Process description	
Technology and Automation status	
Technology and Automation Contingencies	
Technical Issues	
Process status	
Measurement System Status	
Process capability	
Expected yield	
Scrap Cost	
Process FMEA	
Process Cycle Time Data to Date	
Process Risk	
Risk Mitigation Plan	
Overall Risk Assessment	

3.0 Swaging

Process Work instructions	
Process description	
Technology and Automation status	
Technology and Automation Contingencies	
Technical Issues	
Process status	
Measurement System Status	
Process capability	
Expected yield	
Scrap Cost	
Process FMEA	
Process Cycle Time Data to Date	
Process Risk	

Risk Mitigation Plan	
Overall Risk Assessment	

4.0 Final Inspection

Process Work instructions	
Process description	
Technology and Automation status	
Technology and Automation Contingencies	
Technical Issues	
Process status	
Measurement System Status	
Process capability	
Expected yield	
Scrap Cost	
Process FMEA	
Process Cycle Time Data to Date	

Section B: Approval

Approver	Role	Signature	Date
			N/A
			N/A
			N/A
			N/A
			N/A
			N/A

Appendix B: Actual Process Assessment Form

Section A: Process / Technology Assessments

The process / technology Assessment section serves to provide a comprehensive overview of the process improvement effort throughout the production. It is the place where targets are set, gaps are recorded, key issues and risks surface, and risk mitigation plans are described.

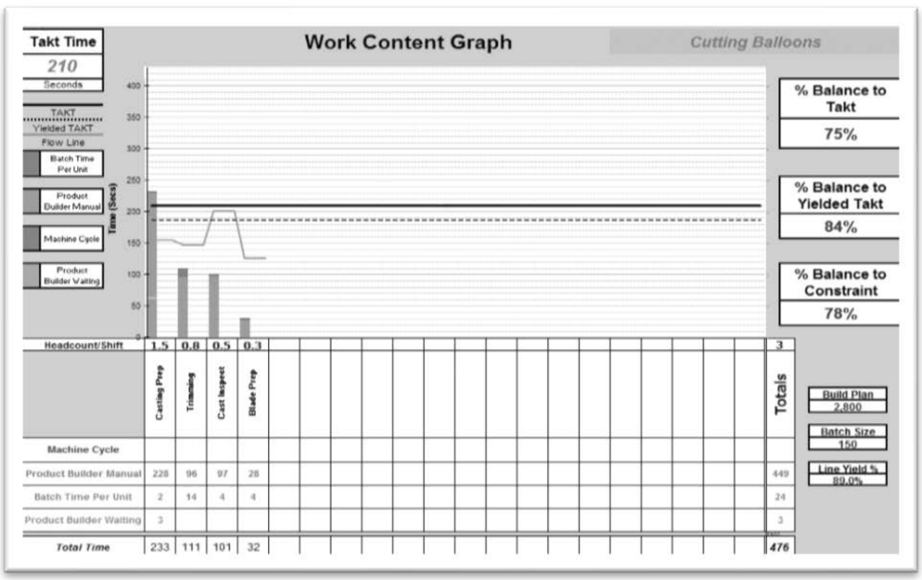
1.0 Purchased Components

Process Work instructions	N/A
Process Description	Currently marker bands are purchase from a new Company and supplied to the assembly Line One for crimping
Technology and Automation status	N/A
Technology and Automation Contingencies	N/A
Technical Issues	Process is developed for external vendor once the contract is agreed
Process status	
Measurement System Status	N/A – External Vendor
Process capability	N/A-
Expected yield	N/A
Scrap Cost	N/A
Process FMEA	N/A
Process Cycle Time Data to Date	N/A
Process Risk	Marker band supplier capacity SLE timeline to meet the submission. Marker band meet all FARE requirement
Risk Mitigation Plan	Standby Supplier. (Grade B.)
Overall Risk Assessment	Probability= Medium (Probability of experiencing identified risk Severity= High (Severity to project if identified risk occur)

2.0 Marker bands (Crimping)

Process Work instructions	Smart Marker Band Crimping

Process description	Press the HOME STAGES button on the touch screen to begin the homing sequence. Follow screen prompts and hold down both opto switches to move nest and hardtop into the HOME position. Check mandrel is straight and Teflon coating is intact. Insert correct distal laser weld mandrel (non-coated/stepped end) into proximal end of necked inner. aligned distal end of mandrel approximately 4" beyond the distal end of the inner. Put marker band(s) in proximal and distal nests (distal nest only for single marker band). High density swabs may be used to aid in positioning marker bands into nests.
Technology and Automation status	Smart marker band crimping system
Technology and Automation Contingencies	Smart marker band crimping system- Contingencies manual loading of marker bands
Technical Issues	Loading and handling of Marker bands
Process status	Active, no issues
Measurement System Status	If machine does not cycle, look at the screen for a FAIL condition. If a failure is shown in any of the inspection boxes, take the part and confirm that the correct quantity of marker bands is present, the Teflon coating extends beyond the distal end of the inner, and the part is free of FM.
Process capability	

<table>
<tr><td>Expected yield</td><td>Yield targets as detailed in Terms and Conditions
<table>
<tr><th></th><th>DV Complete</th><th>2016</th><th>2017</th><th>2018</th><th>2019</th></tr>
<tr><td>Blade Bonding</td><td>80%</td><td>N/A</td><td>N/A</td><td>87%</td><td>100%</td></tr>
</table>
Yield Targets directly impact COGS,
Yields results need to be based on all print outputs being inspected,
Failure to achieve targets will require remediation activity post PV.</td></tr>
<tr><td>Scrap Cost</td><td>TBD</td></tr>
<tr><td>Process FMEA</td><td>9253213</td></tr>
<tr><td>Process Cycle Time Data to Date</td><td>Work Content graph completed on the marker band crimping process, current line constraint is Crimping Height Setting,
2nd crimping height setting vision system was put in place to elevate constraint

</td></tr>
<tr><td>Process Risk</td><td>Crimping Height setting cycle time</td></tr>
<tr><td>Risk Mitigation Plan</td><td>Extra crimper head was purchased to increase capacity</td></tr>
<tr><td>Overall Risk Assessment</td><td>Probability= Medium (Probability of experiencing identified risk
Severity= High (Severity to project if identified risk occur)</td></tr>
</table>

3.0 Swaging

Process Work instructions	**N/A**
Process description	**N/A**
Technology and Automation status	N/A
Technology and Automation Contingencies	N/A
Technical Issues	N/A
Process status	N/A
Measurement System Status	N/A
Process capability	N/A
Expected yield	N/A
Scrap Cost	N/A
Process FMEA	N/A
Process Cycle Time Data to Date	N/A
Process Risk	N/A
Risk Mitigation Plan	N/A
Overall Risk Assessment	N/A

4.0 Final Inspection

Process Work instructions	N/A
Process description	N/A
Technology and Automation status	N/A
Technology and Automation Contingencies	N/A
Technical Issues	N/A
Process status	N/A
Measurement System Status	N/A
Process capability	N/A
Expected yield	N/A
Scrap Cost	N/A
Process FMEA	N/A
Process Cycle Time Data to Date	N/A

Section B: Approval

Approver	Role	Signature	Date
	Manufacturing Engineer	Reviewed and approve content	N/A
	Process development Engineer	Reviewed and approve content	N/A
	Operations Manager	Reviewed and approve content	N/A
	Process Development Manager	Reviewed and approve content	N/A
	Quality Manager	Reviewed and approve content	N/A
	Production Supervisor	Reviewed and approve content	N/A