Implementing Lean Manufacturing Principles in a Manufacturing Environment

by

Rodney S. Rogstad

A Research Paper
Submitted in Partial Fulfillment of the
Requirements for the
Master of Science Degree
in

Manufacturing Engineering

Approved: 3 Semester Credits

James Keyes, Ph.D.

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Title: ***Implementing Lean Manufacturing Principles in a Manufacturing Environment***

Graduate Degree/ Major: MS Manufacturing Engineering

Research Adviser: **James Keyes, Ph.D.**

Month/Year: **December, 2010**

Number of Pages: **53**

Style Manual Used: **American Psychological Association, 6th edition**

ABSTRACT

With the importance of being competitive in today's medical market, Company X was focusing their efforts towards lean manufacturing. With the mindset of building products cheaper, faster, and better to gain a competitive edge in the market, lean manufacturing helped Company X get there. This paper covers some of the lean principles that Company X used to give them the competitive advantage by using value stream maps, time studies, and spaghetti diagrams. Using these tools gave this company a good understanding of how product flows through their facility, where the value is, and the lead times associated with building the product. Having a good understanding of these lean tools allowed for a better understanding of the waste that was in the production line and the importance of eliminating it.

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Acknowledgments

First and foremost I would like to thank my wife Dana for her patience as I spent many late nights and long weekends over the last 2 ½ years working towards the completion of my degree. I can't put into words how much I appreciate your support! Next I would like to thank Professor Keyes for not only his support and input during the writing of this paper but also for the classes that he taught. The amount that I have learned about Lean is incredible and I can't thank you enough for the knowledge that you have provided. To UW-Stout; thank you for offering the great program of Master of Science in Manufacturing Engineering. Last but not least I want to thank my entire family for their support....I love you all!

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Chapter I: Introduction

This project was completed at Company X in a western suburb of the Twin Cities in Minnesota. The current product is a medical device that is approximately nine years old and has been manufactured using the same production techniques for the life of the product. Company X wanted to change the way the product was produced and flowed through the factory so the Company could become lean within their manufacturing environment. Company X was experiencing large amounts of work-in-process from the final assembly line to the close-up area.

The final assembly line consists of three assembly stations. Each station is responsible for assembling specific components into the front housing of the device prior to forwarding to the next assembly station. The close-up station consists of one work station that is responsible for closing the front housing to the back housing prior to forwarding to the next station.

By recognizing the benefits of lean manufacturing using a pull system as opposed to a push system, Company X made the decision to implement the techniques conducive to one piece flow by implementing lean principles and promoting a pull system. By taking one area and implementing lean principles allowed the company to make the successful transition to lean manufacturing per assembly area rather than try and implement lean into the entire production floor all at once. This project focused on final assembly line through close-up. This particular area was chosen for this project due to excess work-in-process.

To gain a better understanding between one piece flow and batch manufacturing, one piece flow is the process of moving one work-piece at a time between operations. Batch processing is producing lots or quantities of parts at one operation and them moving the product to the next operation. Batch manufacturing has the appearance of a disorganized production line and creates excessive rework of product if an error was discovered down the line. By implementing one-piece flow, Company X was able to have an organized assembly line, reduce rework, and significantly reduce work-in-process.

Statement of the Problem

Batch processing results in more units being worked on than is necessary and produces excess work-in-process. To reduce work-in-process, Company X wanted to move from batch processing to one-piece flow utilizing lean manufacturing principles.

Purpose of the Study

This study analyzed the existing state of manufacturing and testing the medical devices in batches. An implementation plan was developed to implement lean manufacturing principles to support one-piece flow. The plan was implemented and the results of the implementation resulted in improved productivity and resulted in a reduction in work-in-process.

Assumptions of the Study

The assumptions of this study are:

1. The work performed by the operators was performed using the detailed manufacturing procedures in which they are required to be trained to.
2. The operators understood and followed the training provided for one piece flow.
3. The reduction in work-in-process was the result of implementing one piece flow.
4. The improved throughput is the result of implementing one piece flow.
5. No significant changes were made to the product that impacted one piece flow.

Definition of Terms

Batch Processing. Manufacturing process in which components or goods are produced in groups (batches) and not in a continuous stream. (BusinessDictionary.com, n.d.)

DMAIC. Define, Measure, Analyze, Improve, Control. (George, 2002)

IPK. In-process kanban – Determines the amount of WIP (Work In Process) that can be kept between any two operations in a process. (Chapados & Perlinska, n.d.)

Kanban. Kanban is Japanese for sign or designated place. It is used in manufacturing to mean a visual signal that tells when it is time to get or make more of something. (Chapados & Perlinska, n.d.)

Kaizen. Kaizen means "continuous improvement" in Japanese. (George, 2002)

One piece flow. This concept starts at the customer, whereby the customer purchases a single piece and the manufacturing system should replenish only that piece. Hence, the Lean system stives tomake one piece at a time, this is true one piece flow. (Wilson, 2010)

WIP. Work in Process. All materials in the production process once they are withdrawn from the storehouse until they are stored as finished goods. (Wilson, 2010)

Limitations of the Study

The limitations of the study are:

1. The results of this study are limited from final assembly through close-up.
2. The study does not include all lean manufacturing principles.
3. The study is intended to show the results of implementing lean manufacturing principles.
4. This study is specific to Company X.

Methodology

A literature review was used to review the principles of lean manufacturing. An implementation plan was developed to implement lean manufacturing principles within the assembly through close-up area. A floor layout plan was designed to show the future state of the assembly line. Operators were used to assist in making the improvements to the assembly line and implement these principles. Before and after illustrations were used to show the impact of implementing the lean principles. Data was collected and presented in this research to show the improvements in throughput and the financial impact to reduction in work-in-process.

Summary

This chapter provides an introduction to Company X and the market in which they serve along with the manufacturing issues that were addressed to help better position them to be more competitive in the medial market. This chapter also lays the foundation for which the rest of this study provided by helping Company X achieve their goal of using lean manufacturing principles in their production process.

Chapter II: Literature Review

Introduction

The purpose of this literary review is to gain insight into lean manufacturing and how it can be applied within a manufacturing environment. With global competition, it is important for manufacturers to remain competitive in their respective markets and to understand the principles of lean manufacturing and the steps to implement them to ensure that they are on the leading edge of manufacturing. This literary review describes these key principles.

Origins of mass production and the birth of lean.

Fred Winslow Taylor, a foundry manager from Philadelphia, laid the foundation for mass production (Dennis, 2002). He was the first to systematically apply scientific principles to manufacturing. His many innovations included: Standardized work – identifying the best and easiest way to do the job; Reduced cycle time – the time it takes for a given process; Time and motion study – a tool for developing standardized work; Measurement and analysis to continually improve the process. The key to mass production was not the assembly line (Dennis, 2002). Rather, it was the thorough interchangeability of parts and ease of assembly. These innovations, in turn, made the assembly line possible.

Henry Fords' conveyor system at the Ford plant, allowed for mass production (Tapping, 2007). The moving assembly line brought the car past the stationary worker. (Dennis, 2002) The assembly line reduced walk time, and most importantly, linked sequential processes. Thus, slower workers sped up and faster workers slowed down. No other company had this technology and could not compete with the Ford plant (Tapping, 2007). Ford's system catapulted the company to industry leadership (Dennis, 2002).

In the spring of 1950, a young Japanese engineer named Eiji Toyoda visited Ford's vast Rogue Plant in Detroit (Dennis, 2002). He studied every corner of the Rogue, the world's biggest and most efficient manufacturing complex. Upon his return to Japan, Eiji and his production genius, Taiichi Ohno, concluded that mass production would not work in Japan. Taiichi Ohno already knew that workers were his most valuable resource. In the years to come, Ohno and his team developed activities to fully involve team members in improvement – an utterly novel idea.

The Toyota Production System, or lean production, was the solution to Toyota's problems (Dennis, 2007). Over the next thirty years, Taiichi Ohno solved these problems one by one and pushed his system through Toyota. Today, the Toyota Production System (TPS) is used synonymously with "lean manufacturing" throughout the world (Tapping, 2007). But today we face the same daunting problems that Toyota faced a half century ago. Ohno's system is more relevant than ever (Dennis, 2007).

What is lean manufacturing?

Lean manufacturing can best be described as eliminating waste in a production process (Womak and Jones, 1996). Anything that does not add value to the end product is waste. Womak and Jones (1996) stated that lean thinking can be summarized in five principles: precisely specify value by specific product, identify the value stream for each product, make value flow without interruptions, let the customer pull value from the producer, and pursue perfection.

The first requirement in making a successful transition to lean is to have a clear vision of what the company will become (Henderson & Larco, 2003). You can get there, there is no doubt, but the journey will take time and discipline. All the while you must hold tight to the vision and take consistent actions.

Essentially, lean manufacturing seeks to produce a product that is exactly what the customer wants, when the customer wants it, while minimizing all non-value added activities in production (Womack & Jones, 2005). In the literature, value is simply defined as what the customer is willing to pay for. Non-value added activities are generally understood to be either waste, or incidental activities that are necessary but add no value to the product. The best example of a non-value added activity is quality assurance. Quality inspections do not add value to a product; they merely detect defects before they reach the consumer. The foundation of the lean system is *stability* and *standardization* (Dennis, 2007). The walls are *just-in-time* delivery of parts of products and *jidoka*, or automation with a human mind. The goal (roof) of the system is customer focus: to deliver the highest quality to the customer, at the lowest cost, in the shortest amount of time. The heart of the system is *involvement:* flexible motivated team members continually seeking a better way.

Very often, we tend to see business leaders, project managers getting honored by the Managing Director of an organization for completion of a successful project (Prasad, 2007). Good business results were achieved and there comes the CEO or Managing Director recognizing them in front of all the other top guns. That is good but isn't enough. The important point here is in order for a company to stay competitive and healthy in business, it does not only need the commitment and contribution from these top people, but the entire population of the organization. The population here is referred to the 'line workers' that means the line operators, technicians or shop floor personnel.

When the time comes to begin the transformation to lean, management will need to get people together and let them know what is going to happen, and what they can expect (Henderson & Larco, 2003). A meeting or series of meetings should be held in which plans, objectives, strategies, and the reasons for the transformation are communicated. The purpose of the meetings is to create a vision for the immediate future, a road map that will eliminate as much uncertainty as possible during what is sure to be an uncertain time in the company. People should understand why the decision to go lean has been made, that it is essential to remaining competitive, and that it is the only way to achieve the company's goals. They can expect the company to grow and expand which will create opportunities, some of which will flow to them.

The lean transition is, at its core, an organizational culture transition and it follows that managing lean, particularly during the initial phases, is actually more about managing the change process than managing lean tools and techniques (Csokasy & Parent, 2007). By initial phases we are referring to the time period in takes to create a culture that does not automatically revert back to the "old ways of doing work" when faced with a challenge. Until the desired new behaviors become firmly established, that is to say that the culture has been truly changed, they are at risk of being subordinated by the old behavior and disappearing. Culture change takes time; it cannot be accomplished overnight or in a few weeks. With hard work and determination combined with a little luck, significant culture change might be accomplished in a few years.

The seven types of waste in a manufacturing process.

The key principle of Lean is that waste ("muda") is the underlying driver of operational inefficiency (Garfein & Menawat, 2006). To become more efficient, companies should identify waste from the customer perspective and then determine how to eliminate it. Waste is defined in general terms as activities that do not add value to the product/service and that the customer would not want to pay for.

Toyota has identified seven major types of non value-adding waste in business or manufacturing processes, which are described in Table 1 (Liker, 2004). These can be applied to product development, order taking, and the office, not just a production line.

Table 1

Definitions for the seven types of waste in a manufacturing process.

Type of Waste	Description
Overproduction	Producing items for which there are no orders, which generates such wastes as overstaffing and storage and transportation costs because of excess inventory.
Waiting (time on hand)	Workers merely serving to watch an automated machine or having to stand around waiting for the next processing step, tool, supply, part, etc., or just plain having no work because of stock outs, lot processing delays, equipment downtime, and capacity bottlenecks.
Unnecessary transport or conveyance.	Carrying work in process long distances, creating inefficient transport, or moving materials, parts, or finished goods into or out of storage or between processes.
Over-processing or incorrect processing	Taking unneeded steps to process the parts. Inefficiently processing due to poor tool and product design, causing unnecessary motion and producing defects. Waste is generated when providing higher-quality products than is necessary.
Excess inventory	Excess raw material, work-in-process, or finished goods causing longer lead times, obsolescence, damaged goods, transportation and storage costs, and delay. Also, extra inventory hides problems such as production imbalance, late deliveries from suppliers, defects, equipment downtime, and long setup times.
Unnecessary movement	Any wasted motion employees have to perform during the course of their work, such as looking for, reaching for, or stacking parts, tools, etc. Also, walking is waste.
Defects	Production of defective parts or correction. Repair or rework, scrap, replacement production, and inspection mean wasteful handling, time, and effort.

When these elements of waste exist, all they do is increase costs and add zero value to the manufacturing process (George, 2003). Ohno considered the fundamental waste to be overproduction (Liker, 2004). Producing more than the customer wants by any operation in the manufacturing process necessarily leads to a build-up of inventory somewhere down stream: the material is just sitting around waiting to be processed in the next operation.

Lean organizations are adept at processing only what the subsequent step in the process requires (Garafein & Menawat, 2006). The processing is done when it is needed and at the right quality levels. By identifying and eliminating waste, the remaining work is only what is needed to convert the product or service into a form that the customer is willing to pay for. An implicit assumption with this approach is that eliminating waste reduces cost.

Steps to eliminate waste in a manufacturing process.

Process improvement is the only way to improve the results that your company wants to improve (George, Rowlands, & Kastle, 2004). You have to examine how work flows from one person or workstation to the next. You have to look at variation and how it affects the process.

A good place for any company to begin the journey to lean is to create continuous flow wherever applicable in its core manufacturing and service processes (Liker, 2004). Flow is at the heart of the lean message that shortening the elapsed time from raw materials to finished goods (or services) will lead to the best quality, lowest cost, and shortest delivery time. Flow also tends to force the implementation of a lot of the other lean tools and philosophies such as preventive maintenance and built-in quality.

A lean process is one in which the value-added time in the process is more than 25% of the total lead time of that process (George, 2002). To get to world class, the value added time divided by the total lead time must equal 25% or greater.

The goal of lean is to virtually eliminate wait time (George, 2002). In order to eliminate the waste and eliminate the wait time, the company has to be able to look at the value stream of the manufacturing process. What is it that adds value to the product and what is it that does not add value to the product. This process is known as the value-stream. The value-stream is simply going through the entire manufacturing process and looking at the things that add value to the product and the things that do not. Once those key factors are determined, the process of eliminating waste can begin by concentrating on those things that do not add value.

From a lean perspective, the first thing you should do in approaching any process is to map the value stream following the circuitous path of material (or paper or information) through your process (Liker 2004). It is best to walk the actual path to get the full experience. You can draw this path on a layout and calculate the time and distance traveled and then give it the highly technical term of "spaghetti diagram".

A "spaghetti diagram" is a very useful tool in that it gives the true path of how material is flowing through the process. Once this diagram is on paper, it gives people a good visual understanding as to the path the material is flowing and how much distance is wasted during the transfer of material. With this visual tool, it allows people the opportunity to start working towards a more efficient flow of material and eliminate the unnecessary travel distance that is currently in their system.

With this knowledge, we can manage decision points, form a future roadmap for implementation, and identify opportunity areas (George, 2002). Value stream mapping also provides a communication tool to stimulate ideas by capturing critical organization knowledge and identifying locations for data gathering and process measurement. The key insight is that a lot of non-value-added costs are in fact required to move the product through the "molasses" flow. You can't remove these costs until you remove the underlying causes; trying to do so will just create greater costs in the long run.

You will have identified your discreet value streams early in the lean implementation process; it is within these value streams that we apply lean tools to reduce lot sizes, lead time, inventory and cost (Dixon, 2009). One vital step toward excellence is the co-location of process elements in the value stream, which is a layout issue. Until we physically isolate the value streams, we are quite limited in our ability to remove waste. On the other hand, when we have "shuffled the furniture" to create cells and focused factories, we have set the stage for major waste reduction. We can now foster a lean culture characterized by an abiding commitment to continuous improvement.

Just as activities that can't be measured can't be properly managed, the activities necessary to create, order, and produce a specific product which can't be precisely identified, analyzed, and linked together cannot be challenged, improved (or eliminated altogether), and, eventually, perfected (Womack and Jones, 1996). Lean benchmarkers who discover their performance is superior to their competitors' have a natural tendency to relax while mass producers discovering that their performance is inferior often have a hard time understanding why. They tend to get distracted by easy-to-measure or impossible-to-emulate differences in factor costs, scale, or "culture"' when the really important differences lie in the harder-to-see ways value-creating activities are created. Don't worry about your competitors; compete against perfection by identifying all activities that are waste and eliminate them.

You will become a World Class performer one Kaizen event at a time (Dixon, 2009). Use resources who know how to structure and facilitate effective events, as well as help develop inhouse people. It is critical to use report-outs at the end of each Kaizen event to educate management and recognize efforts.

What is Lean Six Sigma

The term "Six Sigma" is a reference to a particular goal of reducing defects to zero (Pande, Neuman, and Cavanagh, 2002). The sigma, or standard deviation, tells you how much variability there is within a group of items (the "population"). The more variation there is, the bigger the standard deviation. In statistical terms, therefore, the purpose of six sigma is to reduce variation to achieve very small standard deviations so that almost all of your products or services meet or exceed customer expectations.

Lean Six sigma is a methodology that maximizes shareholder value by achieving the fastest rate of improvement in customer satisfaction, cost, quality, process speed, and invested capital (George, 2002)

Since Lean Six Sigma starts with customers, its goal is clear – to eliminate anything that doesn't meet their needs (George, Rowlands, & Kastle, 2004). What's also important in Lean Six Sigma is checking on the consistency in your products, services, and processes. How likely is it that customers will consistently get something they're happy with? If you deliver what they want one day, but not the next day, they may take their business elsewhere.

The Principle of Lean Six Sigma: The activities that cause the customer's critical-to-quality issues and create the longest time delays in any process offer the greatest opportunity for improvement in cost, quality, capital, and lead time (George, 2002). Though each piece of the Lean Six Sigma process can add value to your organization, the real gains will come from seeing the methods as a complete process that help you determine and implement clear direction from the board room to the frontline office or factory.

Lean Six Sigma combines the two most improvement trends of our time: making work better (using Six Sigma) and making work faster (using lean principles) (George, et al., 2004).

Establish metrics that are meaningful for the health of your business (Wheat, Mills, & Carnell, 2003). Metrics – measures against which current procedures and finished products can be compared – will be different for each organization. These metrics will be the goals that the company should always be working to achieve. If it matters, it will be measured.

Lean Six Sigma Process Tools

"Process Improvement" refers to a strategy of finding solutions to eliminate the root cause of performance problems in processes that already exist in your company (Pande, et al., 2002). Process Improvement efforts seek to fix problems by eliminating the causes of variation in the process while leaving the basic process intact. In Six Sigma terms, Process Improvement teams find the critical Xs (causes) that create the unwanted Ys (defects) produced by the process.

5S is a set of techniques, all beginning with the letter "S" (Wilson, 2010). They are used to improve workplace practices that facilitate visual control and lean implementation. The 5Ss are: Separate, Set to order, Shine, Standardize, Sustain. George, et al, (2005) state that 5S enables anyone to distinguish between normal and abnormal conditions at a glance. 5S is the foundation for continuous improvement, zero defects, cost reduction, and a safe work area and is a systematic way to improve the workplace, processes, and products through production line employee involvement.

As defined by George, et al (2005) the 5S definitions are as follows in Table 2.

Table 2

Definitions of 5S

Term	Definition
Sort	Clearly distinguish needed items from unneeded items and eliminate the latter.
Set in order	Keep needed items in the correct place to allow for easy and immediate retrieval.
Shine	Keep the work area swept and clean.
Standardize	Standardize cleanup.
Sustain	Make a habit of maintaining established procedures.

DMAIC (Define, Measure, Analyze, Improve, Control) is a structured problem-solving methodology widely used in business (George, Rowlands, Price, Maxey, 2005). These phases lead a team logically from defining a problem through implementation solutions linked to underlying causes, and establishing best practices to make sure the solutions stay in place.

These tools are worth the effort (George, 2002). They have been proven in practice, time and again, that they can bring nearly miraculous progress to what you thought were "intractable" problems. They are the tools that can achieve breakthrough performance improvements in quality, cost, and lead time.

As outlined by George, et al. (2005) in Table 3, the DMAIC process covers the following:

Table 3

Definitions of the DMAIC process.

Term	Definition
Define	Review project charter, validate problem statement and goals, validate voice of the customer, validate financial benefits, create communication plan, select and launch team, develop project schedule, complete define gate.
Measure	Value Stream Map for deeper understanding, identify key metrics, develop operational definitions, develop data collection plan, collect baseline data, determine process capability, complete measure gate.
Analyze	Determine critical inputs, identify potential root cause, reduce list of potential root causes, prioritize root cause, complete analyze gate.
Improve	Develop potential solutions, evaluate and select best solutions, develop and implement pilot solution, develop full scale implementation plan, complete improve gate.
Control	Implement mistake proofing, implement SOP's and process controls, implement solution and ongoing process measurements, complete control gate, transition monitoring/control to process owner.

You should apply the concepts of Lean Six Sigma to build upon your existing development capabilities and provide your design teams the knowledge and tools to help them generate more profitable products faster to grow your business (George, et al., 2005).

There are no shortcuts to "world class" (Wheat, et al., 2003). Bringing the tools of Lean Enterprise into an organization requires commitment and culture change. There is no more powerful tool in an organization than the excitement of its employees.

Summary

A review of literature suggests that the implementation of lean principles is not a one-time look at a process and through implementation, perfect results are achieved. Lean implementation is a journey that takes many years and requires a cultural change. If the principles are applied correctly, significant results can be achieved in the manufacturing process by understanding the use of value stream maps, performing time studies, utilizing spaghetti diagrams, and focusing on incremental changes to the process through the use of Kaizen events. By utilizing the principles of lean manufacturing, and applying them systematically, will help any manufacturing facility drive out the waste that is currently in their process. As it was stated in the literature review, there are no shortcuts to “world class”.

Chapter III: Methodology

This study analyzed the existing state of manufacturing and testing the medical devices in batches. An implementation plan was developed to implement lean manufacturing principles to support one-piece flow. The plan was implemented and the results of the implementation resulted in improved productivity and resulted in a reduction in work-in-process.

The objective of the study was to evaluate the potential opportunity to develop a process that incorporates lean manufacturing principles into an existing product assembly line and to evaluate the effectiveness of the implementation.

This chapter describes the methods and procedures used to achieve the objective of this study. The importance of maintaining lean manufacturing principles was addressed with employees through training at each of their assembly steps.

Current Assembly and Close-Up Process

Opportunities for improvement in the assembly process for one piece flow such as improved assembly techniques, improved assembly tools, improved material location along with ergonomically correct work stations were analyzed. The current assembly process of the assembly line through close-up was evaluated through the use of time studies of each assembly process. Areas for ergonomic improvements to eliminate wasted movement, which helped reduce cycle time within the process, was noted.

Instrumentation

The study required the use of data collection sheets. The data collection sheets consisted of each step within the assembly and close-up process. Each process step was observed and timed to gain an understanding of the current individual process steps and overall cycle time. As the example shows in Figure 1, each process assembly and close-up step time was recorded five times and an average taken.

Time Study - Assembly Station 1

	Assembly Step	Time 1	Time 2	Time 3	Time 4	Time5	average
Station 1	Clean Upper Weldment, install internal s/n label, install transducer label, install power label, install damping grommets, install grounding straps	2:40	2:01	2:02	2:25	2:30	2:19
	install female luer, insall male luer, install barb fitting	1:18	1:16	1:24	1:00	1:05	1:12
		4:27	3:38	3:45	3:51	3:58	
	install rotary switch, install knob	0:29	0:21	0:19	0:26	0:23	0:23
	install main board	1:24	1:22	1:19	1:19	1:19	1:20
						6:30	
	install membrane panel	0:58	1:04	1:23	1:12	1:13	1:10
	install sounder alignment tool	0:18	0:19	0:19	0:17	0:17	0:18
	install sounder	0:38	0:34	0:43	0:49	0:39	0:40
	install power board	0:52	0:53	1:02	0:49	0:58	0:54
	QC1	0:34	1:14	0:25	0:37	0:38	0:41
						Average (mm:ss)	8:57

Figure 1. Assembly station 1 time study

Upon implementation of one-piece flow, times were again recorded using the same data collection sheets shown in Figure 1. Ergonomic improvements were also recorded to help during the implementation of one-piece flow and cycle-time reduction.

The study also required the use of a spaghetti diagram. As the example in Figure 2 shows, a spaghetti diagram can show the flow of the product, paperwork, etc. through its process. Figure 2 is for explanatory purposes only and does not show the actual flow of Company X's product. Chapter IV will show and describe the product flow through the use of a spaghetti diagram for Company X..

Creating a spaghetti diagram allowed the distance the product flowed, to be mapped. This gave the current state of the process and provided a visual tool to see the flow of the product and the distance in which it traveled.

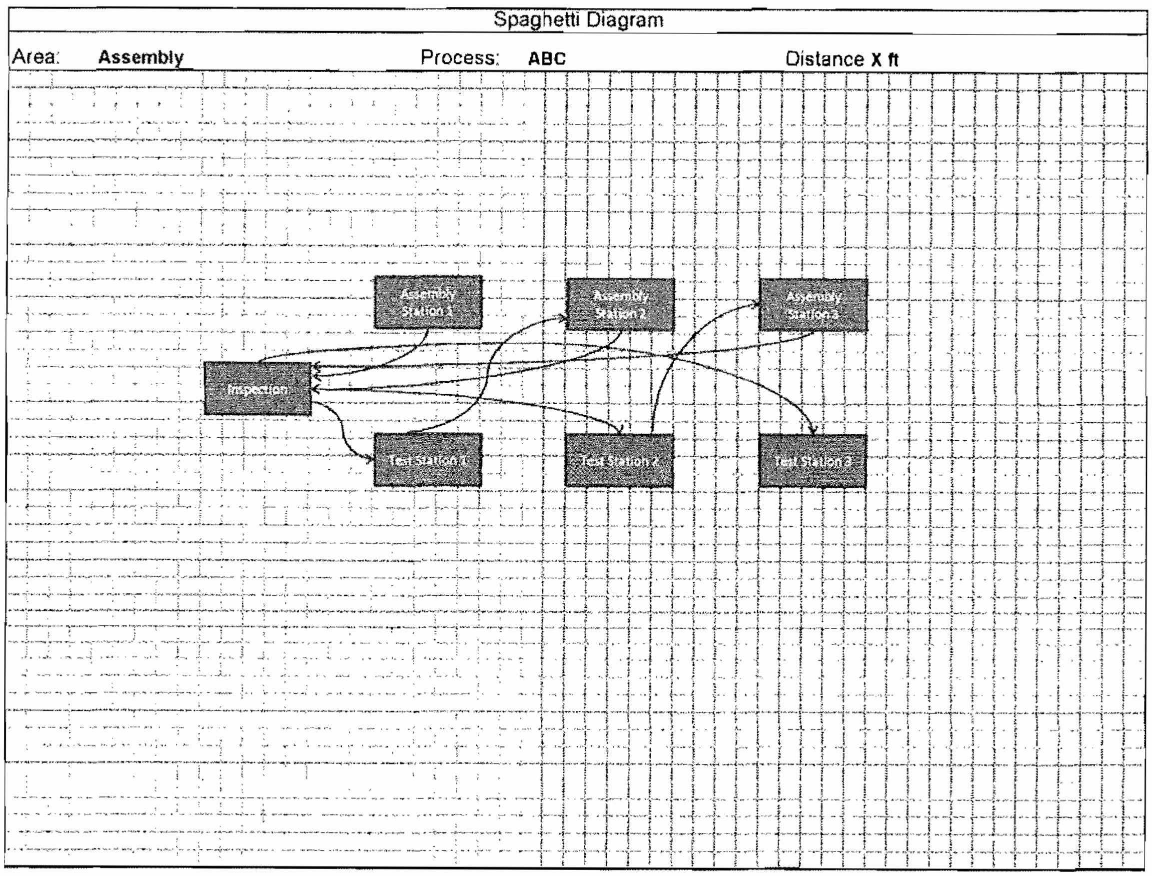

Figure 2. Example of spaghetti diagram

Also used in the study was a value stream map. By creating the value stream map, the Kaizen team was able to see where the waste in the process was, record the times, and make the necessary changes to eliminate the waste that was found. An example of a value stream on Figure 3 shows the typical information that is entered into the value stream map. By entering the information into the value stream map provides the necessary information required to make the appropriate decisions as to where non-value activities are located within the process and where it can be eliminated.

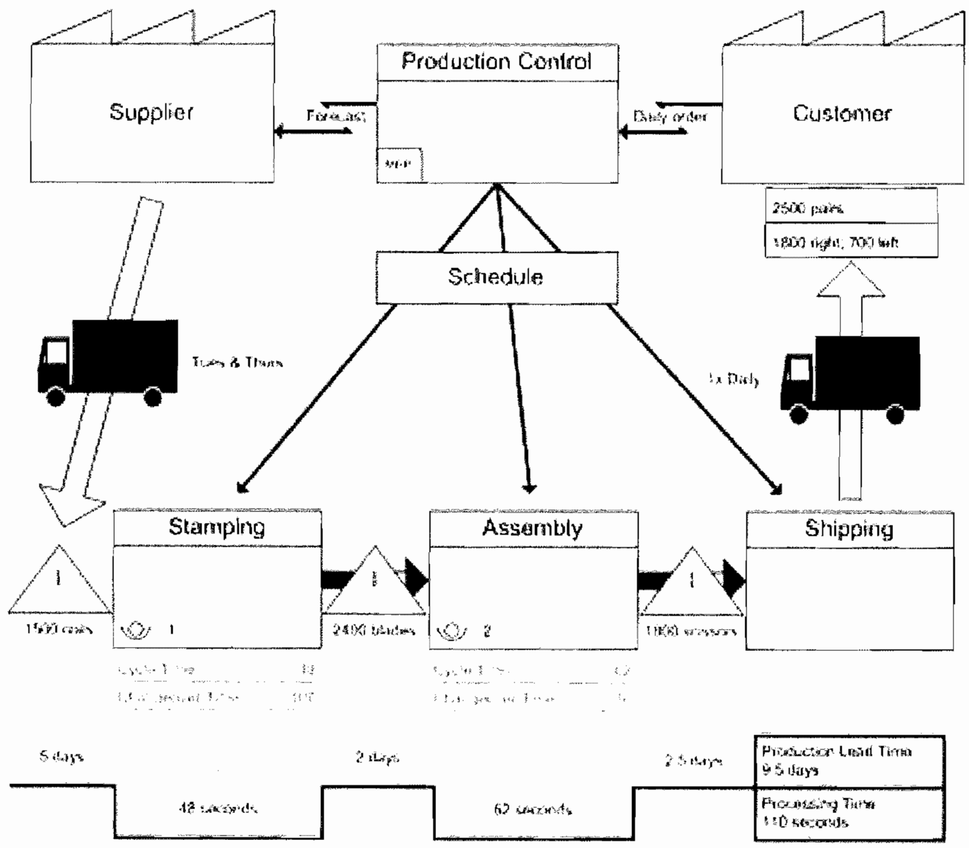

Figure 3. Example of value stream map.

Data Collection Procedures

The data collected in the study consisted of time studies conducted to eliminate wasted movement, through improved ergonomics, during the assembly process in the final assembly line. Additional data collected consisted of time studies of each assembly station to evaluate the cycle time of each operation at each assembly station.

Data Analysis

The data collected for this study was used to evaluate the opportunity to implement lean manufacturing principles in the assembly process. Through the use of Kaizen events, the team was able to make the small, incremental changes required to improve the assembly line and close-up area. Members of the Kaizen team were assigned an assembly station to record the times of each operator. Each time study was documented and this data was then evaluated by comparing the times of each assembly process using batch manufacturing and one-piece flow. By comparing the data, Company X was able to take the reduction in time for each process using one-piece flow as opposed to batch manufacturing, and convert that time into a cost savings per medical device. With the time standards captured for one-piece flow, each workstation was adjusted to equal time to improve line efficiency and eliminate work-in-process build-up within the assembly line.

By performing the time studies, in-process kanban's (IPK's) were calculated and larger work-in-process racks removed and replaced with smaller in-process kanban racks. This provides a visual aid to the operator that if the in-process kanban rack is full, the operator must stop building and move to another station that is not full. The operator will not move back to their original work location until there is another space available for the product to be placed. Through the use of in-process kanban racks, the production floor has was able to reduce the amount of work-in-process by forty five percent.

Limitations

1. The results of this study are limited to the final assembly line through close-up at Company X.

2. The results of this study do not include all lean manufacturing principles.

Summary

This chapter addresses the methods that were used by Company X to obtain the data for making improvements to their final assembly and close-up area through the use of time studies, a spaghetti diagram, and a values stream map. This data forms the basis for the results of this study which are presented in chapter IV.

Chapter IV: Results

This study analyzed the existing state of manufacturing and testing the medical devices in batches. An implementation plan was developed to implement lean manufacturing principles to support one-piece flow. The plan was implemented and the results of the implementation resulted in improved productivity and resulted in a reduction in work-in-process.

To obtain the desired results of the study, Kaizen teams were put together for the Assembly and Close-up stations. Each station had time studies performed to better understand the work load and balance of each station. The Kaizen teams then reviewed the work content and times recorded to ensure the proper balance of work to eliminate waste at each station.

This chapter will review the results of the time studies and the actions taken at each station to create a balanced work load and improved flow from the Assembly through Close-up stations.

Final Assembly Findings

The findings in the final assembly line through close-up revealed how unbalanced the assembly line was and how far the device had to travel through the process. The first step to understanding the travel distance of the device was to create a spaghetti diagram as shown in Figure 4.

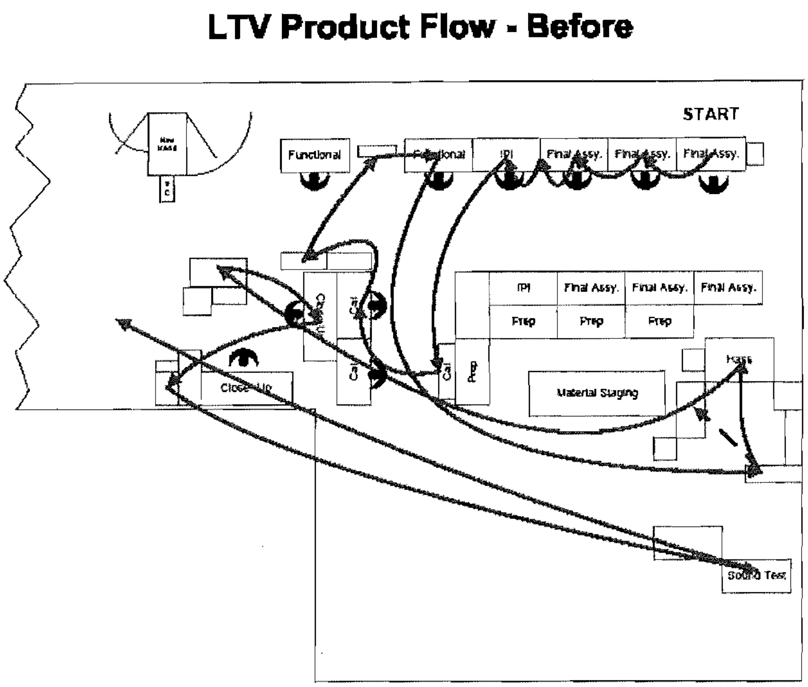

Figure 4. Assembly line through close-up spaghetti diagram - before

This helped define the problem and give the team a clear picture as to how to start formulating a plan for the improvements of the layout and reducing the assembly time. By conducting a Kaizen event for the assembly line and using the DMAIC tools allowed the engineers and operators to work closely together to look at how the assembly procedures could be streamlined by eliminating waste and balancing out each workstation to ensure flow through the assembly line. Prior to starting the Kaizen event, time studies were conducted to evaluate and measure each assembly station to see the differences in times between each station.

The team then put together a value stream map as shown in Figure 5. The Value Stream map was completed using Post-It notes which allowed the team to analyze and re-arrange process steps to assist in creating a balanced work load.

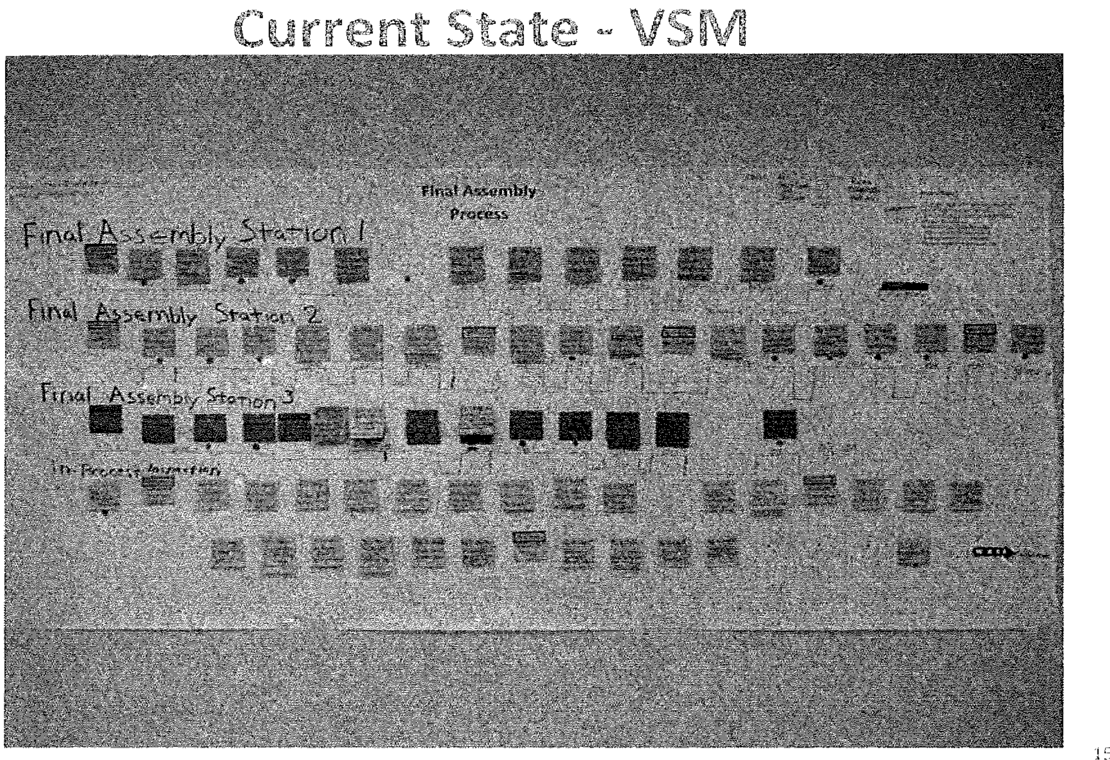

Figure 5. Assembly line current state value stream map

Once the time studies and the value stream map were completed, the team evaluated the types of waste and indicated which activities could be eliminated, per Appendix A and B. Some of these activities were pushed up-stream to the sub-assembly areas to perform the prep work prior to assembly. The materials group also worked with the suppliers to work on packaging alternatives to eliminate the need for operators to remove components from bags.

Upon completion of identifying the activities that were waste, the Kaizen team calculated the time savings, per device, as shown in Appendix C. Once the workloads were balanced; a future-state value stream map was created as shown in Appendix D.

The next step was to make the improvements to the assembly line. The team laid out the new configuration of the assembly line and created a future state spaghetti diagram as shown in

Figure 6. This gave them the blueprint as to how the product would flow and how each of the stations would be set up.

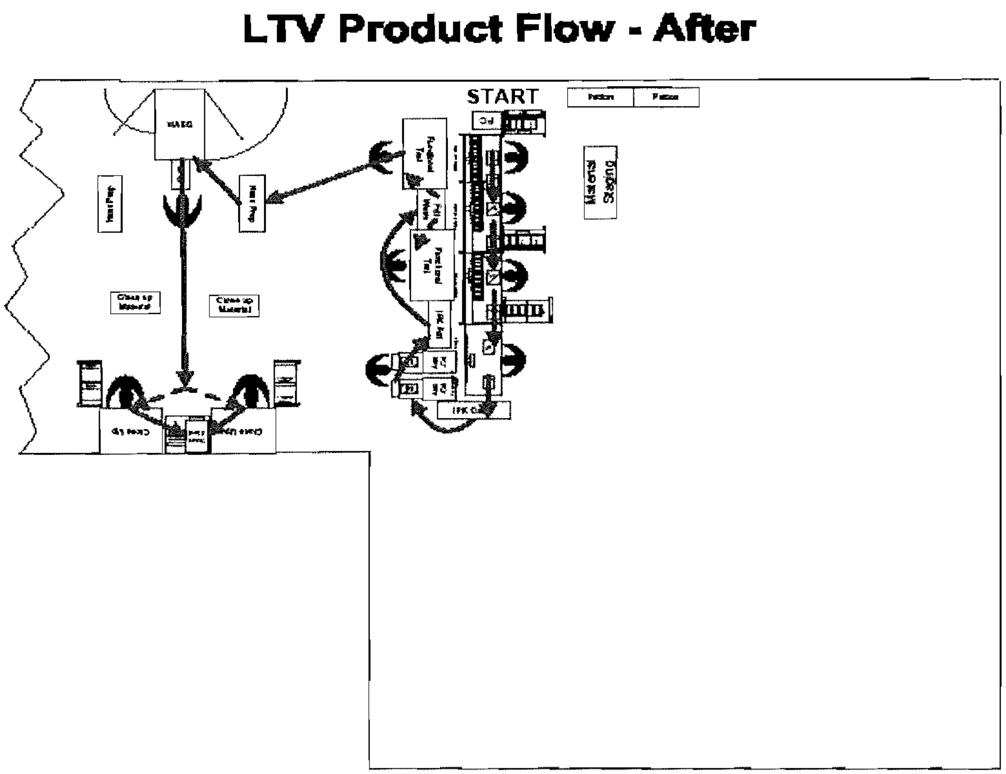

Figure 6. Assembly line through close-up spaghetti diagram - after

Through the use of the DMAIC process, the Kaizen team was able to eliminate an entire assembly line by replacing the existing work stations, as shown in the Appendix E "before" picture, with more ergonomically correct work stations, as shown in the Appendix E "after" picture, and rearranging how material was stored at each station. Each station was equipped with a material rack that holds the larger components which puts the components closer to the operators. Each work station was shortened by two feet and the depth of the work stations were reduced by six inches. This allowed easy access to the material during the assembly process and eliminated the need for the operators to stand or over-extend themselves while reaching for components. Each station was also equipped with a holding arm and a touch-screen computer monitor which was located at eye level in the center of the work station. This allows the operator to look directly in front of them when entering information into the database rather than reaching to the side of their work station to enter information.

By implementing lean principles by improving flow and eliminating waste on the assembly line has provided a projected savings for the assembly line of $23,732.00 per year.

Close-Up Findings

A Kaizen team was also put together to evaluate the Close-Up area within the production line. As with the Final Assembly Kaizen event, the team evaluated the Spaghetti Diagram, as shown in Figure 4, to have a good understanding as to how product flowed through the Close-Up area. The team then created a current state value stream map, per Appendix F, and looked at the operations that were redundant. What was found is that there was duplicate inspection that was being performed. Much of the inspection performed at the assembly line was also being performed at Close-up. Also, when a device that may have failed anywhere between Final Assembly and Close-Up was sent to the Production Repair Department, Close-Up would inspect the work that was performed at Production Repair. This level of inspection was again a redundant inspection.

To eliminate the redundant inspection, the team made procedural changes so that inspection was being performed at the source of the work. By making these changes to ensure that quality was being built into the product, the Close-Up area was able to eliminate four minutes and thirty seven seconds of processing time from each device as shown in Appendix G. The arrangement of material was also evaluated. The old workstations had two operators at one station, as shown in Appendix H, which didn't allow for the material to be adequately held at the work station. The team ordered new work stations that were more ergonomic for the operators and capable of holding more bins so the operators did not have to walk to a material rack to obtain parts. Two work stations were ordered for the Close-Up area to give the operators more room to perform their job along with the ability to hold the required parts at their station. Each station was also equipped with a holding arm and a touch-screen computer monitor which was located at eye level in the center of the work station as shown in Appendix I. This allows the operator to look directly in front of them when entering information into the database rather than reaching to the side of their work station to enter information. A new alarm-volume test chamber was also developed which took up a much smaller footprint than the previous alarm-volume test chamber. This allowed for the chamber to be placed between the two Close-Up stations, as shown in Appendix L, for easy access for each operator with approximately four feet of travel to perform the alarm-volume test. Previously, the operators had to take each device and walk it approximately 75 feet to the old alarm-volume test chamber. The placement of the new alarm volume test chamber has eliminated approximately 150 feet of round-trip travel for the operator.

Summary

By implementing lean principles by improving flow and eliminating waste at the Close-Up area has provided a projected savings for the Close-Up area of $10,020.00 per year. By performing the two Kaizen events and streamlining both the Final Assembly line and the Close-Up stations, the teams were able to eliminate a total of 9 minutes and 24 seconds of processing time from each device with a projected savings of $33,752.00. Along with the cost savings, the team was able to take the distance the vent traveled, which was 638 feet, to its current state of 374 feet for a total reduction in distance traveled of 264 feet. Also, the team reduced the production floor space from 4,471 square feet, to its current state of 3,365 square feet, for a total floor space reduction of 1,106 square feet.

Chapter V: Discussion

This study analyzed the existing state of manufacturing and testing the medical devices in batches. An implementation plan was developed to implement lean manufacturing principles to support one-piece flow. The plan was implemented and the results of the implementation resulted in improved productivity and resulted in a reduction in work-in-process.

Chapter I outlined why Company X wanted to implement lean principles within its manufacturing facility and Chapter II reviewed the literary content as to how companies can learn and implement lean principles in their organization. Chapter III outlined the methods used to collect the appropriate information and the steps used to collect and analyze the data. Chapter IV outlines the results of the implementation to implement lean manufacturing principles to support one-piece flow along with the results in improved productivity by the elimination of waste within the process.

Limitations

The limitations of the study are:

1. The results of this study are limited to final assembly through close-up for Company X. The current state value stream maps created only included the final assembly and close-up areas. Any additional improvements would have been outside the scope of this study. The Future state value stream map, though all inclusive to the entire production process, was only updated with the information from the final assembly and close-up area.

2. The study does not include all lean manufacturing principles. The Kaizen teams utilized existing knowledge of lean principles and relied on the expertise of production personnel, involved in the Kaizen events, to perform their job functions as they would on a day-to-day basis so the collection of data was as accurate as possible by giving a true representation of the current state value stream.

3. The study is intended to show the results of implementing lean manufacturing principles within a manufacturing environment. Creating the spaghetti diagrams and value stream map was critical to understanding the manufacturing process from final assembly to close-up. It also gave the team the necessary tools required to present the findings to upper management and show that the improvements would be turned into a cost savings for the company.

Conclusions

The results of the study were a success with the implementation of using lean principles. Production personnel were instrumental to the success of each Kaizen event. By applying their knowledge to the processes allowed the teams to provide the best solutions to the issues within the process.

With this product being a medical device, each individual involved in the Kaizen events had to keep in mind that each one of the proposed changes had to be justified not only from a financial standpoint but more importantly from a Regulatory and Quality Systems standpoint. All of the changes required an engineering change notice with a minimum of three signatures from appropriate departments in order for the changes to be implemented.

With the product being a medical device, any changes to assembly procedures had to ensure that the design of the device was not impacted. Verification that the design of the device was not impacted was captured in the engineering change notice prior to approval.

With the elimination of over 9 minutes of process time per device along with a savings of over $30,000.00 annually shows that correct implementation of lean principles can have a positive impact within any organization. Through proper training and starting with smaller projects, Kaizen leaders and teams can get a good understanding on how to effectively run and participate in Kaizen events and use the proper tools to find and eliminate the waste that is in any manufacturing process.

Recommendations

The following recommendations are the result of looking at two areas within Company X's manufacturing facility: Company X has over 12 stations that can be evaluated using lean principles. Company X should continue to apply all of the lean principles that have been learned through this study and have Kaizen events for each station.

Each production person should be part of a Kaizen event to not only learn the tools of lean manufacturing but to also provide their input and expertise to the area in which they work. This will help all production personnel understand the concepts of lean and recognize areas of waste that can be eliminated through continuous improvement. This will create an enthusiastic environment as the Company continues down the path of eliminating any waste that is found.

Not only does the elimination of waste help the company but it has a major impact on the production workers with their engagement in the Kaizen events. Production workers see the commitment from management to make improvements within the organization and know that their input is not only vital to the area that they work in but also to the overall success of the company.

Continuous improvement needs to be a mindset within the company. Each individual needs to recognize that each Kaizen event is a small step towards a large goal. Through each Kaizen event becomes an accomplishment of achieving the goal of becoming a lean manufacturing environment Continue to look for areas of improvement even in the areas that have already been improved. There are always ways to make improvements while on the journey to a lean manufacturing environment.

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Appendix A

Assembly Station 1 and 2 Waste Analysis

TIMWOODR Analysis Station 1

TIMWOODR
M, I, O_1, R- Unbagging/ unboxing
M, O_2- Aligning power label
O_1- Grommet/ Grounding straps tweaking
R- Loctite application
I, D- Black nut w/ rotary switch
M, O_2-Membrane Switch
M, O_2- Sounder alignment tool
O- QC1 self- inspection

T: Transportation
I: Inventory
M: Motion
W: Waiting
O_1: Overproduction
O_2: Overprocessing
D: Defects
R: Resources

TIMWOODR Analysis Station 2

TIMWOODR
M, I, O_2, R- Unbagging/ unboxing
D- Bracket
M- Fan prep
R- Solenoid Manifold prep
M, O_2, D -Long wire and short tubing on Solenoid Mount
M, R, O_2 – Analog PCBA
O_2- QC2 self- inspection

T: Transportation
I: Inventory
M: Motion
W: Waiting
O_1: Overproduction
O_2: Overprocessing
D: Defects
R: Resources

Appendix B

Assembly Station 3 Waste Analysis

TIMWOODR Analysis Station 3

TIMWOODR
M, I, O_2, R- Unbagging/ unboxing
M, O_2, R –Grounding straps alignment
M, R – Prep screws O2 Blender/ Block
R, I, M, O_2- Flow Valve bag, spiral wrap, tube length
M – Vent from St. 3 to IPI
T – Parts and sub assemblies
R, I- Turbine Manifold planning/ communication
O_2- QC2 self- inspection

T: Transportation
I: Inventory
M: Motion
W: Waiting
O_1: Overproduction
O_2: Overprocessing
D: Defects
R: Resources

Appendix C

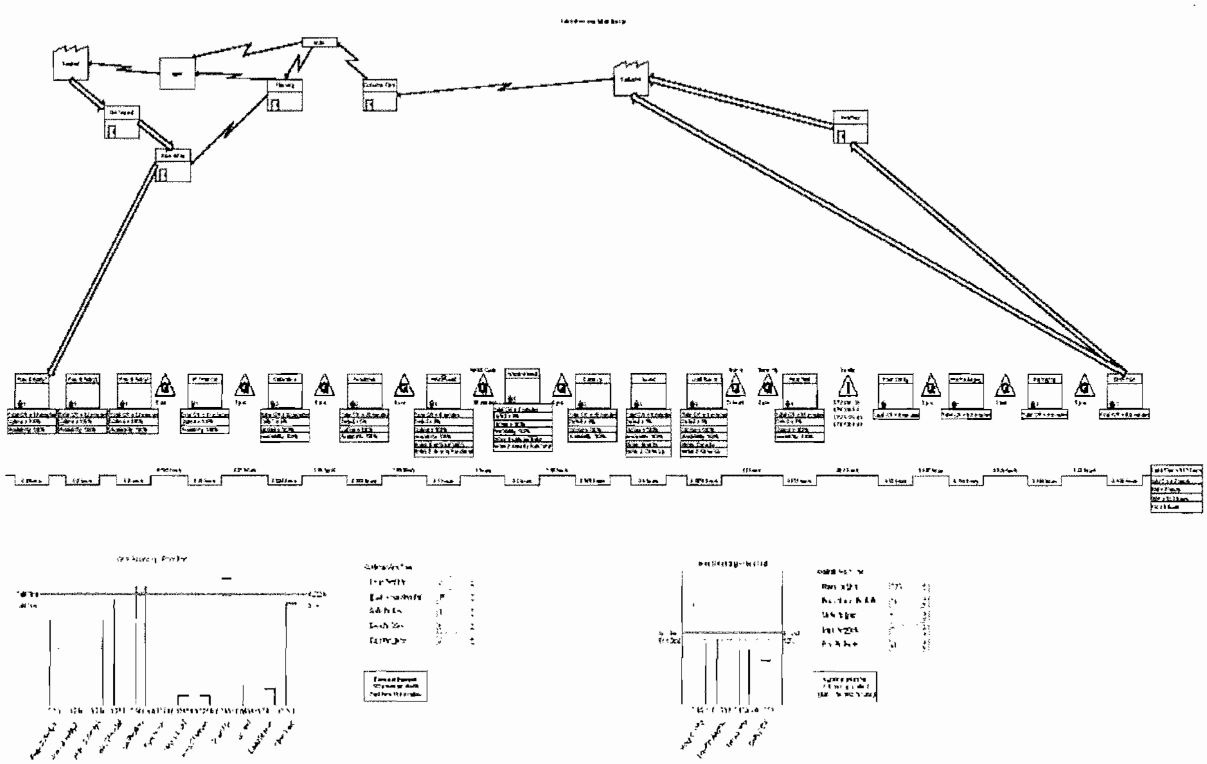
Final Assembly Time Reduction

Assembly and Inspection Time Reduction

Area	Activity	Time
Station 1	QC1 Inspection	0:16
	Unbagging	0:35
	Station 1 Time Savings	0:51
Station 2	remove caps Analog PCBA	0:07
	Install Tubing Analog PCBA	0:25
	QC2 Inspection	0:58
	Unbagging	0:20
	Station 2 Time Savings	1:50
Station 3	remove spiral wrap	0:18
	Cut flow valve tube for 1200	0:05
	QC2 (inspection only)	0:31
	Unbagging	0:22
	Station 3 Time Savings	1:16
IPI	Duplicate Inspections	0:50
	IPI Time Savings	0:50
Total Time Savings per Device (mm:ss)		**4:47**

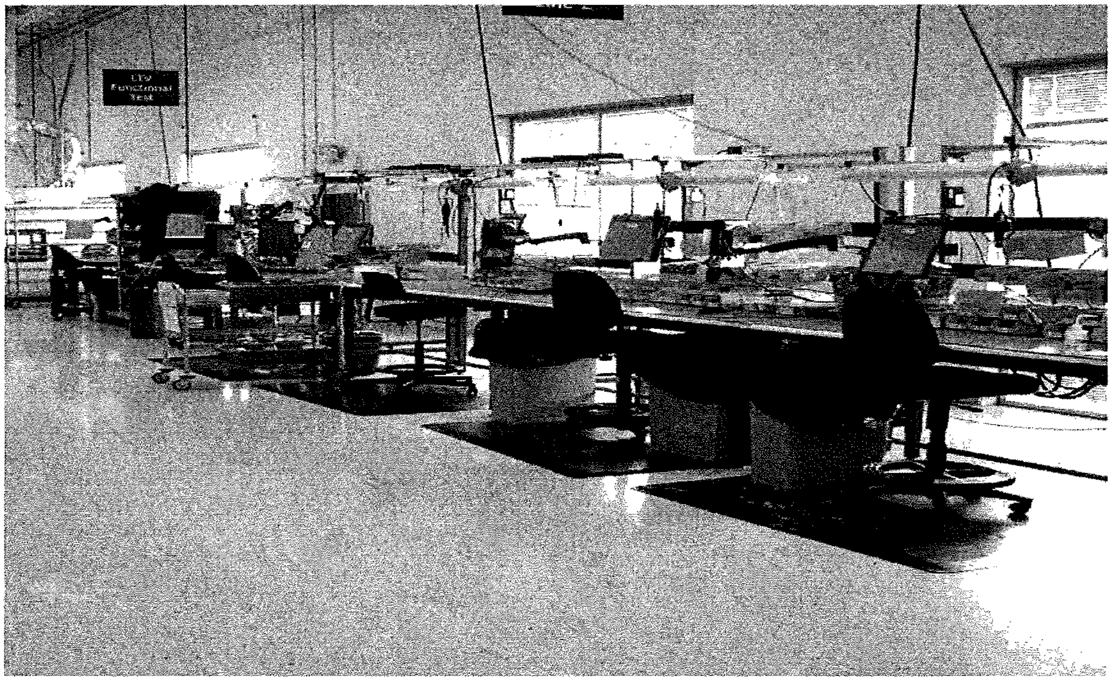
Appendix D

Future State Value Stream Map

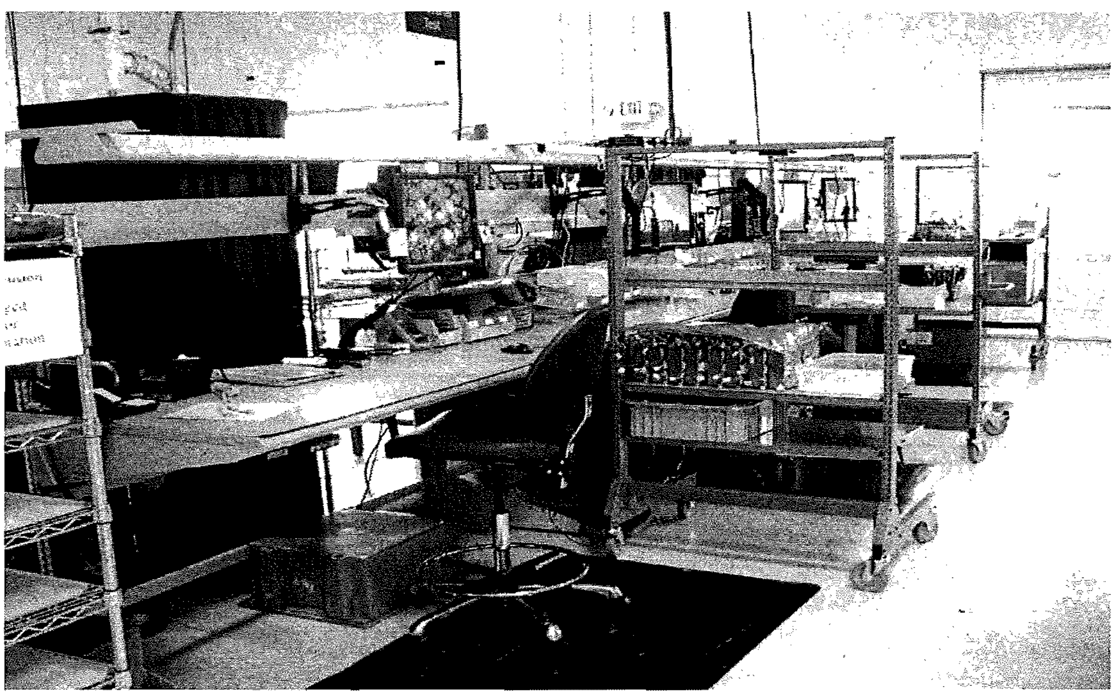


Appendix E

Final Assembly Line – Before



Final Assembly Line – After

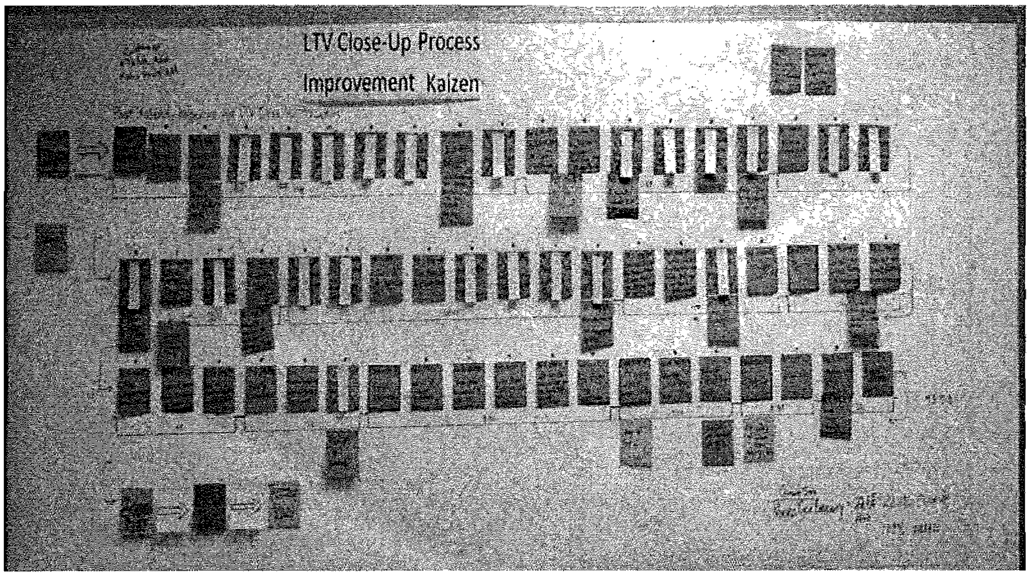


Appendix F

Close-Up Current State Value Stream Map

Value Stream Map (VSM) Current State

LTV Close-Up Process Improvement Kaizen



Appendix G

Close-Up Time Savings

Time Savings

Step	Current	Proposed	Time Saving
Op 1 Steps 1- 8	1:49	:39	1:10
Op 1 Steps 9- 14	1:47	:27	1:20
Op 1 Steps 15- 21	1:21	:33	:48
Op 1 Steps 22- 29	:47	:08	:39
Op 1 Steps 30- 33	:44	:40	:04
Op 2 Steps 1- 3	:45	:35	:10
Op 2 Steps 3- 6	:48	:48	0
Op 2 record comp./QC1	:22	:11	:11
Op 3 Steps 1- 4	3:32	3:32	0
Op 4 Steps 1- 5	17:09	16:52	:17
Op 4 Step 6	3:39	3:39	0
Op 5	:22	:22	0
Total Time Saving Per Vent (mm:ss)			**4:37**

Appendix H

Old Work Station – Close-Up

Appendix I

New Work Stations – Close-Up