Increase of Manufacturing Line Capacity using Lean Manufacturing on a Medical Device Company

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Abstract *— The competition between Medical Devices companies is increases every day. Many medical devices companies are marketing products that compete between each other. They challenged to obtain long term contracts to supply their product to important customer around the world. The customers are the greatest benefactor of this competition but the medical devices companies are facing challenges. To be competitive, the industry is seeking for tools to be used in order to reduce cost and improve manufacturing capacity without compromising the quality of the products. One methodology used to reduce manufacturing cost and increase process capacity is Lean Manufacturing. This methodology is used to reduce sources of muda or in other words, waste. Muda can be associated to downtime, waiting time, unnecessary movements among others things that do not create value to the customer. This article discusses the improvement of the manufacturing line capacity of a Medical Device Company. The methodology used for the improvement was Lean Manufacturing using the DMAIC tool as a systematic approach.*

Key Terms *— Capacity, DMAIC, Lean Manufacturing, Process Flow.*

INTRODUCTION

Medical devices companies around the world are competing against each other in order to obtain long terms contract with the clients that use the products. To be competitive and obtain their contracts, medical devices companies are recurring to methods to reduce manufacturing cost but at the same time, improve the manufacturing capabilities of the production line in order to comply with the increased demand. Therefore, many medical devices companies are recurring to Lean Manufacturing and Six Sigma Tools in order to achieve the desirable results.

Research Description

A medical device company is competing for a long term contract for a product that has the greatest demand in the market, in other words, it is high runner product. The competition to win the contract is very important for the company since it imply that the manufacturing demand will increase from 2.5 million to 7 million products per year. On the other hand, the loss of the competition for the contract implies a loss of actual demand and the product will not be longer manufactured. Saying this, losing the contract is not an option for the medical device company since implicates the loss of many jobs due to the volume reduction. In order to obtain the contract, the company needs to demonstrate that it has the capacity of manufacturing the increased product demand and at the same time reduce the manufacturing cost of the product. In order to be competitive to win the contract and beat the competition.

Research Objectives

This research is designed to analyze the current manufacturing process in order to identify opportunities to improve the manufacturing line capacity to produce more products per hour due to the increased demand of the high runner product in a medical device company. Design and implementation of a strategy to reduce product manufacturing cost in order to sell the product at a competitive price without compromising the quality of the product.

Research Contributions

The research discussed in this article will contribute to the medical device company to

increase its manufacturing capacity. In addition, the research contributes in reducing costs associated to the manufacturing process of the product without compromising the quality of the product. The goal of the research is to provide a product to the client at a more competitive price to the market. From the client perspective, the client will receive a product with high quality at a lower actual sell price. The medical device company will increase its capacity to meet the customer demand for the product.

LITERATURE REVIEW

Medical devices companies are facing an aggressively competitive environment in order to attract new customers but at the same time, to retain the existing customers. Since most of the products on the medical devices companies are not depending on product patents, many companies are marketing a product portfolio that competes against others since customer and hospital utilize them for the same use. Examples of products under this category are syringes, respiratory machines and blood filters among others. In order to be more competitive, the medical devices companies are recurring to the Lean Manufacturing methodology as a technique to improve manufacturing costs by eliminating the process muda. Muda is a Japanese word that means waste.

Lean Manufacturing methodology is utilized by many companies as a systematic approach to eliminate process muda with the objective of reducing manufacturing cost, processing time and excess of inventory. In the Lean Manufacturing technique, muda refers to activities that are performed to a process that does not add value to the customers. Taiichi Ohno (1912-1990), the Toyota executive who was the most ferocious foe of waste human history has produced, identified the first seven types of muda [1]. The types of muda on a manufacturing process are:

- Defects - defective products and rework to fulfill customer needs.
- Overproduction – produce more than or sooner than is required by internal or external customers
- Waiting – any delay between activities; idle time due to operator, machine or material
- Transportation – transport or double handling of materials or products
- Inventory – excess supply of raw material, sub-assemblies, work in progress (WIP) or finished good at any point in time
- Motion - physical motion of people or machinery that do not add value (searching, walking, stretching, bending, etc.)
- Extra Processing – to do more than the customer requires, activities that are transparent to the customer.

The Lean Manufacturing technique can be used as a systematic approach by companies to increase their production capacity. According to the article written by M. Subburajan [2], three strategies can be used to increase the capacity of machine: add new facility or machine, increase machine availability and debottleneck process/duplication. The addition of new facility or machine to increase the capacity of production on medical devices companies is drastic and costly since it involves constructions of new facilities, buying new equipment, installation and qualification of the equipment and product qualification. Before pursing this option, many companies try to improve current process and perform Return of Investment (ROI) analysis to determine if this option is cost effective. Second alternative to increase manufacturing capacity is to increase the machine availability. This strategy can be achieved by improving change over time and causes that create downtime of the equipment. Finally, the third strategy that can be utilized to increase the capacity of machine is the debottleneck process.

The debottleneck process is the removal of the causes of bottleneck. A bottleneck in a manufacturing process is when a machine or equipment has high processing time compared to others equipment on the same manufacturing line

and the product accumulate in the slower station waiting to be processing. A bottleneck limits the capacity of the process and affects the output of products per hour that a manufacturing line can produced. Bottlenecks affect the continuous flow of the manufacturing process. In the article "The Bottleneck conundrum" [3], the author described the bottlenecks characteristics that can be presented in the process. The author establishes that some bottleneck can be associated to the equipment capacity and performance and may not be easily identified. Also, a bottleneck can be caused by mechanical problems, problems with equipment yield and changeovers.

Many companies working with to increase the production capacity are identifying the equipment that takes more time to perform the process in order to eliminate bottlenecks. The identification of process bottlenecks can be very difficult but four (4) methods can be utilized. The methods to identify the bottleneck according to Tommy White [4] are:

1. The equipment most active with no interruption.
2. The equipment with the biggest processing time.
3. The equipment with the biggest quantity of products waiting to be processed.
4. The equipment with the biggest utilization on the process.

Lean Manufacturing

The Lean Manufacturing methodology has the objective of eliminating and/or reducing muda (waste) to a process to reduce costs and improve efficiency. Muda can be classified as Muda Type one or Muda Type Two. Muda Type One is the waste that do not add value to the customer but cannot be eliminated because it is necessary to the process and current technology cannot be used to eliminated it. On the other hand, Muda Type Two is the activity that do not adds value to the customer and can be eliminated immediately. Figure 1 shows the five (5) principles of the Lean Manufacturing methodology.

1. Value – Value of a process can be only defined by the customer. Companies need to improve the process considering the Voice of Customer (VOC). In this principle, the company needs to understand the customers and their requirements. In others word, the companies need to understand what the customer want for a specific product.

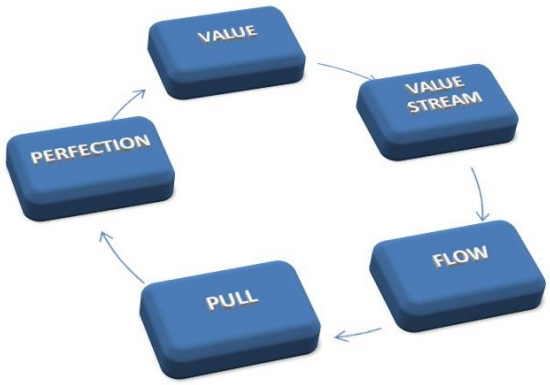

Figure 1
Lean Principles

2. Value Stream – The value stream is the activities required to produce a product or service required by the customers. This principle has the objective to create a process map (Value Stream Mapping) of the activities required to produce a product or service in order to determine which activities creates value or not creates value from the customer perspective.
3. Flow – This principle is used to eliminate waiting times or obstacles that do not allow the process to be performed without interruptions or continuous flow.
4. Pull – This principle allows the customer to pull the product from the manufacturing facilities as needed instead of pushing the product to the customer. In other words, manufacturing facilities will produce their products only if it is required by the customers.
5. Perfection – The perfection principle is not the end of the process. On the other hand, perfection refers to repeating the Lean cycle to continue with the improvement process to offer the product that the customer wants.

METHODOLOGY

A systematic approach needs to be used as a methodology to achieve the goals of the project. Since the purpose of the project is to improve the manufacturing line capacity on a Medical Device company, the Lean Manufacturing methodology was selected. The Lean Manufacturing methodology is used to eliminate the muda (waste) and non-value activities of any process. The project will be divided into five phases (Figure 2) following the DMAIC tool (Define, Measure, Analyze, Improve and Control). Each phase will be reviewed before continuing to the next phase.

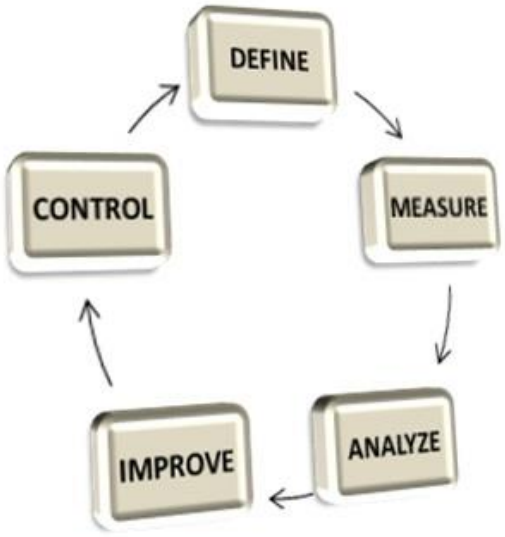

Figure 2
DMAIC Process Steps

Define Phase

The define phase is utilized to determine the direction of the project and serve as a commitment of the team members that will be working on the project. The objective of this phase is to reach an agreement with the customer, the team members and the champion of the project. The agreement includes the problem statement, project goal, team members, business impact and project start and end date. As part of this phase, the deliverables include a Project Charter and a SIPOC diagram.

- **Project Charter** – Defines the scope, objective and overall approach of the project to be completed. The project charter is a critical element for initiating, planning and executing the project. The document defines the project goals, objectives, team members. Also the document is a commitment between the project team and project sponsor.
- **SIPOC Diagram** – The SIPOC diagram is utilized as a high level view of the process. The SIPOC diagram helps to understand which are the suppliers and customers of the process, the input and output variables of the process, and finally the process steps.

Measure Phase

The measure phase is used as a data gathering of the actual process to understand its current state. This phase provides a clear focus on the improvement effort by collecting information and relevant data on the current situation in the manufacturing process. One goal of the measure phase is to establish a baseline of the current process using the data gathered in order to identify the problem. The deliverables of the measure phase includes a Process Map and metrics related to the objective and goal of the project.

Analyze Phase

The analyze phase is used to identified the causes that affect the current process by using the data gathered during the measure phase. During this phase, the team will document potential causes of the problem that are impacting the process. In addition, the team will identify causes that are creating muda on the process that are affecting the manufacturing line capacity in order to increase the quantity of product that the line can produce.

Improve Phase

The improve phase has the objective of performing changes to the process in order to eliminate the root causes of the problem identified during the analyze phase. During the improve phase, the potential solutions are documented and prioritized.

Control Phase

The control phase has the objective to install mechanism or processes that help prevent the problem recurrence and sustain the gains. During this phase, new and/or updates documents are added to procedures that are in place. Operators are trained on the procedures and metrics established to monitor the process.

RESULTS AND DISCUSSION

The results obtained during the project execution are discussed in this section following the systematic approach of DMAIC.

Define Phase

A project charter was developed on the define phase with the purpose of defining the project scope and objective. The project charter is a live document that was signed by the departments involved in the project. The project charter defines the problem statement, goals, business impact and the team members of the project. Figure 3 presents the project charter that was developed and approved by the team members and the champion.

In addition to the project charter, a SIPOC diagram was developed in order to define the suppliers, input, output and customers of the manufacturing process related to the project. The SIPOC diagram of actual process is defined in Figure 4.

Measure Phase

The current manufacturing process flow is defined during the measure phase to understand the current manufacturing process. The process flowchart on Figure 5 is the current manufacturing process.

PROJECT CHARTER			
Project Tittle	Increase of Manufacturing Line Capacity		
Project Leader	Rosana González	**Champion / Sponsor**	Manager of Engineering Department
Start Date	08-01-13	**Target Close Date**	01-31-14
Problem Statement	The Company is competing for a long term contract for the product that has the greatest demand in the market (high runner product). The new contract implicates an increase of the product demand from 2.4 million to 7.0 million of product per year. Actually, two (2) lines are dedicated for the manufacturing process of the product. Due to the increased demand, the capacity of manufacturing line need to be improved before determining if new manufacturing lines needs to be created in order to supply market demand.		
Project Goal	Increase the quantity of product manufactured per hour by 20% or more. Reduction of manufacturing costs by at least $50,000 per year.		
Team Members	Rosana González – Project Leader Manufacturing Department Maintenance Department Quality Department Operators Technicians and Employees of the Medical Device Company		
Business Impact	Increase on actual manufacturing capacity Reduction of manufacturing cost per product		

Figure 3
Project Charter

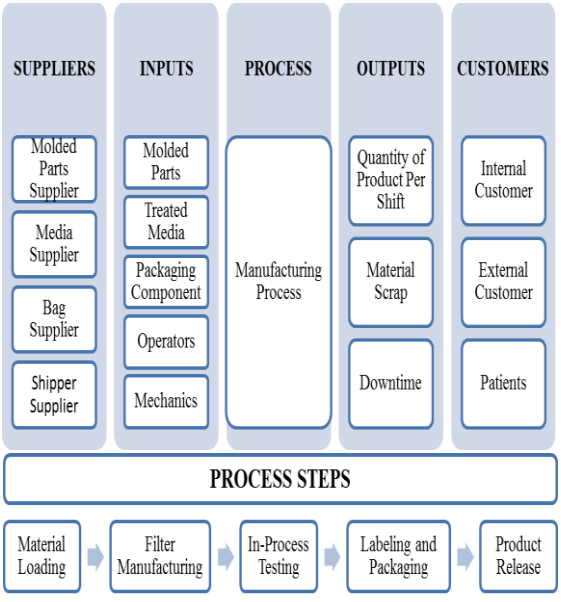

Figure 4
Filter Manufacturing Process SIPOC

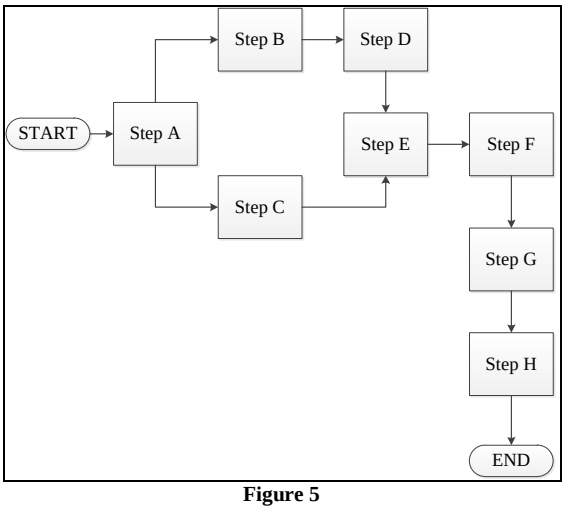

Figure 5
Process Flowchart of Current Manufacturing Process

Since the scope of the project is to increase the manufacturing capacity of the line, the cycle time of each machine was measured in order to determine the processing time each step takes to perform (Table 1).

Table 1
Processing Time per Each Manufacturing Machine

Manufacturing Line Machine	Processing Time per Product (Seconds)	Step that must Preceded	Comment
A	1	-	1 Product
B	4	A	1 Product
C	4	A	1 Product
D	10	B	1 Product
E	15	C, D	1 Product
F	3	E	1 Product
G	20	F	2 products tested at the same time (Machine time = 40 sec)
H	2	-	1 Product
Total	**59 Seconds**		

The manufacturing line was monitored for a period of four (4) weeks to determine which manufacturing line step contributes more to manufacturing process downtime. The results of the manufacturing line monitoring are displayed on Table 2.

Table 2
Manufacturing Downtime per Manufacturing Line Step

Manufacturing Line Step	Downtime (Minutes)			
	Week 1	Week 2	Week 3	Week 4
A	0	10	20	10
B	255	65	340	80
C	200	320	109	247
D	65	35	45	50
E	50	90	50	15
F	30	905	0	0
G	289	10	916	159
H	270	80	65	260

In addition, the manufacturing line output of product per hour was monitored during the four (4) week period (Table 3).

Table 3
Average Product Output per Hour

Monitored Week	Average Product Output per Hour		
	Shift 1	Shift 2	Shift 3
Week 1	260	245	239
Week 2	234	258	260
Week 3	255	240	247
Week 4	248	250	228
Average	**249**	**248**	**244**

Analyze Phase

A Pareto Chart (Figure 6) was created with the intention of obtaining a visual indicator of which manufacturing line step is causing the greatest downtime during the product assembly process.

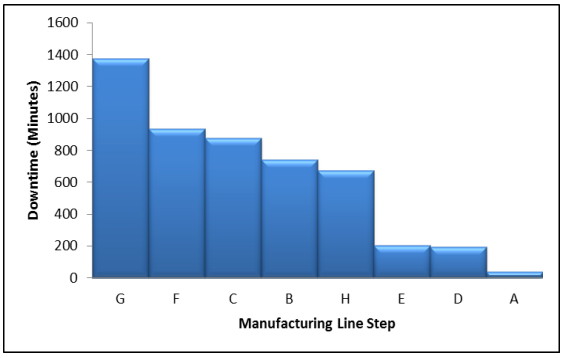

Figure 6
Manufacturing Line Step Downtime

The analysis of downtime during the product assembly process shows that the manufacturing line step G represents the greatest offender of downtime during the process. The equipment of step G is a pressure tester station. On the other hand, the second greatest offender causing downtime on the manufacturing assembly process was the manufacturing step F. The equipment of the manufacturing step F is an inkjet printer that puts the lot number to the product.

A brainstorming technique with operators, technicians and manufacturing engineering was performed to analyze the causes of downtime related to equipment on manufacturing step G and manufacturing step F. During the brainstorming exercise it was identified the causes of this equipment downtime.

1. Manufacturing Step G – Represent a bottleneck to the assembly process. Equipment is composed by two (2) testing stations that work at the same time. During the measurement phase, it was noticed that this step takes 40 seconds to test the product (Processing time mean of 20 seconds since 2 products are tested at the same time).
2. Manufacturing Step F – In this test, an inkjet printer is used to put the lot number of each product. Most of the downtime created by this equipment was related to equipment malfunction because an excess ink was deposited on the product. In addition, the equipment needs to be maintained some hours by an external contractor in a monthly basis.

Improve Phase

During the improve phase, the team decides to install two (2) new testing stations to manufacturing step G in order to reduce the mean processing time per product. The installation of the additional testing stations represents an opportunity to double the quantity of product that can be process at the same time and reduce the bottleneck on the assembly line. Instead of testing two (2) products at the same time, now this step will test four (4) products at the same time. The machine processing time on the step remains the same (40 seconds) but the processing time per product was reduced from 20 to 10 seconds per product.

The second strategy implemented during the project was performed on manufacturing step F. The strategy was the replacement of the inkjet printer by a laser printed in order to reduce downtime related to equipment malfunction and maintenance. This change represents a cost saving of $96,000 per year on ink buying and equipment maintenance to an external contractor. During the equipment improvement on manufacturing step F, the manufacturing step time per product were not affected. In addition, this change creates a benefit to the medical device company since the laser provides a tool to identify the manufactured products with a unique serial number in order to improve product traceability.

Finally, the team implemented a change in the layout of the manufacturing assembly line. Equipment on the manufacturing line step H was relocated to the beginning of the process with the purpose of reducing the cost of product rejection due to equipment malfunction. Since this step does not require a predecessor manufacturing step in order to be completed. The cost reduction of product rejection in this station is because process step A, B, C, D, E, F and G will not be performed before process H anymore. The cost reductions are because now only one molded part will be scrapped instead of the product assembled. The new implemented manufacturing process flow is given by the process flowchart on Figure 7.

As part of the implementation process, validation activities were performed to the new equipment and to the process. The validation activities consisted of:

1. Installation/Operational Qualification (IOQ) of New Laser Station.
2. Installation/Operational Qualification (IOQ) of Additional Testing Equipment on Manufacturing Step G.
3. Process Validation on Manufacturing Line.

During the implementation phase, the product output of the manufacturing line was monitored in order to compare the initial product output with the new product output after the implementation of the changes in the manufacturing line. The new product output on the manufacturing line is illustrated on Table 4.

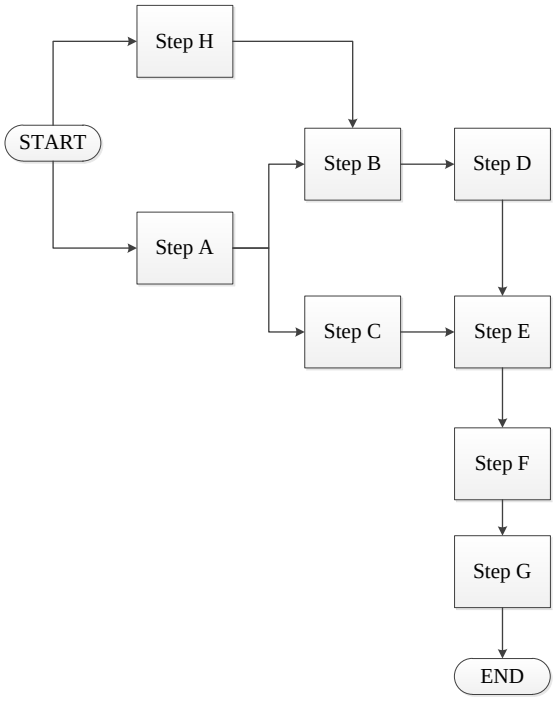

Figure 7
Process Flowchart of Implemented Manufacturing Process

During the implementation phase, the product output of the manufacturing line was monitored in order to compare the initial product output with the new product output after the implementation of the changes in the manufacturing line. The new product output on the manufacturing line is illustrated on Table 4.

Table 4
New Average Product Output per Hour after the Implementation of the Changes

Monitored Week	Average Product Output per Hour		
	Shift 1	Shift 2	Shift 3
Week 1	350	354	351
Week 2	328	360	341
Week 3	342	325	328
Week 4	351	323	330
Average	**343**	**341**	**338**

Control Phase

Standard Operating Procedures (SOP) were created for each of the new equipment implemented for the assembly process. The SOP are used as a tool to train the operators to performs the manufacturing assembly process in a standardized way in order to prevent that the process is performed incorrectly. Maintenance Guidelines (MG) procedure of the new equipment were created as a tool for the technician to follow when a troubleshooting need to be performed to the equipment and as a guide of how to start up and shut down of the equipment. Finally, the assembly line manufacturing procedure was revised to incorporate the new layout of the line and to train the operators how the process will be performed after the implementation of the changes.

As part of the control phase, a metric about the product output on the manufacturing line was revised. The new target of manufacturing product per hour is 343.

CONCLUSION

The manufacturing line capacity using Lean Manufacturing on a Medical Device Company can be improved by using tools of Lean and a DMAIC as systematic approach. By using this approach, source of muda on the process were identified. In the process, sources of waste were associated to the

interrupted flow of the manufacturing lines due to an equipment bottleneck and downtime causes by maintenance of equipment. Improvements performed to the manufacturing lines were performed on the layout to improve the manufacturing flow and the addition of new equipment to improve the processing time per product. By performing the improvements, the goals of the projects were achieved.

The first goal of the project was to increase the quantity of product manufactured per hour by 20% or more. The results of the project demonstrate that this goal was achieved. The manufacturing line capacity increases from 247 to 343 products per hour. This improvement represents an increase of 39% on the manufacturing line capacity.

The second goal of the project was oriented to decrease manufacturing costs with a reduction of by at least $50,000 per year. To achieve this goal, the company purchased new equipment. The investment will be recuperated in one (1) year. The new equipment represents a cost saving of $96,000 per year in material and maintenance. Another benefit of the change is the reduction of downtime due to equipment maintenance and the implementation of a unique serial number to improve the traceability.

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