Manufacturing Space Optimization and Productivity Improvement using Lean Manufacturing on a Medical Device Company

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Abstract *— Medical Devices industry has been experiencing a competitive environment and striving hard to find methods to reduce manufacturing cost, waste and improve quality. 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. The proper utilization of existing man and machine is a challenge for the manufacturing industries. The layout of the manufacturing floor plays a key role in influencing productivity, throughput time and cost of the product. This article discusses the manufacturing space optimization to a particular Business Unit of a Medical Device Company with the objective of improve productivity applying Lean Manufacturing principles. The methodology used for the improvement was Lean Manufacturing and the DMAIC (Define, Measure, Analyze, Improve &, Control) tool was applied as the systematic approach. To optimize space the layout of the manufacturing floor was modified from Flow-line layout to Cellular Manufacturing layout. Results are compared with the current layout. The results revealed an improvement of 10% in productivity. Several Standard Operation Procedures (SOP) were improved by eliminating redundant inspections, addition of Go/No Go tools, merged of some equivalent SOPs and re-arranged SOP's steps.*

Key Terms *— Capacity, DMAIC, Lean Manufacturing, Process Flow, Wastes ("Muda"), Cellular Manufacturing.*

INTRODUCTION

With rapid increase in demand of production, Medical Devices industries need to improve their potentials in production & effectiveness to compete against their competitors. At the same time, the production process has to be ready with the ability to have abated costs with higher proficiency. Hence the route to simplify the problem regarding the production is of paramount importance. The improvement plan is focused in maintaining the quality of the product, the security and performance. 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 needs to deploy a new model product. This new model is an improvement realized to one of the current products manufactured by the medical device company. The improvements made in the new model were materials change on one of it sub-assemblies and the overall length. Due to this new model is similar as the one improved; the intent by the high level management is to manufacture this new model using the current manufacturing line (with the existing man and machine). The suggestion of an alternate shift implementation to comply with the demand was rejected from higher-level management. Also overtime and other extra manufacturing floor work assignations were not

considered available for this project. Is expected that a Year Over Year of 5% improvement. The principal cause for this lean manufacturing project development was the new product length. The physical structure of the line does not has the required space to manufacture the new model length neither the expected demand quantity. A new manufacturing layout is a most. Volume reduction is not part of the project charter when talking about productivity and competiveness. This Medical Device Business Unit needs to demonstrate that it has the capacity to manufacture the new product model and supply the required increased demand. At the same time the company needs to reduce the manufacturing cost of both the new and legacy products that will be manufactured through the new proposed manufacturing layout.

Research Objectives

This research is designed to analyze the current manufacturing process in order to create the appropriate infrastructure to manufacture current and new products and create a self-sustained cell, which lead to a continuous improvement environment in the medical device company.

Research Contributions

The research discussed in this article will contribute to the medical device company to increase its manufacturing capacity embracing the future of the new products to be manufactured. Furthermore, the research contributes in reducing costs associated to the manufacturing process of current legacy products and the new products, without compromising the quality of the end products. The field intent of this project is to deliver to the client competitive products with high quality, reliability, and with lower market price.

This company will increase its capacity to meet the customer demand for all available product models. Is expected that at project closure the company be more competitive and can manage variables economical situation. Also is expected a productivity increment of ten (10) percent and year over year of five (5) percent.

LITERATURE REVIEW

With global competition is important for manufacturer 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 no the leading edge of manufacturing. The origins of Lean started on 1950, when a Japanese engineer Eiji Toyoda visited Ford's vast Rogue Plant in Detroit [1]. He studied every corner of the Rogue, the world's biggest and most efficient manufacturing complex. Upon his return to Japan, Eiji and his productions genius, Taiichi Ohno, concluded that mass production would not work in Japan. Ohno and his team developed activities to fully involve team members in improvement. The Toyota Production System, or lean production, was the solution to Toyota's problems. Over the next thirty years, Taiichi Ohno solved these problems one by one and pushed his system through Toyota. Today, the Toyota Production System is used synonymously with "lean manufacturing" throughout the world.

Lean Manufacturing

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.

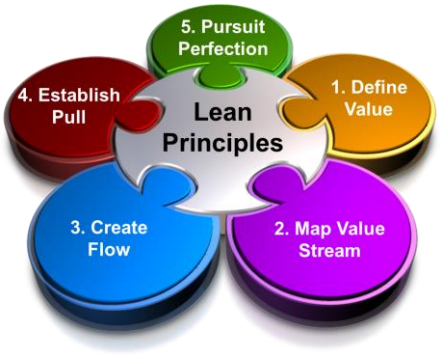


Figure 1
Lean Principles

The first requirement in making a successful transition to lean is to have a clear vision of what the company will become. You can get there, there

is no doubt, but the journey will take time and discipline. The lean transition is, at its core, an organizational culture transition that does not automatically revert back to the "old ways of doing work". Until the desired new behaviors become firmly established and standardized, that is to say that the culture has been truly changed.

Essentially, lean manufacturing seeks to produce a product that is exactly what the customer wants, when the customer wants, while minimizing all non-value added activities in production. Lean manufacturing can be described as eliminating waste in a production process [2]. Anything that does not add value to the end product is waste (known as Japanese term "muda" in the Toyota Production System).

Table 1
Definition for the Seven Types of Waste in a Manufacturing Process

Type of Waste	Description
Overproduction	Is to manufacture an item before it is actually required. Overproduction is highly costly to a manufacturing plant.
Waiting (time on hand)	Workers merely serving to watch an automated machine or having to stand around waiting for the next processing step, tool or supply.
Unnecessary transport or conveyance	Carrying work in process long distances, creating inefficient transport 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.
Excess Inventory	Excess raw material.
Unnecessary Movement	Any wasted motion employees have to perform to perform during the course of their work.
Defect	Production of defective parts or correction. Repair, rework and scrap means wasteful handling time and effort.

Non-value added activities are generally understood to be either waste, or incidental activities that are necessary but add no value to the product. For example quality inspections do not add value to the product; they merely detect defects before they reach the customer. When "Muda" (waste) elements exist, they will increase the cost and add zero value to the manufacturing process. In order to eliminate "muda" the company has to be able to look at the value stream of the manufacturing process. The value stream is simply going through the entire manufacturing process and looking at the things that add value to the product and things that not. The "spaghetti diagram" gives the true path of how material is flowing through the process.

Lean Six Sigma Tools

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 [1]. 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). "Process Improvement" refers to a strategy of findings solutions to eliminate the root cause of performance problem in processes that already exist in your company. In term of Six Sigma, Process Improvement finds the critical Xs (causes) that create the unwanted Ys (defects) produced by the process.

The Six Sigma DMAIC (Define, Measure, Analyze, Improve, and Control) methodology can be thought of as a roadmap for problem solving and product/process improvement. These tool lead 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.

Cellular Manufacturing

Cellular Manufacturing and workcells are at the heart of Lean Manufacturing. Cellular manufacturing is a manufacturing process that produces families of parts within a single line or cell of machines operated by machinists who work only within the line or cell. A cell is a small scale, clearly defined production unit within a larger factory. This unit has complete responsibility for producing a family of like parts or a product. All necessary machines and manpower are contained within this cell, thus giving it a degree of operational autonomy. Each worker is expected to have mastered a full range of operating skills

required by his or her cell. Complete worker training is needed to ensure that flexible worker assignments can be fulfilled. Communication is easy since every operator is close to the others. This improves quality and coordination. Proximity and a common mission enhance teamwork. By breaking the factory into small, homogeneous and cohesive productive units, production and quality control is made easier.

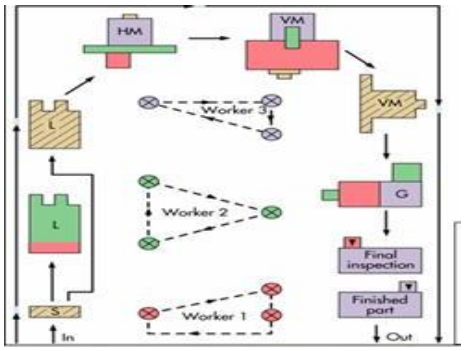


Figure 2
Cellular Layout [4]

METHODOLOGY

The methodology to achieve the goals of the project that established purpose is to analyze the current manufacturing process in order to create the appropriate infrastructure to manufacture current and new products and create a self-sustained cell, will be the Lean Manufacturing methodology. The Lean Manufacturing methodology is used to eliminate the "muda" (waste) and non-value activities of any process. The Six Sigma DMAIC (Define, Measure, Analyze, Improve, Control) methodology will be applied to complete the objectives of this project.

Figure 3
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. The 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.

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 Cycle Time 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 operator to revert back to the "old ways of doing work". During this phase, new and/or updates documents are added to procedures that are in place. Operators are trained on the procedures changed, new layout and metrics established to monitor the process.

RESULTS AND DISCUSSION

The results obtained after the implementation of the manufacturing space optimization of a Medical Device Company in order to improve productivity are discussed in this section following the systematic approach of DMAIC.

PROJECT CHARTER			
Project Title:	Manufacturing Space Optimization and Productivity Improvement		
Project Leader	Jonathan Maldonado	Champion/ Sponsor	Manufacturing Management of Business Unit
Start Date	Q2 FY14	Target Close Date	Q2 FY15
Project Description	The physical structure of the line does not have the required space to manufacture the new model length. In order to create the appropriate infrastructure to manufacture the new model we need to create a self-sustained cell which leads to a continuous improvement environment.		
Project Goal & Measures	Transform current manufacturing layout to Cellular manufacturing layout in order to manufacture the new model. Improve actual Yield =96.5% and Lead Time= 3.5 day. Year over year (YOY) of 5% productivity improvement.		
Team Members	Black Belt consultants, Project Leader- Jonathan Maldonado, Sponsor, Manufacturing Department, IT Engineer, Quality Engineer, Technicians and operators.		
Support Required	Weekly team meetings, Management support.		
Expected Customer Benefits	Increase in Manufacturing Capacity, Quality on the product and Reduction of manufacturing cost per product.		

Figure 4
Project Charter

A project charter is a statement scope, objectives, and participants in a project. The charter includes the reason for pursuing the project, the goal, a basic project plan, scope and other considerations, and a review of roles and responsibilities. In fact, the Charter usually changes over the course of the DMAIC project. Figure 4 presents the project charter that was developed and approved by the team members and the champion. 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 5.

Supplier	Inputs	Process	Output	Customer
Same Company Other Site Employees Engineering Department Development Department Planning Department Technical Service Department Authorized Row Materials Supplier	Equipment Row Material New and Current Sub-Assemblies Materials New Workbench SOP's Improved Energy Consuption Technician Cost of Labor (Operators) New Fixtures/ Tooling	Manufacturing Processes	New Model End Item Product Current End Item Rework Down Time Material Scrap Product Scrap System Error Yield Improvement	Patient Shipping Department Same Company Other Site (Internal Customer)
Process Steps				
Body Assembly	**Assembly Drying**	**Pre-Sterile Packaging**	**Final Inspection**	**Shipping**

Figure 5
SIPOC Diagram for Define Phase

Measure Phase

The current assembly process of the assembly line was evaluated through the time study of the overall process during the measure phase to understand the current manufacturing process. The time study on Figure 6 is the current manufacturing process. The study required the use of a standardized data collection sheet. Areas for ergonomic improvement to eliminate wasted movement, which helped reduced cycle time within the process, was noted. Each process step was observed and timed to gain an understanding of the current individual process step and overall cycle time.

Customer Daily Demand	36	unit/day
Yield	96.9%	
Total time available(8.5hrs)	510	min

Shift elements to consider		
Lunch	30	min
Tier 1 Meeting	5	min
Break 1	15	min
Break 2	15	min
Ergonomic Excersices	5	min
ST up Gown on	4	min
BK1 Gown off	2	min
Bk1 Gown on	4	min
Lunch Gown off	2	min
Lunch Gown on	4	min
SD off Gown off	2	min
Problem Solving	10	min
Clean/Sanitize w/s	15	min

Daily Operation Time	397	min/shift
	23820	secs/shift
Shifts	1	

Facts:

- Cells = 1
- Shifts = 2
- MTMs = 15
- Lead Time = 4.76
- Yield = 96.5%
- Space Util. = 848 ft^2
- WIP = 112 units

Figure 6

Assembly Station Time Study

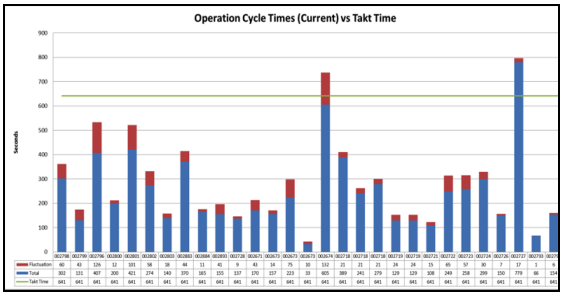


Figure 7

Current Cycle Times (Current) vs Takt Time

To increase the manufacturing capacity of the line, the cycle time of the machine was measured in order to determine the processing time each step takes to perform (Figure 8). Also the cycle time was compared to the Takt time, which is the rate at which a finished product needs to be completed in order to meet customer demand. After the implementation of one-piece flow, times were again recorded using the same data collection sheets.

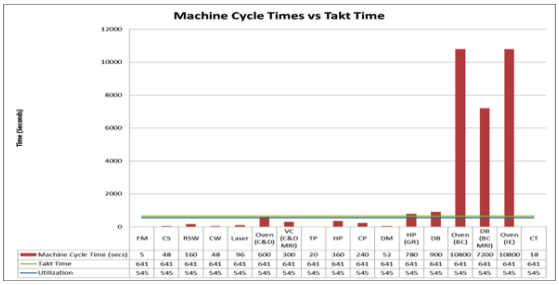


Figure 8

Current Cycle Times (Current) vs Takt Time

The manufacturing line was monitored for a period of twelve (12) weeks to determine which manufacturing line step contributes more "muda" in the manufacturing process.

Analyze Phase

The analyze phase determines the root causes of poor performance. The data collated (12 weeks of data) was used to evaluate opportunities using lean manufacturing principles. The team evaluates the types of waste and indicated which activity could be eliminated or improved. Also the material department worked with the supplier to eliminate the need for multiples materials handers.

The analysis Machine Cycle time vs Tack Time (Figure 8) shows that the ovens represent the greatest offender of time consuming during the process. The ovens cycle time, which is the time to complete a product batch, was 10800 seconds. The second greatest offender was the Drying Boxes with a value of 7200 seconds. Those machines are essential to the process due the manufacturing process were validated with those equipment.

About the operation cycle time (Figure 7), the greatest offender is the Molded Carrier Inspection operation. This operation consisted of trimming the

product, drying (using a dry box) and final inspection. The cycle time of this process was 406 seconds.

A Kaizen (is a Japanese term that means continuous improvement) team composed by operators, technicians and manufacturing engineering was performed to analyze the causes of the elevated cycle time to the manufacturing equipment and the process. The kaizen team will review and identify the causes of this equipment with greatest "muda". They will ensure the proper balance work load and improvement flow from the assembly.

The team identified to improve the current layout to a cellular layout in order to balance the workload of the manufacturing operations (Figure 9). Also they need to select the best configuration that will guarantee the best results (Figure 10). They identified the need to change product batch flow (or large-lot production) to one-piece at a time, at a rate determined by the customers. In order to change to one-piece flow and cellular configuration the productions machines needs to be replaced with small, flexible machine to fit well in the cell. Due to budget limitation the machines will be modified as per structure modifications as required and then previously qualified.

To not compromise the yield, equipment and system must be modified to stop and signal when cycle is complete or when problem occur, applying automation (Jidoka). The new operators responsibilities need to be clarified and standardized.

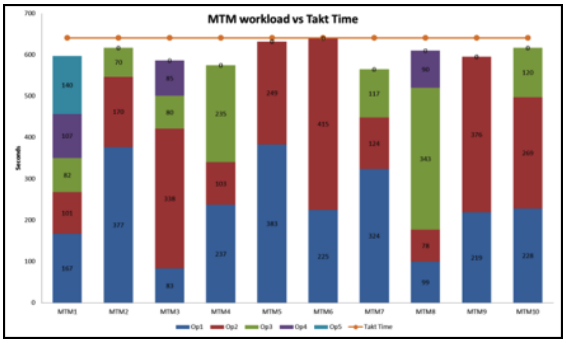


Figure 9
Operator Workload vs. Takt Time

Figure 10
Different Proposed Cellular Layout

Improve Phase

During the improve phase, a re-layout of the current manufacturing process was performed to transform current manufacturing lines to lean lines. Several process operations were improved by eliminating redundant inspections, improving drying methods, additions of Go/No Go tools, merging equivalents process operation and rearranging steps.

A cellular manufacturing layout was implemented (Figure 11). Operators work in different cells and assemble to customers. Assembly workcells were setup so that processing steps of different types are conducted immediately adjacent. New ergonomically workstations were installed. Each workstation was equipped with a material rack that holds the components and puts the components closer to the operators. Material handler was included as part of the cell since this allowed easy access to the material during the assembly process and eliminate the need for the operators stand or over-extended themselves while reaching for components. Each stations was also equipped with touch screen computer monitor which allow the operator to look directly in front of them when entering information into the data base

rather than reach the side of the work station to enter information.

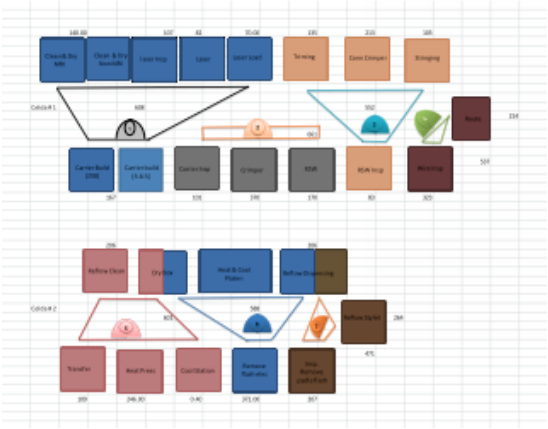


Figure 11
Cellular Layout

Table 2
Infrastructure Improvement Summary Table

KPI's	BEFORE	AFTER
Cells	1	3
HC Total	12	10
Team Leader	1	2
Material Handler	1	1
Space	848 sq-ft	1165 sq-ft (94 sq-ft for Problem Solving Area)

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.

Table 3
New Average Product Output per Hour after the Implementation of the Changes

Key KPI's:

KPI's	Baseline	Result	End Target
UPLH	0.23 units / Lhr	0.30 units / Lhr	0.33 units / Lhr
Lead Time	4.76 Days	N/A	3.5 Days
WIP	112 units	89 units	91 units
Yield	96.5%	100.00%	96.85%

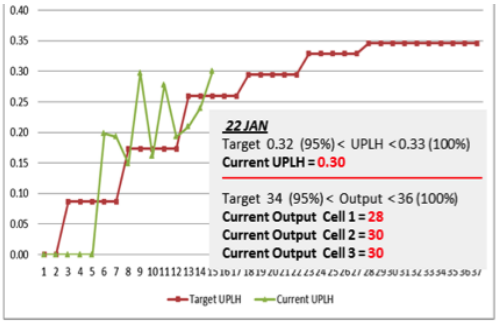
Better than Baseline but not in Target | On Target or Better

As part of the implementation process, validation activities were performed to the new equipment. Equipment previously used and qualified and stated as movable in it validation were not validate. Due to the layout change a confirmation run was performed to validate that the software/system was within specification. An overall line confirmation run was performed to the process.

Control Phase

This phase is about holding the improvement achieved by the project team. This phase is to maintain the control of the future process state to ensure that any deviations from the expected target are corrected in time before the end up being defects. By maintaining the control of the process we reduce the probability of having more defects. To maintain the control the team implemented a statistical process control (SPC) to maintain the gains and continue improvements. The operators were train in their respected procedure to avoid any kind of misinterpretation during the execution of the operation due to the implementation of the Lean manufacturing.

As part of the control phase, a metric about the product output on the manufacturing line was established and monitored as standardized until further improvements (Figure 12).



Unit per Labor Hr. (UPLH) = (Total Output) / [(Headcount * 8 hrs) + (Headcount * OT)]

Figure 12
Units per Labor Hours Monitoring

Financial Benefits	
Labor Benefits	$70,886
WIP Reduction	$14,267
Total	$85,153

Figure 13
Final Benefits

CONCLUSION

By implementing lean principles by improving and eliminating waste at the Medical Devices Company has provided a savings for the Business Units of $85,153 per years. Also team maximized the production floor space from 848 sq-ft to 1165 sq-ft in order to manufacture the new model. The Units Labored per Hours (UPLH) was increased from 0.23 units/Lhr to 0.33 units/Lhr. Due to this project is still running on the control phase the final Lead Time was not documented, but is expected to be closer to 3.5 days. The final Work In Process (WIP) obtained was 89 units, which was lower that expected. The Yield after all changed applied reached 100%. Another thing that was not expected was the stability reached on less then 8 weeks. The goal of improve productivity more than 10% was obtained.

By performing the improvements, the goals of the projects were achieved. The cooperation of all members of the manufacturing company is needed for a successful implementation and maintenance of lean manufacturing principles. This will create an enthusiastic environment as Company continues down the path of eliminating was found.

REFERENCES

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[2] J. Liker, *The Toyota Way*, New York: McGraw-Hill, 2004.