Lean Manufacturing Implementation in Medical Devices Industries

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Abstract *— This research provides information about the advantages of transforming non-automatized manufacturing lines to lean non-automatized manufacturing lines in medical devices industries established in Puerto Rico implementing lean manufacturing. This research was focused on a non-automatized manufacturing line from a medical device organization unable to reach the demand of 360 units per day. By implementing lean manufacturing and using tools as spaghetti diagram, cell infrastructure analysis, 5s, visual management, time analysis, standardize work and walk path design, the units per day increase to 384. The contribution of this research is not only for the medical devices industries, but for any organization that needs to be transformed to be able to fulfil any customer requirement or service.*

Key Terms *— Lean Manufacturing, Medical Devices, Standardize Work, Unit Per Labor Hour*.

INTRODUCTION

A non-automatized manufacturing line from a medical device organization is not able to reach the demand of 360 units per day. Based on this situation, this research is focus on how lean manufacturing could increase the productivity of non-automatized manufacturing lines using lean tools.

Lean considers any part of the enterprise which does not directly add value to the final product to be superfluous. Lean focuses on value creation and the elimination of waste and non-essential processes. Primary, it considers the product or service from the consumer's perspective to determine what is of value; then examines at the process with the aim of reducing all its aspects except for the value-adding ones. Industries have different approach when it comes to manufacturing processes. Some industries may operate in small or large batch sizes or in a continuous flow which also is known one-piece flow. The batch process consists of a sequence of one or more steps that should be performed in a defined order. A determinate quantity of the product is produced at the end of the sequence, which is repeated to produce another product batch. Generally, batch is a process that results in the production of limited quantities of material through subjecting quantities of raw materials to a set of processing activities over a significant period of time with the use of one of more pieces of equipment. Processing of successive batches must wait until the completion of the current batch.

A continuous process involves moving a single work unit at a time between every step of the process without any breaks in time, substance, sequence or extend. The flow of product or material is continuous. Every machine operates in a steady state and performs a certain processing function. Traditionally, one-piece flow manufacturing is conducted in cell operating system (COS) cells usually arranged in “U-shape” design. Continuous flow saves costs, energy and time. When this process is properly implemented, it can reduce waste, improve quality by making it easier to identify and correct errors, increase productivity and adapt to the needs of customers more efficiently than batch processing. However, continuous process is more expensive than batch process compared to the cost of equipment. But, when comparing the production rate, batch process has lower rate than the continuous process.

LITERATURE REVIEW

Lean enterprise is sometimes referred to as "lean". Both terms came into use in the 1990s by Toyota Production System. “The lineage of Lean manufacturing and Just-In Time (JIT) Production goes back to Eli Whitney and the concept of interchangeable parts" [1]. Whitney development considered the interchangeable parts in 1799 and there were people concerned about what happens between processes, how the chain of processes functioned as a system and how each worker went about a task. This scenario changes in the late of 1890's due to Frederick W. Taylor, Frank Gilbreth and Lillian Gilbreth works.

Frederick W. Taylor looked at individual workers and work methods and the result was time study and standardize work. Frank Gilbreth focused on non-value-added activities [1]. Lillian Gilbreth brought psychology by studying the motivations of workers and how attitudes affected the outcome of a process. At this time, the idea of eliminating waste was originated. Around the 1910, Henry Ford and Charles E. Sorensen took people, machine, tooling and products and arranged them in a continuous system for manufacturing the model T automobile. Taichii Ohno and Shigeo Shingo, at Toyota Motor Company, incorporated the Ford production into an approach called Toyota Production System or Just-In Time. Shingo and Ohno, worked on the setup and changeover problem reducing setups to minutes and seconds allowing small batches and an almost continuous flow, which result in flexibility [1].

- Primary Role of a Value Stream Manager: The value stream manager should be "able to understand the key system constraints and be able to quickly spot critical process issues" [2].
- Type of Waste [3]: Lean manufacturing define waste as any activity that takes time, resources and space but do not add value to product. The seven types of waste are: overproduction, waiting, transporting, inappropriate processing, unnecessary inventory, unnecessary / excess motion and defects.
- Tools for Waste [4, 5, 6]: A value stream map is a lean manufacturing technique used to document, analyze and improve the flow of information or materials required to produce a product or service for a customer. Takt time is the maximum amount of time in which a product needs to be produced to satisfy customer demand. The bar chart is a tool of standardized work to determine line balance and distribution of operators. Spaghetti Diagram is a tool that helps to reduce the waste on transportation, motion and waiting time.
- Standardize work [7]: It is a critical step in ensuring that the lean culture in the organization prospers. It established a baseline of tasks completion to achieve consistency. By documenting the current best practice, standardized work forms the baseline for kaizen or continuous improvement.
- Poke-Yoke: Poke-Yoke or Mistake proofing seeks to prevent mistakes from becoming defects and getting through the system and reach the customer [8]. The purposes of Poke-Joke are to not accept a defect for the process, not create a defect and not allow a defect to be passed to the next operation.
- Material Flow: Flow is how work progresses through a system. When a system is working well, it tends to move steadily and predictably, whereas, not working well flow means the work starts and stops. A smooth material flow could not be achieved it there are too many stops by operators during process execution, stops by material handler or missing or lack of materials from supermarkets [9].
- 5s: The 5S represent Japanese words that describe the steps of a workplace organization process. The 5S methodology helps a workplace remove items that are no longer needed (sort), organize the items to optimize efficiency and flow (set in order), clean the area to more easily identify problems (shine), implement color coding and labels to stay consistent with other areas (standardize) and develop behaviors that keep the workplace organized over the long term (sustain) [10].

METHODOLOGY

The methodology of this research was experimental by increase unit per labor hour

(UPLH) by 15% by designing an operational cell for a non-automatized traditional manufacturing line of a medical device industry in Puerto Rico. The following steps were executed to achieve the goal of this research, which is to demonstrate how lean manufacturing could increase the UPLH using lean tools:

- Spaghetti Diagram
- Cell Infrastructure
- Heijunka
- Material Replenishment
- 5s
- Standardize Work
- Visual Management
- Takt Time
- Walk Path Design
- Cell Capacity
- Cost Analysis

RESULTS AND DISCUSSION

Lean manufacturing tools were employed to gather data and the current state of the non-automatize manufacturing lines. All the information was collected by observing the day to day operation in the manufacturing area. The Spaghetti diagram showed the start and end position of a complete cycle of manufacturing process, refer to Figure 1. The blue circles represent the manufacturing team members (MTMs) and the redlines indicates the movement or steps of the MTMs. The purpose of the MTMs to be walking from one side to other was because they needed to reach out for a tooling/fixture, look for documentation and/or move the product to the next station. There are paths with single red lines and other with multiples redlines over each other, which represent the back and forward movement form the employee. By re-arranging the stations layout to cell, the waste of excess motion and transportation could be reduced.

As result of the cell infrastructure analysis, all equipment, fixtures, tooling and manufacturing aids were labeled and located in the workstation in an orderly manner. Also, equipment's and tooling considered as safety hazard were properly secure to avoid any safety issue.

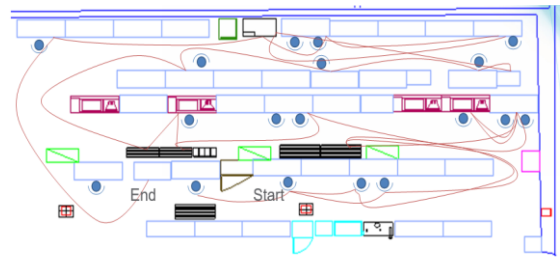

Figure 1
Spaghetti Diagram

A process flow was developed to analyze each manufacturing process and be able to split the manufacturing process steps by stations. After splitting the manufacturing process, a line balancing was executed to distribute the task time evenly between processes. Refer to Figure 2 for process flow.

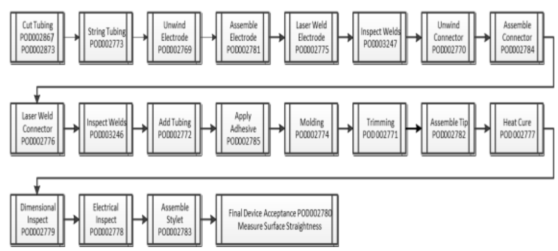

Figure 2
Process Flow

A Heijunka analysis was performed to understand the customer demand and be able to react on demand change and utilize the capacity to best way possible. The analysis shows a current demand of 43,000 units of SNS lead in average per year and the forecast demand shows 30,000 units per year with an increase of 5,000 units year over year up to 2020.

The 5S methodology was implemented in all workstation to helps remove items that were no longer needed. The result of the assessment included the design of a fixture placement and workstation labeling.

Three walk path design for COS cells were developed with all data gathered. Refer to Figure 3 to Figure 5. The color represents the workstation dimension, the blue lines represent the walk path flow for each team member and the number within the blue lines the time it takes to complete a full cycle.

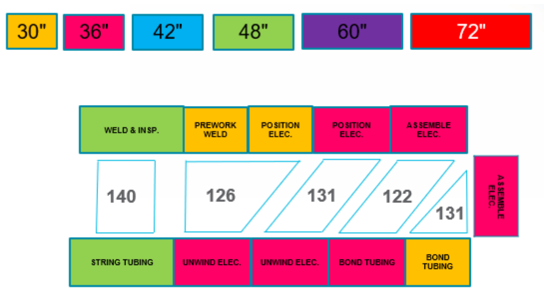

Figure 3

Walk Path Baseline Scenario

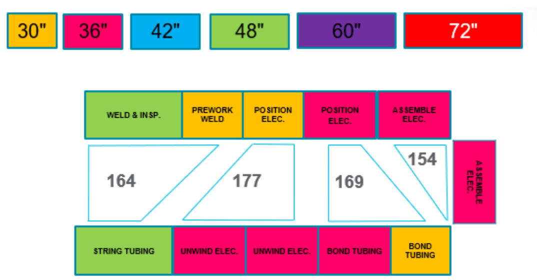

Figure 4

Walk Path -1 Scenario

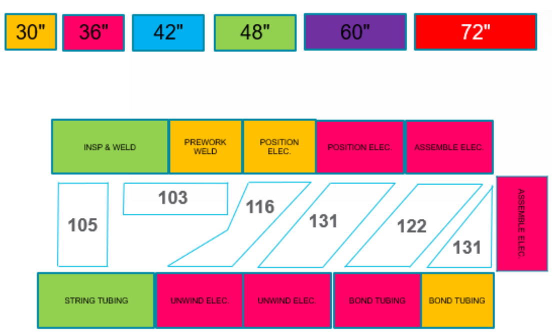

Figure 5

Walk Path +1 Scenario

	Monday, Wednesday, Friday					Tuesday, Thursday				
	AVAILABLE TIME (sec/shift)				24600	AVAILABLE TIME (sec/shift)				23100
	Cell	BaseLine	(+1)	(-1)	Takt 95%	Cell	BaseLine	(+1)	(-1)	Takt 95%
First Shift	1	175	187	145	139	1	165	176	136	139
	2	176	183	123	139	2	166	172	115	139
	3	173	173	117	139	3	162	162	110	139
	4	174	195	113	139	4	163	183	106	139
	5	117	117	73	243	5	110	110	68	243
	6	173	173	173	139	6	162	162	162	139
	7	76	107	41	324	7	71	100	38	324

	Monday, Wednesday, Friday					Tuesday, Thursday				
	AVAILABLE TIME (sec/shift)				24600	AVAILABLE TIME (sec/shift)				23100
	Cell	BaseLine	(+1)	(-1)	Takt 95%	Cell	BaseLine	(+1)	(-1)	Takt 95%
Second Shift	1	171	171	134	139	1	160	160	126	139
	2	176	178	122	139	2	166	167	114	139
	3	168	169	126	139	3	158	159	118	139
	4	170	189	106	139	4	160	177	99	139
	5	117	117	73	243	5	110	110	68	243
	6	173	173	173	139	6	162	162	162	139
	7	76	107	41	324	7	71	100	38	324

Figure 6

Cell Capacity

Each cell was studied and designed to have a capacity of a minimum of four and a maximum of six team members. An output analysis was made with the walk path flows and takt time define by day and shift. Figure 6 shows for the first shift and for Monday, Wednesday and Friday, the output of the cell is of 175 with baseline scenario, 187 for +1 and 145 with -1, assuming the tack time is being reach at least 95%.

After walk path, workstation and capacity evaluation, Figure 7 shows the proposal layout for the manufacturability of SNS and DBS lead. This layout will maximize space, reduce waste as motion, waiting time, transporting and unnecessary inventory.

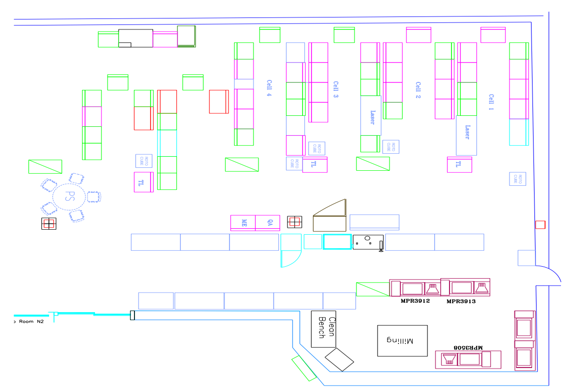

Figure 7

Layout

Financial analysis for the implementation for a cell manufacturing flow was performed. The total value for the implementation of the cell is of \$352,182.06. The financial analysis shows that for the first year of implementation the cash flow will be impacted negatively by \$567,240 but for the next seven years, the cash flow will be good and getting revenues around \$500,000 per year.

CONCLUSION

The problem stated in this research "A non-automatized manufacturing line from a medical device organization is not able to reach the demand of 360 units per day" was resolved using lean tools and with a proposal of the implementation of COS. The implementation of COS could increase the UPLH up to 48 units for a total of 384 per day from a UPLH of 40 units for a total of 320 per day. The result of this project is aligned with the literature and findings due to the positive impact in manufacturing productivity resulted from this continuous system implementation.

The contribution of this research is not only for the medical devices industries, but for any organization that needs to be transformed to be able to fulfil any customer requirement or service.

The limitations of this study are that the analysis was completed based on customer requirement of approximately 380 unit per day, a cell for five MTMs and self-reported data.

The recommendation for future research after lean implementation is to study the response/behavior of team members who work in cell operation systems and determine how long it takes to adjust for big changes that bring lean manufacturing.

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