Optimization of Manufacturing Space and Lead Time for a Medical Devise Process Line

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Abstract *- Product Availability and inventory management are key metrics for every company in order to meet customer satisfaction and cost reduction. For this company this are two important metric in addition to space utilization, Product availability is a direct relation between the customer and the company, inventory management and space utilization is related to improve costs of the company and help them to be more competitive. In this case, this family of product was identified whit that opportunities areas in order to improve a strategy to implement Lean Six Sigma methodology were generated on plant. Implementing a cell manufacturing, one piece flow, standardization, helped company to reduce lead time by 81%, reduce inventory level by 42% and improve space utilization by 52%. Lean Six Sigma strategy promotes a continuous improvement culture on the place where was implemented, that help any company to obtain a continuous grow.*

PROBLEM STATEMENT

Driven for Globalization, companies look to operate with the highest standards and lower cost in order to maintain or gain a better position in the market, for this reason product quality and availability is the main driver to operate the facilities. In order to achieve this, many factors are important to consider like the lead time of the product, levels of inventory, equipment liability, shop floor housekeeping and organization. The company needs to know their metrics and look to improve them in order to grow. Continuous improvement is an ongoing effort to improve products, service or processes in an incremental over time and lean Six Sigma is a philosophy that the fundamental goal is to eliminate waste, emphasized the production of only the required type of units at the required time and the required quantities. Companies that achieve a change on culture to Lean Thinking obtained different benefits like improved quality, visual management, employee morale, customer service, office performance, product and profitability; at the same time increased efficiency, responsiveness and make ease of team management, problem elimination, safer work environment, reduced lead time [1].

Project Description

Actual process to build a product in a Medical Device industry take from 10 to 12 days to ship to customer, at the same time large amount of inventory is between the processes because, the lot size varies from 25 pieces (pcs) to 400pcs per lot, for this reason the operator needs to finish the entire lot in order to pass to the next process. Manufacturing space utilization for this product is about 544 square feet, which represent the 50% of the available space in the plant, in order to transfer new products more available space is need.

Project Objectives

- Reduce Product lead time by 20%.
- Reduce Space for 50%.
- Reduce Inventory by 10%.

Project Contributions

Implementing Lean Six Sigma some indirect contributions are:

- Cost reduction- unit cost reduces as a result of high volume production, in order productivity increase the cost per unit reduces. Lean is focus on waste reduction, and waste represent cost in the product, for this reason implementing Lean Six Sigma on a process, eliminating waste, cost will reduce per unit.
- Product availability- Customer needs a product with the highest quality, the required quantity and at the right time, Lean Manufacturing is looking to improve lead time reducing waste.
- Cultural Behavior for continuous improvement- Lean manufacturing is focus on pursuit perfection; the goal is implement a cultural behavior to always look for opportunities in order to obtain the perfection.

LITERATURE REVIEW

Lean Manufacturing has been shown to improve quality, productivity, lead-time, work-in-process, space, and employee engagement. The objective of

Lean manufacturing is to reduce waste in terms of waiting time, setup time and work- in process inventory. Waste in the context of the manufacturing environment means redundant application of resources that does not contribute value to the product, for which the customer is unwilling to pay. The analysis of case studies dealing with the application of Lean Manufacturing can be found in different sectors, like aerospace, electronics, automotive and aircraft production. The present project was conducted at a medical Device industry. The main objective of this project were to (1) present an overview of Lean Manufacturing; (2) implement a Lean Manufacturing system to improve productivity of this product in the medical device environment.

Lean Manufacturing Overview

Elimination of Waste thinking comes from long time ago, Benjamin Franklin in his Essay "The Way to Wealth" mention that carrying unnecessary inventory will cost more, because lather or sooner they will need to sell for less than they cost. Henry Ford focus on waste reduction thinking while developing his mass assembly manufacturing system. One of the major contributions of ford was the standardization and the manufacturing tolerances that help to reduce manufacturing effort by between 60-90%, because until Ford, a car's components always had to be fitted by a skilled engineer at the point of use, so that they would connect property. By enforcing very strict specification and quality criteria on component manufacture, he eliminates this work almost entirely. During post war economy of Japan were low and the focus of mass production on lowest cost per items to acquire more revenue was important, Kiichiro Toyota thinks that over production had to be avoided an thus the notion of Pull came to underpin production scheduling [2]. This enabled Toyota to become market leader in the worldwide automotive industry. The term lean manufacturing was coined in the 1990s when book titled "The machine that changed the World" was written by James Womack. This book combined production methods practiced in the US, Europe and Japan and referred to in the publication as "lean Manufacturing". Then, many production engineer and expert attempted to make production methods more efficient. Lean manufacturing enables streamlining the production system to achieve cost savings a customer satisfaction and further profit improvement [3].

Six Sigma

Is a disciplined data driven approach and methodology for eliminating defects, driving toward six standard deviations between the mean and the nearest specification limit in any process. The statistical representation of Six Sigma describes quantitatively how a process is performing. To achieve Six Sigma a process must not produce more than 3.4 defects per million opportunities. A Six Sigma defect is defined as anything outside of customer specifications. The fundamental objective of the Six Sigma is the implementation of a measurement strategy that focuses on process improvement and variation reduction through the use of DMAIC (Define, Measure, Analyze, Improve and Control) methodology [3]. There is not a definitive date for the beginning of Six Sigma but about 1987 Bill Smith began improvement projects for Motorola's pager business, that use thinking process derived from Total Quality Management, this initiative obtain prestige when General Electric (GE) proclaimed that was jumping into the Six Sigma game in late 1995. Today many manufacturing companies, service organizations, financial and health services have also embraced Six Sigma as a strategy to achieve process excellence and consistency in the delivery of services to customers [3].

The Define, Measure, Analyze, Improve and Control (DMAIC) Process

Is the Six Sigma Methodology that links the tools and techniques in a sequential manner and a Data driven strategy used to improve process [3]. Consist in sequence of logical steps:

- Define the problem, projects goals, customer requirements, team members, scope.
- Measure actual process performance in order to create a baseline.
- Analyze the process to determine root causes of variations, poor performance.
- Improve process performance by addressing and eliminating the root causes
- Control the improved process and future process performance.

In order to reduce waste by following DMAIC Methodology there are some tool that are used across the process, that tools help to acquire valuable information about the process and how to improve it.

Value Stream Map

Value Stream denotes the sequence of all process where cost is incurred. This tool helps to see and understand the flow of material and information as a product or service from the order generation until the product is delivered to the customer.

U-Shape Layout

Process flow and Layout are the heart of lean manufacturing because the goal is to link process steps to minimize cycle time and travel distance, eliminate crossover points and simulate a continuous flow. This Shape is the most common flow configuration to implement because allows simple path distinguished from entry to exit points, operators have ability to access multiple work stations, operators own entire workflow. The flow direction depends of the company decision, but anticlockwise is the most common because is natural flow for humans to move across a path.

Standardized Work

Is the most efficient method to produce a product (or perform a service) at a balanced flow to achieve a desired output rate alignment with the customer demand. It breaks down the work into elements, which are sequenced, organized and repeatedly followed. Each step in the process should be defined and must be performed repeatedly in the same manner, any variations in the process will cost likely increase cycle time and could cause quality issues. Three necessary components in standard work are takt time, cycle time and Standard work in progress. If this tool is implemented it should allow anyone to perform the work without any variance in the desired output.

Heijunka

Is a Japanese word that means "leveling". When its implement helps organizations meet demand while reducing wastes in production and interpersonal processes. This tool helps leveling the type and quantity of production over a fixed period of time. This enables production to efficiently meet customer demands while avoiding batching and results in minimum inventories, capital costs, and manpower and production lead time through the whole steam. At the same time looks for equity between shifts, because the demand will be balance to perform the same quantity and mix every day every shift.

All this tools and many other will be used to acquire and analyze data regarding the process of manufacture a medical device, in general the process consist in visual inspection, marking inspection, labeling and packing, the demand consist of a mix of 10 different products, where the lot size varies from 25pcs to 400pcs.

Takt Time

Takt time is the maximum amount of time in which a product needs to be produced in order to satisfy customer demand. Takt time will help to deliver the right product at the right time in the right quantity to the customer. It's Calculate dividing demand between available time.

Rolled Throughput Yield (RTY)

Quantifies the cumulative effects of inefficiencies found throughout the process. RTY is the probability that a process with more than one step will produce a defect free unit; and is the product of yields for each process step of the entire process.

METHODOLOGY

In this chapter is presented the qualitative and quantitative methods to develop this project and other Lean Six Sigma tools used to evaluate the process.

Space Utilization

In order to know the actual space utilization all work stations, racks and equipment will be measure in 2 dimensions. It's important to include 2 feet all around per equipment for preventive maintenance and repairs, at the same time consider 3 feet for aisle purpose. A spaghetti diagram will be used to measure the operator movements in order to complete the process; all measurements will be realized with a metric in inches.

Actual and Future Demand

This data is gathered from historical output combined with future forecast requirements to determine with Supply chain the demand of the new cell, it important to identify how many units are required by the customer each month, week, day and shift, at the same time it important to take in consideration review mix over time.

Quality Risk

In order to review Quality Risk in actual processes a First time Quality assessment will be performed, where all actual steps will be evaluated to assure each possible defect or risk is mitigated with any controls that not allow making or shipping a part with a defect. the team players to make this assessment is the quality engineer, process owner, supervisor, manager and some operators, will developed in the manufacturing floor during a regular working day in order to capture all possible risks. Consist of observational assessment and documented in a table, where later in the process (analyze phase) will evaluated with a standard and assigned a prioritization. Another metrics about Quality that will need taking into consideration is related to day to day activities like defect reasons codes, escapes of defective product, corrective actions and preventive actions (CAPAS) implemented in the area, complaints of our customers, Rolled Throughput Yield (RTY).

Actual Work in Process (WIP) per Step

In order to know the amount of WIP in each step of the process a snapshot of the current situation will be taken, this information will evaluate with the final results to determine the percent of improvements after implementation.

5's and Visual Management

Photographs of base line will be taken and documented in order to take in consideration during analyze phase the necessary tools and objects to execute the operation in the line.

Standardize Work

In order to generate the standardize work to team members and team lead a time studies per operation will perform, a video recording of each operation will be recorded to evaluate each of the operations that the person fallow in order to complete the process. Then that series of steps will be evaluated to identify the value added vs. non value added activities, in order to eliminate or decrease those activities.

Lead Time

Lead time will be measure based on retrospective type because will be taken from reports already in company's data base. This information will be used to establish a base line and then after implementation of the project, benefits could be measure.

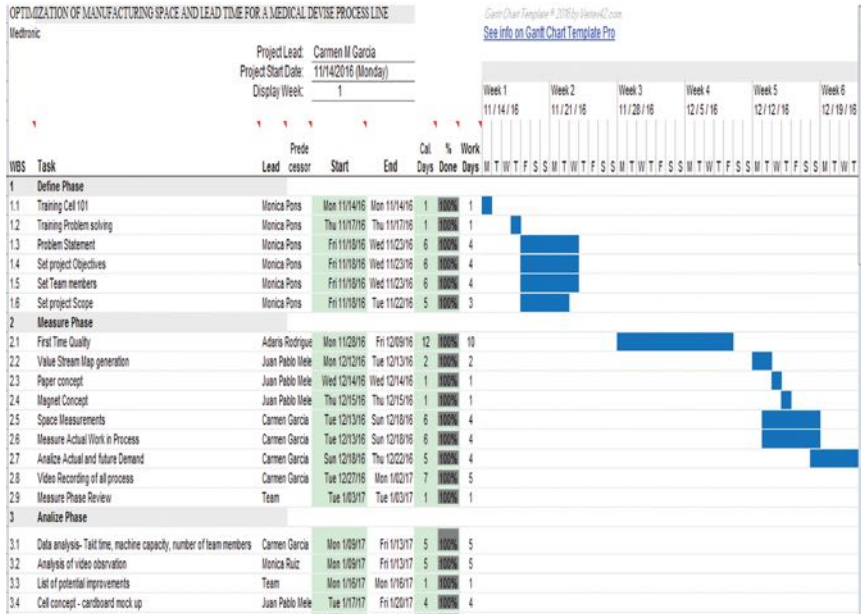

Figure 1. Gantt Chart of the Project

In this Gantt chart is presented all the phases completed of the project, at this moment the project is on Improve Phase and the implementation date is first week of March 2017.

RESULTS AND DISCUSSION

In this chapter is presented the results achieved after implemented the cell on space utilization, lead time and work in process metrics, at the same time in cultural behavior.

Space Utilization

In order to know the actual space utilization all work stations, racks and equipment where measured in 2 dimensions. At the same time spaghetti diagram where used to measure the operator movements. The actual space utilization is about 92 Square feet, this analysis include all work in process (WIP) racks between each station, machines and stations related to inspection thru final pack of the product.

This data helped us to determine the demand of all products that will run in the new cell, at the same time it's important to determine the mix of product for this family. The average Weekly demand is 26,839pcs as show in Figure 2 and a daily demand is 5,529pcs per day after yield increase of 2%. The product mix is represented in Figure 3 and show that is compound of 12 part numbers where part number 7 represent the highest volume on the product mix this information is important in order to calculate the target cycle time correct and to calculate the changeover in order to identify

Stations	Actual
Station 1	9
Station 2	6
WIP Rack 1	4
Station 3	12
WIP Rack 2	4
Station 4	12
WIP Rack 3	4
Station 5	6
WIP Rack 4	4
Machine 1	12
WIP Rack 5	4
Machine 2	9
Station 6	12
Wip Rack 6	8
Total square Feet	106

Table 1. Actual and Future Demand

Total Time	495
Deductions	
Tier 1	10
Ergonomics Exercises	10
Break	15
Lunch	30
Problem Solving	0
Walk Times (NVA)	15
Total Deductions	80
Total Available Time/Shift	***415***

Table 2. Available Time per Shift in Minutes

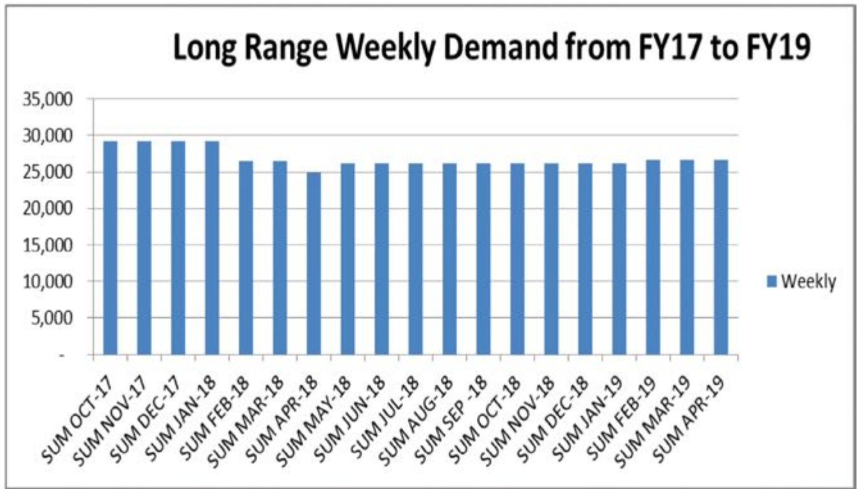

Figure 2. Demand Data for Family of Products that will be Running on the Cell

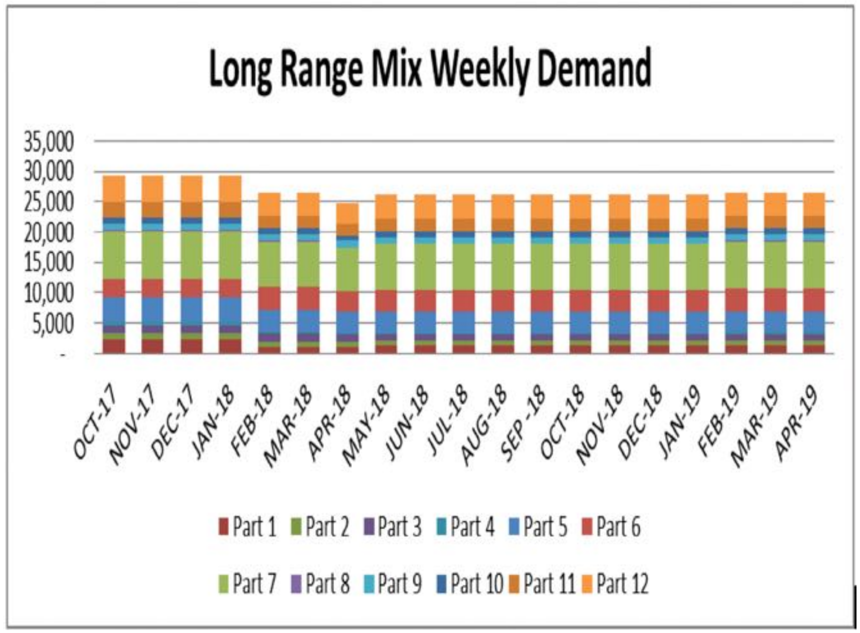

Figure 3. Demand Data for Family Mix

Main Family	Average Weekly demand	Average Daily Demand	Average with 3% Scrap	Average Daily w/3% Demand	Target cycle time	Average demand * TCT
Break Off M8	814	163	5	168	17	2850
Break Off essence	1445	289	9	298	17	5061
Set Screw	3629	726	22	748	19	14205
Venture	1015	203	6	209	19	3971
Zevo	2148	430	13	443	19	8409
Legacy FAS	1212	242	7	250	19	4743
Twin Cities	351	70	2	72	19	1373
Atlantis	7649	1530	46	1576	19	29936
Premier	84	17	1	17	19	327
Zephir	1055	211	6	217	20	4346
Vertex Set Screw w outser	3518	704	21	725	18	13043
Vertex Select	3921	784	24	808	20	16153
Total	26839	5368	161	5529		104418

Table 3. Calculations to Obtain the Total Average Demand per Target Cycle Time in Order to Calculate with this Data the Weighted Cycle Time

the right amount of output that the cell could produce in a daily basis. Using information of Actual demand and available time a takt time was calculated, available time is considering deducting time per daily meeting, breaks and ergonomic exercises. A total of 415 min are available per shift and a demand of 5,529pcs per day is required from the client, a takt time of 27sec/part is necessary to meet customers' requirements. In order to meet customer requirements cycle time needs to be lower than takt time, for this reason is important to calculate this metric, for this project takt time is 27 sec and the higher cycle time of the family of product is 19 sec per part.

This project was implemented for a family of product that have different part numbers and each part number have some differences in the walk path, one of them requires more inspection time and other not required some tasks, for this reason Table 3 was created in order to present this differences on cycle time.

Based on this information of product MIX and demand, a weighted cycle time where calculated using data from Table 3 and Equation 1, the result is that every 19 seconds in average a product will be finish the process in the cell and deliver to client.

$$Weighted\ Cycle\ Time = \frac{Demand_A \times CT_A + Demand_B \times CT_B + Demand_C \times CT_C}{Total\ Demand} \quad (1)$$

$$Weighted\ Cycle\ Time = \frac{104{,}418}{5{,}529} = 19\ Sec$$

Quality Risk

In order to review Quality Risk in actual processes a First time Quality assessment was performed and a detailed review for all potential risks was completed by the team including certified team members to confirm FTQ risks were real, prioritize and generate solutions with assigned owners. Direct observations and Gemba walks were completed for all work steps on the transformation. During the assessment 230 potential risks were identified for this transformation and 74 potential risks were identified as Priority #. Only 37 open risks from this conversion will be addressed.

PROCESS	RISK IDENTIFIED
Station 1	24
Station 2	21
Station 3	7
Station 4	10
Station 5	6
Station 6	8

Table 4. Quantity of Risk Identified per Station

Regarding Quality, no CAPAs where identified, no manufacturing related complaints and no internal or external escapes was viewed for this process. The average for the past 9 months was 97%, as show in figure 4, where the major offender was during June 2016. On Figure 5 is showing the Pareto defects with major defects for this family of product, about 6 defects where identified that cover the 80% of the scrap in the process, actions where identified in order to addressed and improve this occurrences of defects.

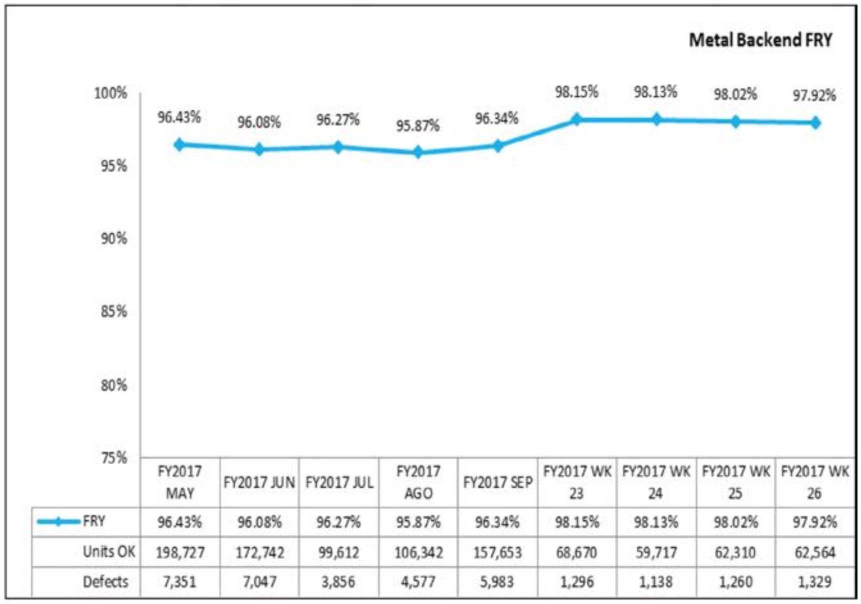

Figure 4. First Run Yield for Actual Process

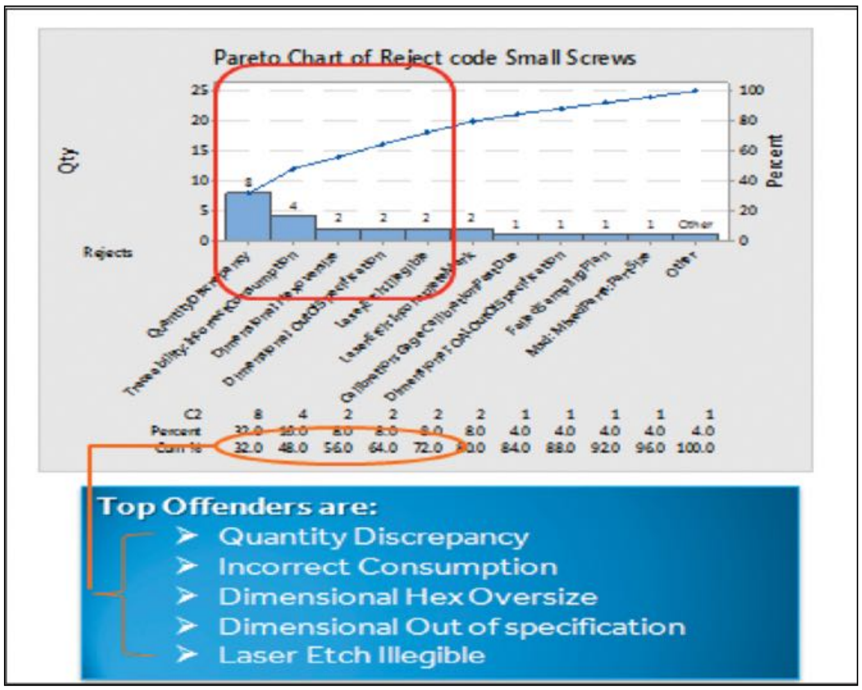

Figure 5. Pareto Chart showing Reject Codes that Impact 80% of the Scrap in the Actual Process

Stop and Fix Standard

There is a need to define and standardize an escalation system and criteria to ensure all operators stop the process when an abnormality occurs, escalate to communicate, in order to fix the abnormality with the appropriate countermeasures. The goal for this mythology implement an escalation process is to empower employees to stop their work and escalates for help to return work to normal. Figure 6 shows some common abnormalities and the communication escalation that the team member needs to follow in order to assuage good function of the cell.

Actual Work in Process (WIP) per Step

In order to know the amount of WIP in each step of the process

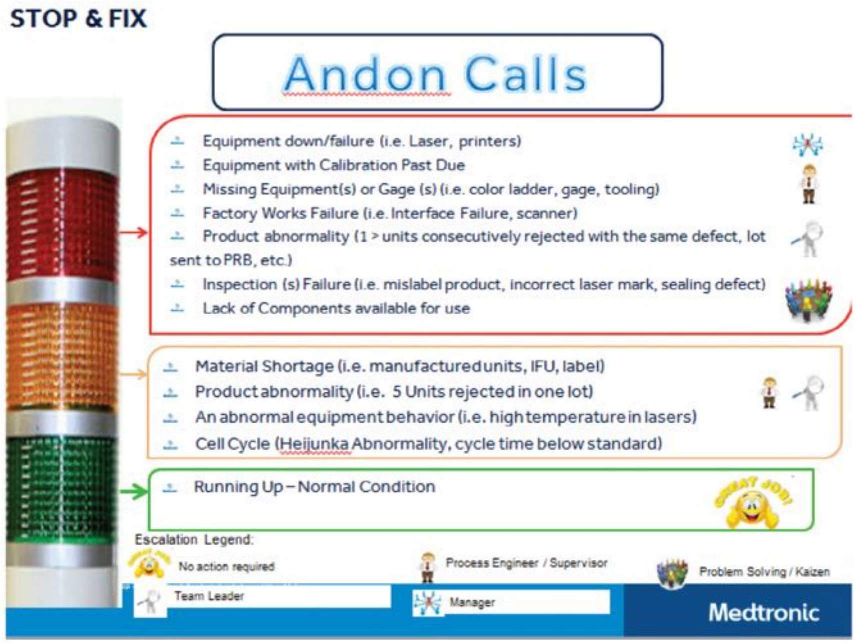

Figure 6. Common Abnormalities and Standardize Communication System

a snapshot of the current situation was taken, this information was evaluate with the final results to determine the percent of improvements after implementation. During that snapshot 2,086pcs where identified in different area of the regular processes. Figure 7 shows a Value Stream Map, where value added and no Value added times where calculated and localization of WIP.

5's and Visual Management

Photographs as show on Figure 8 (next page) of base line was taken and documented in order to take in consideration during this phase the necessary tools and objects to execute the operation in the line.

Standardize Work

Video was recorded for each operation in order to evaluate each of the operations that a person fallow in order to complete the process, then that series of steps will be evaluated to identify the value added vs. non value added activities, in order to eliminate or decrease those activities. When all steps are clear, was generating a cell concept on paper, considering all value added steps. This exercise helped to determine the order of the process and the arrangement of the tables, machines, in order to improve the pro-

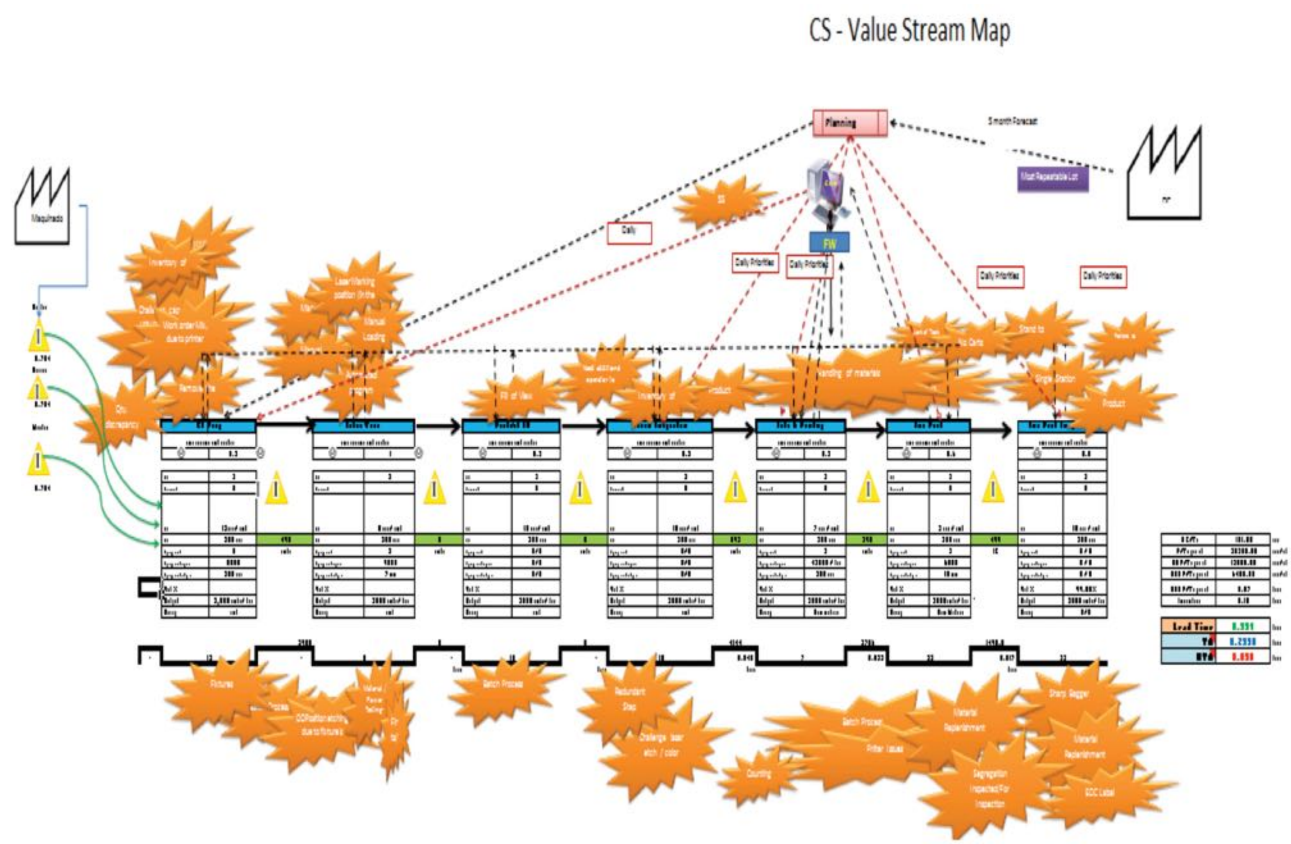

Figure 7. Value Stream Map that shows the Current Process of the Product

duct and operator flow this concept is presented in Figure 9.

Before paper concept a magnet concept was generated, in this exercise the goal was to incorporate computers, fixtures and other items that are necessary over the table to execute the process, at the same time was established the flow of the operators, figure 10 shows this concept.

Finally the concept was physically established with a scale cardboard of the future cell, as presented on Figure 11, where all the details that will need the cell are constructed with carton and place on the specific place, this concept allow to simulate the movements of the operators and make any changes on the infrastructure before buy anything. After this simulations a standard work was developed and make trials with real parts and certified operators in order to confirm times, flow and movements.

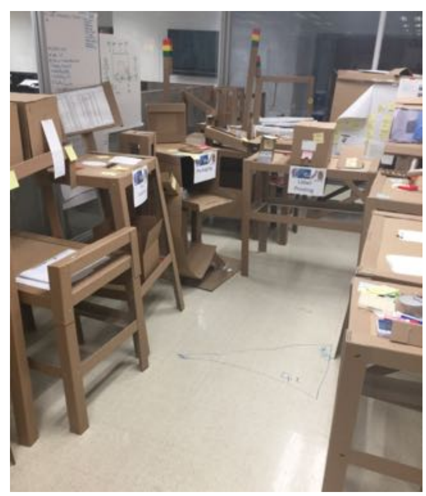

Figure 11. Cardboard Concept for Future Cell

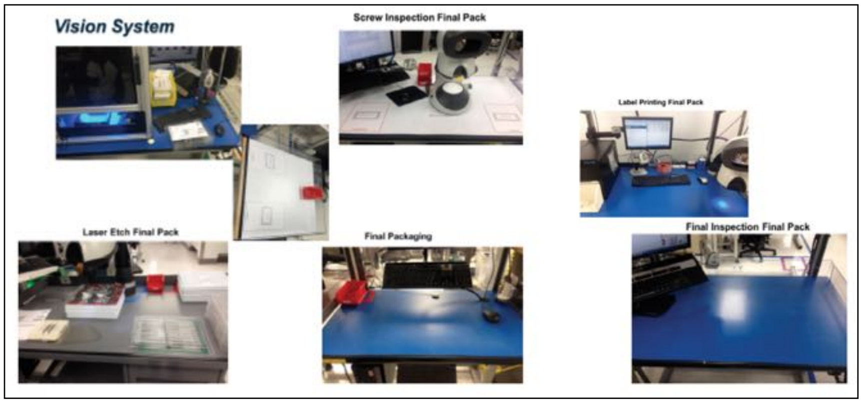

Figure 8. Pictures that shows the Actual Visual Management of the Current Stations

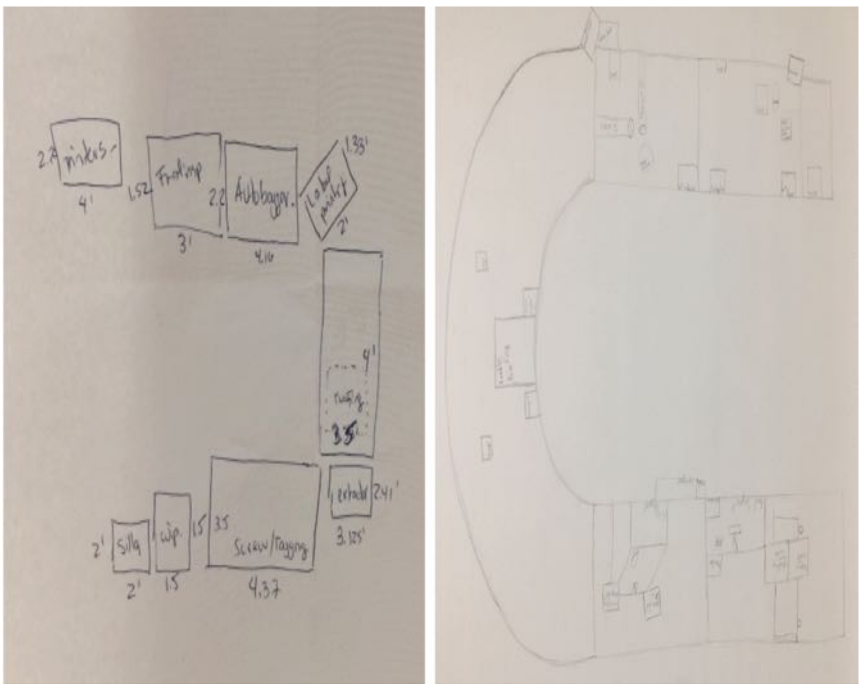

Figure 9. Paper Concept for Future Cell

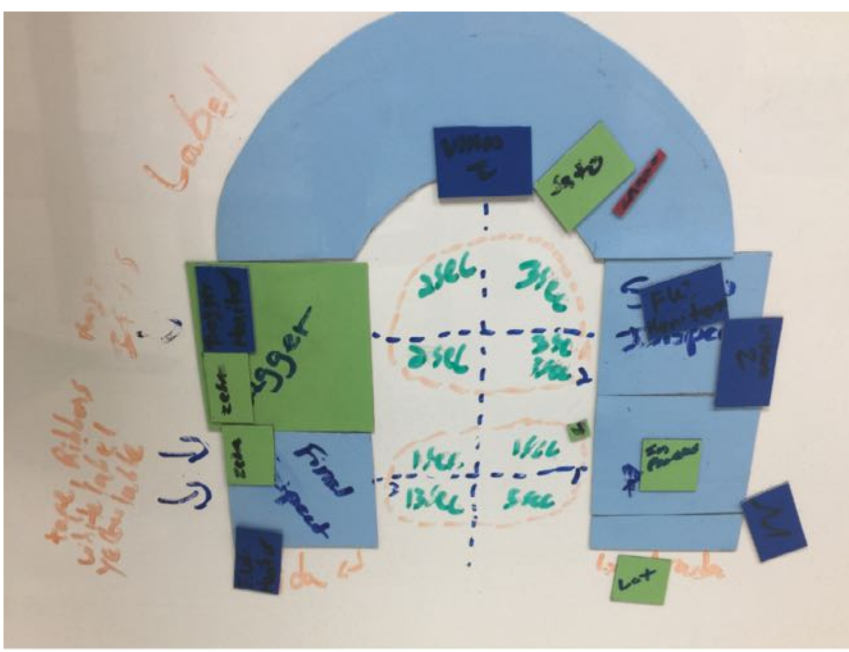

Figure 10. Magnet Concept for Future Cell

Material Replenishment

In order to assure that line not stop because don't have materials, a plan per part was developed, this plan per part take in consideration the Bill of Material of each part number, and calculate

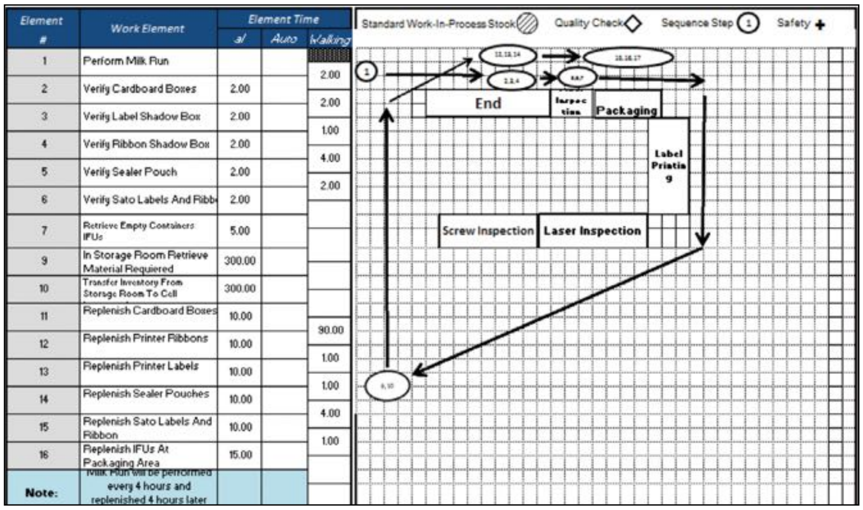

Figure 12. Material Replenishment Standard Work

the quantity of sub components, packaging materials and other elements needed to produce this family of product like gloves and hair net. The purpose is have a two bin system, where one bin had the quantity of supplies required for at least 4 hours of work, and the other bin Is a safety bin. Part of this material replenishment system, is a standardized work for the material handler, where was established the points of use of each material and the quantity needed, the material handler need to assure that every 4 hours the material is replenish, in order that the line have a continuous flow. Figure 12 is present this standard work with the spaghetti diagram corresponding with all tasks designed for the material handler.

CONCLUSIONS

After analyze phase, cell infrastructure was established, standard work was created, material replenishment was implemented and all other subsystems, like Heijunka, visual management, stop and fix, continuous learning, problem solving, and 5's was implemented on the cell in order to start up the cell. Regarding the achievement of the goals, the space utilization improves by a 52%,

Stations	Actual	Cell
Station 1	9	12
Station 2	6	12
WIP Rack 1	4	2
Station 3	12	12
WIP Rack 2	4	0
Station 4	12	0
WIP Rack 3	4	0
Station 5	6	0
WIP Rack 4	4	0
Machine 1	12	9
WIP Rack 5	4	0
Machine 2	9	4
Station 6	12	0
Wip Rack 6	8	0
Total square Feet	106	51

Table 5. Space Utilization Result before Cell Implementing

because space for work in process racks where eliminated; only one is part of the cell to place in lots. From 6 work stations where merged and converted in only 3 stations, machines tables where fit to each machine in order to eliminate not need. Table 5 shows the improvements on space utilization.

With the implementation of the cell infrastructure and eliminated the work in process (WIP) racks, the inventory levels reduce by 42% this was driven by established an specific amount of WIP per step, on Figure 13 is showing the point where WIP is present around the cell steps. First point is the IN lots the maximum capacity is 800pcs, Point A represent the lot inside the cell, the amount at this point depend of the amount already out of the cell on point B and the 18pcs that are on inspections steps inside the cell. In overall 1,200pcs inside the cell is the maximum amount of WIP per standard.

Reduce cycle time was the third goal of this project, implementing Cell Operating System for this family of product a reduction of 81% of cycle time was obtained. During analyze phase a Value Stream Map was developed for Actual process, where a Cycle time of 101 seconds per part was calculated, this is because the lot is moving in batches. This batches varies from 25pcs to 400pcs depends of the demand per part number. The theory around this is that implementing a Cell with a one piece flow, the product arrives in less time to the client, versus producing the lot in batches, where the first proceed

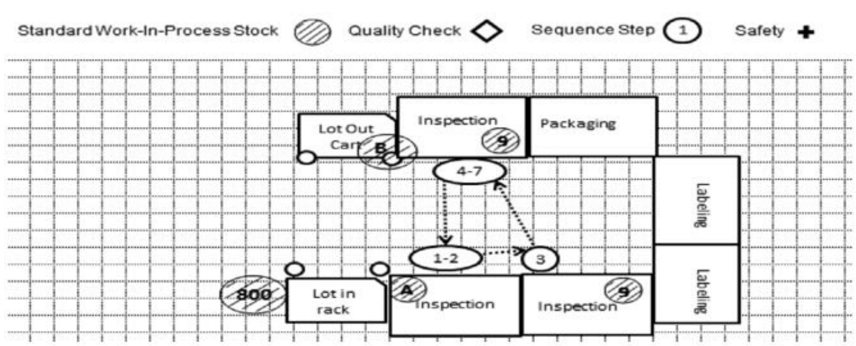

Figure 13. Cell Infrastructure with Amount of Work in Process per Step

piece is waiting in the table for the last piece and then all batch move to the other step. In Cell System, the part is moving step by step in a continuous flow. After cell implementation a Cycle time of 19 seconds per part was implemented, this means that every 19seconds the client will receive a good part. Cycle times improvements driven another soft improvements like costs, for this specific project a reduction of operators was documented as a cost reduction, because for regular process was necessary about 7 operators per shift and now in cell only need 3 operators per shift, was a reduction of 4 operators that where relocated in order to enforce another areas that had the necessity of operators. Another soft improvement was increase product availability this is because with the reduction of cycle time, the client receive the product with less lead time and the distribution center have inventory of the product that the client need when they need. Cultural Behavior for continuous improvement is another soft improvement obtained during this project, implementing a schedule to make a problem solving weekly per shift. This problem solving consists in follow DMAIC methodology solve problems identified by the operators. The process begging when an opportunity was identify by the operator, team leader, supervisor, engineer of other support team from the cell, a card is open with the concern and place for evaluation, during daily meeting all cards are evaluate and assign an owner, the ones that represent a "do it now" where implemented and the others an A3 process is working during the weekly problem solving section. Figure 14 represent the alignment of the cards on the roto cube board.

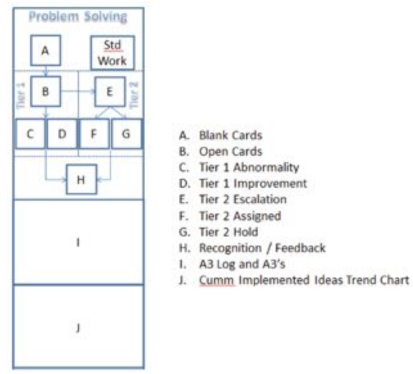

Figure 14. Standard for Problem Solving Cards Management

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