Medical Device Manufacturing Area Waste Elimination and Efficiency Improvements Project

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Abstract

This project describes a process for waste elimination and efficiency improvements in a manufacturing area at a medical device company. It uses the DMAIC methodology for the development of the improvements. Through the elaboration of the project, there were different Lean tools applied. These tools supported the understanding of the current state of the area, the identification of non-value added activities and the generation of the future state. As a result of this project, wastes such as over processing, inventory, motion, transportation, among others were eliminated, resulting in 24% increase in productivity. In addition, lead time of the product and traveled distance required to manufacture it were improved by 80%. The results of this project contributed in over $200k savings to the company, in addition of having a positively impact in the performance metrics of the device manufacturing area.

Introduction

This project aims to develop a strategy for waste elimination and efficiency improvements in a specific medical device manufacturing area. Currently, this area is one of the highest product demand and their inefficiencies are impacting the company performance. In addition, if these inefficiencies are not resolved, they could lead to backorder issues thus impacting customer lives.

Background

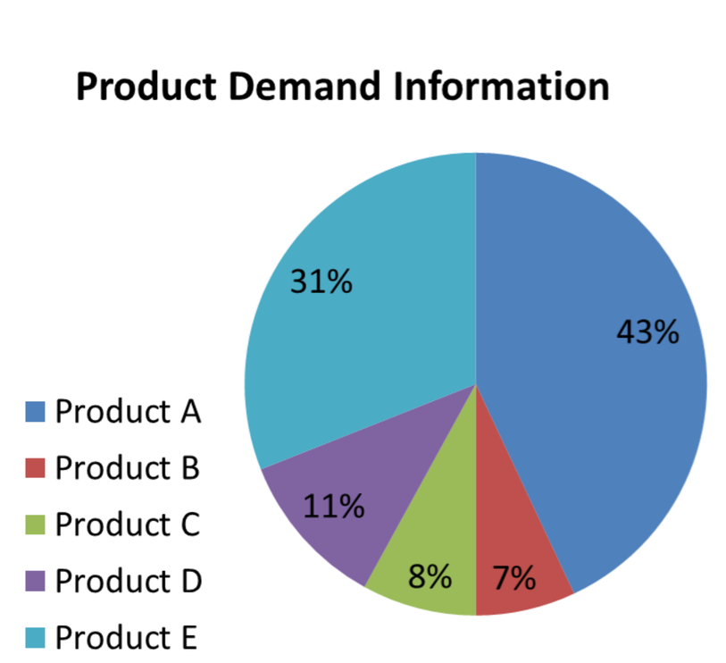
This medical device manufacturing area has 13 operating cells to manufacture five (5) different products. These products have different sizes and features, and they represent 83 different items codes distributed as shown in Table 2. These products are manufactured in the cells listed in Table 1, but each of them requires specific process steps and times. In addition, the demand is not equally distributed, therefore there are some cells requiring more capacity than others. Refer to Figure 2 for product demand information.

Table 1: Manufacturing Cells and Quantities

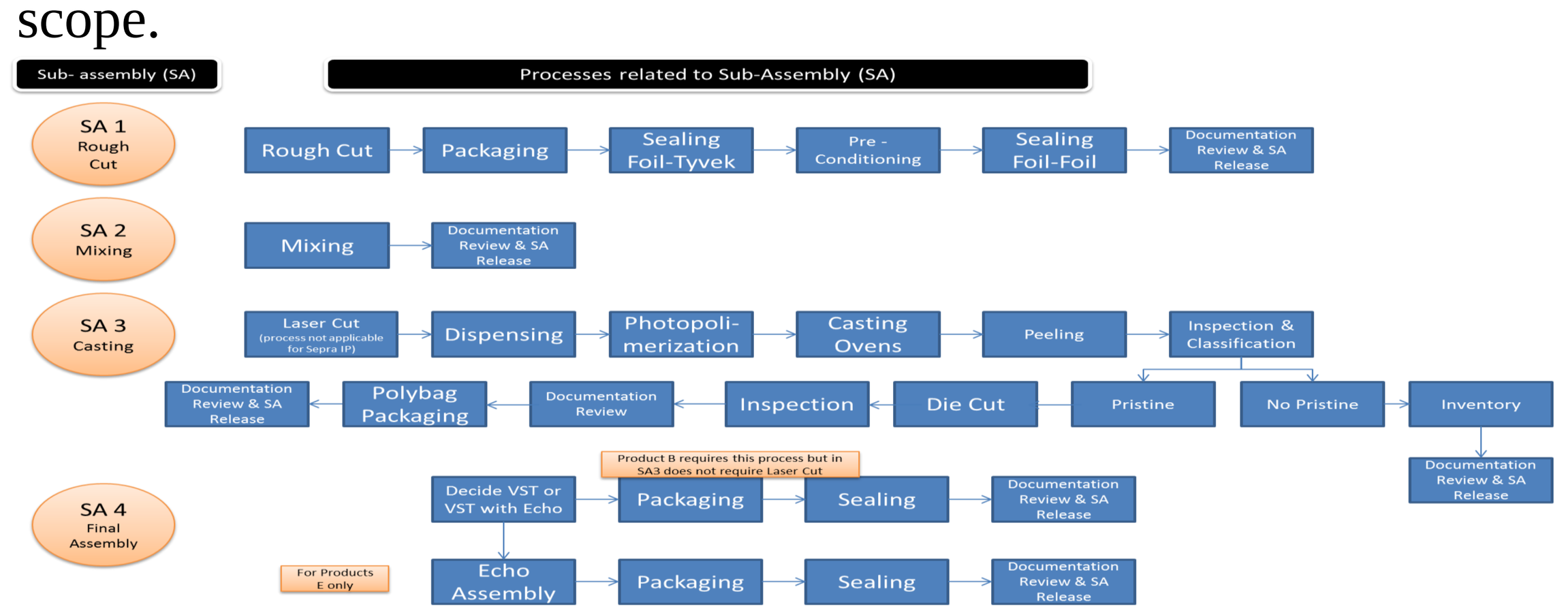
Rough Cut (1)	Cutting & Inspection Cell (2)
Pre-Conditioning (1)	Echo Manufacturing Cell (1)
Sealing Process (3)	Post Conditioning Ovens (1)
Photo-polymerization (3)	Blending (1)

Table 2: Quantity of product codes per product type

Product Name	Qty of Product Codes
Product C	34
Product D	24
Product A	10
Product E	10
Product B	5



Due to the complexity of the process, the products in scope require four (4) Sub-Assemblies (SA), together with their work orders, to complete one (1) End Item (EI). Diagram below shows the process flow of the SAs required to manufacture these products. For the purpose of this project, the SA2 is out of the scope.



Problem

Medical Device Company X is high mix – low volume facility dedicated to manufacture medical devices for Surgical Specialties, Urology, Oncology, among other medical devices areas. One of the highest product demands is known as the Product A,B,C,D,E Family. This area consists of different products dedicated to repair hernia diseases in different areas of the human body.

This medical device area consisted of approximately 34 employees distributed in two (2) shifts. The area was evaluated and the following opportunities were found:

- Lack of continuous flow: Area uses batching processes to manufacture the required items. This leads to a higher effort by the time of planning and scheduling of the manufacturing area.
- High Inventory of Work In Process (WIP) material in the area (12,160 units / 21 Lots)
- Lead Time from Rough Cut process to Sub Assembly Sealing is around 17 days for Product A and 34 days for Product B.
- Productivity: 15 units per employee per day.
- There is a space utilization opportunity in the manufacturing area leading to transportation wastes. In addition, the area in not enough for the resources needed thus having safety opportunities.

PROJECT GOALS	METRIC	CURRENT	GOAL	% CHANGE
Units per Day	Units/day	520	~600	15%
Productivity	Units/operator	15	~25	67%
Inventory	Lots	21	~15	28%
Lead Time	Days	17-34	~10	70%
Transportation	ft.	~1050	~200	80%

Other Expected Project Results

- Generate new work stations and perform area re-layout thus eliminating transportation and movement waste, while impacting 5S and Safety.
- Generate Processes Standard Works
- Create tools for sustainability
- These improvements aim to produce a cost saving impact to the company equivalent to $200,000

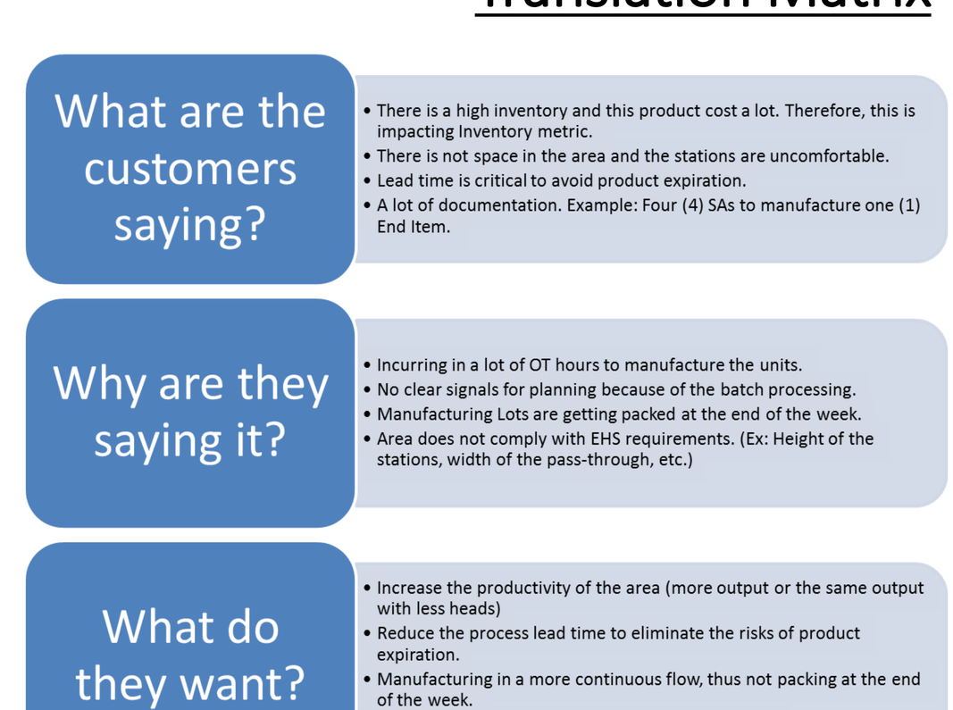
Methodology

For the purpose of this project the DMAIC Methodology was used. The specific tools used within each phase area detailed in the results and discussion section. In addition, for change management, the ADKAR methodology was used. In there, a communication strategy was established for better handling the change once implemented.

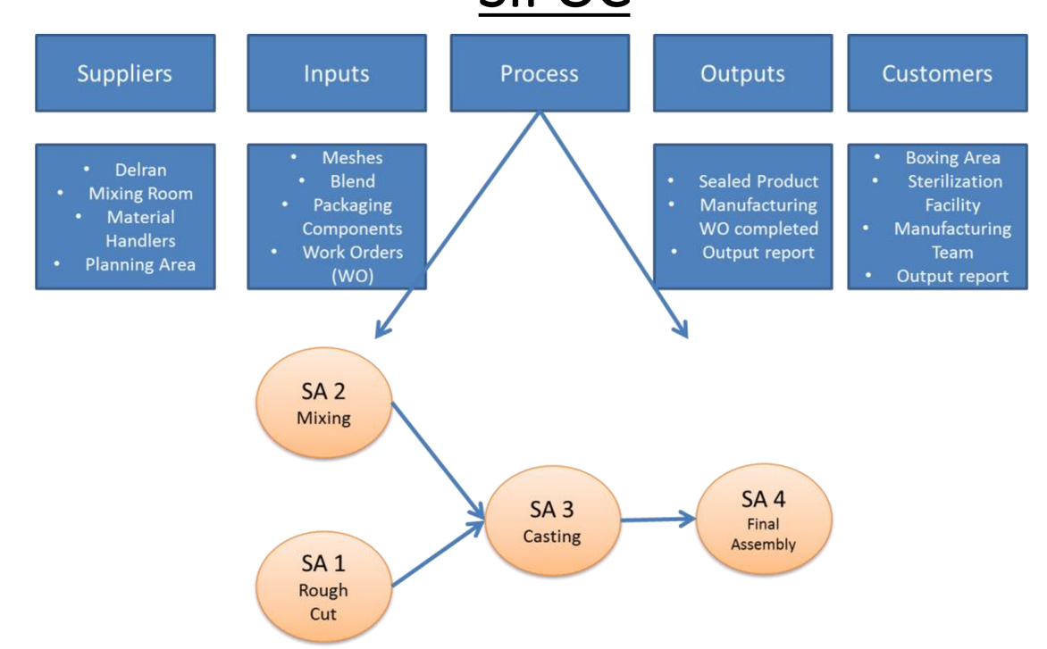
Results and Discussion

DEFINE

Voice of the Customer Translation Matrix



SIPOC

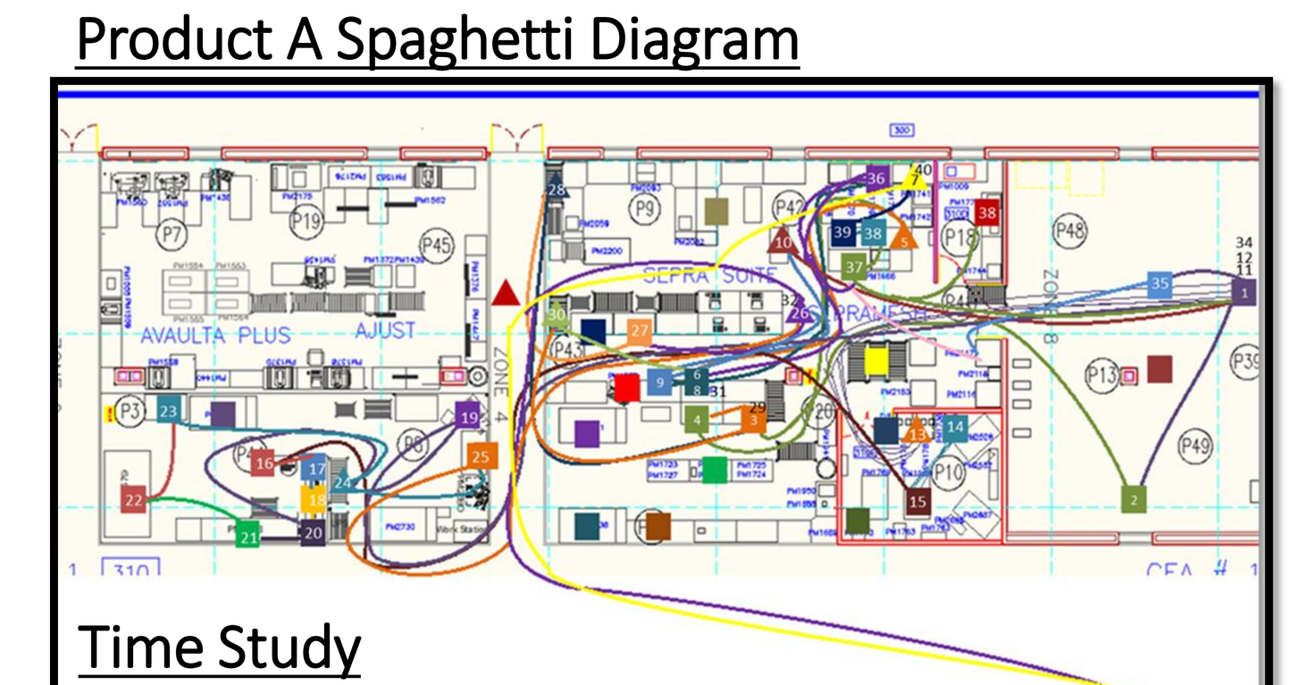


Area Pictures – Current State

MEASURE

Current State of Ventralight ST (VST) Area

Product A Spaghetti Diagram



Current Area Layout:

- Transportation Waste
- Batch Process
- Incorrect Space Utilization
- Space Constraints
- Not Ergonomic Stations

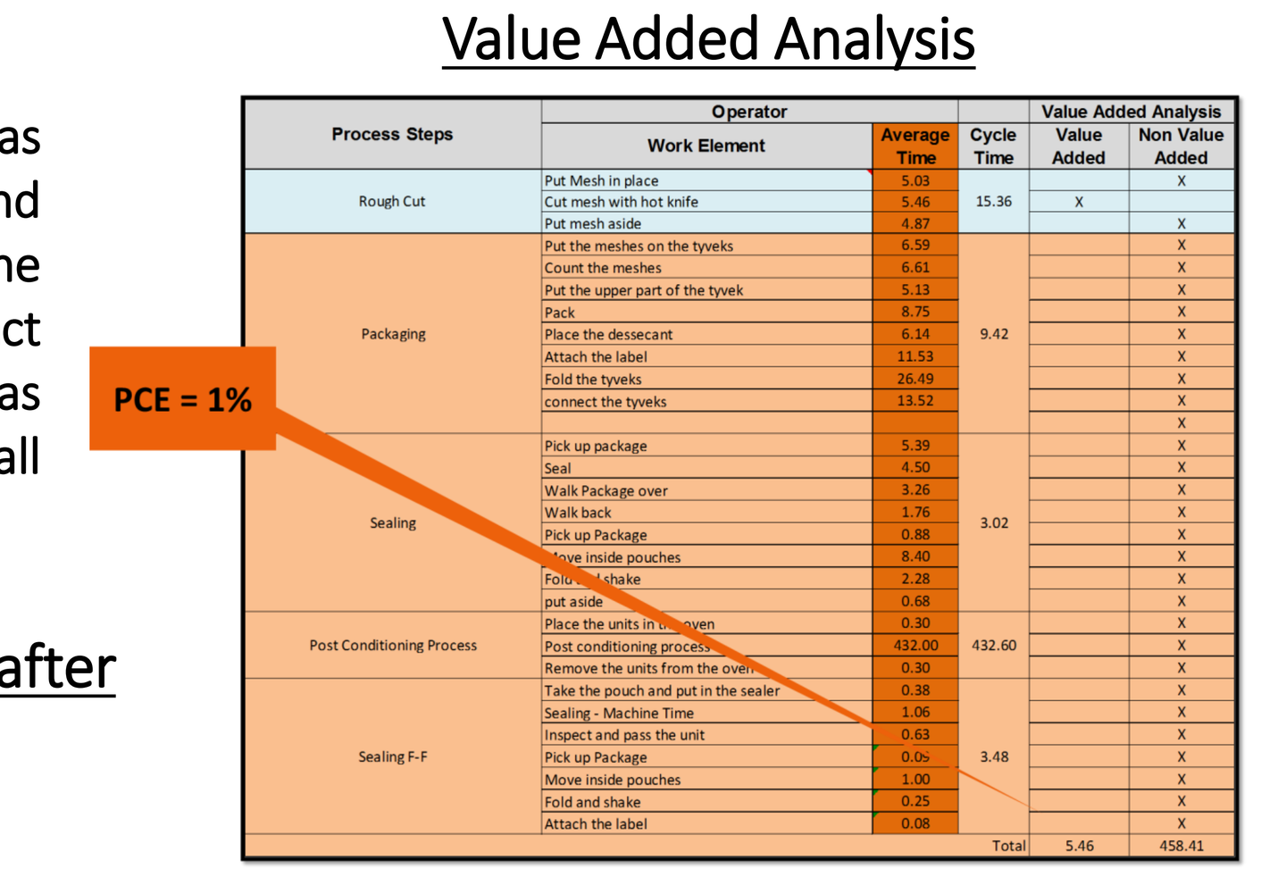
Time Study

Process Steps	Operator			
	Work Element	Average Time	Cycle Time	
Rough Cut	Put Mesh in place	5.03	15.36	
	Cut mesh with hot knife	5.46		
	Put mesh aside	4.87		

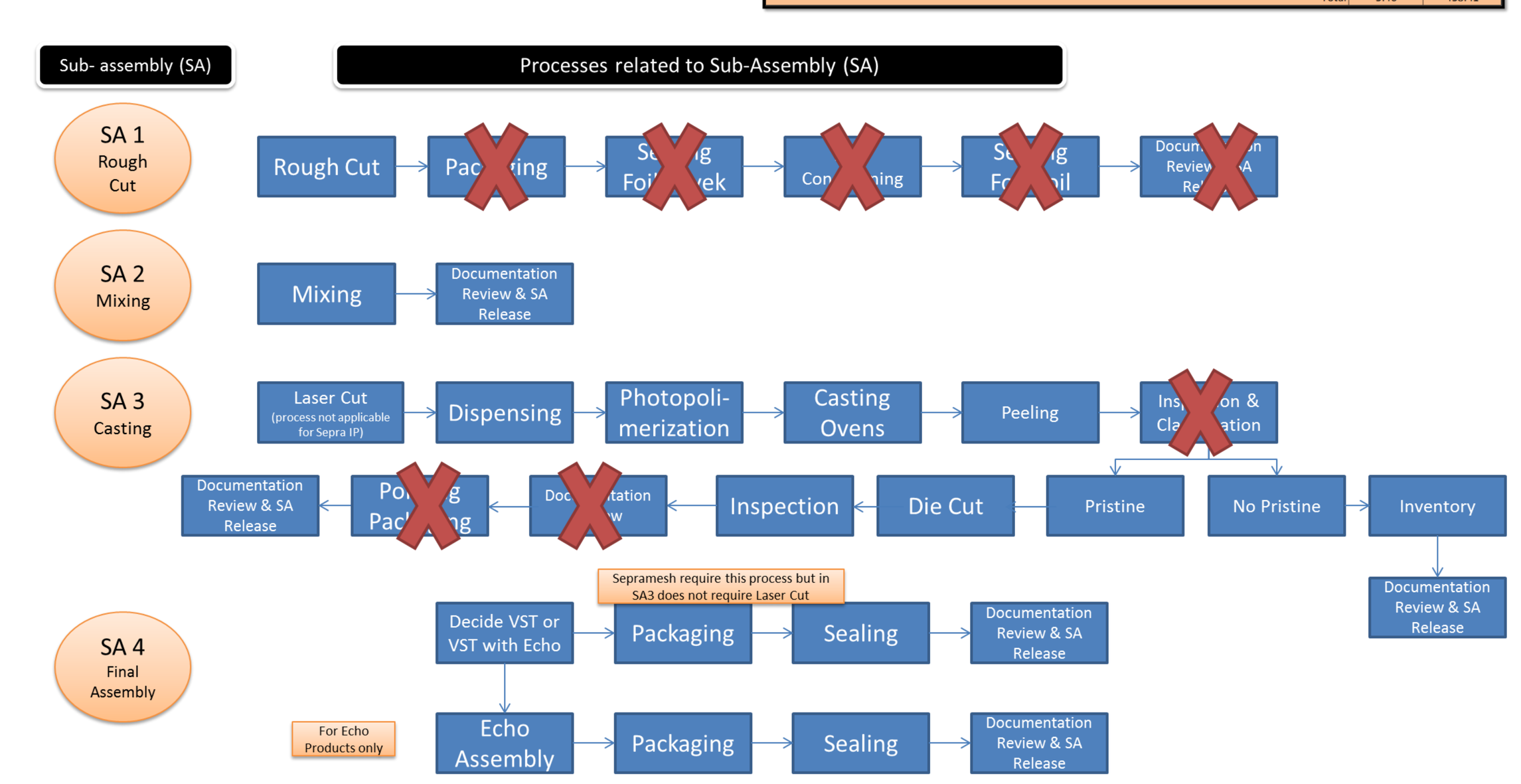
ANALYZE

Value Added Analysis

Value added analysis was performed for every product and process, determining the opportunities having higher impact for the future state. This was completed using Cycle Time of all the processes.

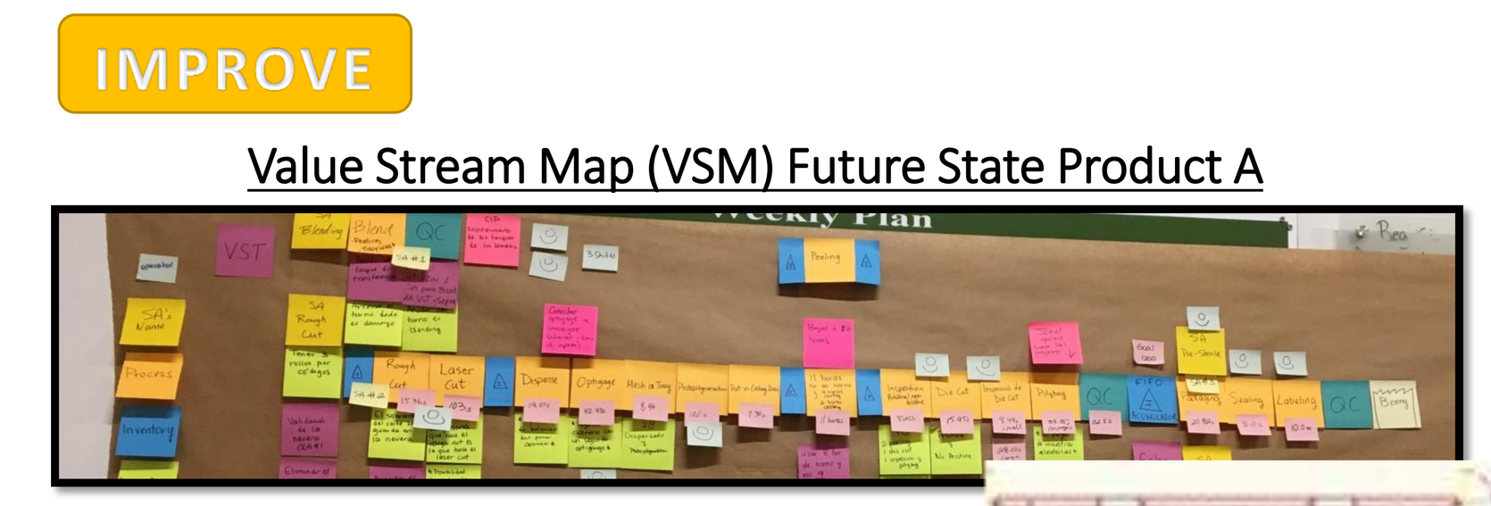


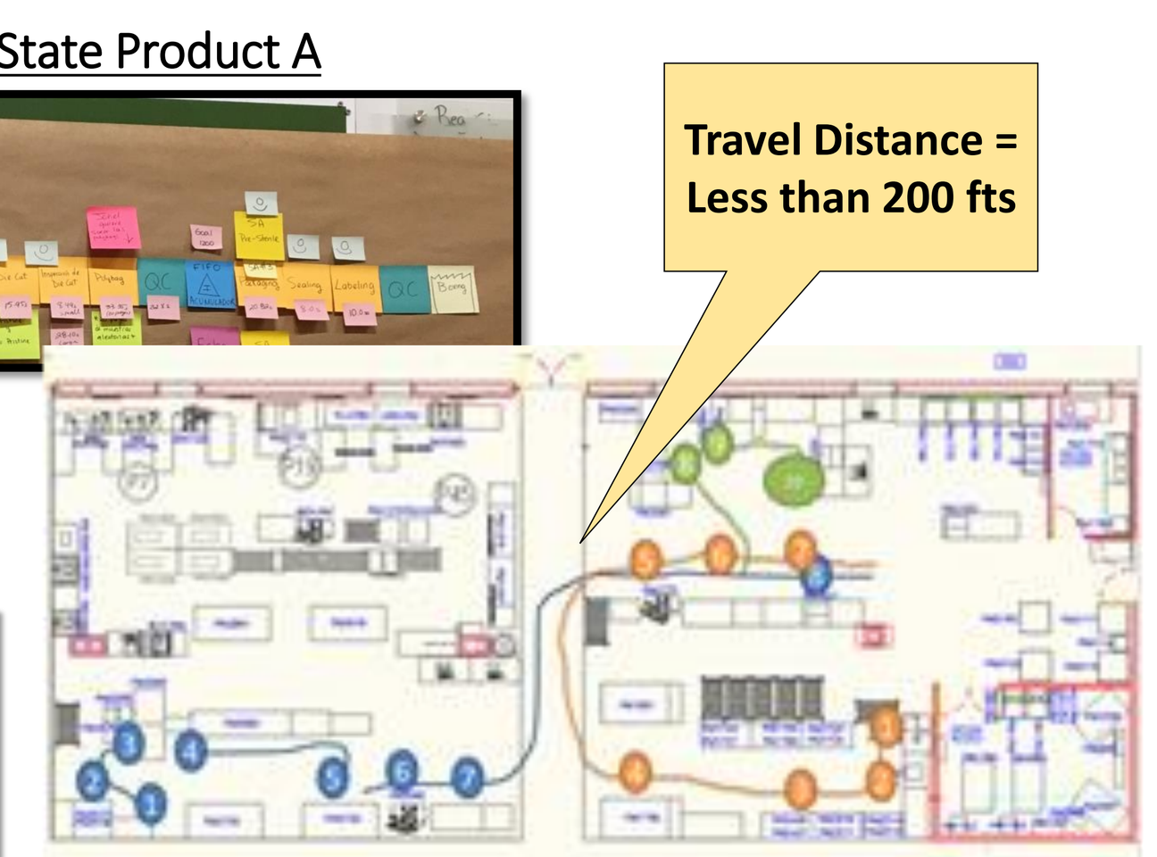
Overall Process Map Impact after Value Added Analysis



IMPROVE

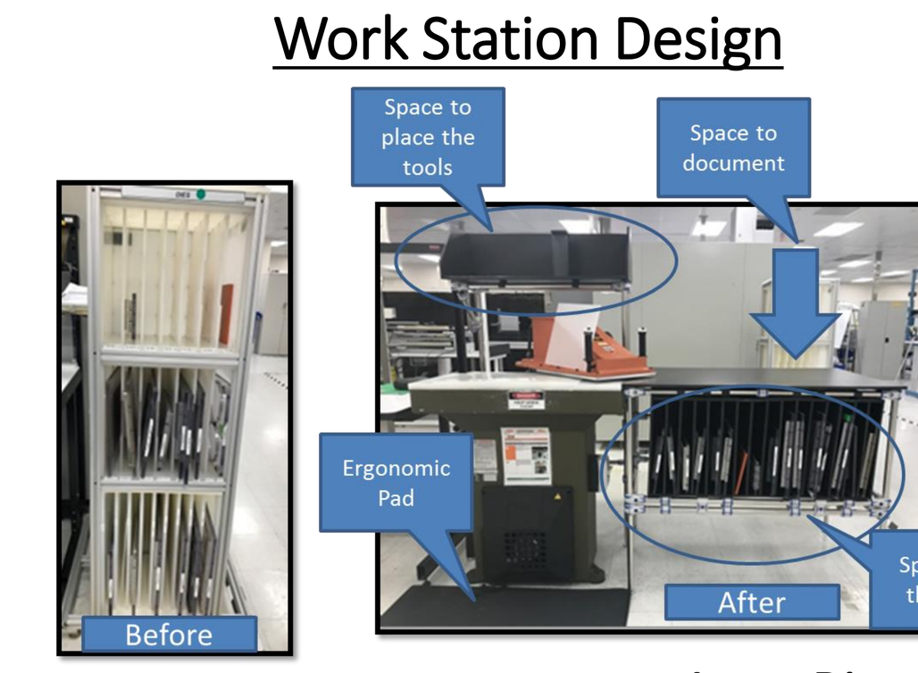
Value Stream Map (VSM) Future State Product A





Spaghetti Diagram

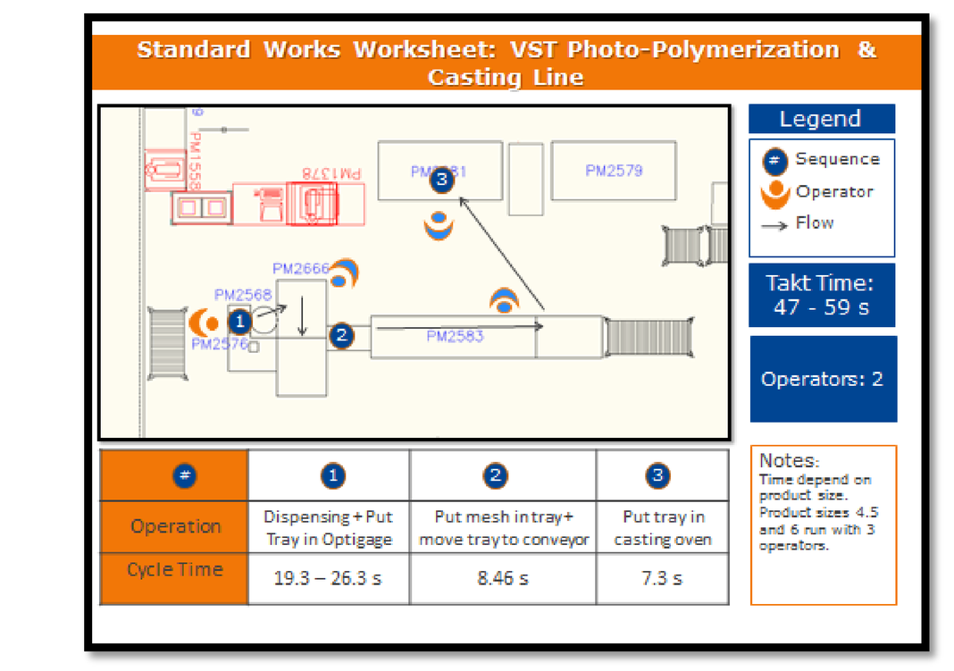
Work Station Design



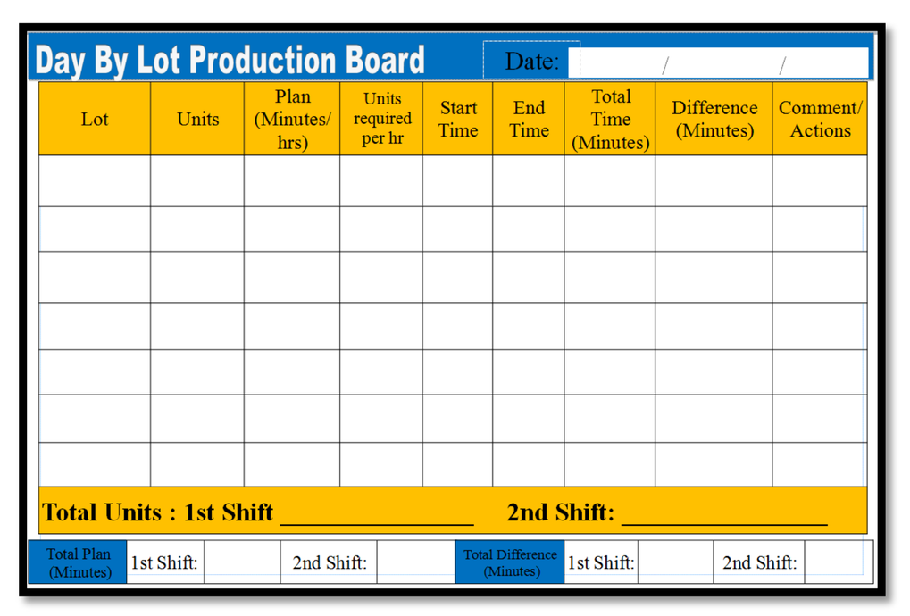
Area Pictures – Future State

CONTROL

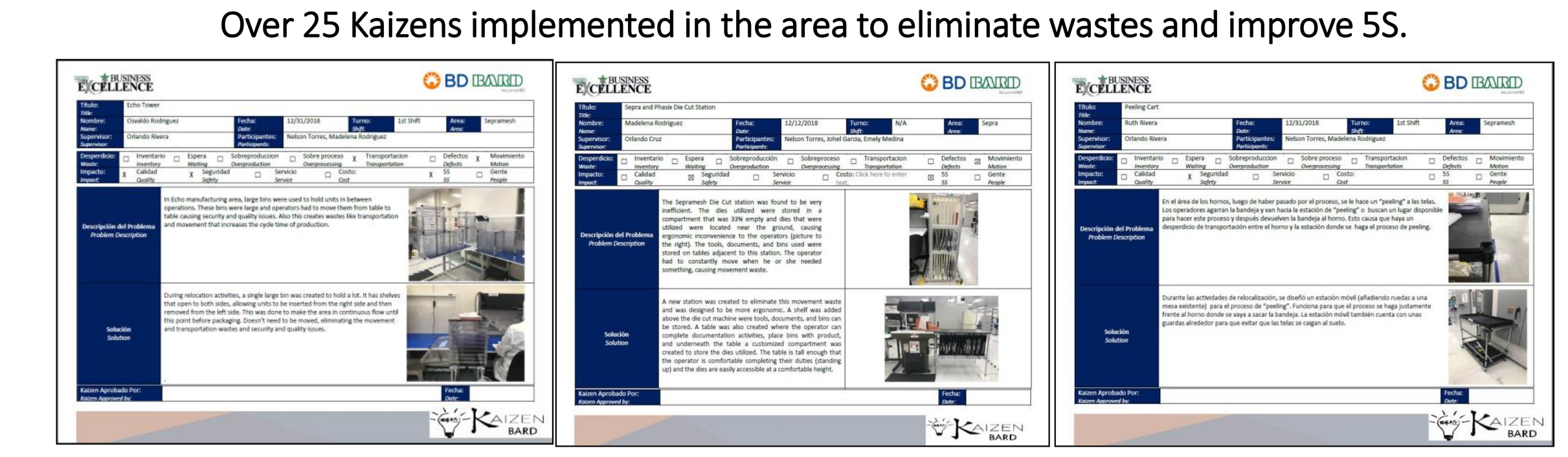
Standard Works by Product per Cells



Day by Lot Board to monitor Hour / daily production



Over 25 Kaizens implemented in the area to eliminate wastes and improve 5S.



Conclusions

This project used the DMAIC methodology for its development. Using the applicable lean tools, the current state of the area was captured and understood. Then, using tools such as value added analysis; the different process wastes were identified. Using this information, a future state was developed eliminating and reducing non value added activities and implementing a more continuous flow. In addition, a new layout, together with new workstations, was implemented in the manufacturing area. In order to sustain the changes, standard works were implemented together with day by hour boards. These tools are in constant monitoring to ensure sustainable results.

The following table details the summary of the project results.

Metric	Before	After	% change
Units per day	520	650	25%
Productivity (units/operator)	15	25	67%
Lead Time (days)	34	10	71%
Transportation (ft)	1050	200	80%
PCE	1%	36%	35%
Savings	More than $200k		

Future Work

As potential future research alternatives, it should be considered the studying of the photo-polymerization and casting ovens cycle times. The photo-polymerization process solidified the units in the trays for then passes to the casting ovens. The time for this process to be completed ranged from 2 minutes to 6 minutes per units. This lead to waiting times because of the machine cycle time. In addition, the casting process requires that the product stays nine (9) hours in the oven. A DOE should be performed to better understand this process and look for alternatives to reduce the times.

Acknowledgements

To my family; for all the support and considerations through the completion of my master degree. To my company; for being a firm believer of people development and for facilitating me the completion of this goal.

References

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2. PROSCI. (n.d.). *prosci*. Retrieved from What is the ADKAR Model? : https://www.prosci.com/adkar/adkar-model