# *Medical Device Manufacturing Area Waste Elimination and Efficiency Improvements Project*

*Emely Y. Medina Chaparro*
*Master in Manufacturing Competitiveness*
*José A. Morales, Ph.D.*
*Department of Industrial Engineering and Systems*
*Polytechnic University of Puerto Rico*

***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. Throughout 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 a 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 to having a positive impact in the performance metrics of the device manufacturing area.*

***Key Terms*** *— DMAIC, Efficiency, Medical Device, Waste Elimination.*

## PROBLEM STATEMENT

Medical Device Company X is a 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. Currently, they are working ten (10) hours shifts from Monday to Saturday. This is equivalent to 50 hrs. per employee per week. 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.

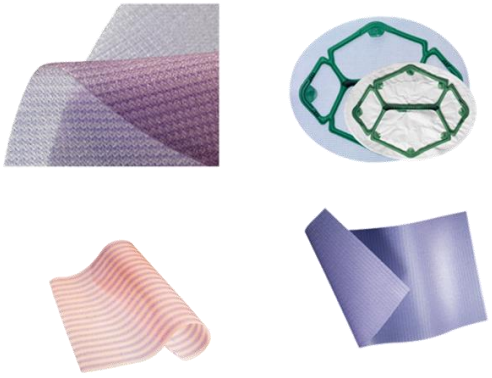

**Figure 1**
**Area Products [1] - [4]**

Based on the above opportunities, this project will focus on eliminating process wastes and increase the productivity and efficiency of the manufacturing area. This is important since all these wastes are impacting different business metrics in the areas of Safety, Quality, Delivery, Cost and even personnel engagement. Therefore,

this project aims to evaluate the above opportunities with the intention of improving them.

## Project Description

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

## Project Objectives

As part of this project, the following objectives will be pursued in the selected manufacturing area at a Medical Device Facility.

- Understand the current manufacturing process of the area.
- Identify and Evaluate process wastes and work to eliminate or reduce them.
- Create a process continuous flow thus reducing changeover/waiting times and WIP/Inventory.
- 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
- Increase Labor Efficiency and Productivity by at least 20%.

## Project Contributions

This project presents a strategy to perform waste elimination and efficiency improvements in a regulated industry such as the medical device one. It presents the use of the DMAIC methodology with examples of the different Lean tools that can be applied through each of the phases. In addition, it adds tools such as ADKAR to better handle and manage the change within the areas and employees impacted.

## 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**
**Area Manufacturing Cells**

| 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 Item**

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

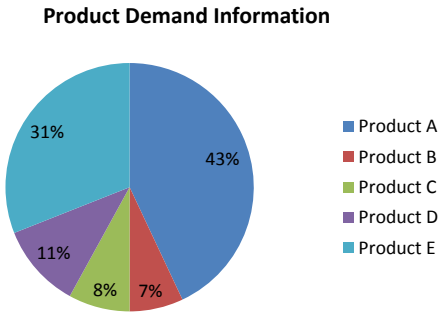


**Figure 2**
**Products Demand Information**

This area has assigned 34 employees distributed in two (2) shifts. Currently, they manufacture 530 units per day, which could be translated to 15 units per employee. For the purpose

of this project, we are going to focus on Product A, Product B, and Product E.

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).

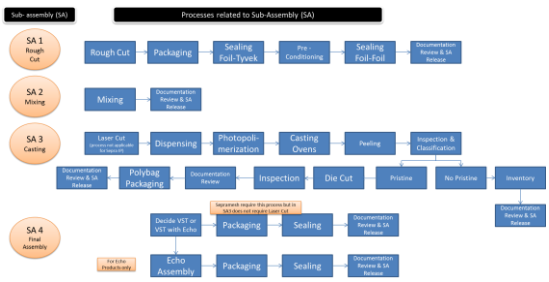


**Figure 3**
**Process Mapping – SA Structure**

As it can be observed from the above diagram (Figure 3), each SA has a documentation review and SA release step. This does not allow a process continuous flow and result in inventory. In addition, the manufacturing area and the product have to wait until this documentation review is completed and then proceed to the next step.

The rough cut sub assembly (SA1) requires a rough cut process with a hot knife; then, the units are packaged in a pouch in groups of nine (9) together with tyveks to avoid marks on the product, and desiccants to avoid humidity. After this, the units are sealed foil to tyvek as preparation for the pre-conditioning process. In the pre-conditioning process, the units are placed in an oven for 24 hrs and then removed to be sealed foil to foil. While this process is taking place, the Mixing Room is preparing the blend to be used in the casting process.

The units previously sealed foil to foil are removed from the pouches and cut in a laser machine for Products A and E or go directly to dispensing for Product B. The dispensing process consists on supplying a specific amount of blend (depending on the product code) to a tray, putting the mesh previously cut in the tray with the blend and passing that tray through the photo-polymerization lights for solidification. Then, these units are placed in the casting ovens for around nine (9) hrs to remove humidity. Once this process is completed, the units are peeled off the trays and inspected for pristine or no pristine classification. Pristine means that the units are free of defects. No Pristine means that the unit has a cosmetic defect in a specific area of the mesh, but it can be reused in a smaller product code size. All these no pristine units go to an inventory area until enough units are grouped and later on manufacture them as a specific lot following the same process as Pristine. Once the units are classified, they are cut using the applicable die in terms of size and shape, and then they are inspected to make sure they comply with the specification. Once the inspection is completed, a quality representative completes the documentation review and the units wait until this process is completed. After this review, the units are packaged in groups of 20 using polybags. These polybags are identified with a manual documented label that also is included in the bin were the units are placed once packaged. After this, the documentation is reviewed again and the units are placed in an inventory area. This step closes the SA3.

For the SA4 to start, the manufacturing leader goes to the inventory area and decides whether to pull the units for Product A, B or E. Product A and B go to the same process, the units are placed in a pouch and sealed foil to tyvek, then the pouch is inspected and the units are labeled with the product information for sterilization purposes. If the manufacturing leader decides to produce Product E, then the product goes to the Echo Assembly process, where a balloon is attached to the units and then it goes through the same process as Product A and B.

For the purpose of this project, we will focus on the abovementioned SAs. However, once the product is sterilized, the units go back to the company for post-conditioning process, final packaging, and release.

This project will use Lean tools to understand the current state of the area, evaluate improvement opportunities, and develop a future state eliminating or reducing the wastes identified.

## METHODOLOGY

In order to develop this project, the DMAIC methodology was used. DMAIC stands for Define, Measure, Analyze, Improve and Control. It is a "data-driven quality strategy used to improve processes" [5]. During the define phase, a project charter was developed and agreed with all the team members and stakeholders. In it, the problem statement and objectives of the project were defined as well and the expected project timeline and benefits. Refer to Figure 4 for project timeline information.

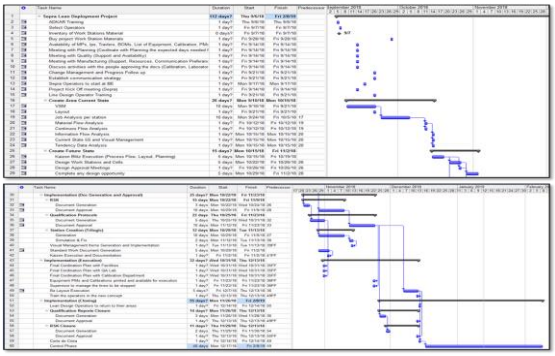

**Figure 4**
**Project Timeline**

In addition to project charter, Voice of the Customer (VOC) and SIPOC tools were employed. The purpose of the VOC was to better understand area needs and customer expectations. For this exercise, manufacturing operators, manufacturing leaders and different stakeholders were interviewed. The SIPOC was employed with the intention of having knowledge of the process in scope, as well as the inputs, outputs, suppliers and customers. The most important thing regarding this phase was the development of a communication strategy using the ADKAR change management tool. ADKAR "is a goal-oriented change management model that guides individual and organizational change" [6]. Applying this model, the communication strategy was developed to keep informed all the stakeholders and impacted areas, and make them part of the project, thus promoting collaboration and people engagement. In addition, an operator from this manufacturing area was selected and trained with all the needed DMAIC tools and Lean concepts so he can understand the project and the different phases of it, as well as support on sharing all the information being developed with his peers.

As part of the measure phase, tools such as Value Stream Mapping (VSM), time studies, spaghetti diagram, among others, were employed to understand the current state of the area. The time studies were evaluated and divided into elements to perform then the value added analysis. Also, during this phase, the traveled distance to manufacture a product was calculated using the spaghetti diagrams. In addition, an ergonomic evaluation was conducted with the Environmental, Health and Safety (EHS) department thus having their inputs and recommendations for the new workstation and layout design.

During the analyze phase, line balance analysis, value added analysis, prioritization matrix, among other tools were used to identify and select the opportunities to be pursued as part of the improvement phase. Through the improvement phase, a VSM with the selected opportunities was developed aiming to reduce process waste and increase area efficiency. Based on that VSM, a detailed plan was put together for the project implementation. It included the applicable changes in procedures and the documentation required to perform the layout activities.

Once the project was implemented, tools such as standard works, day by hour, and 5S audits were employed as part of the control phase. This phase will require continuous monitoring to confirm sustainable changes.

## RESULTS AND DISCUSSION

For this project the DMAIC methodology was used. In order to better understand the customer needs and expectations, a VOC was applied. The results were summarized in the following VOC Translation Matrix (Figure 5).

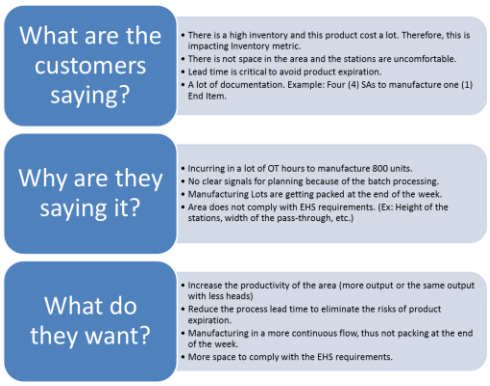


**Figure 5**
**VOC Translation Matrix**

Based on this information, the project charter was put together and approved by the design and steering teams. In order to understand the inputs, outputs and the process in scope, a SIPOC tool (Figure 6) was developed. At this step, it was decided to treat the Mixing Area as a supplier for Product A, Product B, and Product E processes, due to the enormous scope that it was going to add to the project.

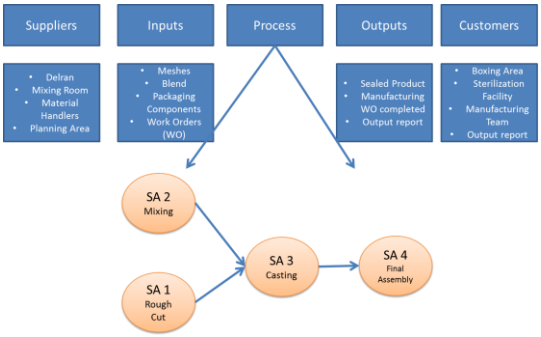


**Figure 6**
**SIPOC Diagram**
**(Refer to Figure 3 for details on SA components.)**

During the measure phase, a VSM of the area current state was developed (Figure 7). From there, the different process steps, inventory information, cycle times per operation, and manufacturing procedures impacted were gathered.

By performing this exercise, it was found that there were 21 lots in the Inventory area representing 12,160 units. This could be equivalent to around $878K waiting in the area. In addition, it was found that the product lead time for Product B was around 17 days, while for Product A and E was around 34 days.

**Figure 7**
**VSM Current State**

A spaghetti diagram was used to understand the traveled distance of these products. Figure 8 and 9 show the spaghetti diagrams of the products in scope. As observed, there was a lot of transportation and motion wastes associated to the manufacturing of one (1) lot. The traveled distance for the products in scope ranged from 973 ft. to 1054 ft.

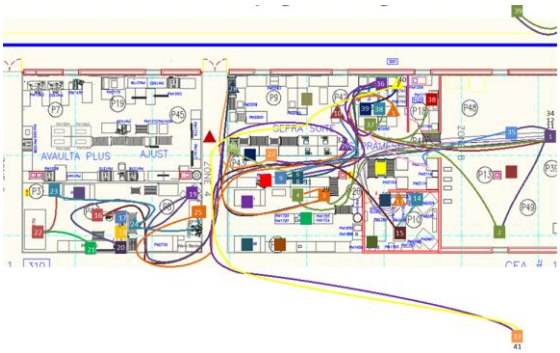


**Figure 8**
**Product A Spaghetti Diagram**

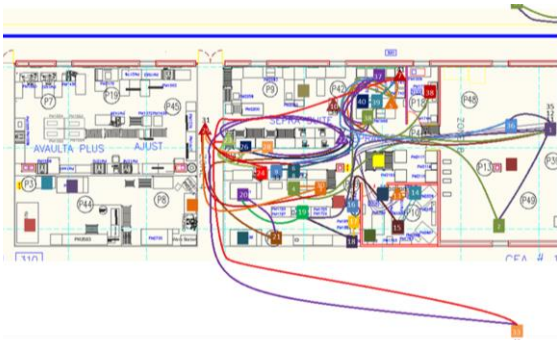


**Figure 9**
**Product B Spaghetti Diagram**

In addition to spaghetti diagrams, time studies were conducted. From there, the time of the different elements, as well as the cycle time of the applicable processes was established. Table 3 detailed an example of a time study performed to one of the processes included in SA1. Using the

same strategy from Table 3, all the times for all the processes involved in scope were determined. Table 4 shows an example of the times associated to SA1.

**Table 3**
**Example of a Time Study Exercise**

| Process Steps | Operator | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Work Element | Observed Times | | | | | | | | Cycle Time | Total Time |
| Rough Cut | Put Mesh in place | 4.16 | 4.30 | 4.29 | 4.56 | 5.36 | 6.10 | 5.03 | 5.36 | 4.88 | 5.03 |
| | Cut mesh with hot knife | 5.09 | 5.76 | 4.95 | 5.32 | 5.48 | 5.91 | 5.21 | 5.51 | 5.70 | 5.46 |
| | Put mesh aside | 4.80 | 4.82 | 4.22 | 4.98 | 5.42 | 5.36 | 4.64 | 5.26 | 4.96 | 4.87 |

Table 4 also shows the Value added analysis of the SA1. After investigating the current process and performing engineering tests, it was determined that the pre-conditioning process was not required because the manufacturing of this product is conducted in a controlled room complying with the requirements of the material. Because of that, the packaging, sealing (Foil to Tyvek), pre-conditioning process and sealing foil to foil process do not add value to the product. The value added time associated to SA1 was 5.46s/unit while the non-value added time was 458.41s/unit. This resulted in a Process Cycle Efficiency (PCE) of 1%. The same analysis was performed for all the processes in scope and by doing a prioritization matrix, the opportunities having higher benefits with the lower efforts were pursued as part of the improve phase.

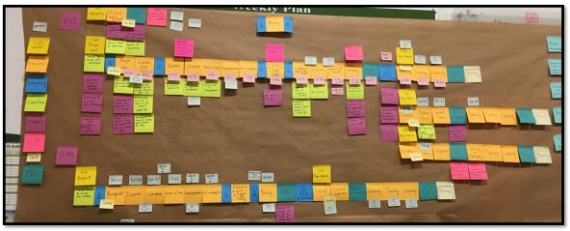

**Figure 10**
**VSM Future State**

As mentioned in Table 5 ahead, the overall layout and workstations were improved.

As observed, more continuous and straight flow was implemented as part of this layout. When compared with Figure 8 and 9, it can be concluded that the area now has enough space for the manufacturing process and it complies with the EHS requirements. The overall traveled distance for all the products in scope is now less than 200fts, thus having an improvement of 80%. In order to perform this re-layout activity, a risk assessment was generated and approved by all the impacted areas. Then, installation qualification activities for relocation purposes were conducted for all the impacted equipment, including calibration, preventive maintenance, utilities verification, and functional testing activities. Since it is a controlled manufacturing area, environmental monitoring was performed in order to release the area for manufacturing purposes.

**Table 4**
**Value Added Analysis for SA1**

| Process Steps | Operator | | | Value Added Analysis | |
|---|---|---|---|---|---|
| | Work Element | Cycle Time | Total Time | Value Added | Non Value Added |
| Rough Cut | Put Mesh in place | 5.03 | | | X |
| | Cut mesh with hot knife | 5.46 | 15.36 | X | |
| | Put mesh aside | 4.87 | | | X |
| Packaging | Put the meshes on the tyveks | 6.59 | | | X |
| | Count the meshes | 6.61 | | | X |
| | Put the upper part of the tyvek | 5.13 | | | X |
| | Pack | 8.75 | | | X |
| | Place the dessecant | 6.14 | 9.42 | | X |
| | Attach the label | 11.53 | | | X |
| | Fold the tyveks | 26.49 | | | X |
| | connect the tyveks | 13.52 | | | X |
| | | | | | X |
| Sealing | Pick up package | 5.39 | | | X |
| | Seal | 4.50 | | | X |
| | Walk Package over | 3.26 | | | X |
| | Walk back | 1.76 | 3.02 | | X |
| | Pick up Package | 0.88 | | | X |
| | Move inside pouches | 8.40 | | | X |
| | Fold and shake | 2.28 | | | X |
| | put aside | 0.68 | | | X |
| Post Conditioning Process | Place the units in the oven | 0.30 | | | X |
| | Post conditioning process | 432.00 | 432.60 | | X |
| | Remove the units from the oven | 0.30 | | | X |
| Sealing F-F | Take the pouch and put in the sealer | 0.38 | | | X |
| | Sealing - Machine Time | 1.06 | | | X |
| | Inspect and pass the unit | 0.63 | | | X |
| | Pick up Package | 0.09 | 3.48 | | X |
| | Move inside pouches | 1.00 | | | X |
| | Fold and shake | 0.25 | | | X |
| | Attach the label | 0.08 | | | X |
| | | | Total | 5.46 | 458.41 |
| | Total Time | | 463.87 | PCE | 1% |

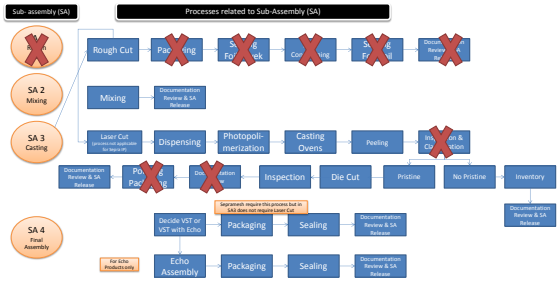


**Figure 11**
**Process Map – Processes Eliminated**

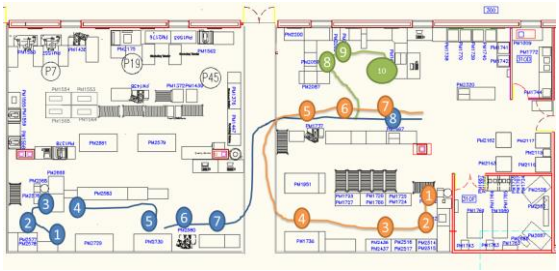

**Figure 12**
**Implemented New Layout**

**Table 5**
**Opportunities Pursued during the Improve Phase**

| SA # | Opportunities / Wastes |
|---|---|
| SA1 | • Elimination of the Pre-Conditioning Process. This eliminated the packing, sealing foil to tyvek, pre-conditioning, and sealing foil to foil of this SA.<br>• Since this SA was going to include only the rough cut process, in order to reduce and eliminate documentation, it was decided to include this process in the SA3 (Casting). By doing this, the process can now be connected. This means that the rough cut can be performed in a one piece flow followed by the laser cut or dispensing process. This eliminated a documentation review step (waiting waste) and also the inventory at this stage. As a consequence, this improvement impacted the lead time of the product.<br>• Before the change, there were employees dedicated to Rough Cut and other employees dedicated to Laser Cut and dispensing. The lead time associated with the machine time of the Laser Cut and dispensing process is very long. Therefore, by putting together these SAs, the same person performing the Laser Cut and Dispensing processes can perform the Rough Cut process during the machine cycle time. |
| SA3 | • Elimination of the redundant inspection of pristine and no pristine units: By studying the elements associated to this process, it was found that there were three (3) redundant inspections of pristine and no pristine. As detailed in Figure 3 (process map), the first one took place after the peeling process, then it was observed that prior the die cut process the operator performed this inspection again because the procedure required it. After the die cut process, the inspection was performed again. Therefore, it was determined to eliminate the first two (2) inspections and keep the last one thus eliminating over processing waste.<br>• One of the advantages of eliminating the redundancy of pristine and no pristine inspection was that after investigating, it was observed that there were units classified as No pristine, but the cosmetic defect was outside the die cut area. Therefore, by eliminating the redundant inspection, the yield of this process increased. Now, all the units are cut and those having the defect in the outside cut area are considered pass. The other ones are segregated and separated as No Pristine in order to be used in smaller product sizes.<br>• The documentation review step was eliminated since it was not adding value to the process. The documentation review step was redundant. This step was repeated at the end of this SA, therefore it was eliminated.<br>• The polybag packing process was eliminated as well. This process required to pack the units in groups of 20 in a polybag and complete a manual label to be attached in the polybag. It was observed that all these polybags were then placed together in a bin with the same label information included in the bin. The units were then removed from the polybag and placed all together for further processing. Therefore, all these steps are considered over processing waste. Now, the units are inspected and then placed in a bin with the corresponding information. |
| SA4 | • Packing Cells were established with their corresponding standard works thus having clear the quantity of operators needed per cell and the time required to complete each step.<br>• This included changes in workstations and layout. |
| Overall | • Overall layout was improved having more space and complying with the EHS requirements. In addition, new workstations were implemented, making them more efficient and ergonomic. |

As an example of workstation design exercise (see Figure 13), for the die cut station, they only had a cart with the die tools and the die cutter next to it. They did not have space to document and place the tools neither ergonomic pad to perform this standing operation. The station was redesigned with space available for tools, documentation and dies. An ergonomic pad was added to minimize fatigue while performing this process.

In order to sustain the changes, the operators were trained in the standard works and these documents were placed visible in the area (see Figure 14). These standard works detail the process sequence, the quantity of operators required, the flow direction, and the time required by each operation.

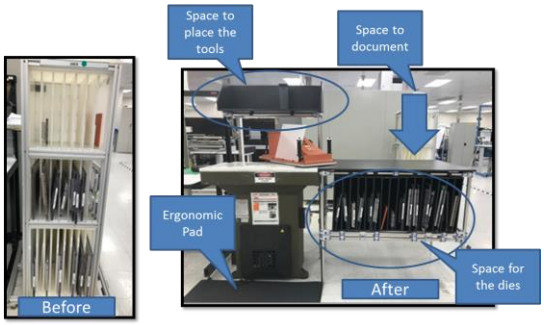


**Figure 13**
**Example of Work Station Design – Die Cutter**

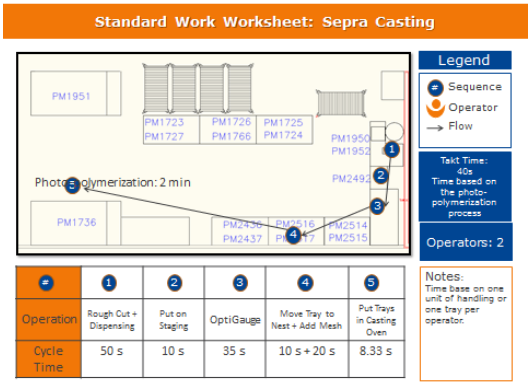


**Figure 14**
**Example of a Standard Work Implemented**

In addition, Day by hour (DBH) boards and 5S audits were established to monitor the progress and sustainability of the changes.

As a result of all the improvements mentioned above, the inventory was improved by 25%, and the lead time was reduced to ten (10) days. In addition, safety and ergonomic concerns were addressed by the new layout and workstation designs. Now, the area is producing increased output to 650 per day with eight (8) people less. This means an increase in productivity of 67%. In addition, the process cycle efficiency was calculated and resulted in a 35% increase.

## 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.

This project contributed to eliminate process wastes and increased the productivity of the area by 67%. The overall daily output increased by 25% and the process cycle efficiency by 35%. Now, this manufacturing area produces 130 units more with eight (8) resources less. In addition, this project eliminated non value added steps of the process such as pre-conditioning step, inspection steps and polybags steps, among others. By doing that, the process lead time was reduced by at least 71%. In addition, by having a more continuous flow, the inventory of the area was reduced by 25%. This continuous flow was also possible because of the implementation of the new layout which improved the traveled distance by 80%. All these improvements contributed in more than $200k in savings to the company.

As potential future research alternatives, it should be considered the studying of the photo-polymerization and casting ovens cycle times. The photo-polymerization process solidifies the units in the trays to pass them afterwards to the casting ovens. The time for this process to be completed ranges 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 design of experiment (DOE) should be performed

to better understand this process and look for alternatives to reduce the times.

## REFERENCES


[1] BD. (2018). *BD Products: Ventralight ST Mesh* [Online]. Available: https://www.crbard.com/davol/en-US/products/Ventralight-ST-Mesh. [Accessed Feb. 09, 2019].

[2] BD. (2018). *BD Products: Echo PS Positioning System with Ventralight ST Mesh or Composix L/P Mesh* [Online]. Available: https://www.crbard.com/davol/en-US/products/Echo-PS-Positioning-System-with-Ventralight-ST-Mes. [Accessed: Feb. 09, 2019].

[3] BD. (2018). *BD Products: Sepramesh IP Composite* [Online]. Available: https://www.crbard.com/davol/en-US/products/Sepramesh-IP-Composite. [Accessed: Feb. 09, 2019].

[4] BD. (2018). *BD Products: Phasix ST Mesh* [Online]. Available: https://www.crbard.com/davol/en-US/products/Phasix-ST-Mesh. [Accessed: Feb. 09, 2019].

[5] ASQ. (2019). *The Define Measure Analyze Improve Control (DMAIC) Process* [Online]. Available: https://asq.org/quality-resources/dmaic. [Accessed: Feb. 09, 2019].

[6] PROSCI. (n. d.). *What is the ADKAR Model?* [Online]. Available: https://www.prosci.com/adkar/adkar-model. [Accessed: Feb. 09, 2019].