MANUAL PROCESS TO SEMI AUTOMATIC PROCESS FOR ELECTRICAL DISCHARGE OF STERILE PACK TRAY

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Abstract

During fiscal year 2018, sterile pack manufacturing business identified a manual ionization process with its manufacturing line, that was affecting output and yield. This resulted in a problem-solving session to identified different variables affecting process output and yield. Problem solving team used to address these situations and was composed of quality engineers, operator, manufacturing engineers and supervisors. DMAIC methodology was used to structure problem solving scope. Data output and scrap was gathered from October to November to see process impact. This project will be focus on improving manual process, resulting in an improvement of output and yield.

Project Description

According to manufacturing line production process, electrical discharge process should take 15 seconds or less. The primary focus of this research will be converting the manual process to a semi-automatic process where the operator can perform other tasks during tray electrical discharge. A dust collector will be implemented to collect all particles and foreign materials removed from tray will ionization process is performed.

Objectives

- Change in process from manual to semi-automatic
- Improve production output
- Improve yield
- Reduce scrap

Methodology

Manufacturing production line process involves the utilization of an ionizing air gun, where the sterile pack tray is exposed to ionized air for a least 15 seconds. This process is completely manual and takes too much time. The operator performs this task in batches, with sizes of approximately 20 to 30 trays discharging in the process. Once trays are discharged, the air stack up. The main objective of this research is to change the process from a manual one to a semi-automatic process, were the operator can perform additional tasks during sterile pack tray discharge process. Another important objective is to convert process from a batch to a one-piece flow. The reason for this is that during the tray stack up, tray charges with surrounding static. Discharging tray by tray will help rapid consumption until packaging is perform. For this specific scenario, DMAIC methodology is the best option. Brainstorming session are imperative. Time and exposure ionized air are two of the most important input that can be used on equipment characterization. A static meter is the tool to be used to measure successful discharge of each tray before and after using equipment designed for this purpose, so that is highly necessary to proof concept.

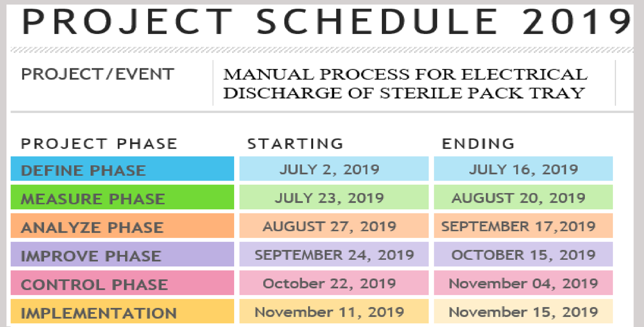
Results and Discussion

Define Phase

During this initial phase, he had several key issues identified that would help project execution. For project development, the following steps are a must:

- Workflow
- Manual Process
- Takt time
- Handling

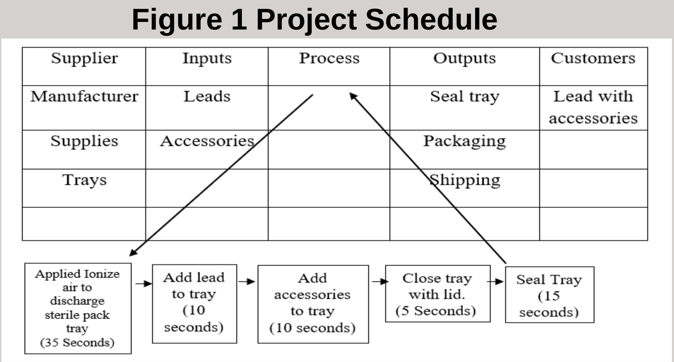
Project Scope - Manual process does not satisfy business need manufacturing line output. Process needs to be changed or upgraded. Process output scrap reduction by 15 % and process output increase by 15 % per business needs. Process need to be change to a one-piece flow.



PROJECT SCHEDULE 2019

PROJECT/EVENT	MANUAL PROCESS FOR ELECTRICAL DISCHARGE OF STERILE PACK TRAY	
PROJECT PHASE	STARTING	ENDING
DEFINE PHASE	JULY 2, 2019	JULY 16, 2019
MEASURE PHASE	JULY 23, 2019	AUGUST 20, 2019
ANALYZE PHASE	AUGUST 27, 2019	SEPTEMBER 17,2019
IMPROVE PHASE	SEPTEMBER 24, 2019	OCTOBER 15, 2019
CONTROL PHASE	October 22, 2019	November 04, 2019
IMPLEMENTATION	November 11, 2019	November 15, 2019

Figure 1 Project Schedule



Supplier	Inputs	Process	Outputs	Customers
Manufacturer	Leads		Seal tray	Lead with accessories
Supplies	Accessories		Packaging	
Trays			Shipping	

Figure 2 SIPOC Diagram

The SIPOC chart (Figure #2) created provides an overview of the process. It helps identify all key elements such as relevant steps, inputs, outputs, and ultimately who will receive the final product. Total process time to have a finish tray is 75 seconds (1.15 minutes).

Measure Phase

The following are key for project development:

- Output
- Scrap
- Process Takt Time

Figure 3 Current Process

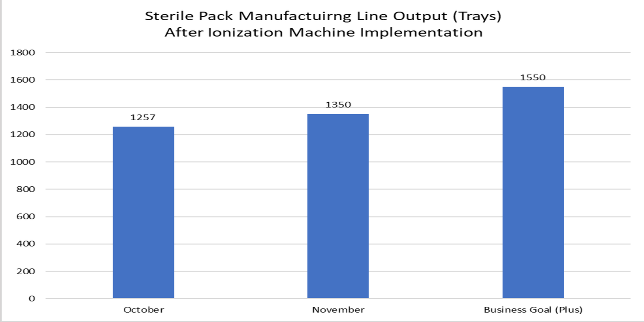


Figure 4 Process Output Graph

As shown on Figure 4, sterile pack business did not reach business goal by 253 trays, which result in a 19% of deficiency. For November, 200 trays were processed for a 13% deficiency; although shows an improvement, did not reach goals.

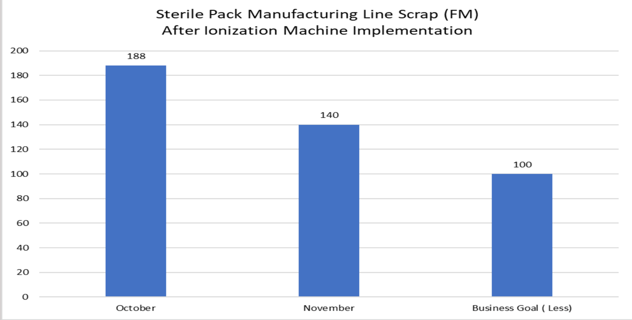


Figure 5 Process Scrap Graph

As shown Figure 5, the amount of scrap generated by manufacturing line was too high. Process takt time was measure and took about 35 seconds to complete tray discharge. For the ionize exposure per process required to be 15 seconds or less to have a successful discharge.

Analyze Phase

Analyze Phase - For the Analyze phase, a brainstorming session and a fish bone diagram (Figure 6) was performed [4], were ideas develop and process most important variable were identified.

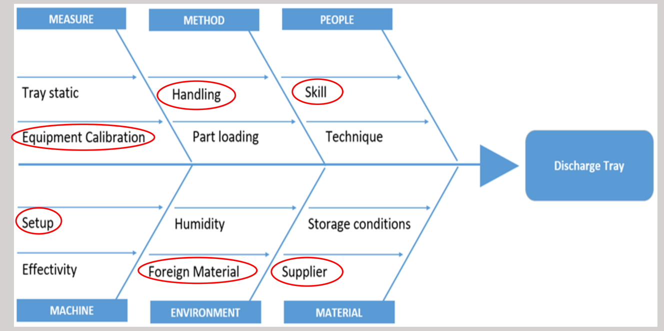


Figure 6 Fishbone Diagram

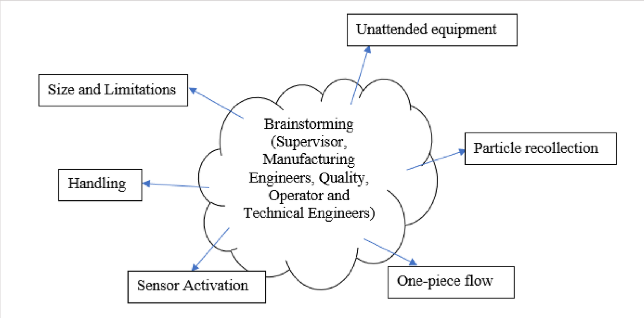


Figure 7 Brainstorming

Great ideas came from brainstorming session (Figure 7): to have a semi-automatic equipment was suggested.

Important variable identified during fish bone exercise are:

Measure

- Equipment calibration: how much exposure time process need for tray to be discharge.

Method

- Handling: trays current handling can collect foreign material.

People

- Skill: The application process steps may change.

Machine

- Setup: Correct speed and time of exposure.

Environment

- FM: Critical for process to be effective.

Material

- Supplier: Possibility of having just one supplier.

Improve Phase

Design and build a custom equipment to satisfy experiments is needed. The equipment that was developed was able to clean and discharge tray in a chamber; also, that machine will collect particles coming from trays or environment while manufacturing operator perform other tasks. Machine will control exposure time and provide an unattended solution.

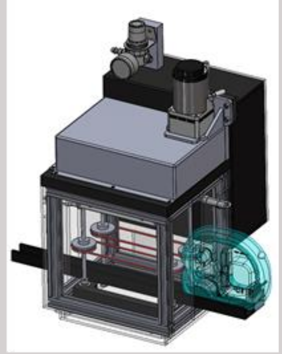
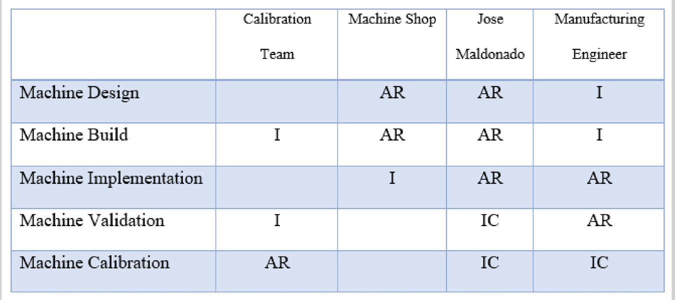


Figure 8 Ionization Machine Design

Ionization Machine Design (Figure 8) gears and servo motors for movement. A belt conveyor was included to handled tray. For the frame, structural anodized aluminum was used to comply with product biocompatibility. For floor conveyor, Delrin material was used so sterile pack tray will slide without causing friction. For chamber wall, polycarbonate plastic was used. The machine controls movement using a presence sensor to active system. For the time, a timer relay was used to control it. Two air knifes were used so the tray will have airflow uniformity through all its area. Machine bottom chamber is used for dust collecting. All machine movement and electrical panel was design and build by core team. Various design reviews were performed so the management and impacted employees by this project agreed and gave their inputs. Following these steps, a more robust project and machine complies with every person's needs.

Figure 9 Ionization Machine Build

As show in Figure 9, Ionization Machine final design was built in the manufacturing area.



	Calibration Team	Machine Shop	Jose Maldonado	Manufacturing Engineer
Machine Design		AR	AR	I
Machine Build	I	AR	AR	I
Machine Implementation		I	AR	AR
Machine Validation	I		IC	AR
Machine Calibration	AR		IC	IC

Legend: R=Responsible, A=Accountable, C=Consulted, I=Informed,
Figure 10 RACI Matrix

The responsibility assignment matrix was performed for the knowledge of teamwork necessity to achieved project goal.

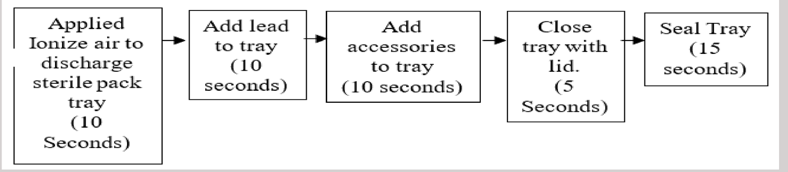


Figure 11 Improved Process Flow

Total improved process time for having a finish tray is 50 seconds which means a reduction of 25 seconds of process time (Figure 11). Machine implementation will consist on training manufacturing operator on setup of machine which is quite simple since the machine uses a presence sensor to see tray and once that happens machine work alone.

Control Phase

Electrostatic field meter (Figure 12) was implemented to measure static, before and after, machine [5]. Trays initial static was 14.2 KV after tray were exposed to ionized air for 10 seconds in machine chamber; then, the static measure was down to 0.10 KV, which was a significant improvement. A 1-hour training was implemented to trained operators on machines correct handling. Machine has a fail sensor that monitors ionization output. A monthly verification of this sensor has been implemented on a Preventive Maintenance manual.

Control Phase (cont.)

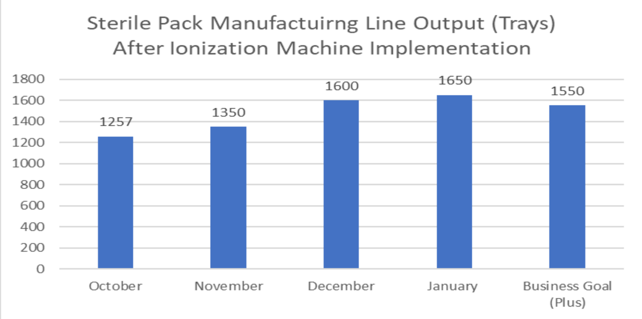


Figure 13
Process Output Graph after Machine Implementation

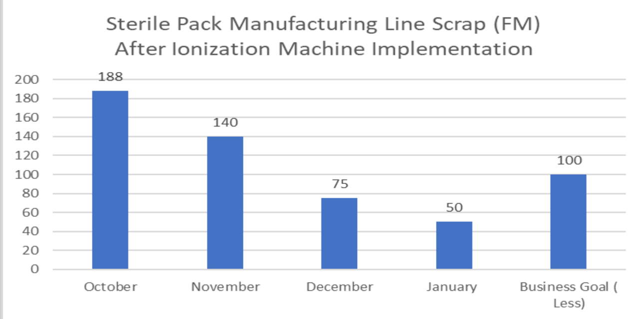


Figure 14
Process Scrap Graph after Machine Implementation

As shown on Figures 13 and 14 for December, sterile pack reached business goals by exceeding a total of 50 trays compared to the worst-case scenario of previous months, with an increase of 20%. January sterile pack business reached business goals by exceeding a total of 100 trays compared to the worst- case scenario of previous months, with an increment of 25%. For the scrap reduction, a significant drop was identified. By collecting particles scrap, reduction will continue.

Conclusion

Project purpose was achieved because there was an improvement in yield of 20%, a necessary requirement defined in the objectives to be successful. An unattended equipment was designed and built in other to satisfy manufacturing line and business needs. Process scrap due to FM and particles was controlled by adding dust collector. Process takt time was reduced to increase output and still comply with ionization requirements. Manufacturing Business is satisfied with obtained results and are evaluating other possible manufacturing areas where equipment can be used. They have identified at least six manufacturing lines where equipment can be used. Overall DMAIC process is a powerful tool that allow understanding and project guidance.

References

- D. Book, "What is an Air Ionizer?," Breath Equality, April 28, 2019. [Online]. Available: https://breathequality.com/ionizer/. [Accessed Sept 9, 2019].
- S. Seidl, F. z. Nieden and R. Gaertner, "Study of the Discharge Current created by an Ionizer," Electrical Overstress/Electrostatic Discharge Symposium (EOS/ESD), Reno, NV, 2018, pp. 1-6. Available: 10.23919/EOS/ESD/2018.8509692. [Accessed Sept 24, 2019].
- J. P. C. Tong, F. Tsung, & B. P. C. Yen, "A DMAIC approach to printed circuit board quality improvement," Int J Adv Manufacturing Technol 23, 523–531, 2004. [Online]. Available: https://doi.org/10.1007/s00170-003-1721-z. [Accessed Oct 2, 2019].
- M. Coccia, "The Fishbone Diagram to Identify, Systematize and Analyze the Sources of General-Purpose Technologies," Journal of Social and Administrative Sciences, vol. 4, no. 4, pp. 291-303, Jan 11, 2018. [Online]. Available: https://ssrn.com/abstract=3100011. [Accessed October 8, 2019].
- P. S. Riehl, K. L. Scott, R. S. Muller, R. T. Howe and J. A. Yasaitis, "Electrostatic charge and field sensors based on micromechanical resonators," Journal of Microelectromechanical Systems, vol. 12, no. 5, pp. 577-589, Oct, 2003. [Online]. Available: DOI: 10.1109/JMEMS.2003.818066. [Accessed October 27, 2019].