Increase of Manufacturing Process Output

Yeisha De Jesus Flores
Master in Manufacturing Engineering
Rafael Nieves, Pharm D
Industrial Engineering Department
Polytechnic University of Puerto Rico

Abstract *— Haemonetics Puerto Rico, a medical devices manufacturing site of blood filters, identified that approximately the 11% of the monthly plan of the manufacturing line #3 cannot be made using the available manufacturing time of the line. The objective of this project is to increase in at least 20% the manufacturing line output by identifying and eliminating the wastes in the manufacturing process of line #3. To achieve this goal, the DMAIC methodology will be used to identify the possible root causes and improve them adequately. After following DMAIC methodology and provide improvements, the line output increased in a 22%, which means that the line will only require 37 shifts per month to complete the manufacturing plan from the 40 shifts available. With this improvement, line #3 now can comply with the monthly plan.*

Key Terms *— Filter manufacturing, lean manufacturing, process output, Six Sigma*

PROBLEM STATEMENT

Currently, the manufacturing line #3 of Haemonetics Puerto Rico manufactures approximately 1,850 good filters per shift, with two shifts of 7.58 hours of manufacturing time per day. The monthly plan require a total of 82,800 good filters from this line, which mean that approximately the 11% of the plan cannot be made. This implicate that the operators need to work extra hours to comply with the monthly plan.

Research Description

Line #3 of the manufacturing plant of Haemonetics Puerto Rico is producing 11% less good blood filters than was required. According to this, the researcher tries to increase the output of the line. Currently, line #3 need to increase the filters output per shift, to comply with the monthly manufacturing plan for the line, without incurring in extra labor hours.

Research Objectives

The objectives of this research are to identify the wastes in the manufacturing process of line #3 in Haemonetics Puerto Rico. Once the wastes were identified, the next objective is developing solutions that increase the filters output per shift in at least 20%.

Research Contributions

With the completion of this project, Haemonetics Puerto Rico will comply with the manufacturing plan of line #3 without incurring in extra labor hours and extra direct costs by improving the manufacturing process flow and performance metrics. This will result in the achievement of the corporate schedule attainment metric of 98%, as a minimum per month, for the product manufactured in this line.

LITERATURE REVIEW

Haemonetics Puerto Rico is a medical devices manufacturing site located in Fajardo, Puerto Rico. Haemonetics manufacture blood filters used during blood donations and blood transfusions, with different intended uses like leukocyte reduction. The leukocyte reduction filter is an enclosed filter that is used to reduce the leukocyte content of transfusable blood and blood components. Manufacturing process of Line #3 is manual. The line is composed by nine stations where eight operators work.

In the medical devices industry, process output can be defined as the results produced by the process [1]. As mention is the tangible product, that is delivered at the end of the process [2]. The manufacturing line #3 of Haemonetics is

responsible for meeting our customers order requirements. Due to this fact, the line #3 needs to have a good effectiveness and efficiency to comply with the outputs requirements of the line without incurring in extra hours that increase the filter cost.

However, to obtain an output, a process is required. This process received inputs, like resources, raw materials, equipment, among others, that are processed to convert it into the process output. The final process output depends by the correct resources, materials, equipment, processes, and layout. If during the process, operators are using the correct elements, manufacturing line can obtain good products and the output will increase.

The selected problem-solving methodology to follow was DMAIC. This methodology was selected since is a robust tool that can be applied to many different problems. The methodology will help to identify the possible root causes and improve them adequately. The DMAIC methodology is divided into five steps: Define, Measure, Analyze, Improve and Control.

The DMAIC methodology is part of the Six Sigma approach. Six Sigma is focused on reducing the variation of the processes to improve them. The efforts of Six Sigma consist of three main areas: improving customer satisfaction, reduce cycle time, and reduce defects.

METHODOLOGY

During this research, the problem-solving methodology that will be used to increase the process output of line #3 is DMAIC, an acronym for Define, Measure, Analyze, Improve and Control. The American Society for Quality (ASQ) defines DMAIC as "a data-driven quality strategy used to improve processes" [3]. The five letters of the acronym represent the five phases used during the improvement process.

Define Phase

As per ASQ, this phase "define the problem, improvement activity, opportunity for improvement, the project goals, and customer requirements" [3]. Some of the tools that can be used are project charter, voice of the customer, value stream maps, among others.

Measure Phase

As per ASQ, this phase measures the process performance [3]. The objective of this phase is collecting data of the current process to visually represent the current state of the process using process maps, capability analysis, pareto charts, among others.

Analyze Phase

As per ASQ, this phase "analyze the process to determine root causes of variation and poor performance" [3]. The objective of this phase is to identify the root cause of the problem by the use of cause and effect diagram, value stream maps, failure mode and effects analysis (FMEA), among other tools.

Improve Phase

As per ASQ, this phase "improve the process performance by addressing and eliminating the root causes" [3]. The objective of this phase is optimizing the current state of the process to eliminate the problem based on the data analysis performed in the previous phase. Some of the tools that can be used are design of experiments (DOE), kaizen events, among others.

Control Phase

As per ASQ, this phase "control the improved process and future process performance" [3]. The objective of this phase is establishing controls and procedures to avoid recurrence of the same problem in the process. Some of the tools that can be used are quality control plans, statistical process control (SPC), 5S, mistake proofing, among others.

RESULTS AND DISCUSSION: DEFINE PHASE

The purpose of the Define phase is identify the problem and the improvement opportunity. To define the problem, essential to know why this

project is needed. Haemonetics Puerto Rico has three manufacturing lines for dual disc blood filters. Two of them are used for 2.18" filter and the other for 3.5" filter. The last one is the line #3, which manufactures about 1,850 good filters per shift. The line #3 has a monthly manufacturing plan of 82,800 good filters, which mean that the plan cannot be completed right now with the actual process. Due to this fact, Haemonetics employees are forced to work extra hours in line #3 to comply with the manufacturing plan and the schedule attainment metric of 98%. This situation affects negatively the site, since the manufacturing process is increasing their costs, and this is not paid by the client.

Project Charter

During the define phase of the project, a project charter was generated to shows the details of the project, description, the scope and working team.

Voice of the Customer (VOC)

The Voice of the Customer (VOC) helps to see the problem from the customer perspective and identify the areas of opportunity to solve the problem. For develop the VOC of the project, the planner, line supervisor, and plant controller were interviewed.

After performed the VOC, it can be concluded that the planner wants that the line complies with the schedule attainment. By the other hand, the line supervisor wants committed operators that comply with the manufacturing plan for line #3. Finally, the plant controller wants that the manufacturing plan will be completed without extra time, which increase the labor and overhead costs.

Critical to Quality (CTQ) Tree

The Critical to Quality (CTQ) Tree is used to establish metrics that solve the customer needs. A CTQ Tree was developed to determine which things are critical in the process to make it a good quality one. As per CTQ Tree development, it was evaluated six indicators: machine, material, method, measurement system, personnel, and environment. In addition, 10 CTQs are required to comply with the six drivers.

Table 1
CTQ Tree

Customer Need	Driver	CTQ/Goal
Increase the Manufacturing Line #3 Output	**Machine** • Capable and stable Process • Equipment working properly	• Yield ≥98% • Downtime >90 minutes average • Preventive Maintenance ≥99%
	Material • Available materials with good quality	• Incoming material defective rate <0.5%
	Method • Smooth process flow • Organized working stations	• Schedule Attainment ≥98%
	Measurement System • Pressure tester working properly • Indicator working properly • System calibrated	• Downtime >90 minutes average • Preventive Maintenance ≥99% • All of the equipment calibrated on or before the due date
	Personnel • Trained personnel in the applicable SOPs	• Certification Score >80%
	Environment • Adequate working conditions	• Room Temperature ~ 76 °F

SIPOC

The SIPOC helps to understand the process by identifying the suppliers, customers, inputs, and outputs from the process, with the purpose of better visualize the process and those who collaborate in it. A SIPOC was developed to know the process.

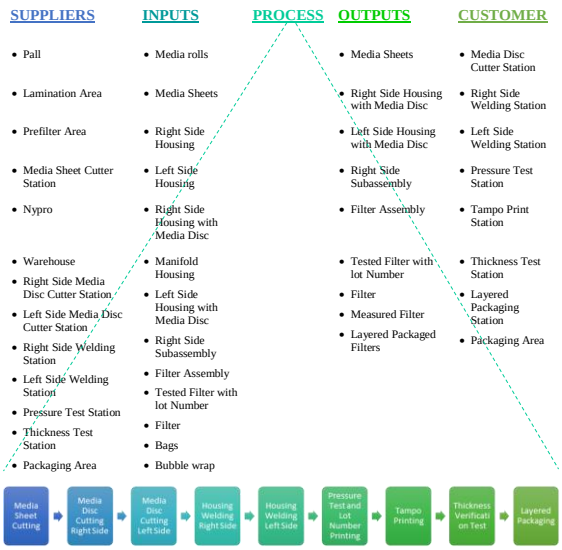

Figure 1
SIPOC Diagram

Results and Discussion: Measure Phase

The purpose of the Measure phase is identifying the current state of the process by

collecting data that support this state. It will be necessary to choose one or more characteristics to be measured, by establishing a data collection plan. This phase will be assured that the data are accurate, clear and reliable. To starts measuring the problem, it is fundamental to know what is and the current state of the process.

Process Map

Currently, line #3 has nine working stations to manufacture a dual blood filter. A process map was developed to show in details the manufacturing process of the line #3. The process map explains the operations, the decisions in the process, and when happened. The process in line #3 starts when the material is received in the line and ends when the device history record (DHR) documentation was completed and closed.

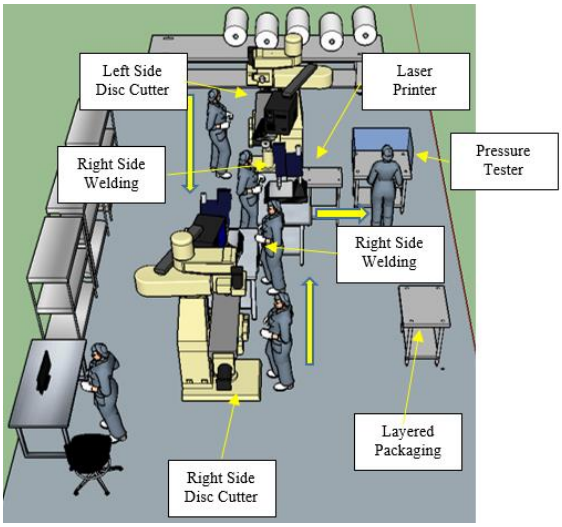

Figure 2
Proposed Process Layout

Waste Walk

Waste can be found in any process and this can be defined as any task in a process that adds no value [5]. In other words, are these steps in the process for which the customer does not pay. Wastes are classified in eight categories: defects, overproduction, transportation, waiting, inventory, motion, extra processing, and non-utilized talent. These wastes are translated into losses in time and money that negatively impacts the performance of the process. A waste walk was performed in the manufacturing process of line #3 in Haemonetics Puerto Rico to identify what wastes are present in the process and which can be eliminated. A waste walk is a visit to the process to observe what is happening to identify the wastes [6].

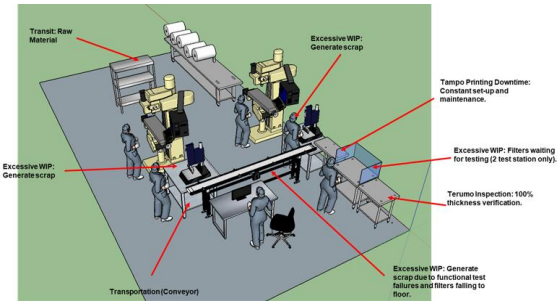

Figure 3
Current Layout with Waste Identification

Data Collection Plan

It is critical to establish what questions are needed to be answer by the data collected during the measure phase. For this purpose, a data collection plan was developed. The data collection plan is a tool to establish what questions, how, and where the data will be collected, in what frequency, among other details.

Collected Data: Time per Station

A time study was performed to know how much time take per part each station. With the data obtained in the study, it can be concluded that the bottle neck of the process is the Right Welding station with 11.68 seconds. This station is the third step of the process and mark the rhythm of the line. Every 11.68 seconds approximately one unit will be completely manufactured.

Collected Data: Packaged Filters

A report of production data from August 1, 2019 to November 27, 2019 was used to know how many filters are packaged per shift. Data of packaged filters between 1st and 2nd shifts of Haemonetics Puerto Rico were graphed in a time series plot. The time series plot shown that, for the month of August, the first shift had more variation than the second shift. However, the first shift was

able to package more filters. For both shifts, data had random variation in this month. For the month of September, the first shift had more variation than the second shift and both shifts had random variation. In October, both shifts started the month with less packaged filters and ended with more packaged filters, resulting in a cycle movement. Finally, in November, both shifts started with more filters packaged and ended with less filters packaged resulting in a cycle movement too.

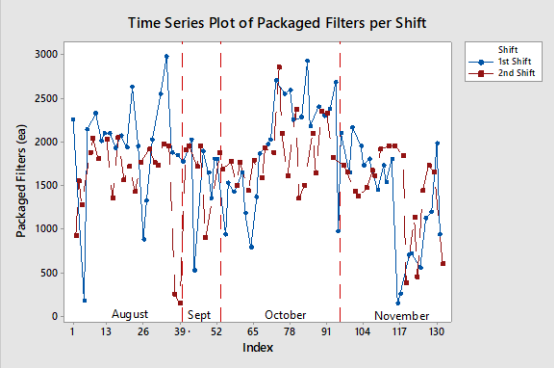

Figure 4
Times Series Plot of Packaged Filters per Shift

Data of packaged filters between 1st and 2nd shifts of Haemonetics Puerto Rico were graphed in a boxplot to compared both shifts. The graph concluded that the first shift had more variation than the second shift. Second shift is more consistent than the first shift. However, in average, the first shift can package more filters than second shift, with a difference of 106 filters approximately.

Collected Data: Scrapped Filters

A report of production data from August 1, 2019 to November 27, 2019 was used to know how many filters are scrapped per shift. Data of scrapped filters between 1st and 2nd shifts of Haemonetics Puerto Rico were graphed in a time series plot. The time series plot shown that for the month of August, the first shift scrapped more filters than second shift and data had random variation. For the month of September, random variation was observed for both shifts. In October, first shift started the month with less scrapped filters and ended with more packaged filters, resulting in a cycle movement. However, second shift shown random variation for the month of October. Finally, in November, both shifts shown random variation.

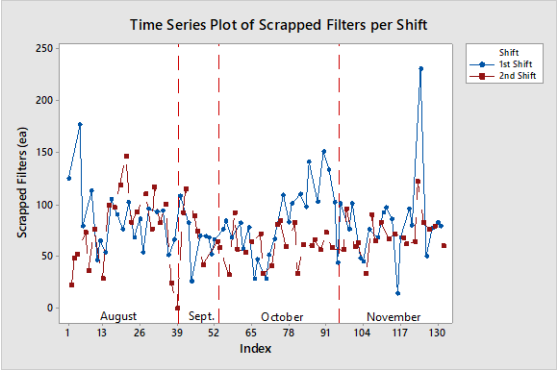

Figure 5
Times Series Plot of Scrapped Filters per Shift

Data of scrapped filters between 1st and 2nd shifts of Haemonetics Puerto Rico were graphed in a boxplot to compared both shifts. The graph concluded that the first shift had more variation than the second shift. Second shift is more consistent than the first shift. In average, the second shift scrapped 13 filters less than the first shift.

Data of scrapped filters per defect were graphed in a pareto chart. Between August 1, 2019 and November 27, 2019, the operators of line #3 scrapped 3,501 filters due to particles, followed by tampo print errors.

Collected Data: Downtimes

A report of production data from August 1, 2019 to November 27, 2019 was used to know how much downtimes are reported. In average, the month with more downtime reported was November with 110.37 minutes. By the other hand, the month with less downtime reported was September with 41.55 minutes.

Data of downtimes reported in line #3 of Haemonetics Puerto Rico were graphed in a time series plot. The time series plot shown random variation. No trend was observed.

Data of downtimes were graphed in a pareto chart to show how many times operators report downtimes categories. Between August 1, 2019 and November 27, 2019, the operators of line #3 reported 69 times the breaks category, 63 times the

other category, 48 times the start-up category, 14 times the blade replacement and lot change categories, 9 times lack of plastic component category, and 7 times the leak problems category. This means that these seven categories are the 20% of the total downtimes categories that cause the 80% of the downtimes counts reported by the operators. Nevertheless, an additional pareto was graphed with the same data to present the total downtime in minutes reported by the operators.

Data of total downtimes in minutes was graphed in a pareto chart to show how much time operators report per downtimes categories. Between the same period frame, the operators reported 11,208 minutes of breaks category, 5,265 minutes of leak problems category, 3,195 minutes of start-up category, and 3,133 minutes of others category. This means that these four categories are the 20% of the total downtimes categories that cause the 80% of the downtimes reported by the operators.

Results and Discussion: Analyze Phase

The purpose of the Analyze phase is to determine the root cause of the process variability. It will be necessary to analyze the data obtained in the measurement phase to identify the input factors of the process that affect the output.

Cause & Effect Diagram

To identify the root cause of the problem a Cause and Effect Diagram was developed. As defined by the ASQ, the Cause and Effect Diagram identifies many possible causes for an effect or problem [8]. Once established the effect of the problem, it was identified the possible root causes.

The effect used was “low filters output”, that it is the problem investigated. With this effect, it was identified the possible root causes of the effect. After analyzing the possible root causes, the investigation will focus in the causes circulated in diagram. In the Improve phase it will be provided possible improvements to the effect using the selected causes as a basis.

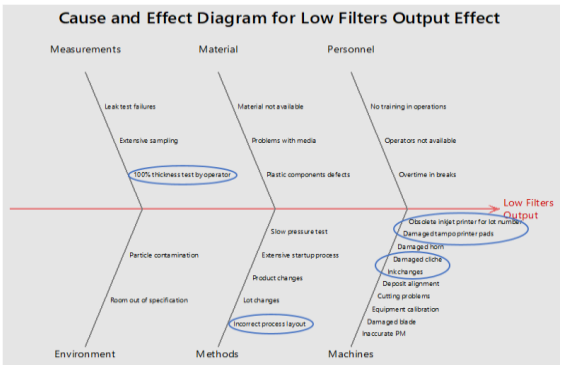

Figure 6
Cause and Effect Diagram for Low Filters Output Effect

Hypothesis Test: Packaged Filters

A hypothesis test was performed to understand if exists a relationship between the variances of packaged filters of the 1st shift and 2nd shift. As shown in Figure 7, the P-Values obtained was 0.051, with a confidence level of 95%. Since the P-Value is greater than 0.05, the null hypothesis is accepted. Therefore, there is a relationship between the variances of the first shift and the second shift.

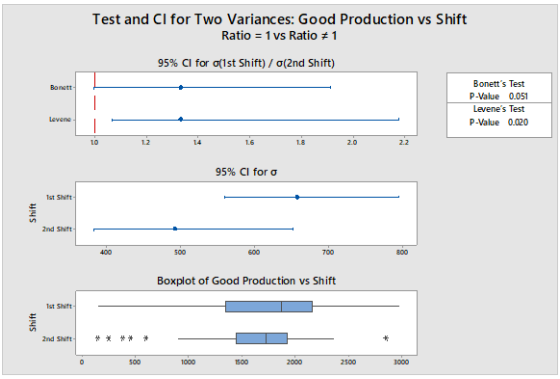

Figure 7
Hypothesis Test of Packaged Filters between 1st and 2nd Shifts

Hypothesis Test: Scrapped Filters

A hypothesis test was performed to understand if exists a relationship between the variances of scrapped filters of the 1st shift and the 2nd shift. As shown in Figure 8, the P-Values obtained was 0.248 with a confidence level of 95%. Since the P-Value is greater than 0.05, the null hypothesis is accepted. Therefore, there is a relationship between the variances of the first shift and the second shift.

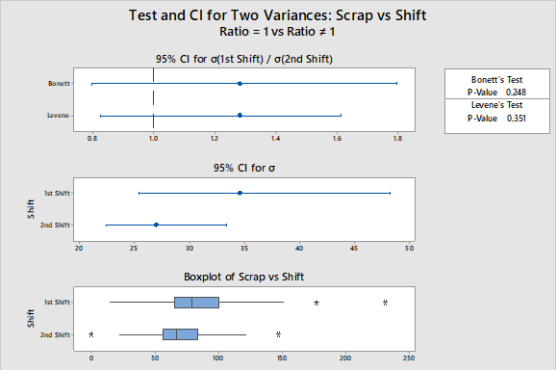

Figure 8
Hypothesis Test of Scrapped Filters between 1st and 2nd Shifts

Regression Analysis

The regression analysis is a standardized method to locate the correlation between, at least, two groups of data and create a prediction model. A regression analysis was performed to understand the correlation between the total scrapped filters and the scraps related to tampo print station.

According to the data from the linear regression, the P-Value obtained was less than α of 0.05. This indicates that there is a statistically significant effect on the total number of filters discarded due to the rejections obtained at the tampo printing station. Therefore, if filters are discarded due to damaged tampo print, the total scrapped filters quantity is affected significantly. According to the R-sq obtained, 26.21% of the variation is represented by the rejections of the tampo printing station.

Results and Discussion: Improve Phase

The purpose of the Improve phase is to improve the process performance by eliminating the root cause(s) of the problem based on the data analysis performed in the Analyze phase. To start the improve phase for the output problem in line #3, a new process layout was proposed to reduce de work in process (WIP) between stations. As part of the new layout, new stations for lot number printing and pressure test were proposed too.

Lot Number Printing Station

Currently, the lot number is printed in each filter during the pressure test with an obsolete inkjet printer that causes printing errors and ink problems that add scrap and/or downtimes to the process. To eliminate these problems, a new lot number printing station was proposed. It is required to replace the inkjet printer by a laser printer to standardize with the rest of the manufacturing lines of Haemonetics Puerto Rico.

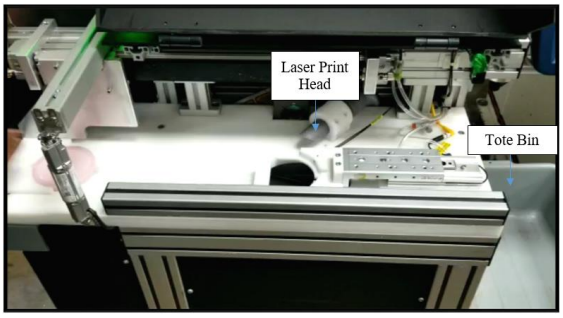

Figure 9
Proposed Laser Print Station

The proposed laser print station is an automatic station, where the left side welding operator will place the final filter assembly. When the sensor detects the presence of a filter, the nest is moved to the laser head to print the lot number. Once the filter printed the lot number, a pick and place take the filter and deposit it in a tote bin. After that, the filter is ready to be tested in the pressure test station.

Pressure Test Station

Currently, the pressure test station tests two filter at the same time to confirm that do not has leaks. This station takes 9.36 seconds in testing two filters and print the lot number.

To increase the pressure test capacity, a new pressure test station was proposed. The proposed pressure test station contains four modules and nests to test four filters at the same time. When the sensor detects the presence of a filter in a nest, the module of this nest closed the plungers and starts to test the filter. Each nest has a light below; if the filter passed the test, the light turns green, and if the

filter did not pass the test, the light turns red. This is helpful to the operator since he or she can identify if the filter pass or not the test.

Figure 10
Proposed Pressure Test Station

Tampo Print Station

Currently, the filters from line #3 are tampo printed, using a cliché and ink, to identify them with the name and description of the product, the company logo and an arrow that mark the flow of the filter. As mentioned in the measure phase, the ink changes related to the tampo print station, causes downtimes to the manufacturing process. In addition, 355 filters were discarded during the manufacturing process in a period of four months, due to tampo error defects. This defect was the second cause of defects reported, as explained in the measure phase.

In the analyze phase, different causes related to tampo print station were identified as possible root causes for the low filters output effect. In addition, as per regression analysis performed in the same phase, it was concluded that if filters are discarded due to damaged tampo print, the total scrapped filters quantity is affected significantly. Due to these facts, improvements were proposed for tampo print station.

To eliminated downtimes and scraps related to the tampo print station, this process will be replaced. Instead of performing tampo print to the filters, etched process to the plastic components will be performed by the supplier. These means that no station for tampo print will exists in the process.

Thickness Test Station

Currently, the thickness test is performed 100% as a request of the customer. This process is performed manually by one operator assigned to measure each filter for thickness verification with a drop gage. As part of the data evaluated in the measure phase, no rejects were reported due to failure in this test.

To reduce the time of verify the thickness of each filter, the new pressure test station, previously explained, was designed to perform this test simultaneously to the pressure test. For this purpose, the nest was designed with the maximum height accepted for filter thickness. As part of the pressure test in the new station, the operator inserts the filter into the nest to perform the pressure test. If the filter does not enter in the nest means that the filter is higher than the acceptance of the thickness verification test.

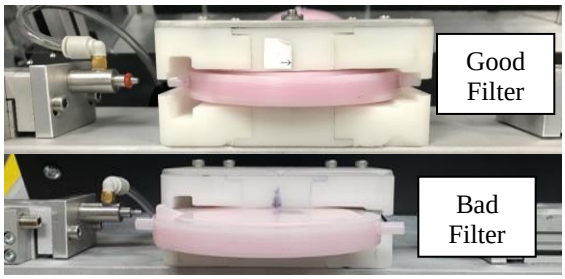

Figure 11
Proposed Thickness Test

New Layout

Currently, line #3 has the following stations:

- One media sheet cutter station
- Two media disc stations
- Two welding stations with a conveyor for transfer subassemblies between both stations
- One tampo print station
- One pressure test station
- One thickness verification test station
- One layered packaging station

As part of the current process excessive WIP is waiting between each station, especially in the conveyor between the right and left welding stations.

In order to eliminate some of the wastes identified during measure phase, reduce the time between stations, reduce the defects and improve the process flow of the units a re-layout of line #3 was proposed. The proposed layout includes the elimination of the conveyor between right and left welding stations, the tampo print station, the current inkjet printer, the current pressure tester and the current thickness verification station. In addition, includes the introduction of the new lot number printing station and the new pressure and filter thickness tester. Finally, in the proposed layout, a relocation of each station was recommended. One of the benefits of the proposed layout is the reduction of operators in the process from nine to seven.

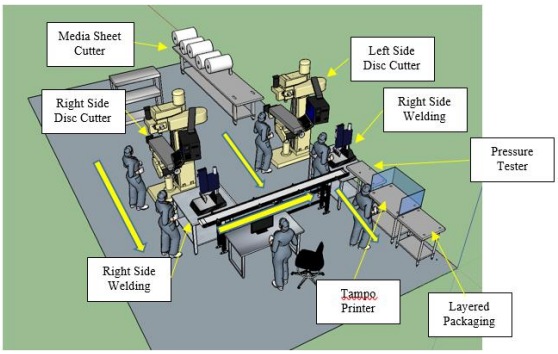

Figure 12
Current Process Layout

RESULTS AND DISCUSSION: CONTROL PHASE

The purpose of the Control phase establishes controls to avoid recurrence of the problem in the process. To maintain the improvements implemented in the Improve phase, some tools were used.

5S

To maintain the new layout after the implementation, 5S tool was used. The 5S tool consists of removing from the working area all those elements that are not necessary to carry out the work [4]. In addition, the equipment spaces were identified in the floor to sustain the correct position.

Validation

As part of the implementation of new equipment and new layout, performing a validation process was required. For the new equipment, an Installation Qualification (IQ) was performed. In addition, a Process Qualification (PQ) was required to validate the new process layout. The Food and Drug Administration (FDA) defines process validation "as the collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality product" [9]. The validation helps to assure that the process and the filter performance are not affected by the new equipment and layout.

Poke-Yoke

The new pressure test station has nests with the maximum height accepted for the filter thickness. These nests were designed as a Poke-Yoke tool. If the filter does not enter in the nest means that the filter is higher than the acceptance of the thickness verification test and filter need to be discarded by the operator. If the filter entered in the nest, the filter is considered as a good unit for thickness verification test. In addition, a thickness meter was implemented to verify, at the startup of each shift, if the nests complied with the requirements of the test and no damage was occur as part of the usage. If the green part entered in the nest, the nest has no damage. But, if the red part entered in the nest, the nest has damage and need to be replaced.

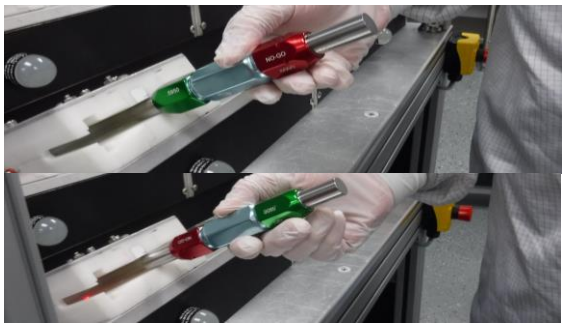

Figure 13
Nests Verification with Thickness Meter

Procedure and Training

Standard Operating Procedures (SOPs) that support the manufacturing process of line #3 were revised to include the new equipment and layout. Visual aids were added to the SOPs to serve as a visual guide to the operators. In addition, training was provided to the applicable operators.

CONCLUSIONS

After using the DMAIC methodology, it was possible to define the problem investigated, low filters output in line #3 of Haemonetics Puerto Rico, and provide a plan for the project. In addition, the current state of line #3 was presented and data were collected as established in the data collection plan developed. The process flow was studied to identify wastes in the process that can be reduced or eliminated. The data collected were measured and was confirmed that line #3 packaged an average 1,850 filters per shift. Also, it was identified that the bottle neck of the process was the right welding station. Finally, data were analyzed to perform conclusion before providing improvements. As part of the analysis, the possible root causes were identified. Once the data were collected, measured, and analyzed, improvements to eliminate the possible root causes were proposed. As part of the improvements, new equipment, process elimination or replacement and a new layout were recommended.

With the improvements implemented, line #3 was capable to increase the line output in a 22%. This means that the line only needs 37 shifts per month to complete the manufacturing plan from the 40 shifts available per month. It can be concluded that the DMAIC methodology helps in the achievement of the proposed improvement in the define phase after the project completion.

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