

Reduction in Waste of Raw Material Generation N and D of the Manufacturing Processes in a Medical Device Industry

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Abstract — *This article discusses how the industry of Medical Devices handles the reduction of waste in manufacturing processes. Companies have money losses, that can be reduce with an optimization of the manufacturing processes. Steps to accomplish a reduction in a waste initiative are: educate 100% of the employees to raise awareness of the significance of Waste, align the processes of dispatch in the manufacturing area, train coworkers to create awareness of the impact on the loss of material and reduce Waste to 33%. To carry out the study, the technique of DMAIC was implemented. In the end, the project was obtained from the support of the plant personnel, working together to mitigate the company's culture, make changes in the flowchart to improve dispatch processes, train staff to monitor the magnitude that has the report of lost material to identify areas of opportunity and meet the goals set by the company.*

Key Terms — *DMAIC, Lean Manufacturing, Six Sigma, Waste in the Raw Material.*

PROBLEM STATEMENT

Regulated industry, as is the division of Medical Devices focuses in the areas of health services. Focused to build and produce market equipment to meet the needs of customer's conditions and health needs. The instruments are made to help the rehabilitation of operations or disease, pain, injury, tools to perform surgeries and other areas. Meeting goals set to produce products that have met safety standards, compatibility with the end-user and high quality measures.

This industry has impacted the world with its products on the health services. It arrives on Puerto Rico in 1988 and is located in the east area of the island. It specializes in products to cover from

simplest to most complex procedures on surgeries. For example: procedures to heal wounds of a cut in the skin to internal bleeding wounds. Their approach is to work with quality in product from the beginning and bring production to the next level. This is measure are implemented since their mission is to save one more life with the use of their product.

The waste initiative seeks to implement models of improvement, where the manufacturing personnel focus is to obtain identity of losses of their processes. The main focus should be to bring the message of culture. How to start educating and training coworkers, asking them if they know the concept of what is Waste and what are the causes that impact the processes.

Research Description

The initiative is aimed at structuring and reducing losses of processes of the industry through culture, technology and process excellence. How to work in reducing Waste processes. The first step is to educate the associate the meaning of Waste and impacting the entire industry. Identify with coworkers by the way of "Gembas", "Round Table" and Washthideas" the different areas of opportunity. Train the staff to implement improvement in the processes.

Research Objectives

All papers must follow the following layout:

- Educate 100% of the employees of the plant workers to raise awareness of the significance of Waste;
- Align the processes of dispatch of material in the manufacturing area;
- Train coworkers to create awareness of the impact on the loss of material; and
- Reduce Waste to 33%.

Research Contribution

Carrying out this initiative in the industry helps raise awareness of why it is important not to dispose any leftover material in a worked batch. Understand the implementation of improvements; of much more automated processes and new technologies. According to studies, from 2000 to 2010 approximately there has been an increase in manufacturing costs. Since the percentages of expenditures are affected by the raw material. Which today many companies have opted on making changes to their processes, identify areas for improvement, to maintain company profits or to helped it reach the next level, that is, continue climbing and gaining ground and grow as a company. It can be clearly stated that globally the economy have been going through a recession that have affected every human being, from minimizing home expenditures, implement efficient work measures in company or better manage personnel and on extreme cases be employee/ boss in their own business. For example, many of the industries in Puerto Rico have been affected with the increase in costs of using electricity. This has made business owners make changes in their equipment, such as: the lightning equipment, air units and even make an investment in an installation of renewable energy system to reduce their energy costs.

LITERATURE REVIEW

In regulated industries with high expectations on the results, their manufacturing processes are applied and are constantly revised to identify improvements and minimizing waste. Waste is one of the main causes of increased loss of profit in plants. What would be the possible causes that affect the cost in waste? Release of incorrect material on production, over production, rework, transportation, material movement, time schedule, among other reasons, for example are some ways responsible for creating waste in the operation process of a plant. So as it is in many industries, where costs of production are minimized, many analysts are employed to

answer, in what way can the impact of waste cost in a plant can be minimize?

One of the first steps is to identify a team that has knowledge in different areas and work at the ground site. For the initiative of Waste working, that is within a regulatory industry, the departments involved to try to identify waste ideas would be: finance, process excellence, material supply, quality, manufacturing and engineering. These departments tend to work to create a structure, to identify areas of opportunity within the plant and develop a plan to reduce the costs in waste for a large impact; this at the end is simply to make changes. The response in the change is not which does it the best, firstly and foremost is that the departments and the workers know and understand the process that they work on, [1]. Therefore, teamwork helps better facilitating knowledge, developing personnel changes that improve the industry and the interests of the company. What kind of tool could help structure the plan of action, so that to continue working on improvement in the area that has greater impact on waste?

Nowadays the industry and workforce are within a competitive world and over the years the companies seek to implement ideas that improve its processes and production. Seeking better production, quality and market gain, it is beneficial to understand the importance in recognizing that quality of products in the industry has to improve constantly. But, for the product to be of high quality, it is good to start working with the internal process of the plant. One way to start is, to set goals to achieve, establish the definition of the criteria's to meet at the end of the project and in the process to identify the hidden opportunities in the manufacturing process. Through a methodology that will shape the problem and help minimize losses in the manufacturing processes in the production of the products worked on.

What methodology can be used that is aimed to improve the manufacturing process, educate the workers in achieving efficient ways to work, reduce losses and work with business objectives? Lean Six Sigma methodology based on the combination of Lean Manufacturing and Six Sigma DMAIC a

standard procedure (Define-Measurement-Analysis-Improvement-Control) can help achieve these. This methodology helps maintain a uniform progress through the project and carries a clear language of communication for all parties to work with the project documentation [2]. It can be said that Lean Manufacturing is one of the strategies used by the Toyota, but nowadays it is referred to by them as "The Toyota Way" as published and written [3]. Toyota Lean Manufacturing processes are based on two broad concepts: on continuous improvement and respect for people.

Lean Six Sigma is used with a strategy based on five steps, they are defined as follows:

- *Define*: Project objectives, process requirements and build an effective team;
- *Measure*: The current process performance, determine what will be measured, develop and validate the measurement system, determine the current process performance;
- *Analyze*: To determine the root cause of the problem its defect, understand variation and identify potential causes, identify process improvements;
- *Improve*: Select, develop, verifies and win the final solution;
- *Control*: Implement the solution, guarantees that the improvement is sustainable and ensures that new problems are quickly identified.

These five strategies are capable of carrying out a clear project structure and layers to satisfy the needs and satisfaction of the product user, customer, product designers, company, but above all the community.

METHODOLOGY

This work is directed to help identify areas of opportunity in an industry for medical devices. It identifies various situations that occur in day to day operations. The first step taken was to work with a Voice of Customer (VOC), where 100 percent of the workers of the plant were the key components to get the results of the survey. This builds the second step,

which is to work the waste initiative with a methodology that helps organize the team when performing an action plan. The methodology will be based on Lean Six Sigma DMAIC format, which is a tool focused on improvements of existing processes. DMAIC is written by five letters, which are defined as: Define, Measure, Analyze, Improve and Control. What is the significance of each phase of DMAIC?

- *Define*: The objectives and expectations of the project are identified, the project scheduler hands the tasks to be completed per phase and the team members are chosen. In the himself will start the search for ideas that will help the processes improvements. One example would be to conduct a survey VOC (Customer voices) to identify the major concerns of the clients regarding the understanding of the importance of the word "Waste" within their workspace.
- *Measure*: The objective is to measure the process that is sought to improve, through a collection of data. The client presents effects and solutions; these are evaluated to identify improvements in the various processes outline.
- *Analyze*: Anything that does not add value to the existing processes; determine the root cause of the problem in the process and opportunities for improvements. Given the weight or importance in the process for the client.
- *Improve*: Designing the solution to work with the root cause according to the analyzed priority. Until reaching the expectations identified by the client and develop a monitoring plan.
- *Control*: Phase where the control function is implemented and ensures that changes in the process will be kept stable.

Below it can be seen what would be the defined action plan to begin working with the initiative of waste within a plant that has interest on minimizing losses in their processes through its client, that are in this case the workers (Figure 1). This would be the Proposal Project Scheduler to work with:

Proposed Project Scheduler

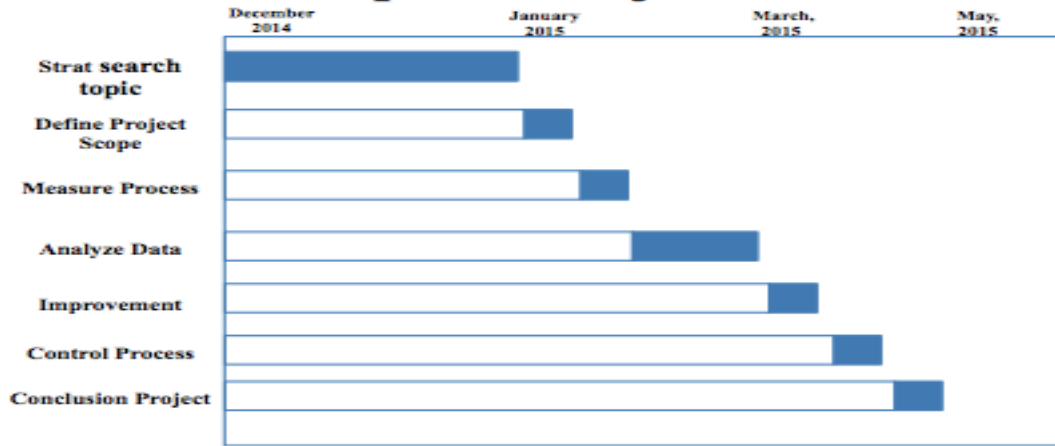


Figure 1
Proposal Project Scheduler

RESULTS AND DISCUSSION

This section presents the problem, analysis, results and improvements using tools of Lean Six Sigma and DMAIC methodology.

Define Phase

The Objectives and expectations of the project are to identify what/where are the greatest impacts on losses of process within the plant. To carry out the definition of the project, a project charter (Figure 2) was created. It identifies the project planning phase, team members, tasks performed by phase and the initiation of searching for ideas that will help processes improvements.

Other tools used to define this phase, was to work with a "Voice of the Customer" (VOC). In it, ten (10) questions were formulated, which obtained 97% reply rate of plant personnel that answered the questions. The survey sought to obtain that all plant personnel identified how important is the "Waste" initiative for the company. For the ten questions personnel had five options as answers, which were: completely disagree, disagree, neither agree nor disagree, agree and completely agree.

The responses would help formulate a Voice of Customer (VOC) to identify how important it is for the plant to reduce Waste. For this type of survey, ten questions were performed. The questions were:

1. Understand the reasons of business of why it will be worked with the Waste Initiative?

2. Understand the objective of the Waste Initiative?
3. The Management has told me about the concerns of this change?
4. Understand how the Waste initiative goes along with other efforts to improve the company?
5. The structure of the organization is flexible and can adapt to changes associated with this initiative.

Project Charter				
PROJECT NAME	Reduction in Waste of Raw Material Generation N and D of the Manufacturing Processes in a Medical Device Industry			
PROJECT LEADER	Capacity Planner of Automation Area			
PROJECT SPONSOR	Automation Manager and Finance Manager			
PROJECT DESCRIPTION	Create and implement a model that governs waste reduction activities on the ground to become more competitive and reach the next level. The initiative is aimed at structuring and reducing losses of processes of the industry through culture, technology and process excellence.			
PROJECT STATEMENT	During the 2010, \$24 million in manufacturing components were wasted and 11 million of those 24 million were in raw material N.			
BUSINESS CASE	Reduction goal of \$7.1 million in Usage & Losses, educate 100% of the employees of the plant workers, and increase yield 3% in the machine packaging area.			
PROJECT SCOPE	Reduce 33% of Waste in all the plant and educate 100% of the employees of the plant.			
HARD DOLLAR	SOFT DOLLAR	TARGET		
\$24,000,000	\$7,100,000	\$16,900,000		
Define Phase	TARGET DATE	OWNER		
Define Phase	Jan-10-2014	All Team		
Measurement Phase	Mar-20-2014	All Team		
Analysis Phase	May-29-2014	All Team		
Improvement Phase	Oct-31-2014	All Team		
Control Phase	Dec-11-2014	Team/Manufacturing Packaging Area		
Closing and Lessons Learned	Dec-18-2014	Leader/COOP		
METRICS	BASELINE	GOAL	DATE	
Education of all personnel of the plant in theme of Waste.	75%	100%	31-Oct	
Align the processes of dispatch of material in the manufacturing area	25%	35%	11-Dec	
Reduce Waste 33%	20%	33%	11-Dec	
% Time	Role	Availability	Comments/Issues	
Y. Martinez	75%	Leader	Yes	Capacity Planner
L. Serrano	25%	Member	Yes	Senior Finance Analyst
G. Molina	25%	Member	Yes	Process Excellence Engineer
F. Quiñones	25%	Member	Yes	Quality Engineer
R. Rodriguez	60%	Member	Yes	Senior Engineer
J. Rivera	25%	Member	Yes	Senior Engineer
J. Santana	25%	Member	Yes	Facility Line
N. Nolasco	10%	Member	Yes	Operator
H. Hernandez	10%	Member	Yes	Operator
Z. Sierra	100%	Member	Yes	COOP
POTENTIAL RISK	Action (s)	Owner (s)	Due Date	Comments
Meet the goal of reducing waste.	Education all plant	All member	Feb-14	N/A
Limitation of money for new projects.	Present impacts of improvement to sponsor and high staff	All member	Dec-14	N/A

Figure 2
Project Charter

6. Understand that the Initiative Waste will bring benefits to the company.
7. Understand that the Waste initiative will bring benefits for the operators of manufacturing.
8. Have the company kept us informed concerning this initiative?
9. Has the management remained positive concerning this initiative?
10. In the long term, do I believe that this initiative will be good for the company?

With the results obtained from this survey, 100% of the population was impacted (Figure 3). Results of the ten questions of this survey showed that on average: 4% completely disagree, 2% disagrees, 5% neither agree nor disagrees, 30% agrees and 60% completely agrees.

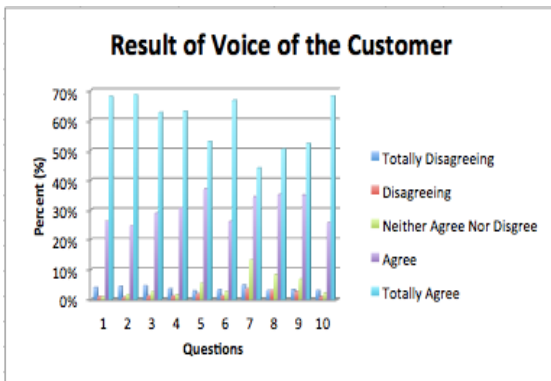


Figure 3
Result of Voice of the Customer (VOC)

Therefore one might conclude that the majority of the personnel of the plant completely agree that an analysis is performed for Waste reduction in the manufacturing processes. Initiating working with the educating and identifying, which are the residues as major offenders?

Measure Phase

The objective here is to measure the processes that are sought to improve, through a collection of

data. The client presents effects and solutions; these are evaluated to identify improvements in the various processes outlined.

At this stage the processes of how the dispatches of raw material, to create the final product are presented. Also it will be observed what are the steps, that operators identify that can be major contributors for the occurrence of mayor waste. This then, will help to work with the next phase that is to analyze.

Next it will be observed the performance of the flow that takes place in the dispatch of various raw materials that are manufactured in the plant.

The flowchart diagram presented in Figure 4, gives a vision of how to run the raw material orders before they reach production. In it two things can be identified:

- The first would be, when the quantity of raw material is inspected to enter the System 2, the amount to dispatch to manufacturing is not controlled. This can cause that more or even less is sent than required by the work order. The difference is, if dispatch less than 20% as required by the work order system 2 does not approve the dispatch, but if shipped above the work order there is no control over the release the raw material. As a result, it will cause over production in automated production areas.
- Second would be, that there is no control of the amount of raw material that is over dispatch. Therefore, it is said that over production is done. Is not taken into consideration the amount of additional parts worked on and also very little is taken into consideration the Dispenser Box for additional pieces worked above the work order. This usually happens in the automated plant areas.

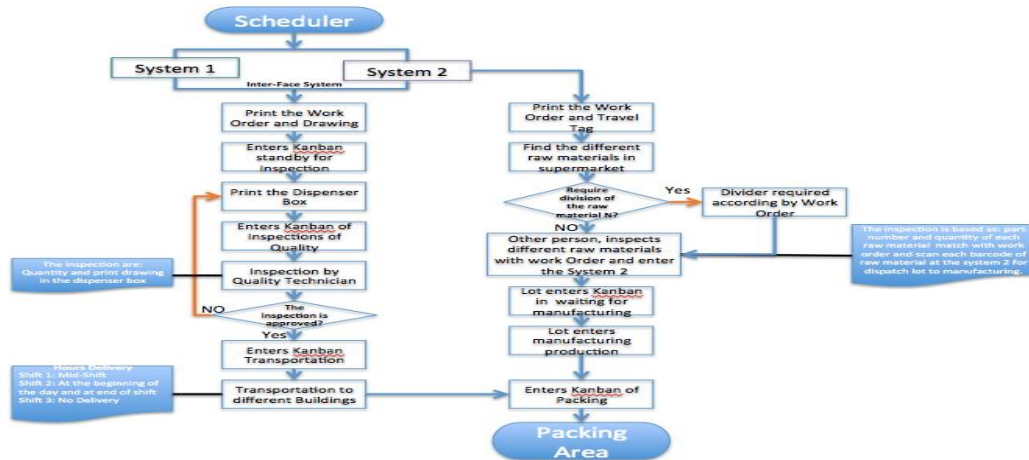


Figure 4
Flowchart for Dispatch Raw Material Actual

This means that a plan of action has to be established. Of how the raw material quantity released for manufacturing can be controlled in system 2. In addition, how to control the volume of finished parts that were not packaged and therefore were discarded; without taking in to consideration the number of all raw material parts assembled and labor performed costs.

It can be said that by making business decisions it is required in some occasions to expand the lots. Which for these exceptions, ordering the additional raw materials D is requested. But this usually occurs when all the pieces were already packed. For example, having ten dozen unpackaged, is the packing operator decision to inform the supervisor for more dispenser box for the scheduler. In this situation, it is identified the need to do rework. That is looking at Figure 4, to repeat the steps from the scheduler, go through system 1 and 2 to make the ordering interface between the two systems. Complete the entire process of creating the dispenser boxes, inspection the time and transportation; assign the packaging operator to pack the dozens that could not be worked because of the shortage of material. The points above are part of the root causes for the plant to have significant monetary impact in the processes when measuring the Waste in manufacturing.

In the next face of analysis, is can be observed a little more detail of how it can be mitigated the losses

raw material N and D. Also it will be affirmed, if these raw materials are the top offenders of all raw materials worked in the plant. Although, it can be concluded, in the measurement phase, that the analysis will focus on two points: first work with over dispatch in system 2 and second match work on the losses in products completed, for not requesting more dispenser Boxes.

Analyze Phase

Anything that does not add value to the existing processes; determine the root cause of the problem in the process and opportunities for improvements, given the weight or importance in the process for the clients.

At this stage the several tools are used, first the fishbone diagrams are used. This is, to identify the various reasons of why such raw materials are occurring in the production processes and the dispatch of materials. Seeing the diagram divided in four areas: materials, facilities and equipment, process, training. In each of them it is identified in what points there should be a greater focus to reduce the impact of Waste in the plant. This will help us evaluate what things do not add value to the processes. Another tool is the division by priority for obtaining positive results. Finally there would be, a statistical analysis using a Pareto. Next in Figure 5 the Fishbone Diagram can be seen.

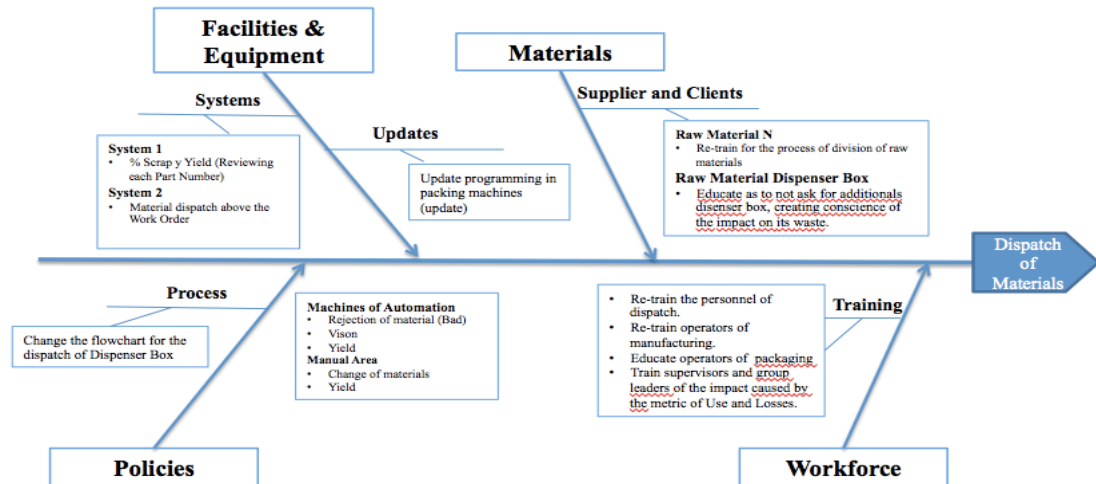


Figure 5
Fishbone Diagram for Identify Cause and Effect

This fishbone diagram helps better interpret the areas of opportunity in the plant to reduce waste.

In Figure 6, the four points identified in the fishbone diagram divided by priority are presented. As can be seen in the first point is, to work the quadrant High High, ie the workforce, next will be the materials and after the Facilities and Equipment and finally the Policies.

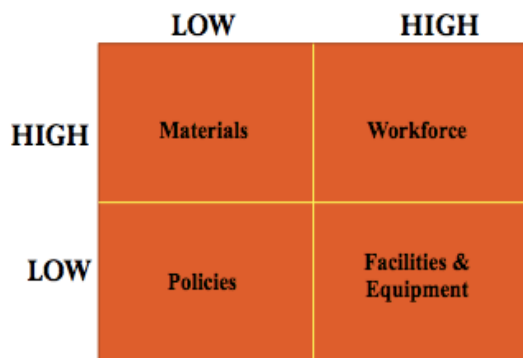


Figure 6
High and Low Impact Difficulty by Priority

The following analysis is worked as a Pareto chart, where this helps to identify the top offenders of different raw materials worked in the plant. For example, the operators identify raw material N, as the most dumped material in the production. This is identified for different reasons. In figure 7 is shown, the identification of the different raw materials used in the plant from the most to the least wasted.

In figure 7, presented above, all raw materials are identified. It can be observed that the raw materials N has a significant loss of \$11,427,401.00; H materials, follows with \$4,749,631.00; the third has a loss of \$2,384,336.00 and the less in loss is L materials with \$169,083.00.

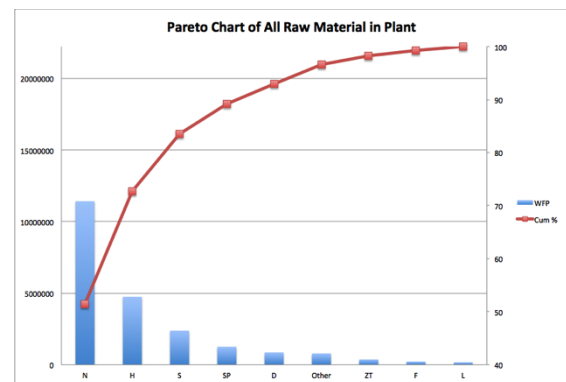


Figure 7
Pareto Chart of All Raw Materials in Plant

Therefore, this gives us a better picture of the raw material that affects more the metric of Used and Losses per trimester and which should be work with priority.

Another area that can be evaluated is how costly is the order of the dispenser box. Since the loss of this raw material can be identified in the duplicated and canceled orders. But, it should be noted that for these two points the cost of labor should be observed and noted.

Table 1
Dispenser Box Cancelled and Duplicate

Cancel & Duplicate By Quarter	Part Qty.	Batch Qty.	Part Unit Cost	Labor Cost
2014-Jan				
Cancelled	-3476	30	\$5.465	\$22,731.750
Duplicate	-4122	81	\$17.036	\$98,504.250
2014-Apr				
Cancelled	-2921	27	\$6.59	\$12,628.75
Duplicate	-5228	117	\$25.39	\$155,754.58
2014-Aug				
Cancelled	-1214	15	\$5.21	\$25,257.50
Duplicate	-11649	185	\$38.90	\$68,195.25
Grand Total	-28610	455	\$98.60	\$383,072.08

Table 1 presents how the duplication of material and cancellation is affected. It can be seen that there is not a significant annual impact in duplicate and cancellation. Since the cost of Dispenser box on average is \$0.46. But even then there is a significant impact on labor. For example, is canceled there is \$60,618.00 in loss and in duplicated it is doubled with \$322,454.08. This affects in the total charge for labor of \$383,072.08.

Improvement Phase

Designing the solution to work with the root cause according to the analyzed priority, until reaching the expectations identified by the client and develop a monitoring plan. The first plan of action for improvement is the workforce. For this improvement, there would have to be a change in company culture, as it is a problem that have major effects in the processes performed at the time of executing the tasks of manufacturing. How it is worked with culture, making training through awareness. One of the Awareness that was worked on was to educate worked 100% of the population of the meaning of what is Waste on the plant. The second was to educate on the importance in returning unused raw material N to reduce waste. In this second, there was a monetary incentive to the operator, to educate about why it is important to make the variance. This was performed for each

variance returned to the raw material dispatch area and its travel tag accompanied to the lot, was deposited in tombola. Then there was a draw every two weeks during the last months of the current year only. Since the month of September to November the raw material N variance increased to 5%. Finally in the training area education was conducted for the Line Facilitators and Group Leaders in the metric of used and losses. This helped, as each line supervisor could make an analysis of why such a material loss over use or by discarding a lot of material.

In the flowchart for the dispatch of raw materials used in manufacturing a change was done to keep track of the quantity dispatch for raw material N. Even a Pilot Test was performed to evaluate how effective could be the dispatch of raw materials D was and observe if this area has the ability to work in parallel to manufacturing. This was done for evaluating the processes of dispatch, can be much more linear with the areas of manufacturing products. For example, how would be the dispatch of raw materials N if the change was made? If the work order 1 requires 2,255 N of part number X, the person shipping the item may have a minimum and a maximum to approve the dispatch of such material raw N. That is, the minimum may not be less than 10% of total required and no greater than 10%, so it would be $\pm 10\%$. For raw material D, the order is made by the scheduler, because the system itself is configured for both orders to execute at once. The only difference is that the operator that creates this raw material will not work until the order is completed by the manufacturing operation. This would help as to not have: cancellation of orders, duplicated material and for not producing more or less than is required, since each process in the loss of material yield is contemplated. But there are cases that because of business reasons that it requires cancellation of batches, ie not working this area or trying to expand it.

The proposed flowchart, for the pilot test run to take control of raw materials dispatched to reduce waste is presented in Figure 8.

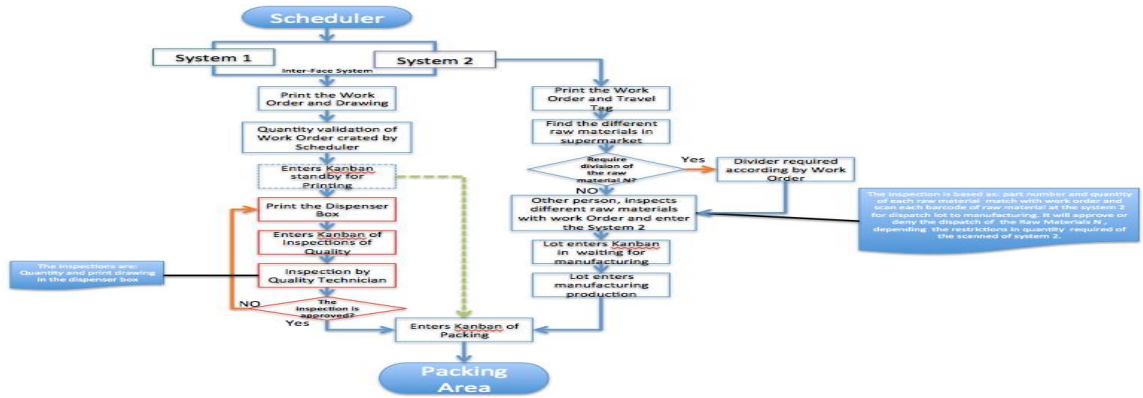


Figure 8
Flowchart for Dispatch Raw Material Feature

As can be seen in Figure 8, the flowchart is presented to help keep a process within all manufacturing steps to be able to reach to the final step of packing. By improving the program flow, it can also include an improvement to have it as part of the change. This is to certify the raw material D is under the plant family to eliminate the quality technician inspection and gain more time to have raw material in the step of "Enter to Kanban of Packing". This future step comes in green color and cut lines in the flowchart.

The awareness of the importance of applying raw material D and not discard the already completed material of manufacturing operators was also conducted for the packing area. The packaging operators were oriented, providing them a table where it was specified the average cost for production code depending on its configuration, line and quantity packaging.

Control Phase

Phase where the control function is implemented and ensures that changes in the processes will be kept stable.

To be able to have control over loss of material, first of all there has to be a constant and continued education. Since in some cases, there are many instances that the personnel that is available, have a culture only producing. Moreover and worrying is when the personnel have the opportunity to present an idea for improvement and see no single action taken by their supervisors. Operators are aware that

with their help the plant can reduce losses in the processes. Another way to mitigate Waste processes is within the layout of the manufacturing equipment to create raw material D. This will help in the reduction of expenses by approximately \$383,072.08 per year. As part of the process that is performed to create and send raw material D, would eliminate five steps to gain time in the schedule and dispatch the product to the customer that make use of the medical device.

The awareness of the importance of applying raw material D and not discard the already completed material of manufacturing operators was also conducted for the packing area. The packaging operators were oriented, providing them a table where it was specified the average cost for production code depending on its configuration, line and quantity packaging.

CONCLUSION

In the end, this project carried out each of the objectives presented. Since the beginning to end, was structured and organized by the tool Define, Measure, Analyze, Improvement and Control (DMAIC). In each of the phases the meaning and importance of each was demonstrated. For example; the Define phase was carried out to make way for the formation of a lean project, where the Voice of the Customer (VOC) was analyzed. To carry the message of the meaning of waste initiative and what it entails working with it to meet each of the objectives. The Measure phase was to understand the

process flow in the areas of dispatch of different raw materials and see what the critical areas were. The Analysis phase showed the impact that causes the different raw materials in the plant and the cost of duplicated labor that significantly affects in waste. In the phase of improvements, the project began by training. Creating awareness, because it is important to reduce loss of material and also working with a pilot test to see if the management office of the material D can be parallel to the manufacturing area. Finally, a control to reduce losses of raw materials N and D was performed. One step was included in the dispatch area a programming to have control of the quantity released for approving of raw materials N and a change in the flow in the dispatch of the raw material D was performed, moving this process directly to the manufacturing floor to have a lean six sigma process, to raise the efficiency and product quality to the next level.

Each of the objectives were met by periods. The first objective "Culture", it could be said was the most difficult, but not impossible to work, because there is already a very strong established culture in the work area and it has to be handled with care. The mission of this objective was to educate 100% of the personnel of the plant in the meaning of waste, by means of kaizen, training, gembas, "Waste Week" and the lottery for raw material N variance. The second objective was to make changes to the flowchart of dispatch of raw materials N and D to reduce material loss and duplication. The third objective, to train manufacturing personnel as; line supervisors and group leaders in order to understand the value of reporting losses of the plant and how it could help them identify areas of opportunity in their production lines. Finally the goal and initiative to reduce 33% of waste in the plant was performed. The same was slightly uphill, as many product losses were present because of defects in the supplier, before reaching the plant. This situation also helped to identify areas of improvement with suppliers of the different raw materials that are manufactured in the plant.

In the end, the waste initiative is an excellent project for any industry, since "Waste" is an easy

way to lose money, which is hard to recover. Therefore, it is recommended to educate the industry employees, to make better use of the tools and know the weaknesses in the manufacturing processes. To identify those defects that affect the production, product quality, waiting time, among others processes. Carrying a model and implement an initiative of waste in the production processes can help make the plant more competitive and reach the next level in efficiency and quality of product.

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