Final Pack Improvement Project to Increase Quality and Productivity

Jacob Velasquez Bon, B.S.M.E
Masters in Engineering Management
Dr. Hector J. Cruzado, Ph.D, P.E.
Civil and Environmental Engineering Department
Polytechnic University of Puerto Rico

Abstract *— A manufacturing final packaging line at medical devices company currently is human dependable and manual handling/inspection. Final Pack process have been performing at a sub-optimal level resulting in recurrent quality events, scrap and manufacturing inefficiencies.*
Pick by light system will now be implemented in order to eliminate the failure modes associated to the quality issues. Also, the implementation of the pick by light system increased the productivity by eliminating the manual assembly of the literature. By implementing this new system, the company will be able to reduce considerable the quality /compliance issues. DMAIC is the methodology used in this project as Define, Measure Analyze, Improve and Control. DMAIC is a popularized continuous improvement method. The goal of this project is to standardize Final Pack lines with the other global plants, implementing automated inspections and Poka-Yoke stations in order to reduce escapes and increase productivity and as a consequence reduce the amount of money that the company is losing due this reason. In this project were used different techniques to maintain a continuous improvement, demonstrating that the DMAIC methodology is a useful one to have an incremental improvement.

Key Terms *— DMAIC, Lean Manufacturing*

INTRODUCTION

Medical Devices Company has a packaging lines designed to meet the needs of an actual demand. The current manufacturing system used is an operator dependent system. With the operator dependent system, the process is vulnerable, susceptive to generate escapes, and quality issues. Human are susceptible to prompt errors that could impact the quality of the product.

There are a lot of solutions to eliminate the human dependent system like automation systems, vision system, poke a joke methodology, etc. The pick by light system is another manufacturing method that although do not eliminate the human dependent it considerably reduced. With the pick by light system and some improvement that eliminate the visual inspection, the production will be semi-automatic, with less opportunity of errors, and with a higher productivity.

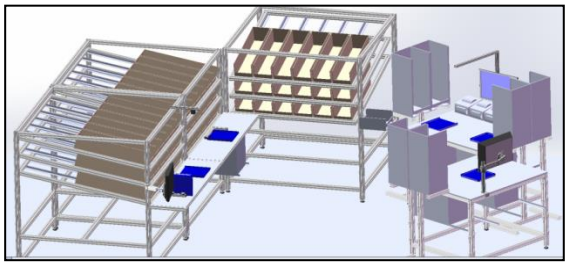

Figure 1
Pick by light new Stations

By using this system, the packaging lines will be capable of increase the lead time and decrease the quality issues. Instead of producing depending completely of the operator the pick by light system will eliminate the human visual inspections, the dependability of the manual handling of the literatures assembly. The purpose of the Final Pack new System is to certify that correct documentation, literatures and printed labels are placed on the right box, with the right device inside. There will be 3 steps for all these operations and for each step there will be multiple checks with different ID. At least, the material handler will use a dedicated PC to manage the component stock. This new packaging methodology will be managed centrally by the Pick

Term System. This new system will be an optimal flexibility for the packaging line.

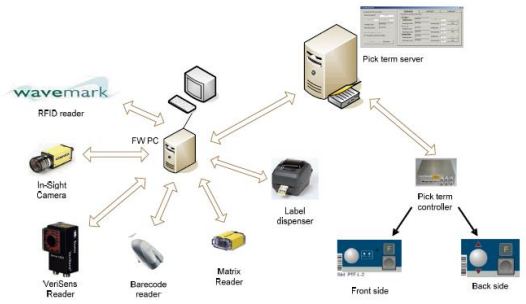

Figure 2
New Components Diagram

Figure 2 illustrates the new components that will be integrated in the new packaging lines. This figure illustrate the use of cameras for automatic inspection, barcode reader for assure correct material consumption and multiples semi-automatic interface to eliminated the dependability of the human.

LITERARURE REVIEW

Six Sigma is a disciplined, data-driven methodology for eliminating defects in any process. To achieve six sigma quality, a process must produce no more than 3.4 defects per million opportunities. According to Devane [1], six sigma's basic value proposition is that principles for process improvement, statistical methods, a customer focus, attention to processes, and a management system focusing on high-return improvement projects result in continuous improvement and significant financial gains.

The prominent Six Sigma objective is to achieve greater revenue and profit for the business and high customer satisfaction. Properly executed, Six Sigma will achieve this through lower costs. However, achieving Six Sigma goals may require significant changes to the system. Change is perceived as a major source for disruption and higher costs. Although every associate in the organization should be a good change agent; Six Sigma assigns special roles to realize effective change. An executive-level manager in the role of champion acts as the official change agent, facilitating the management plans and change process.

According to George [2] Motorola recognized there was a pattern for improvement (and use of data and process tools) that could naturally be divided into the five phases of problem solving, usually referred by the acronym DMAIC. Phase I (Define) this phase is to clarify the goals and value of a project. Phase II (Measure) the purpose of this phase is to gather data on the problem. Phase III (Analyze) this phase is to examine the data and process maps to characterize the nature and extent of the defects. Phase IV (Improve) is to eliminate defects in both quality and process velocity. The last one is Phase V (Control) that the purpose of this phase is to lock in the benefits achieved by doing the previous phases.

The following Figure 3 tell us where is the most failures that produce escapes.

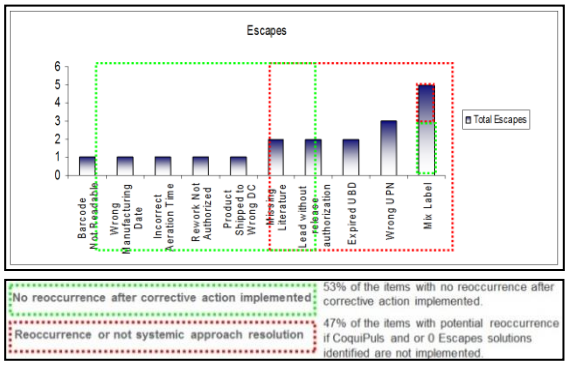

Figure 3
Pareto of Escapes

The most escapes is concentrated in the failure modes of Mix Label, wrong UPN, expired UBD and missing literature. These failures are the one that would be analyzed. Actually the manual final packaging lines has a daily rate of 1,800. In this project the historical data will be collected to be measured and analyzed. Once the data is measured and analyzed it will make various recommendations to decrease the failures and increase the productivity.

Lean Manufacturing Philosophy

This research consists of the design, explanation of the tools to be implemented and the reason for the implementation. It also established the type of analysis and how the data was collected. This research is intended to implement different six sigma tools in order to reduce escapes, quality/compliance issues. The methodology of Six Sigma basics in essence creates improvements by managing variation and reducing deficits in the processes of an enterprise. DMAIC these five elements focus on significant process improvements. You may ask how this process relates to the everyday man or woman. Using data from every conceivable source, the statistical formulas used by the process of the Six Sigma methodology can effectively calculate this data into productive applications. From the time allotments for food car delivery, to the analytical processes used by insurance companies, statistics play a large part in daily affairs, and this approach enables productivity and profit for businesses without neglecting consumer input. The processes of Six Sigma with its statistical perfections that allow increased profits, less defective products, and millions in the bank, is impressive to those that gain such windfall, but the lingering question to ask may be too little, too late[1]. Six-Sigma is a 21st century concept. It represents a process-focused, resource-based and customer-driven concept. Enterprises implement the Six Sigma business concepts to achieve processes and activities perfection. The essence of Six Sigma concepts is that customers' satisfaction can be provided by increasing the quality of products. The quality of products can be increased by increasing the quality of processes. Finally, the quality of processes depends on resources and capabilities and on their combination. Six-Sigma is more than just a business concept. It is a management philosophy that signifies how expensive defects are. Six-Sigma can be implemented through Six Sigma projects, which involve five phases shown in Figure 4. However, the mentioned phases of improvement in Six Sigma ways include very detailed, concrete measures, instruments and techniques. This makes it possible to call them methodology. Six Sigma methodology (DMAIC) helps to improve any process. It suggests that it is usually possible to improve processes' efficiency, not by changing the combination of resources and capabilities, but by eliminating variation and defects, which appear as a consequence of variation. In summary, the Six Sigma basics of statistical findings for business and consumer advancement, heralds as the ultimate process for achievement, yet leaves the mind to ponder its effectiveness upon the human race [2].

Figure 4
DMAIC Methodology

Methodology

In this competitive world, each organization needs to fight for a place at the top. To sustain competitiveness, each organization needs to produce and deliver defect free products. In order to do so, organizations follow many different business management strategies witch one of the most popular strategy is six-sigma. Six-Sigma is a business management strategy that involves betterment of the organization's existing products, to make them defect free. The following paragraphs will help you understand this methodology in detail.

DMAIC Methodology Tools

DMAIC is an acronym which stands for Define, Measure, Analyze, Improve and Control. These are tools of DMAIC, and are used in order to find and eliminate defects in the product. A team of experts is formed which uses the DMAIC methodology to find and eliminate the root cause of

defects. This team has a leader with a six sigma black belt certification. Other members of the team hold six sigma certifications too. These are experts who look at processes and the products. The outcome of their study helps the organization to raise its position in the market, and cut off competition by producing defect free products. Let us proceed to understand the DMAIC methodology [1].

1. D - Define

The team is formed with a specific purpose in mind. This is what the define stage is all about. The team needs to sit together and define the scope, goal, budget, duration and the problem. The leader of the team makes a charter document where they mention all the above aspects in complete detail. Then, work begins. The team defines the problem and then sets about finding the root cause and finding ways to eliminate that cause. The understanding of business process management helps the team at this stage of DMAIC methodology [2].

2. M - Measure

Here, the performance of the process is measured. The feedback of people who manufacture products, feedback from customers who use the products and the way the product is processed, are all measured. The team also takes a look at business growth strategies. At this phase, the problem statement and project contract are commonly refined as a result of establishing an accurate baseline for the metrics being targeted. This can be known as the data collection step too. All relevant data, important to the product, and the processes followed to manufacture the product is collected at this stage [2].

3. A - Analyze

The next step in DMAIC process, analyze, as the name suggests, is analysis of the data collected in the previous phase. It is important to analyze the feedback given by customers, as they are the end users of the product and the product needs to match their needs. In this stage, the root cause of the problem is identified. A process chart, here, helps the team in understanding where the process of manufacturing the product has gone wrong.

4. I - Improve

The process chart helps the team in redesigning the process, after elimination of problems. A complete new process chart is then made, which highlights the changes and improvements to be incorporated, in order to do away with defects. The concepts of total quality management and lean manufacturing are used in this stage. Documentation accompanies the new process chart, which provides the changes made in the process, in detail. Work at this stage becomes easy, if the team has collected enough data [2].

5. C - Control

This is the last stage in DMAIC model. After the new process is designed, the organization replaces the old process with the new one. The team closely monitors the working of the new process and ensures that there are no problems in the new process. They monitor the performance of the new process and ensure that products manufactured are defect free. If there are any further changes to be made, the team makes changes and again measures the performance of the process. Under proper guidance and observance of the team, new process is adopted by the organization [2].

RESULTS AND DISCUSSION

This section discusses all the stages of DMAIC methodology to go to the entire process and capture all the variables using the Six-Sigma Manufacturing Principles.

Define

During the Define the actual process of final pack was defined to assure that the entire process was included. Final Pack process have been performing at a sub-optimal level resulting in recurrent quality events, scrap and manufacturing inefficiencies.

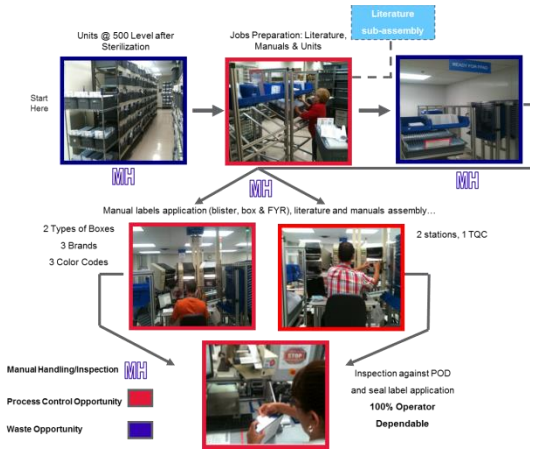

Figure 5
Actual Process of Final Pack

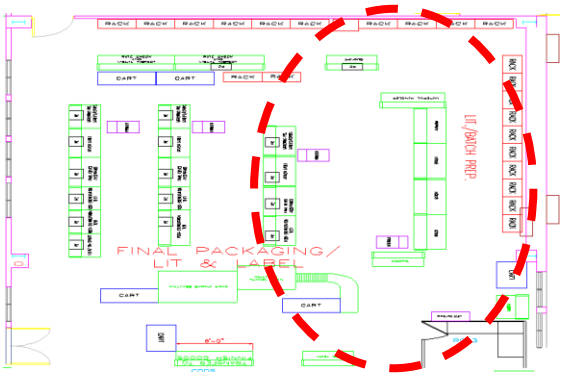

Figure 6
Actual Layout of Final Pack

Figure 5 and 6 are the actual final packaging process that consist of two (2) units lines and one (1) literature assembly line. All lines are human dependable producing multiples quality/compliance issues, especially the manual literature assembly line.

Measure

In this phase all types of data will be collected in order to understand and identify were the root cause for the escapes generated is located in the process. This metric in Figure 7 tell us the quantity of escapes by failures in the Final Pack Lines. Currently from missing literature to mix label are the most impacted failure according to the historical data.

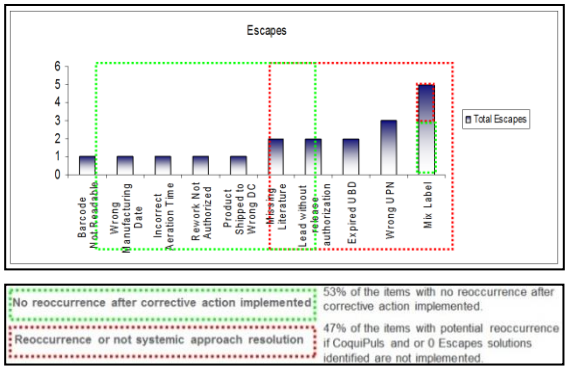

Figure 7
Failures vs. Escapes

Analyze

In this phase of analyze a different tools are to be made to identify the root causes of the offenders of escapes. A Value-Added Analysis is a method in which a process is stripped down to its essential steps, it was important to develop a value added analysis because it gives more detail about each individual task that is being performed per workstation and the time related to that particular task. In this analysis each activity is evaluated to determine the contributions to the customer requirements.

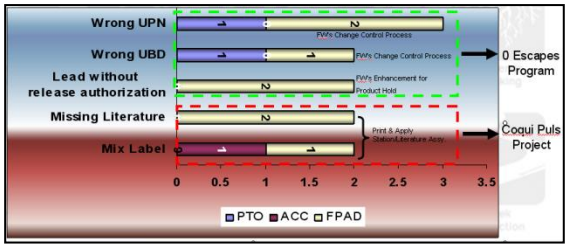

Figure 8
Graph of escapes

Potential Roots Causes

The team, based on the causes of major escapes, identifies the potential root causes of each one. In the Table 1 the causes of mayor escapes are identify and are: mix label, expired use before date (UBD), the missing literature and wrong unique part number (UPN). Each one of these causes has some potential root causes that cause the problem in each one. From the data collected and the analysis that

the team did to each potential cause of escape the following potential root cause were identified:

Table 1
Potential Roots Causes

Offender	Potential Root Cause
Mix Label	Operator Dependable
Expired UBD	Visual Inspection
Missing Literature	Operator Dependable
Wrong UPN	Operator Dependable

Improve

This phase is important to prove that the possible causes of the problem are the correct one. It is used to identify potential failure modes, determine their effect on the operation of the product, and identify actions to reduce the failures. In resume this phase is going to show the implementation of the different tools to make sure that the real causes that is found in the previous phase is the correct and to show the difference of before and after that tells us the causes of the problem was resolved.

In the Analyze Phase the team identified the major potential root causes for the causes of escapes. After the explication here are the solutions for the root causes:

• **Mix Label** – The place of the label depend completely of the operator. Although there are a visual inspection there continue to be human dependable. The solution is to implement an automatic inspection with a camera that will match the label information with the internal. The pick by light system include software that will perform this automatic inspection with several cognex cameras.

• **Expired UBD** – The verification of the use before date (UBD) is completely human depandable suing the 100% visual inspection method. The solution to this failure is to implement an automatic verification. The pick by light system include the automatic verification by the software.

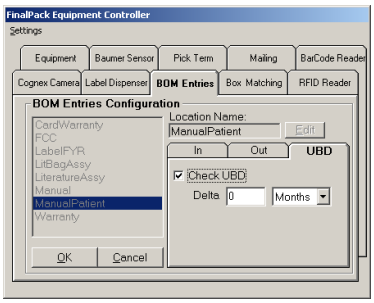

Figure 9
UBD automatic inspection setup windows

• **Missing literature** – The major problem is when an incorrect or missing literature. This offender or failure of the current system is due to the human dependability. In order to eliminate this failure the pick by light system will be implemented. This system indicate the operator the correct literature to choose and will consume by scanning the part number of the literature to assure the correct literature is place in the right box.

Figure 10
Process window for scanning the correct literature

• **Wrong UPN –** This failure is very importat due to the severity and risk to the patient. The solution is to implement an automatic inspection with a telemetric system that will match the outer label information with the internal product in a new process of post sterilization test (PST).

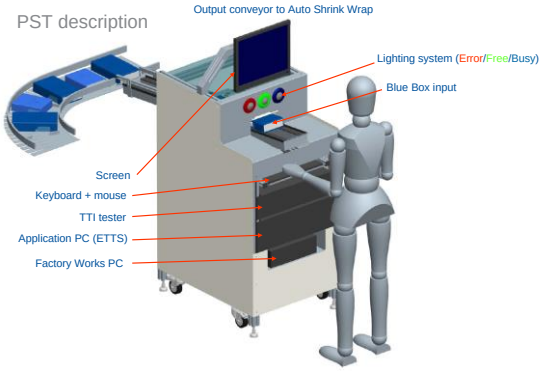

Figure 11
PST Description

After doing the analysis a root of causes was founded and the team does recommendation to improve the problem of escapes. The table 2 shows the economic analysis.

Table 2
Economic Analysis

Category	Current Scenario (*)	Phase I Pick to Light
Capital Investment	-	$620k
Product applications	All	All
Daily Output Devices	1,800 @ 27sec takt time	2,000 @ 25sec takt time
HC Req.	36	28
Productivity Units / DL	50 units	71 units ~42%
ECD	-	Q2 FY13

The economic analysis shows the reduction of eight (8) operator that induce to reduce the head count of the company, this produce a decrease in the operational cost. Also shows a high increase of productivity by increasing the output of the new lines. The figure 12 shows the new layout with the pick by light system. This new layout will allow increase the efficiency of the lines since the process is one piece flow.

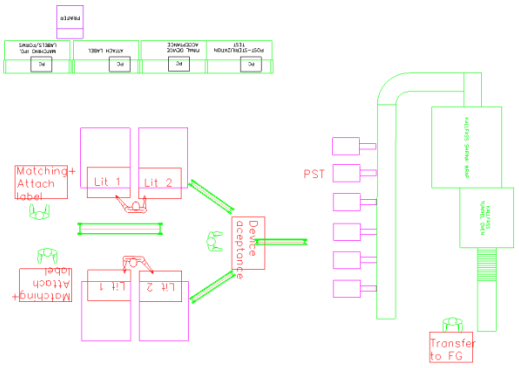

Figure 12
New Layout

Control

The main goal of this phase is to hand off and delivers to the management the control of the improvement done. An implementation plan was prepared as a guidance to complete several tasks. The before and after analysis compare how the project began and the current state of the project. The main problems identified were the mix label and literature missing. The following item will be held in order to sustain the improved process.

- Weekly meeting with Core Team
- Monitor the project updates and reference documentation.
- Project Charter review and agreement between global facilities.
- Work Package Team structure to support project.
- Kaizens meetings and follow-up for labels inspections, parts loading and product segregation.

This plan above is used to ensure the team is making satisfactory progress to the project goals. After the implementation of the strategies presented in the implementation plan, it is important to monitor the progress of the line after these improvements are in place and running. The goal of the monitoring, control and sustain plan is to ease data gathering in order to attain improvement plan's due dates. Implementation can't take place before monitoring how the line is going to be affected by these changes.

CONCLUSION

Manufacturing logistics was improved by implementing the pick by light system a lean manufacturing technique. This system enables the manufacturing companies to automatize the packaging process and inspections instead of depend of the manual process. With a simple change in the system the benefits are:

- The new Packaging line will improve the quality control preventing labeling mix up and missing components. In turn lean initiatives would optimize resources utilization.
- Standardization within the global site plants
- Productivity improvement in Final Pack area
  - Lower lead time
  - Reduction in raw material inventory

- Increased output 42% (lower head count requirements)

During this project the team identifies the real causes of the escapes in the manual packaging line and the improvement was done giving satisfactory results to the company decreasing the quality issues 100%. Before all implementations the escapes of the main offenders was around 14, after implementation the escapes decrease impressively to 0.

The main problem identified were the human dependable in the literature assembly, visual inspections, and non-automatized system. These caused the high amount of escapes and complaint in the field. With the help of additional data the potential causes for these defects were addressed. The causes mentioned above, including the development of an improvement plan, where the causes were strategically organized, based on the results of the prioritization matrix developed in the improvement phase. It is important to monitor the progress of the line after these improvements are in place and running. After two (2) months of project the goal in terms of escapes reduction was achieved.

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