Output Improvement for a Blister Packaging Line using Lean/Six Sigma

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Abstract *— With the pass of the years industries are looking to reduce costs associated to packaging process. In the packaging line analyzed for this project product is packed in blister cells at primary packaging by two blistering machines. Since January 2010, Product A packaging process average output is 44 blisters per minute. The objective of this project is to improve the packaging output and consistently achieve a takt rate of 46 blisters per minute with one blistering machine. Lean Six Sigma Methodology and tools were used to drive the project, analyze data, document results and establish the controls to sustain the improvements. Some of the tools used were: SIPOC, Voice of the Customer, Cause & Effect Diagrams, Control Charts and Analysis of Variance. As project results, objectives were met by increasing packaging takt rate from 44 to 46 blisters per minute and reducing process variability by 45% with one blistering machine.*

Key Words *– Blister Packaging, Primary Packaging, Secondary Packaging, Six Sigma.*

PRODUCT BACKGROUND

Product A is an antiparasitic manufactured by the animal health division of a pharmaceutical company located at the north shore of Puerto Rico. It is traditionally used to prevent the heartworm disease on canines.

The heartworm disease in canines is caused by infected mosquitoes that bite the dogs and introduce the heartworm larvae in the dog's skin. Larvae migrates and reach the dog's heart through bloodstream were they spend their adult life. An adult heartworm can grow up to 12 inches and cause severe damage to dog's health.

Product A is a monthly treatment for the heartworm disease manufactured with beef. Some of its principal ingredients include proteins, antioxidants glucose, animal fat, corn, and salt. The end to end manufacturing process at Puerto Rico plant includes dispense of raw material, manufacturing, and packaging process all in one building.

RESEARCH DESCRIPTION

Since January 2010 the Product A packaging process average output is 44 blisters per minute with two blistering machines. Crews are working during the weekend increasing packaging cost, but this has not been enough to meet the required takt rate of 46 blisters per minute with one blistering machine.

RESEARCH OBJECTIVES

Consistently achieve in average 22,000 blisters per shift (takt rate = 46 blisters per minute) with one blistering machine by second quarter 2010. Reduce process variability associated with the change in product presentations, equipment downtime, and non-standardized work.

RESEARCH CONTRIBUTIONS

The company will be able to supply product demand without incurring in overtime cost. This will contribute for a line efficiency of $93,600. It will reduce inventory levels of finished product waiting to be packed and reduce the probability to exceed expiration dates.

The packaging output improvement reduce the product lead time, assures that the customer receive orders on time, and result in a positive impact on customer service metrics. Improvements will make the packaging area able to absorb unexpected changes in demand as demand increases when customer requires. Also, it will increase the client interest in doing business with the Puerto Rico site.

Product Background

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Packaging Functions

Packaging has four primary functions, contain, protect/preserve, inform/sell, and transport. All of these functions can be found in a single package of any product. The contain function is designed based in the product nature or physical form. It is the primary packaging of the product. Product A physical form is classified as a solid unit and from a perishable nature. Contain refers to protect the environment from the product been packed. Protect/preserve functions are more related to protect the product from the environment. "Protect" refers to the prevention of physical damage, while "preserve" refers to stopping or inhibiting chemical and biological changes." [5] For Product A the primary packaging is a plastic blister sealed with aluminum foil. The blisters cover the containment and protect/preserve functions.

The inform/sell function is covered by the secondary packaging. This function treats to reach customers by captivating their attention. The package design, fonts, colors or illustrations used on labels and, in addition, the package shapes must be in accordance with the targeted audience that the product is developed for. Product A secondary packaging emphasize animal health by presenting illustrations of healthy pets. This way customer can be attracted and motivated to buy the product.

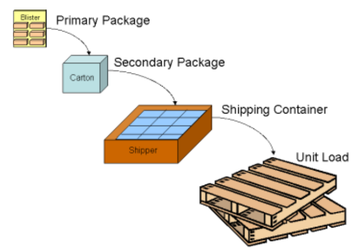

Figure 1
Packaging Levels

Products packaging needs to take in account the transportation function. This function also takes in account that the product could be stored in warehouses before reach its final destination. The movement of products from the point of production to the point of final consumption involves various transport modes, handling techniques and storage. "Transport and distribution is generally regarded as an activity that is hazardous to the product being moved." [5] For that reason the packaging needs to protect the product against unsafe conditions such as excessive external forces or environmental conditions. Product A is collected in trays of ten units, wrapped and then packed in corrugated shipping containments that provide the protection needed for transportation purposes. The four packaging functions of Product A packaging are presented in Figure 1.

As discussed in this section product packaging is intended to contribute to the product life after it leaves the production site. It is as important as any other manufacturing activity and is focused in preserve the product until it reaches the customer.

Unfortunately, after consumers get the product, packages are garbage. For that reason the packaging industry is highly regulated and it is a real challenge to achieve companies intended packaging functions and complies with federal and local regulations at the same time.

LEAN MANUFACTURING

Lean or lean manufacturing, according to a widely accepted definition, is "a systematic approach to identify and eliminating waste (non-value-added activities) through continuous improvement by flowing the product at the pull of the customer in pursuit of perfection." [3] Lean philosophy seeks to eliminate waste along all supply chain. It looks for waste in manufacturing processes, management, systems, inventory, customer relations, supplier networks, services, and so on.

Waste is classified in seven types: overproduction, motion transportation, processing, wait, defects, and inventory.

- **Transportation waste:** is related to moving products or anything else during the production process.
- **Inventory:** Accumulate excess of material in the shop floor between operations or in warehouses.
- **Motion waste:** refers to unnecessary or dangerous moving of workers.
- **Processing waste:** unnecessary process steps that add no value for the customer.
- **Waiting time:** been idle while machines are running or waiting for the previous or next operation.
- **Defects:** defective products incur cost, deplete resources, and negatively impact customer perception.
- Over**production waste:** is to produce more products than required by next process or before the customer require.

By eliminating waste companies cut their operational costs and make their products more accessible to customers at the same time that the company turns more competitive.

SIX SIGMA

Six Sigma has three meanings, first it is a level of quality, second it is a problem-solving methodology, and third is a management philosophy. Sigma is a measure of variation and is used to denote the standard deviation of a sort of values. Achieve a six-sigma level of quality in a process means that it is producing only 3.4 defects per million of opportunities. As a problem-solving methodology focuses in eliminate root causes of defects and it associated cost. It generally consists of five phases: Define, Measure, Analyze, Improve, and Control (DMAIC). As management philosophy Six Sigma focuses in customer satisfaction. "It's a customer based approach that recognizes that defects decrease satisfaction and customer loyalty and increase costs." [3] Six Sigma and DMAIC methodology is used for the packaging output improvement as a problem-solving methodology to be followed.

METHODOLOGY

This chapter describes the DMAIC methodology used to achieve the output improvement desired for Product A packaging lines. The tools used in each part of the methodology are also discussed as well as the events prepared to collect data, analyze it, and determine process changes. This chapter includes from the definition of the packaging line current state to the construction of the desired future state and how to close the gap between the two states.

- **Define Phase:** consist of determine de purpose, objectives, and scope of the project. Its purpose is to have the team and sponsors agreement on the project. It is important to define the project in order to collect the correct information from the customers and the process. In this stage a Project Charter needs to be develop to resume the what, who, when, how, and why the project is been developed.

Other tools used in this phase are:

Supplier-Input-Process-Customer-Output (SIPOC) Diagram – Is created to define and map the core business process on which the project will focus. SIPOC helps to map the current state of the process.

Voice of the Customer (VOC) – Customers are interviewed to recollect their expectations and worries about the project impact on the packaging area. The exercise of VOC will be practiced with personnel directly affected by the results of the process improvement. Personnel from departments such as Quality, Planning, Customer Service, Production, and Safety will be interviewed. The VOC also helps to start mapping how the future state of the process should be as we identify the critical requirement of the customers.

Critical to Quality Tree (CTQ Tree) – The information collected in the VOC is categorized as critical to quality, critical to delivery, and critical to price. This way the project can focuses on those specific requirements from the customers that needs to be meet.

- **Measure Phase:** The purpose is to thoroughly understand the process current state and collect reliable data to be used to expose the causes of problems. In this phase is important to develop a Data Collection Plan and a Measurement System Analysis (MSA). The Data Collection Plan will be used to clarify the data collection goals and determine what, where, when, by who, and how many data will be collected. MSA is to determine if the data been collected is accurate and stable. Reliable data will tell the truth about the process and will be used as a base to make decision.

Other tools used in this phase to understand and analyze data are:

Detailed Process Map – defines the current process and capture process data. Presents information about work in process (WIP), downtime, processing rates, setup time, etc.

Data analysis – compare data between different classifications and process scenarios to help understand and locate areas of opportunities.

- **Analyze Phase:** In this phase problems affecting the key input and output variables are verified. A Cause and Effect Diagram is developed to classify all possible opportunities (problems). Opportunities are classified as they are related to methods, measurements, environment, equipment, people, and materials. Then narrowed down by been reclassified as the specific need to act on in an Affinity Diagram and prioritized using an Prioritization Matrix in terms of process impact and effort. Once all opportunities are prioritized, the ones with more impact on the process and less effort are selected. A 5 Why's exercise is developed to find the root causes of each opportunity and determine an action to mitigate the cause.
- **Improve Phase:** In the improve phase all actions selected as potential solutions in the previews phase are developed. Process performance is measured to monitor the improvement and assure that it sustain. Overall benefits are quantified as part of this phase.
- **Control Phase:** During the control phase procedures are designed to maintain the gains. It is important to assure that every improvement is sustained. The performance needs to be monitored to be aware of any change. For that reason a control plan is developed to specify points to be measure, by whom, where, when, decision rules and corrective actions in case that the process needs to be corrected. Then the process can be hand off to the process owner.

RESULTS AND DISCUSSION

Define stage consist of determine de purpose, objectives, and scope of the project. It is important to define the project in order to collect the correct information from the customers and the process. In this stage a Project Charter needs to be develop to resume the what, who, when, how, and why the project is been developed.

For the Product A packaging line output improvement a project charter was developed to provide answers to some of those questions. Figure 2 shows the Project Charter.

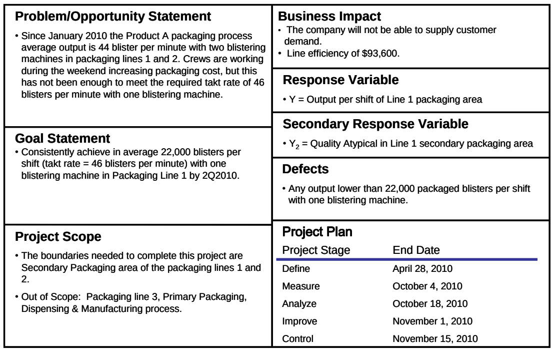

Figure 2
Output Improvement for a Blister Packaging Line using Lean/Six Sigma Project Charter

In this phase a Supplier-Input-Process-Customer-Output (SIPOC) Diagram, as showed in Figure 3, was created to define and map the core business process on which the project will focus. SIPOC helps to map the current state of the process and also the initial measurement goals.

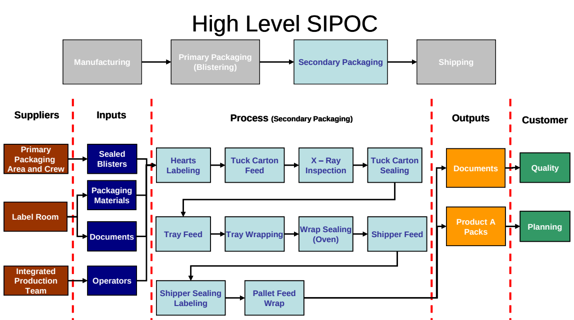

Figure 3
Product A Packaging Output Improvement Project SIPOC Diagram

After define the project focus and use the SIPOC to map the process, customers are interviewed to recollect their expectations and worries about the project impact on the packaging area. The exercise of Voice of the Customer (VOC), showed on Table 1, has been practiced with personnel directly affected by the results of the process improvement. Personnel from departments such as Quality, Planning, Customer Service, Production, and Safety were interviewed. The information collected was used to identify what things are critical to their satisfaction. The VOC also helps to start mapping how the future state of the process should be as we identify the critical requirement of the customers. A summary of the VOC is shown in the next table. The critical to satisfaction requirements are shown in Figure 4.

Table 1
Voice of the Customer for Product A Packaging Output Improvement Project

Voice of the Customer High-Level Need	Service/ Quality Issue	Specific Needs Statement
• Identify problems before they occur. • Behavior that protect the equipment	• Minimize downtime	• Increase production uptime.
• Frequent customer complaints about blisters with empty cavities or shot Product A cubes and empty boxes.	• Minimize secondary packaging defects.	• Minimize discards related to empty cartons.
• We need to assure that safety and ergonomic are sustained.	• No safety reports.	• No safety events.
• Include operators. • Use of video camera so operators can watch themselves and bring ideas. • Give feedback to operators.	• Communication.	• Communica -tion plan during project implementa-tion.
• We need to guarantee the contrated demand with the customer of 2.1 million units/month + 237,832 units of international markets per month. The expectation is that Packaging Line 1 produce at least 28,360 unit/shift. • We need to cover the backorders.	• Maximize Output	• Increase packaging rates.

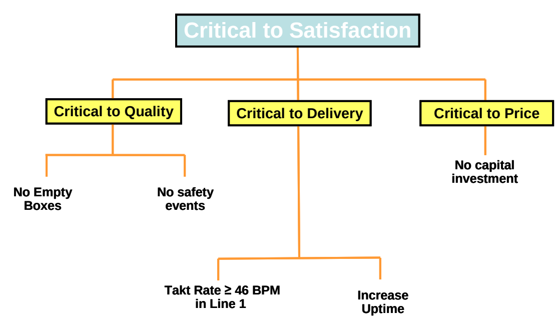

Figure 4
Critical to Quality Tree

During the measure phase a data collection plan is developed to thoroughly understand the process current state and collect reliable data. Data will be used to expose the causes of problems. The Data Collection Plan on Figure 5 will clarify the data collection goals and determine what, where, when, by who, and how many data will be collected.

Clarify Data Collection Goals				Operational Definitions and Procedures	
Measures	Measure Type	Data Type	Purpose of Collection	What	How
Y1: Output per shift of Product A packaging area.	6x Blister units	Discrete	To measure the current performance and improve process.	The quantity of Product A blisters packed in shippers at the end of each shift without changeover.	Supervisor perform manual data entry of output quantities at the end of each shift to an Excel spreadsheet.

Operational Procedures for Collection and Recording				
What	Where	When	Who	How Many
Output per shift will be plotted with weekly data points.	Data collected from Packaging Output Excel Spreadsheet.	Weekly rollup of output per shift data and average output per week, representing Monday through Sunday.	Packaging Supervisors manually enters the output data in an Excel spreadsheet.	All output of shifts that do not run a change over.

Method of Validating Measurement System
Data is part of packaging records and are submitted to GMP audits.
MSA was validated on the shop floor. Output rates per hour and outputs per shift were observed and compared with data documented from April 13 to May 7, 2010. Data was accurate and correctly recorded.

Segmentation Factors
Data Segmentation: By shift, group and week.

Figure 5
Data Collection Plan for Product A Packaging Output

Measure System Analysis (MSA) is to determine if the data had been collected is accurate and stable. Reliable data will tell the truth about the process and will be used as a base to make decision. For Product A data is part of packaging records and are submitted to GMP audits. MSA was validated on the shop floor. Output rates per hour and outputs per shift were observed and compared with data documented from April 13 to May 7, 2010. Data was accurate and correctly recorded. By knowing that data is correct data can be carefully studied and accurate conclusions can be made.

Histogram on Figure 6 shows how Product A output behaves. The P-value of 0.451 (P-value > 0.05) presents that Product A packaging output follows a normal distribution. Output mean is 21,389 units per shift with two blistering machines.

The output mean of 21,389 units is 6,611 units per shift away from the Profit Plan of 28,000 units per shift with a crew of 19 operators working in the packaging line. A standard deviation of 6,590 units per shift it's observed in the current line output. Graphical analysis shows that a reduction of process variability is needed.

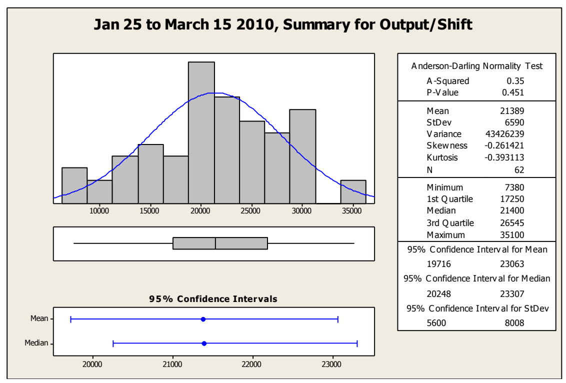

Figure 6
January 25 to March 15, 2010 Baseline Graphical Summary

Data segmentation by product presentation and operators group gives the capacity to analyze the behavior of each presentation (6X and 12X) for each market and each group (A, B or C). Packaging line highest volumes are 6X and 12X doses for United State market, for that reason the project will concentrate on US market. ANOVA analysis on Figure 7 shows the difference between US 6X and 12X presentations.

Hypothesis for the Product A presentation analysis are:

- H0: All mean outputs are equal. (µUS12x = µUS6x)
- Ha: At leas one mean output is different.

```
One-way ANOVA: Product A Output versus Presentation

Source    DF          SS         MS     F      P
Market_1   1   175516432  175516432  4.49  0.038
Error     58  2267396722   39093047
Total     59  2442913154

S = 6252   R-Sq = 7.18%   R-Sq(adj) = 5.58%

                          Individual 95% CIs For Mean Based on
                          Pooled StDev
Level   N   Mean  StDev  -------+---------+---------+---------+-
US12x  16  18825   7559  (-----------*------------)
US6x   44  22693   5727                      (-------*------)
                         -------+---------+---------+---------+-
                            17500     20000     22500     25000

Pooled StDev = 6252
```

Figure 7

One-way ANOVA: Product A Output versus Presentation

From the ANOVA P-value of 0.038 (P-value < 0.05), we can conclude that at one market presentation is statistically significantly different from the other. However, they appear to be statistically different but there is not enough data from US 12x outputs to thrust in this result. Also, an overlap in the range of data from US 6X and 12X is observed. For that reason both market presentations are going to be treated the same.

There are tree operators group that work in the packaging lines, one group for each shift. Next ANOVA analysis on Figure 8 compares the groups versus the output per shift of each one.

Hypothesis for the group analysis are:

- H0: All mean outputs are equal. (µA = µB = µC)
- Ha: At leas one mean output is different.

P-value for Product A Output versus Groups ANOVA analysis is 0.820 (P-value > 0.05), we can conclude that there is no enough data to reject H0.

```
One-way ANOVA: Product A Output versus Groups

Source  DF          SS        MS     F      P
Group    2    17794331   8897166  0.20  0.820
Error   59  2631206237  44596716
Total   61  2649000568

S = 6678   R-Sq = 0.67%   R-Sq(adj) = 0.00%

                           Individual 95% CIs For Mean Based on Pooled StDev
Level   N   Mean  StDev   --+---------+---------+---------+--------
A      20  21928   6339         (--------------*--------------)
B      21  20664   8053   (-------------*--------------)
C      21  21601   5342       (--------------*--------------)
                          --+---------+---------+---------+--------
                         18000     20000     22000     24000

Pooled StDev = 6678
```

Figure 8

One-way ANOVA: Product A Output versus Groups

A detailed process map was built to define the current process and capture process data. Information about downtime, processing rates, and quantity of operators is presented in Figure 9.

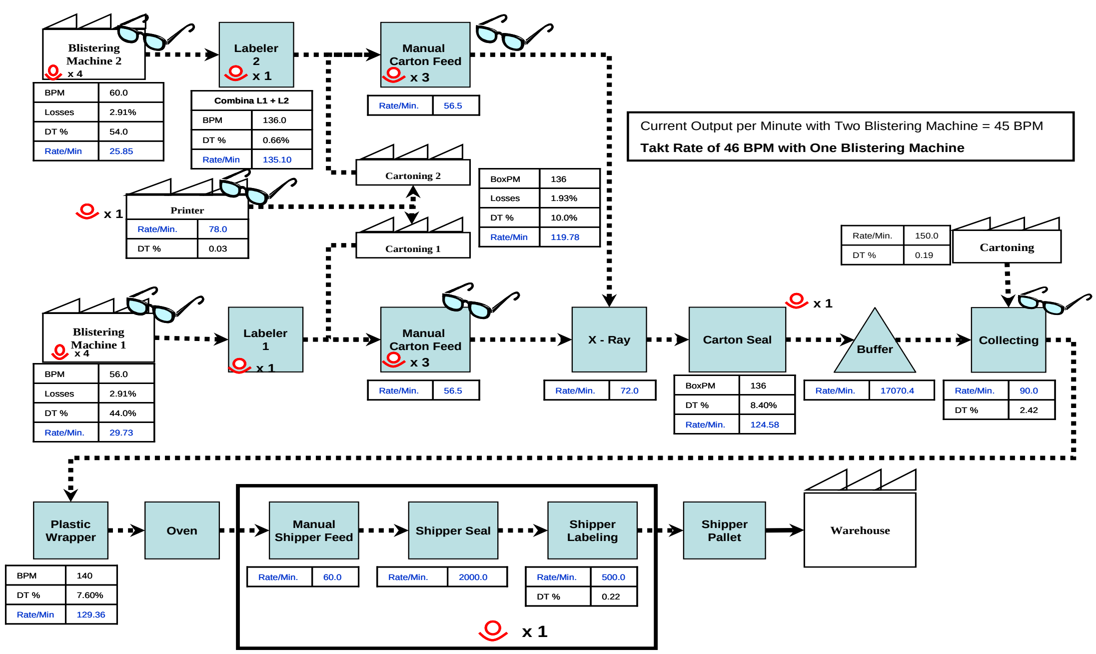

Figure 9

Product A Packaging Line Detailed Process Map

Product A Packaging Line detailed Process Map above presents areas of opportunities were process step do not meet the requirements to achieve desired takt time or steps that add variability to the packaging line output.

The analyze phase use different tools to identify problems affecting the key input and output variables. An opportunities cause and effect are studied to be classified, narrowed down and prioritized. Root caused and solutions to these causes are determined in this phase to mitigate problems.

Opportunities are classified as they are related to methods, measurements, environment, equipment, people, and materials (Figure 10). An affinity diagram on Figure 11 was used to reclassify and narrow down the causes to packaging line specific needs. Using a prioritization matrix in terms of process impact and effort, specific needs were classified and ordered to develop an action plan that will mitigate problems root causes.

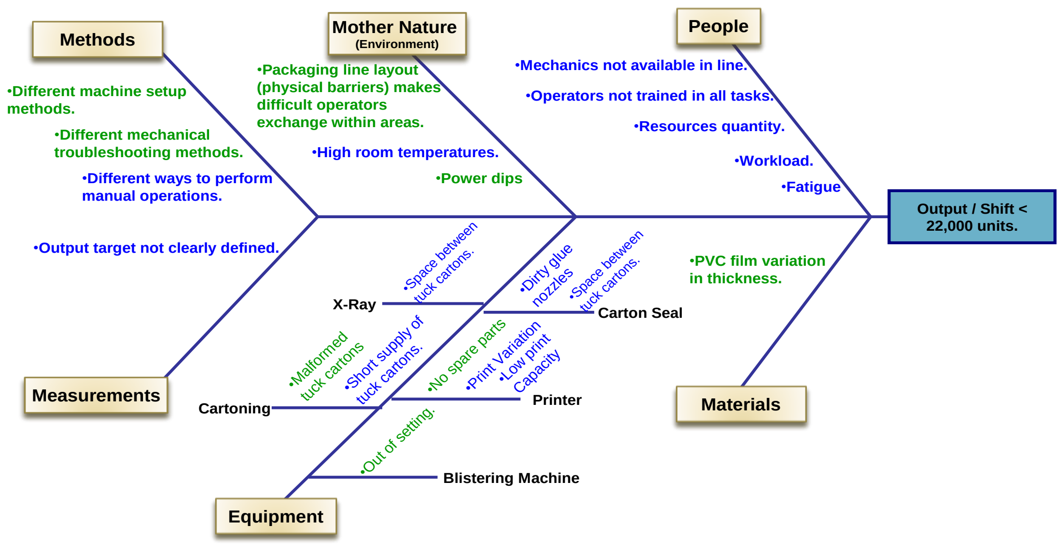

Figure 10
Cause and effect Diagram

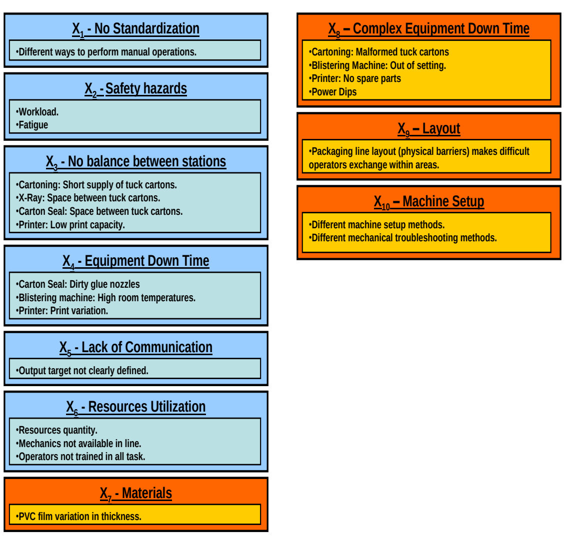

Figure 11
Affinity Diagram

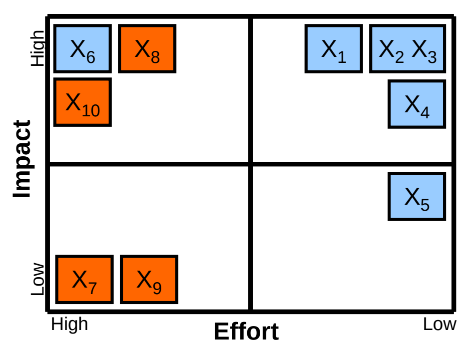

Figure 12
Prioritization Matrix

Opportunities were narrowed down from 22 to 10 common opportunities using the affinity diagram. They were classified as:

- No standardization.
- Safety hazards.

- No balance between stations.
- Equipment downtime.
- Lack of communication.
- Resource utilization.
- Materials.
- Complex equipment downtime.
- Layout.
- Machine setup.

From those 10 opportunities the team decides to work in 6 (blue boxes in Figure 11 and 12) based on the impact and effort matrix, showed in Figure 12. Cause number 6, resource utilization, was classified as a high effort item to work on it. In order to have a standardized process the cause was chosen to be part of the action plan.

A 5 Why? exercise was performed to get to the root cause of each opportunity. An action was determined to each root cause. Table 2 presents the 5 Why? exercise for each opportunity and their respective actions.

In the improve phase all actions selected as potential solutions in the Analyze phase were developed. Process performance was measured to monitor the improvement and assure that it sustain. Figure 13 shows the improvement in packaging output and variability reduction.

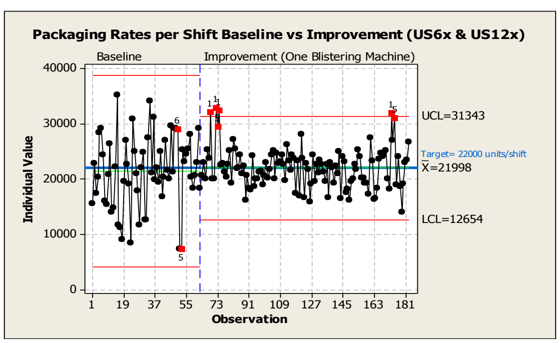

Figure 13
Packaging Output Baseline vs. Improvement Control Chart

A One-way ANOVA analysis was performed to compare the output means of baseline data against the improvement data. Hypothesis for the output analysis were:

- H0: Baseline and One Blistering Machine output means are equal ($\mu 1 = \mu 2$)
- Ha: Baseline and One Blistering Machine output are different ($\mu 1 \neq \mu 2$)

One-way ANOVA: Baseline vs. One Blistering Machine

```
Source   DF          SS        MS     F      P
Factor    1    15211663  15211663  0.66  0.419
Error   181  4197554304  23190908
Total   182  4212765967

S = 4816   R-Sq = 0.36%   R-Sq(adj) = 0.00%

Level           N   Mean  StDev
Baseline       62  21389   6590
One Klockner  121  21998   3592

              Individual 95% CIs For Mean Based on Pooled
     StDev
Level            --+---------+---------+---------+-------
Baseline         (-----------------*----------------)
One Machine                   (-----------*------------)
                 --+---------+---------+---------+-------
              20300     21000     21700     22400
Pooled StDev = 4816
```

Figure 14
One-way ANOVA: Output Baseline vs. One Blistering Machine

The ANOVA analysis on Figure 14 shows a P-value of 0.419, indicating that there is not enough evidence to reject H0. That indicates that after the improvement actions were performed, the packaging output was sustained with only one blistering machine.

A considerable reduction in output variation was achieved. A test for equal variances was performed to compare Baseline and Improvement (one blistering machine) process variation. Hypothesis for the variation analysis were:

- H0: Population (process) $\sigma 1 = \sigma 2$ (variances equal)
- Ha: Population (process) $\sigma 1 \neq \sigma 2$ (variances not equal)

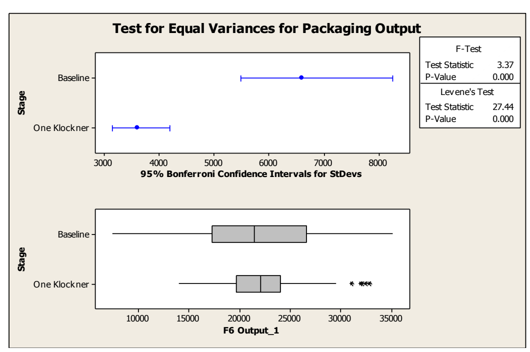

Figure 15
Test for Equal Variances for Packaging Output

The Test for Equal Variance on Figure 15 shows that with a P-value of 0.000 there is enough evidence to reject H0. There is a difference between baseline and improved process variation.

The overall benefits were quantified as part of this phase. The packaging output per shift was quantified as showed in Figure 16.

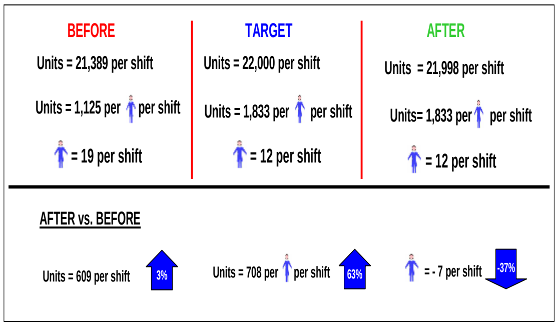

Figure 16

Packaging Output and resource Utilization Improvement

Saving in line efficiency was calculated as follows:

Packaging Output: 21,998/21,389 = 102.8% of the output:

- 19 operators produce 21,389 units
- 12 operators produce 19,943 units
- (102.8%) x (19 op.) = 20 operators are the expected to produce 21,998 units.
- 20 – 12 = 8 operators saved per shift
- (# impacted months/total month per year)(working hours per year)(labor rate)(operators saved per shift)(# shifts) = (3/12)(2,080)($10)(8)(3) = $124,800 line efficiency.

Table 3

Packaging Output Improvement Project Control Plan

Process	Sub Process Step	CTQ		Specification Characteristic	Specification/ Requirement	Measurement Method	Sample Size	Frequency	Who Measures	Where Recorded	Decision Rule/ Corrective Action	SOP Reference
		KPOV	KPIV		USL LSL							
X1 - No Standardization	Tuck Carton Station		x	12 operators/shift	Line Takt Rate = 49 BPM	Tier 1	Shift Output	Every Shift	Supervisor	Tier 2	< 12 operators/shift covering coordination	N/A
X2 - Safety Hazards	Packaging		x	12 operators/shift	Line Takt Rate = 49 BPM	Tier 1	Shift Output	Every Shift	Supervisor	Tier 2	< 12 operators/shift covering coordination	N/A
X3 - No Balance Between Stations	Packaging		x	12 operators/shift	Line Takt Rate = 49 BPM	Tier 1	Shift Output	Every Shift	Supervisor	Tier 2	< 12 operators/shift covering coordination	N/A
X4 - Equipment Downtime	Packaging		x	12 operators/shift	Line Takt Rate = 49 BPM	Tier 1	Shift Output	Every Shift	Supervisor	Tier 2	Glue level and machine speed vs guide rails. / Mechanic	N/A
X5 - Lack of Communication	Packaging		x	12 operators/shift	Line Takt Rate = 49 BPM	Tier 1	Shift Output	Every Shift	Supervisor	Tier 2	Outdated boards. / Supervisor	N/A
X6 - Resource Utilization	Packaging		x	12 operators/shift	Line Takt Rate = 49 BPM	Tier 1	Shift Output	Every Shift	Supervisor	Tier 2	< 12 operators/shift covering coordination	N/A

During the control phase procedures are designed to maintain the gains. It is important to assure that every improvement is sustained. The performance needs to be monitored to be aware of any change. For that reason a control plan is developed to specify points to be measure, by whom, where, when, decision rules and corrective actions in case that the process needs to be corrected. Then the process can be hand off to the process owner. Table 3 presents the control plan for the Product A packaging output improvement project.

Conclusions and Recommendations

Based on the results of the actions implemented for the project improvement phase we can conclude that the packaging line output consistently achieve in average 22,000 blisters per shift (takt rate = 46 blisters per minute) with one blistering machine. The process variability associated with the change in product presentations, equipment downtime, and non-standardized work was reduced by 45.5 %.

The company will be able to supply product demand without incurring in overtime cost. This will contribute for a line efficiency of $93,600. It will reduce inventory levels of finished product waiting to be packed and reduce the probability to exceed expiration dates. Crews are going to be able to complete the weekly output targets from Monday to Friday without having to work during weekend improving their quality of life.

It is highly recommended that the company applies this improvement project to the rest of the packaging lines since they use similar machines and processes. The investment is minimums and the benefits in process efficiency are notable.

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