Quality Sampling Plan Re-Design for Secondary Packaging Operation for the Graduate Program at Polytechnic University of Puerto Rico

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Abstract *— A significant decrease in the lot size has been observed year to year and volumes expected to increase by mid2021. Therefore, there was the need to evaluate alternatives to enhance the current Quality Assurance (QA) Inspection Regime to provide flexibility to the Secondary Packaging Operations. As part of the evaluation, sampling plan alternatives for the Cosmetic Defect inspection were evaluated, which can accommodate lot size variations, provide flexibility to meet service needs and avoid or minimize recruitment of further personnel because of expected volume increase. To archive this goal, it was required a reduction of 30% of the current cycle time for the QA audit process.*

Using lean manufacturing principles and DMAIC methodology to develop this project, a reduction of a 62% in cycle time during the QA audit process was obtained. The implementation of this project exceeded the objectives of the project, sustaining the existing Quality Standards.

Key Terms *— Sampling Plan, DMAIC, Quality Assurance audit, and Statistics.*

PROBLEM STATEMENT

As part of the Secondary packaging process for a Medical Device Manufacturing Company it is required by regulation that a Quality Assurance (QA) audit is performed for each lot prior release as part of the final disposition process. This QA audit currently required an inspection of 13 samples per lot taken strategically (samples must represent the beginning, the middle and the end of the lot) for visual inspection (attribute/cosmetic defects) to assure product compliance. However, this QA audit can impact in the time for the product final disposition due to increase in volume, therefore, the improvement of this QA audit method can enhance the Secondary Packaging Operation.

RESEARCH DESCRIPTION

In this company during the Secondary Packaging Operation, the QA audit process can be identified as a "bottle neck" activity which could impact the release process due to currently inspection methodology and cycle time variation.

RESEARCH OBJECTIVES

This project pretends to determinate the adequate cycle time for the QA audit process, also determinate which factors or variables can directly affect the cycle time and identify the opportunities to improve the QA audit methodology. Reduction of 30% of the current cycle time.

RESEARCH CONTRIBUTION

The main contribution that can be provided by this research is to release the finished product faster assuring product compliance and fulfilling the customer order requirement on time.

LITERATURE REVIEW

Lean Six Sigma tools are commonly used in several industries such as healthcare, technology, financial services, manufacturing, etc., for improving their current processes. Lean six sigma decreases organizations cost by removing "Waste" from a process; waste is any activity within a process that is not required to manufacture a product or provide a service that is up to specification and solving problems caused by a process, in which problems are defects in a product or service that cost the organization money.

Lean Six Sigma not only increases revenue and reduces costs, but it also positively affects people by engaging them in improving the way they work. Since employees are the closest to the actual work of any organization, they become the best resources to understand how to improve the efficiency and effectiveness of business processes. By participating in successful Lean Six Sigma projects, employees can build the confidence and develop the capability to become your business most important assets. Studies show that when employees feel that they have a positive effect on the organization, they perform better, are more accountable and live happier lives [1].

For this project DMAIC methodology will be used to provide structure and assure a solution for the opportunity identified. DMAIC stands for Define, measure, analyze, improve, and control, is a data-driven quality strategy used to improve processes. The letters in the acronym represent the five phases that make up the process, including the tools to use to complete those phases shown in Figure 1. It is an integral part of a Six Sigma initiative, but in general can be implemented as a standalone quality improvement procedure or as part of other process improvement initiatives such as lean [2].

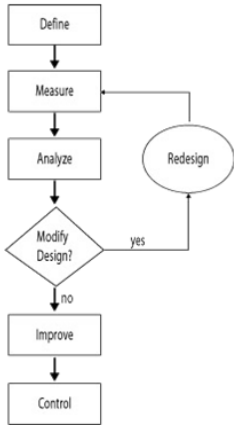

Figure 1
DMAIC Methodology [2]

As follow it is described the DMAIC process [2]:

1. Define the problem, improvement activity, opportunity for improvement, the project goals, and customer (internal and external) requirements.
   - Project charter to define the focus, scope, direction, and motivation for the improvement team.
   - Voice of the customer to understand feedback from current and future customers indicating offerings that satisfy, delight, and dissatisfy them.
   - Value stream map to provide an overview of an entire process, starting and finishing at the customer, and analyzing what is required to meet customer needs.
2. Measure process performance.
   - Process map for recording the activities performed as part of a process; can use SIPOC diagram, which is a tool that allows a team to see their process in relation to all needed inputs, outputs, and suppliers.
   - Capability analysis to assess the ability of a process to meet specifications.
   - Pareto chart to analyze the frequency of problems or causes.
3. Analyze the process to determine root causes of variation and poor performance (defects).
   - Root cause analysis (RCA) to uncover causes.
   - Failure mode and effects analysis (FMEA) for identifying possible product, service, and process failures.
   - Multi-vari chart to detect different types of variation within a process.
4. Improve process performance by addressing and eliminating the root causes.
   - Design of experiments (DOE) to solve problems from complex processes or systems where there are many factors influencing the outcome and where it is impossible to isolate one factor or variable from the others.
   - Kaizen event to introduce rapid change by focusing on a narrow project and using the ideas and motivation of the people who do the work.

5. Control the improved process and future process performance.
    - Quality control plan to document what is needed to keep an improved process at its current level.
    - Statistical process control (SPC) for monitoring process behavior.
    - 5S to create a workplace suited for visual control.
    - Mistake proofing (poka-yoke) to make errors impossible or immediately detectable.

METHODOLOGY

Using DMAIC methodology will assure the achievement of the research objectives, providing structure and a solution for the opportunity identified. Following DMAIC, as part of the "DEFINE" phase, the problem is identified to stablish adequate actions to improve current process. The company have seen an increase in the packaging volume but a decrease of the lot sizes, therefore, there is going to be more volume and more lots for final inspection. The current QA audit needs to be improved by reducing the cycle time inspection by a 30%. Then as part of the "MEASURE", a process map will be developed by using SIPOC diagram (Figure 2) to evaluate the relation to all needed inputs, outputs, and suppliers. Also, data gathering regarding the current cycle time, for capability analysis and pareto chart to evaluate tendencies. Data regarding business forecast will be evaluated to assure process capability.

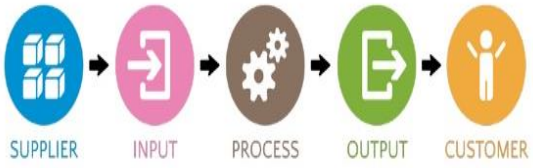

Figure 2
SIPOC Diagram [1]

After gathering all the necessary data, will enter under "ANALYZE" phase, in which all data will be evaluated to identified potential root cause by using problem solving tools such as cause-and-effect or Fishbone analysis diagram (Figure 3). Fishbone analysis diagram is a simple tool that is used by Six Sigma professional to understand the root cause of a problem. By this technique it can identify the areas due to which the quality is not achieved.

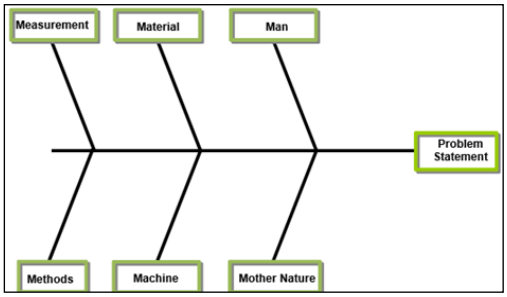

Figure 3
Fishbone Diagram

Then once the root cause is identified will proceed with the "Improve" phase in which the implementation of the corrective action is completed to address and eliminate the root cause of the problem. Since this change need to be implemented, a tool that can help with the implementation will be a Kaizen event to introduce rapid change using the ideas and motivation of the people who do the work. After completing the implementation, then it is proceeded to the last phase "Control"; in this phase it is important to control the improvement done to correct the problem and assure that it is follow for future process execution, therefore, actions such as standard operation procedure (SOP) change, training to personnel, QA audit release application will be update with new inspection plan to simplify quality operators' activities and assure compliance with new process.

As part of the research schedule, Table 1 present the proposed plan:

Table 1
Research Schedule Plan

Item	Milestone	Estimated due date
1	Define	Sept. 30, 2020
2	Measure	Nov. 30, 2020
3	Analyze	Feb. 28, 2021
4	Improve	Mar. 31, 2021
5	Control	Apr. 30, 2021

RESULTS AND DISCUSSION

QA Audit for cosmetic defect inspection as part of the release process in the Secondary Packaging Operation required the following sampling plan: Sample Size (n) = 13; A = 1 / R = 2 (for minor defects) A = 0 / R = 1 (for major and critical defects). As part of the Measure phase of the project, the current cycle time was measured for the QA Audit process. Per Table 2, the QA Audit process has a total average time of 8 minutes/lot.

Table 2
Current Cycle Time for QA Audit Process

Time Study	Observations (mins)					
Lots	1	2	3	4	5	Average time (mins)
Operator Shift A	8.0	7.9	8.3	7.9	8.0	8.02
Operator Shift B	7.8	8.1	8.0	8.0	8.1	8.0
Operator Shift C	8.0	8.1	8.0	7.9	8.0	8.0
Operator Shift D	8.0	8.0	8.1	7.8	8.0	7.98
Total Average Time (mins)						8.00

Therefore, to obtain a reduction of 30%, the average cycle time must be approximately 5.6 minutes/per lot.

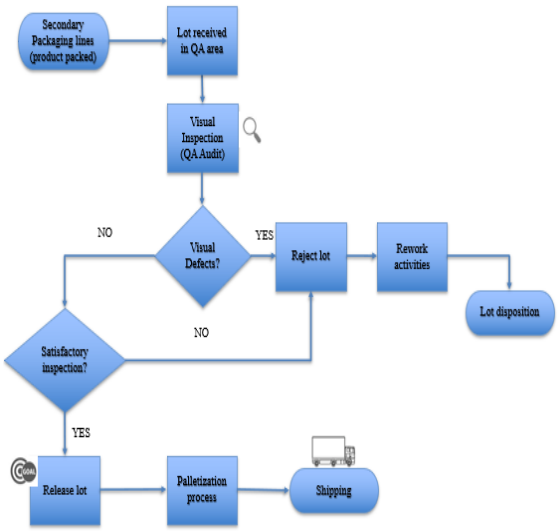

Figure 4
Process Flow Chart for the Operations contained in the Scope of this Project

Through the Process Flow Chart developed and shown in Figure 4, it was easier to see the flow of every step of the operations in scope. As part of the evaluation process, one the process flow was developed, it was discussed with the impacted personnel (QC operators) to receive their feedback regarding the QA audit process. Most of the time the QCs were consisted that when they present more delay during the QA audit process was when packaging lines processed small lot. Therefore, the proposed process improvement should be aligned with the implemented sampling plan as part of the QA audit process.

As part of the Analyze project phase, to identifying potential root causes of this situation, a cause-and-effect analysis was completed and documented using a Fishbone diagram, refer to Figure 5.

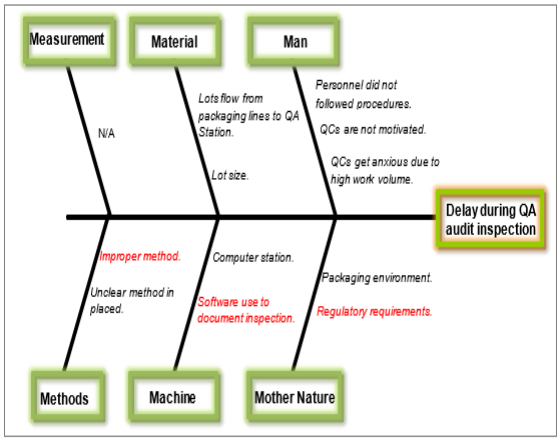

Figure 5
Fishbone diagram for the Cause-and-Effect Analysis

After completing the Fishbone diagram, the causes with higher impact based on the process investigation and interviews with the personnel, were evaluated through the Analyze project phase. Out of the 11 causes brought during the cause-and-effect analysis, 3 causes will be taken to the next project phase, Improve, due to the proven effect these have on the project.

Material

Lots flow from packaging lines to QA Station – During the evaluation process, lots were transferred consistently to the QA station for audit process without any issue. For that reason, this

alternative of root cause (RC) is classified as ruled out.

Lot size – When the packaging campaigns were composed of small lots size, impacted the QA audit process by delaying the process, however this is not the root cause and can be rule out since this action was confirmed with planning personnel that this practice is normal of the process and lot size depend on the customer's order.

Man

Personnel did not follow procedures – QA audit process was evaluated, all requirement stablished in QA audit process were completed correctly and no discrepancies were found between operator and procedure. For that reason, this alternative of RC is classified as ruled out.

Method

Improper method – QA audit procedure was evaluated; visual aid segregation and inspection requirements, are detailed in procedure. However, an opportunity was identified in the inspection method, since no matter the lot size the sample size is the same. For that reason, this alternative can be considered a factor to impact the QA audit process.

Machine

Computer station– Station used to perform QA audit was evaluated and no issue was reported, the personnel have the necessary equipment to perform the inspection. For that reason, this alternative of RC is classified as ruled out.

Software use to document inspection – Software present limitation regarding the QA audit requirements, therefore, this alternative is not a root cause for this issue. However, if the sampling plan is change, the software needs to be update.

Mother Nature

Packaging Environment – Packaging area was assessed in search of possible causes that could contribute to the problem. During the assessment normal production activities were identified as usual. For that reason, this alternative of RC is classified as ruled out.

Regulatory Requirements – As part of the regulation it is required that prior releasing the product to the market the company must assure the product comply with quality standard and the product is safe to be use.

Based on this assessment it was observe that the higher impact was related to the sampling plan. Therefore, it was decided to modify the sampling plan requirements through a QA audit process deviation (effective in February 2021) for data gathering and evaluation of the QA packaging inspection process in the Secondary Packaging Operation.

Current sampling plan (Table 3) for minor defects consist with an Accepting Quality Level (AQL) = 2.81%, samples (n) = 13 / Accept (a) = 1, Reject (r) = 2). This AQL complies with Spec AQL's between 2.5% and 4.0% established in procedure for this type of defect.

Table 3
Current Attribute Single Sampling Plans for Non-conforming by AQL and Lot tolerance percent defective (LTPD)

Classification / Severity Rating	Sampling Plan
Minor / 1&2	n = 13, a = 1, r = 2 AQL = 2.81%, LTPD = 26.8 Level of Inspection = 2
Major / 3 & 4	n = 13, a = 0, r = 1 AQL = 0.39%, LTPD = 16.23
Critical / 5	Critical conditions are inspected during QA Audit for the carton(s) content inspection and are not change by this modification.

To identify an adequate sampling plan in which comply with product requirements, statistical analysis was performed evaluating different scenarios, taking in consideration the operational characteristic (OC) curve, the Average Sample Number (ASN) curve and the Average Outgoing Quality (AOQ) curve. This evaluation was performed to evaluate behavior of the different sampling plans versus the current sampling plan.

This analysis was performed with two different sampling: Single sampling: n = 5, A = 0, R = 1; AQL = 1.02%, LTPD = 36.9 and Double Sampling: $n_1 = 8$, $a_1 = 0$, $r_1 = 2$; $n_2 = 8$, $a_2 = 1$, $r_2 = 2$
AQL = 2.60%, LTPD = 27.0, AOQL = 6.02.

The operating characteristic (OC) curve illustrates the discriminatory power of an acceptance sampling plan. The OC curve plots the probability of accepting lots with varying proportions of nonconforming or defective items using an attribute acceptance sampling plan can be represented graphically by the OC (or Operating Characteristic) curve [3]. The following graphs (Figures 6, 7 and 8) represents a comparison of current sampling plan versus proposed sampling plan to evaluate the potential impact.

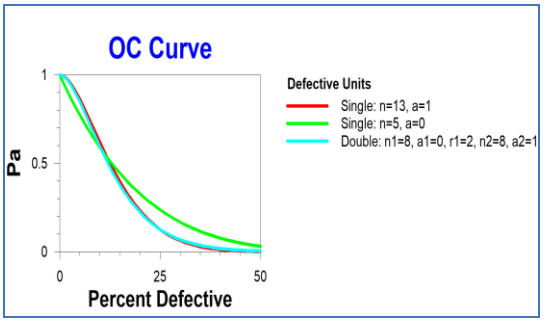

Figure 6
OC Curve Statistical Analysis

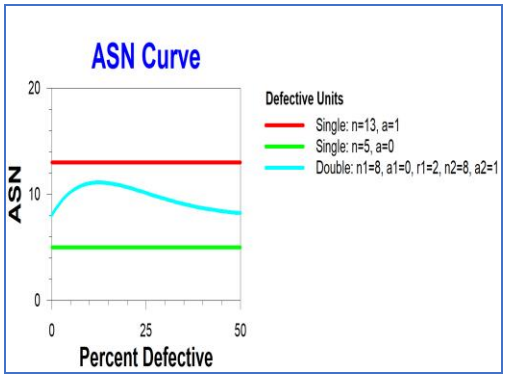

Figure 7
ASN Curve Statistical Analysis

The Average Sample Number (ASN) curve shows the average number of units inspected (y-axis) for different incoming qualities (bottom axis). For single sampling plans the ASN is a constant so the ASN curve is a straight across line. However, for double sampling plans the ASN changes depending on how likely it is that the second sample is selected. When examining the ASN curve it is important to concentrate on that part of the curve that corresponds to the process average [4].

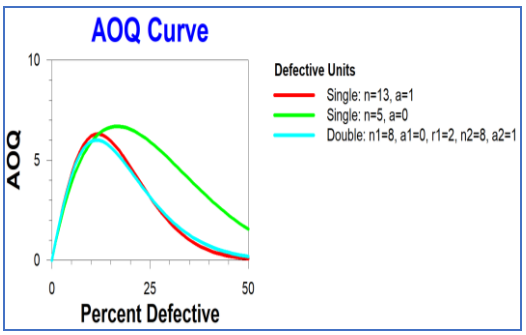

Figure 8
AOQ Curve Statistical Analysis

The Average Outgoing Quality (AOQ) curve shows how outgoing quality (y-axis) depends on the incoming quality (bottom axis). The AOQ is the average percentage defective of accepted lots assuming that rejected lots are 100 percent inspected and defective items in those lots are replaced with good items [5].

High Level Benefits/Challenges

Sample Decrease by Individual Lot (single sampling):

- **Benefits**
  - Quick and simple implementation (configuration change in the Quality Assurance Inspection (QAI) software/SOP updates).
  - Efficiency increase (inspect 50% less of samples per lot/same or less resources).
- **Challenges**
  - Lot will be rejected irrespective of condition severity.
  - Defect per million (DPM) results may be higher because of a smaller base of samples.
  - Double Sampling /Pooled Sampling
- **Benefits**
  - Provide a second opportunity to the lot before initiating a Non-conforming report (NCR).

- Efficiency increase (~70% less sample inspection)

- **Challenges**
  - Software changes are required. Solutions takes longer to implement.
  - All lots sampled hold until reprocess is completed.
  - Adds complexity to inspection. (Induces error)
  - Cultural change for Quality Control Operators.

After evaluation it was decided to proceed with the following proposed sampling plan (Table 4) for minor/major defects has an AQL = 1.02%, n = 5 / (0,1). This AQL complies with Spec AQL's between 2.5% - 4.0% and 0.25% - 1.0% established in procedure for this type of defect.

Table 4
Proposed Attribute Single Sampling Plans for Non-conforming by AQL and LTPD

Classification / Severity Rating	Sampling Plan
Minor / 1 & 2	n = 5, a = 0, r = 1 AQL = 1.02%, LTPD = 36.9
Major / 3 & 4	n = 5, a = 0, r = 1 AQL = 1.02%, LTPD = 36.9
Critical / 5	Critical conditions are inspected during QA Audit for the carton(s) content inspection and are not change by this modification.

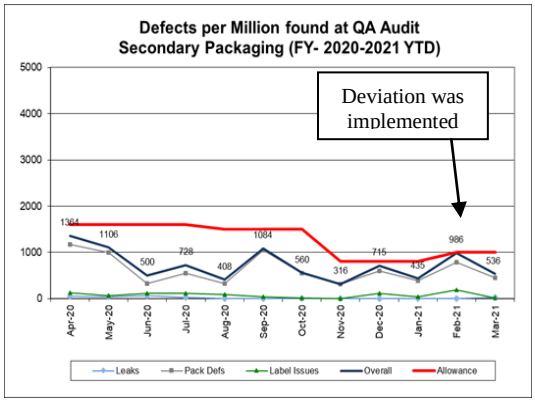

Figure 9
DPMs for Secondary Packaging Operation

As result it was observed an increase on the identification of nonconformities during the QA audit process in the month of February 2021, refer to Figure 9. In addition, Packaging Defects NCR Trend chart corresponding to Feb 2021, was assessed; no adverse trend was identified, it shown to be that the process in under control. Refer to Figure 10 below.

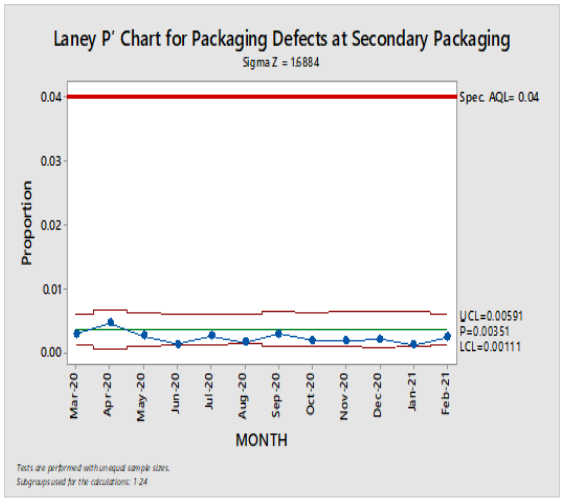

Figure 10
"Packaging Defects" NCR Trend chart

Through the Improve project phase, each element was evaluated to understand the impact in the Secondary Packaging operation. Therefore, new sampling plan described in Table 4, was implemented for the QA audit process in the Secondary Packaging. Impacted SOPs were identified and updated with the new sampling plan instruction. In addition, Quality Inspection software was revised to assure automatic system present the new sampling plan requirements. All Quality Control operators were trained in all the sampling instruction change as part of the regulatory requirement.

CONCLUSIONS

The Quality Sampling Plan Re-Design for the Secondary Packaging Operation was successfully completed with excellent results. Through the implementation of the Improvement plan of this project, in which the sampling was reduce in a 62%. The improvement in the total inspection cycle time was achieved from 8 minutes per lot down to 3 minutes per lot, which represents an improvement of 62% (refer to Table 5). This exceeds the project objective of improving the time by a 30%.

Table 5
New Cycle Time for QA Audit Process

Time Study	Observations (mins) Current Inspection plan (5 samples)					
Lots	1	2	3	4	5	Average time
Operator Shift A	3.0	3.2	3.1	3.0	3.0	3.06
Operator Shift B	3.4	3.2	3.0	3.2	3.1	3.18
Operator Shift C	3.0	3.0	3.2	2.9	2.9	3.0
Operator Shift D	3.1	3.0	3.2	3.0	3.0	3.06
Total Average Time (mins)						**3.08**
Cycle Time Percentage Reduction						**62%**

In addition, the area presents an increase of 40.5% of the lots release amount per month (refer to Table 6 & Figure 11). Which means that there is no need to increase the personnel, since this new process can manage the increment in volume the operation is having and sustain the existing Quality Standards.

Table 6
Data of Lots Quantity Release

Month	Lot Qty.	Lenses Qty.	Ave. Lot Release Qty.	
Nov-20	6,103	65,595,539	6,111	Prior change 13 samples
Dec-20	5,539	53,030,741		
Jan-21	6,691	68,177,821		
Feb-21	8,472	83,787,028	8,585	After change 5 samples
Mar-21	8,697	87,655,173		

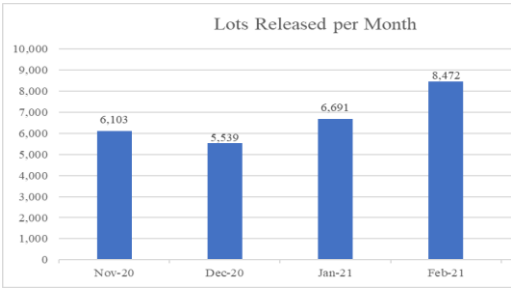

Figure 11
Lots Release data per Month (FY21)

Based on this assessment, modifying to the proposed sampling plan does not present adverse effect in the secondary packaging process and does not affect safety or performance of the product. Impacted procedures were revised under the Document Change Order procedure. In addition, DPM goal will be increase from 800 to 1,000 due to the reduction of sample size (Refer to Figure 9).

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