How the DMAIC Methodology was applied under the CAPA System with Effective Results

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Abstract *-- The proximal spacing is an essential design output where the purpose is to have the proper alignment and contact at the battery to provide electrical pulse therapy at the sacral cord stimulation. If the contact to the battery are not well aligned, the patient will not receive the therapy and the pain can be worst. A corrective action event was generated to address the increase on proximal spacing out of specification defect observed on the manufacturing process for the Sacral Cord Stimulation (SCS) Implantable Lead product for pain reliever during the months of May to November fiscal year 2017. The initial baseline established in the measure phase of 0.836% defect rate was improved after the implemented process improvements to 0.016% defect rate and cost reduction. The development of this study demonstrated how the DMAIC methodology was applied under the CAPA system with effective results.*

Key Terms *— CAPA, DMAIC, Proximal Spacing and Effectiveness.*

INTRODUCTION

The proximal spacing is an essential design output where the purpose is to have the proper alignment and contact at the battery to provide electrical pulse therapy at the sacral cord stimulation. If the contact to the battery are not well aligned, the patient will not receive the therapy and the pain can be worst. A picture of the proximal spacing is shown on Figure 1.

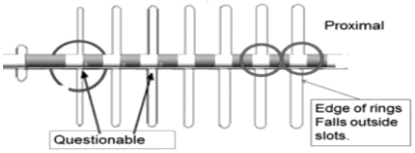


Figure 1
Condition Representation

The Manufacturing process for the SCS Implantable Lead product for pain reliever on the medical device has the controls to detect and contain the defect with a 100%-dimensional inspection that consist in measure the spacing with a certified fixture where the edge of ring must fall between slots for all spacing locations. The trending control chart for overall defects of the spacing out of specification discussed on a monthly trending meeting resulted within control shown on Figure 2.

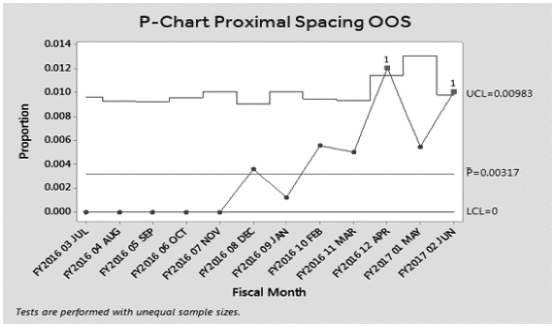


Figure 2
p-Chart Proximal Spacing OOS

However, in the top five defects on Figure 3, the major contributor with an 83.1% was the proximal spacing out of specification (OOS).

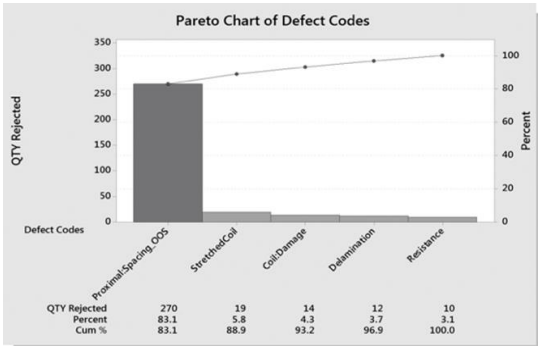


Figure 3
Pareto Chart

The problem was presented on the corrective action and/or preventive action (CAPA) board and

was generated an event for further investigation classified as preventive action.

DESIGN PROJECT DESCRIPTION

In this Article explain "How the define, measure, analyze, improve and control (DMAIC) methodology was applied under the CAPA system with effective results" minimizing the defect rate. This is a real case related to a CAPA event generated to address the increase on proximal spacing OOS defect observed on the manufacturing process for the Sacral Cord Stimulation Implantable Lead product for pain reliever during the months of May to November fiscal year 2017 initial baseline defect rate of 0.836%.

The importance of the development this study is to demonstrate the integration of two quality system tools (DMAIC and CAPA) can be effectively merging to identify, assess and investigate product and potential quality issues to take appropriate and effective corrective and/or preventive action to prevent recurrence.

OBJECTIVE

The objective of this design project will be focus on How the DMAIC methodology was applied under the CAPA system with Effective Results on the reduction of the proximal spacing OOS reject rate by at least 50% by August fiscal year 2018 and the CAPA effectiveness successfully.

CONTRIBUTIONS

The selection of this design project "How the DMAIC methodology was applied under the CAPA system with effective results" applied in the manufacturing process for the Sacral Cord Stimulation implantable lead product for pain reliever on the medical device had value added to the quality of the product, yield improvement, defect rate reduction by 50%, zero customer complaints under the quality system requirements 820.22 industry practice section h of corrective action, and the hard benefits to reduce the defect rate of $80,000 approximately.

BACKGROUND

The project design was based on a potential quality issue where the tools used to identify the root cause of the problem was DMAIC under the CAPA system for medical devices to comply with the quality system regulation 21 CFR 820.100 Subpart J. The question established to develop the project was; "How the DMAIC methodology was applied under the CAPA system with Effective Results".

In Comparison of both systems, CAPA and DMAIC phases, they are systematics and structured. The measure and analyze phase is covered under the CAPA investigation phase. Figure 4, CAPA system and the DMAIC phases [1].

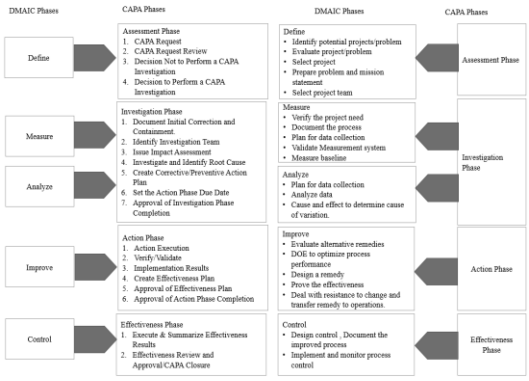


Figure 4
Diagram for Reference

The application of the DMAIC, at a high-level overview, define the current problem that affect the Organization reach their goals, measure the performance of a manufacturing line for SCS Lead product, analyze the process, make improvements based on the analysis, and control the corrected process. A DMAIC based CAPA system must contain critical functionality, which individually and collectively, must be used to properly manage all non-conformities while helping to manage, monitor and document its efforts to comply with regulations, and to help solve the CAPA processes problem. This merge of methodologies helped to

maximize efficiencies while continuously increasing product quality. Some definitions found on the research help to understand and have a clear vision of what the project is intended to demonstrate.

CAPA: "A systematic approach that includes actions needed to correct (correction), avoid recurrence (corrective action), and eliminate the cause of potential nonconforming product and other quality problems (preventive action)" [2].

DMAIC: "Methodology used for Six Sigma approach focusing on reducing variation in processes and preventing deficiencies in product, that involves five phases: define, measure, analyze, improve and, control" [1].

Corrective Action: "An action taken to eliminate the causes of an existing non-conformity, defect or other undesirable situation in order to prevent recurrence" [3].

Preventive Action: "Action to eliminate the cause of a potential non-conformity or other undesirable situation; 1. There can be more than one cause for a potential nonconformity, 2. Preventive action is taken to prevent occurrence" [4].

The problem case CAPA proximal spacing OOS defect rate reduction brought in this design project applied the systematic DMAIC approach that will be explained step by step in project methodology section.

PROJECT METHODOLOGY

The methodologies explained in this project design were the key to get effective and sustainable results. The CAPA process was applied with the integration of six sigma DMAIC methodology to identify the root cause of the problem. The CAPA process followed by the Organization consist of four phases; (1) Assessment phase, (2) Investigation phase, (3) Action phase and (4) Effectiveness phase. The input process output (IPO) illustration on Figure 5 is a CAPA governance high level and six sigma methodologies under a systematic and structured process that was followed.

Figure 5
High Level Input Process Output (IPO)

CAPA Assessment Phase and Six Sigma Define Phase

During the CAPA board review decided to perform a CAPA investigation for the proximal spacing OOS defect. The board members requested more information from the originator to monitor the issue to determine if a threshold has been exceeded for the quality process and at risk. The manufacturing trend assessment was evaluated and resulted on a medium risk which means to evaluate the failure mechanism and mitigate to reduce the probability of occurrence and improve the level of detectability. The initial impact on the potential failure mode effect analysis (PFMEA) for the product was acceptable, with the facts the manufacturing process had the 100% inspection. Applicable tool used to identify the trend was p-chart for defect rate shown on Figure 2.

In the Six Sigma Define phase the Problem was defined using the project charter tool. The project charter establishes the problem statement, set the goal, identify stakeholders, create the team members, define the scope, timeline and, calculate benefits.

At the beginning of the CAPA, the project Gantt chart tool was used to have visual management of all the DMAIC phases integrated into CAPA system to permit better visibility of where start and finish. In addition to provide a summary of primary elements of the CAPA and Six Sigma project.

CAPA Investigation Phase and Six Sigma Measure Phase

The CAPA Investigation phase was issued the impact assessment, mitigations were completed and prepared the data collection plan to measure and create corrective and/or preventive action plan. The plan was discussed with the Board members for approval and the agreements for the next phase. As part of the organization procedures in the investigation phase it is determined the root cause(s) of the quality issue with the six sigma tools explained on measure phase.

Six Sigma Measure phase, data history of reject quantity was gathered since the new fiscal year to establish a baseline to measure the improvement with before and after chart. The process map tool was used to evaluate the current process at a high level to have a clear vision where the spacing out of specification can occur. Data collection was performed to identify which process step has the major effect on spacing shift and possible source of problems.

CAPA Investigation Phase and Six Sigma Analyze Phase

In the CAPA Investigation phase the Cause and effect diagram tool was used to identify all the potential causes using the 6m (method, material, manpower, measurement, machine and Mother Nature) analysis the same tool at the six sigma analyze phase.

Aligned with the Six Sigma Analyze Phase the cause and effect diagram/Ishikawa or fishbone diagram was used to trigger ideas. This tool is defined as; "basic tool for problem solving using brainstorming where possible causes from such sources as materials, machine, method, and manpower identified for starting point. Every possible cause was analyzed and confirmed in the design of experiment (DOE). DOE is an "Experiment methodology where factor levels are assessed in a fractional experiment or full factorial experiment structure" [5].

The DOE was performed with three factors identified on the focus groups for process improvement teams work on incremental improvements and radical changes. The three factors were selected because were the most relevant where the strategy for the DOE was as follows:

Full Factorial Design

- Factors: 3;
- Design: 3; 8 combinations of factor settings; Runs: 27 and Replicates: 3

The full factorial experiment was used to test all combinations of factor levels. For three (3) factors, each at two (2) levels, there are 2 x 2 x 2 = 8. The factors are:

(A): silt quantity

(B): backfill order

(C): handling

Factors Description:

(A) Slit Quantity – One slit is performed in the standard operating procedure SOP2 "Backfill" to allow air to vent during filling on the second end that is backfilled. For the DOE was asked to the manufacturing team member (MTM) to make two slits (one on each side) on 12 leads and do not make any slits on 12 leads, to see if there was a difference in the proximal spacing.

(B) Backfill Order – the SOP2 "Backfill" allows as an option to the MTM to start on either the distal end or the proximal end. On the DOE, twelve of the leads were backfilled by the distal first and 12 of the leads were backfilled by the proximal first.

(C) Handling – on SOP2 "Backfill", the MTM can use fingers to control the air flow and allow quicker flow of air to escape if necessary. The MTMs can expand the expended tubing edges (wings) while backfill along the entire length or can tap with fingers.

The Pareto chart was used to determine the magnitude and the importance of every factor effect. The chart displays the absolute value of the effects and draws a reference line on the chart. Any effect that extends past this reference line is statistically significant on Proximal Spacing.

Additional tools used to confirm possible causes determined under Cause and Effect diagram was Measurement System Analysis (MSA) in Attribute for the fixture used for pass/failing proximal spacing inspection. Attribute agreement analysis was used to evaluate Fixture subjective nominal ratings or subjective ordinal ratings by multiple appraisers and to determine how likely your measurement system is to misclassify a part. The PFMEA was used to determine the Risk Priority Number and the Confidence level for the sample size adequate.

The RPN = Severity (S) x Occurrence (O) x Detectability (D) = 3 x 1 x 3 = 9 for a confidence/reliability level of 95%/90% a minimum of 29 presentations of rejectable samples/parts and minimum of 29 presentations of acceptable samples/parts is required. Sample size was determined as follows:

- Two (2) appraisers (A) were used during this TMV activity.
- One (1) group of samples was created, containing ten (10) acceptable parts and ten (10) rejectable parts (P). Two (2) Repeats of each part by appraisers.

CAPA Action Phase and Six Sigma Improve Phase

In CAPA Action phase the action plan was defined to address the proximal spacing OOS contributors and demonstrates the reduction reject rate of this condition.

Six Sigma Improve phase is aligned with the CAPA phase where: "evaluate alternative remedies, optimize process performance, design a remedy, transfer remedy to operations and prove the effectiveness" [1]. In the Results and discussion section will demonstrate that the actions implemented made an improvement on the proximal spacing OOS condition.

CAPA Effectiveness Phase and Six Sigma Control Phase

CAPA Effectiveness Phase determined whether or not the actions taken addressed the identified cause(s). The effectiveness plan was presented in the CAPA Board as follow:

- Effectiveness Criteria: The criteria were presented at the CAPA Board and agreed with the following statement: No out of control for the proximal spacing out of specification (OOS) defect in the Product manufacturing line area during June FY18, July FY18 and August FY18 associated to the contributors identified in this preventive CAPA. The May FY18 month will be for learning curve. If an out of control is found and the special cause is not related with the one identified in the preventive CAPA the root cause is evaluated through the manufacturing trending and escalation Process Procedure current revision as per our Organization CAPA system.

The Six Sigma Control phase aligned with the CAPA effectiveness phase used a control chart to monitor the implemented process improvements to validate the critical factors controls to address the primary contributors were effective. The control chart (p-Chart) was used to compare initial baseline (before) and current (after) process improvements over the time.

RESULTS AND DISCUSSION

The results and discussion of "How the DMAIC methodology was applied under the CAPA system with Effective results" is presented in this section, step by step and the applicable tools that were relevant to identify the possible root causes and contributors until a controllable and sustainable process achieved.

CAPA Assessment and Six Sigma Define Phase Results

CAPA Assessment phase results present the p-Chart tool used to identify the defect trend showed an out of control in April and June on fiscal year 2017, therefore, the CAPA initiated with the second occurrence of proximal spacing OOS defect as shown on Figure 2.

Six Sigma Define Phase results – It was documented what the project is supposed to achieve and what resources are available to the team. In the Project charter tool on Figure 6, was described the problem statement, goal was set, identified stakeholders, created the team members, defined the scope, timeline and, benefits were calculated.

Project Title: Proximal Spacing OOS	Project Lead: Mayda Haddock Ortiz
Date: AUGFY18	Sponsors: Organization
Problem Statement	**Goal**
An increase on the trend of Proximal Spacing OOS defect rate was observed from February Fiscal Year(FY) 2016 to April FY 2016 in Manufacturing Product Lead. A DMAIC process was completed resulting in a reduction of defect rate (from 1.2% to 0.5%) on MayFY17. However, another out of control was observed during the month of June FY17 of (1.0%) which required further investigation on a CAPA. Initial baseline of Defect rate of 0.836%	Goal: Reduced reject rate by at least 50% by Q3FY17. Project Y: Defect Rate
Stakeholders	**In/Out of Scope**
Organization Customers	In Scope: MFG Product Lead line Out of scope: Other MFG Products
Team and Function	**Benefits of Recommendations**
Team Members: Champions, Black Belts, Green Belts, Manufacturing Team Members, SME	Hard Savings • Potential benefits: $80K • Scrap Cost

Figure 6
Project Charter

CAPA Investigation Phase and Six Sigma Measure Phase Results

In the CAPA Investigation phase the plan was discussed and approved with the Board members with the Project Gantt chart on Figure 7.

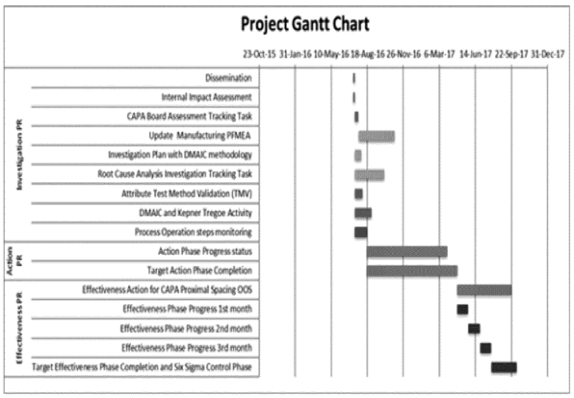


Figure 7
Project Gantt Chart

Meanwhile in the Six Sigma Measure phase data history of reject quantity was gather since the new fiscal month (FY2017) when the CAPA imitated, to establish a baseline (Figure 8). To measure the improvement, before and after chart was traced resulting defect rate calculated of 270 quantity defects out of 32,303 completion units resulting a defect rate of 0.836%.

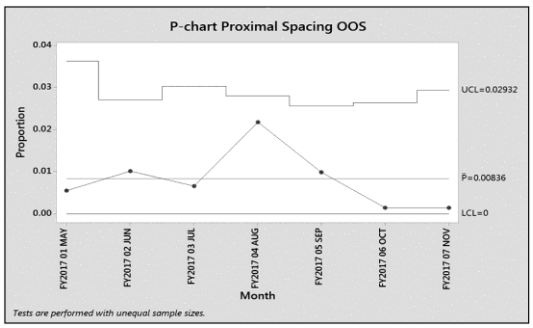


Figure 8
P-Chart Proximal Spacing OOS Baseline

The process map on Figure 9 helped us to evaluate the current process at a high level to have a clear vision where the spacing out of specification can occur.

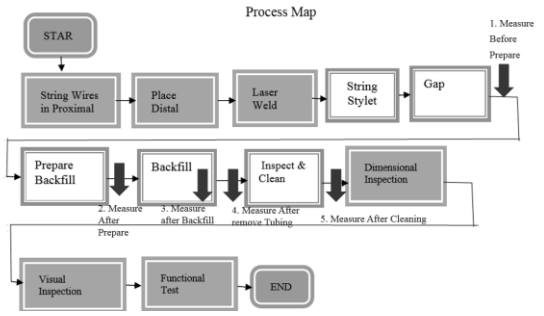


Figure 9
Process Map

Data Collection was performed to identify which process step has the major effect on spacing shift.

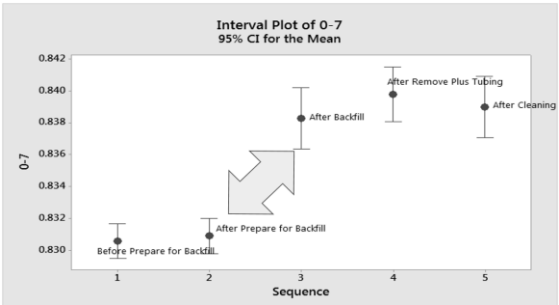


Figure 10
Interval Plot

Results were collected and analyzed in the Interval Plot where the shift effect occurred from

sequence two (2) to three (3) "After backfill process" on proximal location from 0 to 7 (Figure 10).

CAPA Investigation Phase and Six Sigma Analyze Phase Results

During the CAPA Investigation phase, the Cause and Effect diagram shown on Figure 11, was used to identify all the potential causes using the 6m (method, material, manpower, measurement, machine and mother nature) analysis.

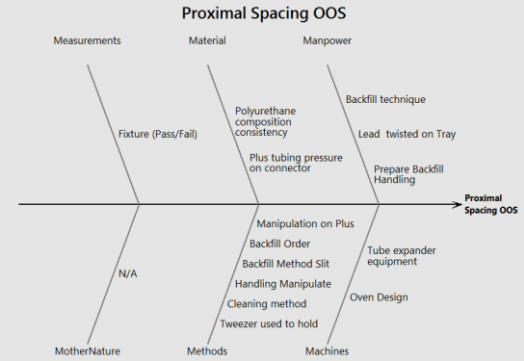


Figure 11
Cause and Effect Diagram

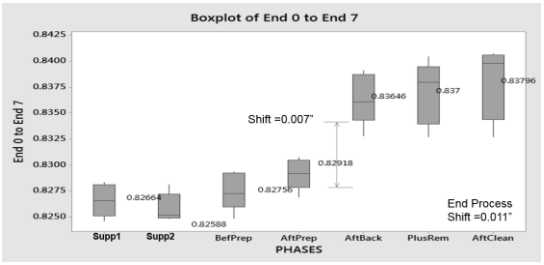


Figure 12
Box Plot

- **Method**: Data was collected through special build on dimensional measurements including suppliers to supplier for to the proximal spacing, before and after processes, SOP1 "Prepare for backfill", SOP2 "Backfill and cure" and SOP3 "Clean and Inspect", to determine the effect on spacing. The data showed that there is an increase in the spacing of .007" throughout the assembly operations and the major increase in the spacing was found after the SOP2 "Backfill". Therefore, backfill method was identified as potential possible cause that may be contributing to proximal spacing OOS requiring additional investigation from Figure 12. There is no significance difference between (Supp1) and (Supp2), therefore, supplier is not a possible root cause of the condition presented.
- **Manpower:** *Lead placement on Tray*: A visual assessment was performed to the lead placement on tray and oven equipment where the following finding were observed on Figure 11. Illustration "A" shows how the lead is placed on a Tray and on illustration "B" shows a small curve or spacing separation that can be up to 0.001 inches. Illustration "C" shows the Oven with several leads inside that have been deformed. Therefore, the leads tray design and the Oven design may be a contributor for proximal spacing OOS.

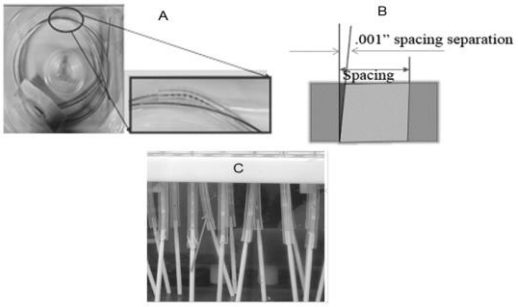


Figure 13
Pictures

- **Machine:** Device history record on equipment for Tubing expanders and Ovens were reviewed to identify if any intervention or nonconformance were reported during the period of (MayFY17 to JulFY17) that could impact in the proximal spacing. There was not found any discrepancy. Therefore, the machine is not the root cause of this condition proximal spacing. The oven hanging design for leads were evaluated and was identified as a contributor factor, however, hanging fixtures were improved on four ovens boxes to avoid leads contact with the bottom surface thus reducing the bending of proximal end area.
- **Material:** Material inspection evaluation request were performed for proximal from Supplier 1(Supp1), and for Bond proximal

tubing from Supplier 2(Supp2) and the results showed measurements that fall within specification at the nominal. Data for the hardness, tensile strength, and elongation was requested to confirm if the composition of the molding may be the cause of proximal spacing shift, however, the data results received from Supp1 with all the lots that were consumed on the manufacturing process had accepted results as per specifications shown on Table 1. Therefore, Polyurethane was not considered neither a root cause nor a contributor factor of the proximal spacing OOS.

Table 1
Point Sizes and Type Styles

	Material	Lot Number					
	Specifications	Lot 1	Lot 2	Lot 3	Lot 4	Lot 5	Lot 6
Hardness	55 +/- 5D	55	55	56	56	55	55
Tensile Strength at Break	>5400 psi	8,687	8,687	9,276	9,276	8,687	8,687
% elongation at Break	> 300%	339	339	406	406	339	339
Weight Average Molecular Weight	>350,000 Daltons	413,333	413,333	551,488	551,488	413,333	413,333
Polydispersity Index	2.0 +/- 0.5	2.1	2.1	2.4	2.4	2.1	2.1

- **Measurements:** Fixture (Pass/Fail): Fixture is used to measure the proximal spacing as per SOP10 Dimensional Inspection. The fixture was designed with tolerance more restrictive than the Product specification. To confirm the Fixture is a possible root cause of the proximal spacing OOS condition, a measurement system analysis (MSA) or test method validation (TMV) was executed with attribute data and demonstrated that the measurement system is capable to producing valid results for its intended purpose, therefore, fixture used for dimensional spacing is not the primary root cause of this condition shown on Figure 14.

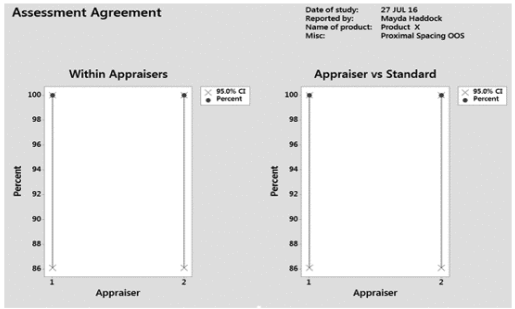


Figure 14
MSA Assessment Agreement

- **Cause and Effect Conclusion:** No primary root cause was identified. However, the following contributors of the proximal spacing OOS were identified:
  1. Backfill method
  2. Tray Design
  3. Oven Design

In the Six Sigma Analyze Phase every possible cause of the proximal spacing OOS defined the cause and effect diagram were analyzed and confirmed in the DOE. Based on the strategy defined, with 24 different combinations of factors performed, measuring the spacing before and after the backfill operation to see the effect of the different factors.

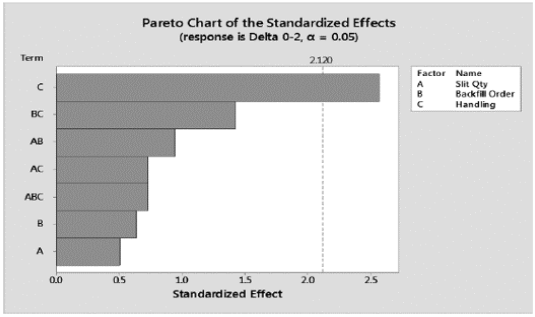


Figure 15
Pareto

The MINITAB data results showed on Figure 15 that the Factor (C) Handling, had a p-value of .021 less than .05 means had significant effect on the proximal spacing.

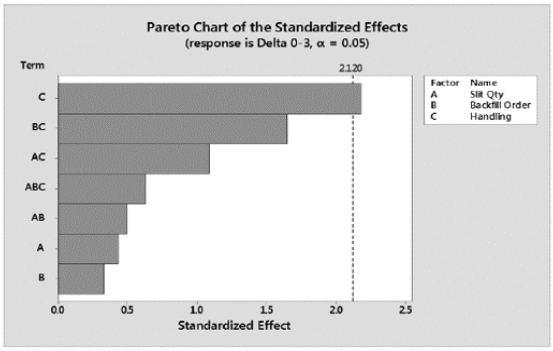


Figure 16
Pareto

Two of the locations (i.e. spacing of location 2 and location 3), the handling (pull the plus tubing

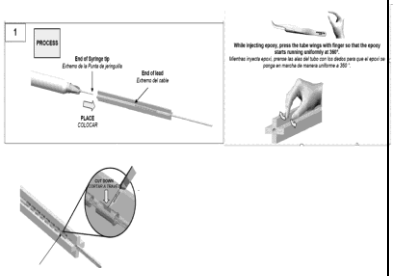
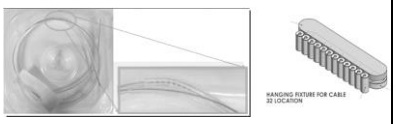
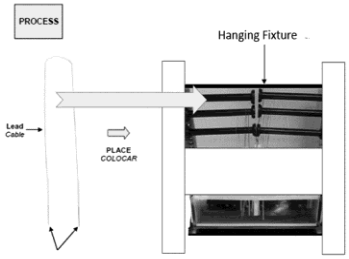
wings while making backfill along the entire length) resulted as significant factor shown on Figure 16.

CAPA Action Phase and Six Sigma Improve Phase Results

In the CAPA Action phase the action plan was defined to address the contributors of the proximal spacing OOS. Action plan in Table 2 below presented in the CAPA board was approved.

Six Sigma Improve phase is aligned with the CAPA phase where the process were optimized and prove the effectiveness. The actions executed to address the contributor's factors were implemented.

Table 2
Action Plan

Contributor factors to address	Implemented actions
(1) Backfill Method	
(2) Tray Design	
(3) Oven Design	

The backfill procedure was standardized, and new design were improved for trays and oven. Another study was performed under a special build to validate the new design on tray and hanging fixture where they resulted adequate to implement.

CAPA Effectiveness Phase and Six Sigma Control Phase Results

CAPA Effectiveness Results: A total of three months were monitored for proximal spacing OOS in manufacturing affected process. According to effectiveness criteria, no out of control results have been reported associated to the condition contributors identified in this CAPA. The results of the effectiveness tasks were reviewed against the criteria established in the effectiveness plan. The effectiveness of the CAPA is adequate and complete. Before and after control chart on Figure 17 was used to demonstrate the improvement by phases.

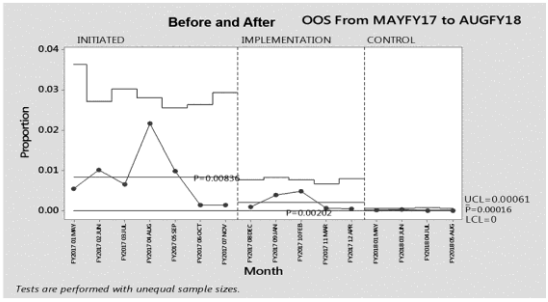


Figure 17
p-Chart Before and After

Six Sigma Control Phase results - The initial baseline established in the measure phase of 0.836% defect rate was improved after the implemented process improvements to 0.016% defect rate. Figure 18 represent the implemented changes addressing the contributor factors.

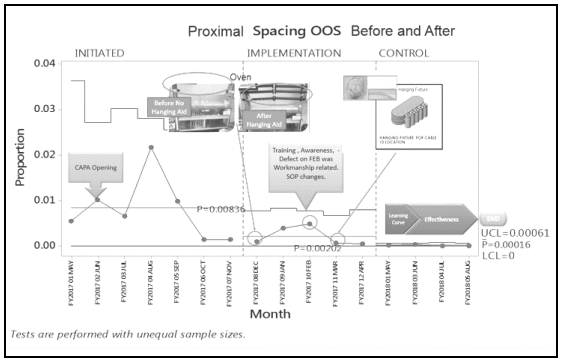


Figure 18
p-Chart Before and After

Benefits: The benefits of the project using the six sigma DMAIC methodology under the CAPA

system were effective, successfully and sustainable. The goal to reduce the reject rate by 50% was achieved and exceed as it shown on Table 3.

Table 3
Benefits

Initial Defect Rate - Final Defect Rate	Built Qty	Benefits ($)
0.820%	59338	$ 138,258.53

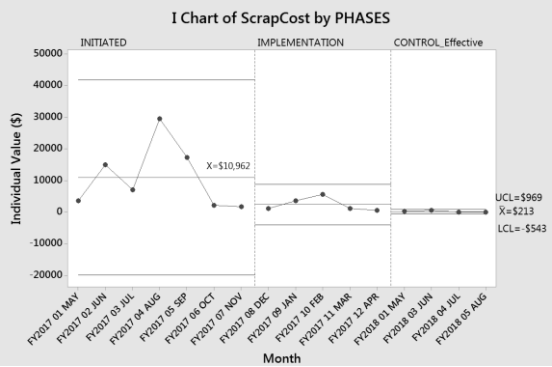


Figure 19
Cost Reduction

The decrease in cost given the reduction of defect rate shown in figure 19 had a significative decrease from $10,962 to $213 average cost per defect rate.

CONCLUSION

The problem stated in this research "How the DMAIC methodology was applied under the CAPA system with effective results" was demonstrated under each phase from both systems.

Most important findings - The application of Six Sigma methodology was the link to keep sustainable gains in the design project. The validation of the primary contributors at the six sigma analyze phase with the DOE was the key to address the real causes of the condition explained in this project. On a previous event with the condition, was used the DMAIC methodology without a CAPA generation, the possible root causes were not challenged, and no controls were placed. The condition disappeared without process changes or improvements.

Constraints – The CAPA system on any organization establish due dates of completion per phases where CAPA investigation phase and six sigma analyze phase may require more time for test and possible causes confirmation. The test for data collection require coordination with manufacturing line which may be tedious and exhausting to manage. It was not identified root cause for the proximal spacing OOS, but Primary contributors were found and implemented controls to eliminate the cause of the condition.

Summary of Contributions – The design project demonstrated that both methodologies can be applied together, therefore the answer to the question "How the DMAIC methodology was applied under the CAPA system with Effective Results" were proved with the positive results that brought to the Organization Quality and Cost Benefits. The initial baseline established in the measure phase of 0.836% defect rate was improved after the implemented process improvements to 0.016% defect rate with hard benefits of $138,258.53.

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