Product Monitoring Improvements Migrating from the Infinity Quality System to an Automatic Interface Data Collection

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Abstract — *This improvement project article is intended to demonstrate how a medical device company can improve its inspection process by developing an Automatic Data Transfer Platform migrating from a platform that does not provides the adequacy to maintain product integrity in terms of failing the qualified inspection process requirements. The success of this migration was achieved following project management and data driven improvement cycle methodologies that concluded with a reduction of the defects by forty-five percent and with an incidence reduction of the product investigations by the Fail Sampling Plan reject code of more than seventy percent.*

Key Terms — *Automatic Interface Data Transfer, DMAIC, Failed Sampling Plan, Infinity Quality System.*

PROBLEM STATEMENT

The manufacturing process of a medical device industry is part of the scope of the Food and Drug Administration (FDA) agency since 1906. However, it is not until 1976 where the specifics for the medical device industry were more broadly defined and became law with the Medical Device Amendments of 1976. Nowadays, FDA base their audit process and reviews of the quality systems using what is stated at the Code of Federal Regulations Part 820 Medical Device Quality System Regulation. For these manufacturing companies, quality of products must be their first imperative as they are for human use. Subpart G and Subpart H of the Regulation Code Part 820 establish the specifics for Production and Process Controls and Acceptance Activities, respectively. These subparts state several times that each manufacturer should have the appropriate controls, monitor processes and acceptance activities to ensure that each device conforms to the quality of its specifications. Currently, the manufacturing inspection process of a medical device company performs their inspection plan with a limited version of the Infinity Quality System (IQS) platform. The IQS platform is a leading provider of Statistical Process Control (SPC) software to automate data collection and analysis during the manufacturing process. However, for this medical device company the limited version of the IQS platform is unable to directly communicate with Manufacturing Execution System (MES). The MES for this manufacturing facility is the platform where all transaction history of the product is recorded to the Device History Record (DHR). The MES platform covers the traceability of the products requirements with the DHR as established by the regulation code Part 820 Medical Device Quality System Regulation Subparts F and Subpart M. With the lack of communication between platforms (MES and IQS), the product monitoring activities are completely human dependent and the inspection or process controls are being documented in a separate platform risking the traceability of such activity. This human dependency generates manufacturing delays and quality or compliance defects related to the amount inspections performed per lot, product specification compliance, and monitoring decisions based on quality risks. This has caused process delays, an increase on the lead time (redundant inspections) and excess of Product Investigations (PI) for the product rejected with the code "Failed Sampling Plan" by the number of samples collected. This medical device industry has decided to develop and explore alternatives of an Automatic Interface Data Transfer (AIDT) platform to work in complete communication with MES system. This monitoring

platform capacity and abilities will be explained and understood during the development of this improvement project article.

Research Description

The main purpose of this improvement project is to standardize the inspection process of this medical device industry with a platform that will serve of a better control and communicates directly with the already established MES. This improvement process will seek the opportunities of developing this new platform without having to invest on expensive built software. This new platform will have to be an extension of the MES and should be able to be managed under the established configuration management systems of the manufacturing site. This improvement will reinforce the quality system and the manufacturing process by assuring product compliance and reducing the manufacturing delays or supply shortage. Moreover, this medical device manufacturing industry will be better prepared against findings during regulatory agencies audits having a robust inspection process platform.

Research Objectives

The objective of this improvement project is to phase out IQS using a developed AIDT platform that has the ability to communicate directly with the MES platform, monitor and control the manufacturing process avoiding defect generation by human dependency. This AIDT platform will account per lot the required amount of samples, process specifications and will avoid further processing with systematic controls that stop or hold the MES if requirements are not met. These controls will immediately trigger alarms in which answers or resolutions will only be managed by designated Quality Assurance Inspectors or Engineers. As a result of this monitoring platform integration the fail sampling plan reject code incidence should be reduced by a ~60% and eliminated for the in-scope product families. In addition, the defective product by part manufactured should be reduced by ~50%.

- **Scope:** The scope for the first phase of this improvement project will be the ~80% (product A's) of the high-volume part numbers of the facility manufacturing process. Product configurations to the AIDT platform must be standardized and managed by the medical device trained staff.

- **Out of Scope or Clarifications:** Low volume part numbers and the remaining ~20 % of the high-volume part numbers will be configured and migrated to the AIDT platform in a second phase of this improvement project. The MES system must not be harmed and the AIDT platform must work as an ad-hoc enhancement.

Research Contributions

The main contributors of this research and improvement project will be quality of products, compliance with the regulation, product availability and lead time reduction. This improvement process will avoid findings or observations during the audit process of the regulatory agencies in terms of the monitoring and traceability controls required by the Regulation Code Part 820. The developed data collection platform will assure quality of the products and reduce rework during the investigation process and product disposition. This reduction in product rejects will increase the product availability and at the same time will reduce the lead time of the manufacturing process.

LITERATURE REVIEW

In this section the most important topics and subtopics will be presented for the understanding of this work.

Background

This research or design improvement project will take place on a medical device industry. Products manufactured within this facility are designed to restore health for patients with back pain issues caused by birth defects, scoliosis, lumbar disc disease, injuries, and accidents, among others. These medical devices consist mainly in screws that are threaded into the patients back

spine, rods that join the screws together, subcomponents assemblies for the screws and plastic cages used as replacements for herniated discs, see Figure 1 for examples.
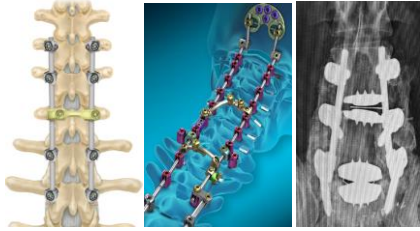

Figure 1
Medical Device Products

These screws, subassemblies, rods or plastic cages are manufactured processing titanium, cobalt chrome, stainless steel and plastic rods as raw material through a machining process. The machining process is the broad term used to describe removal of material from a work piece, cutting in a single-point or multipoint sequence with the cutting tools, each with a clearly defined geometry [1]. These screws, subassemblies, rods and cages are machined at this medical device manufacturing industry using multiple Computer Numeric Controlled (CNC) machine platforms such as the Torno Deco 20a, Index and Citizen machines, each with a unique setup per product family, see Figure 2 for CNC Machine Platforms examples.

Figure 2
CNC Machine Platforms

MES executes when a new work order is opened by the manufacturing operator. Once the manufacturing process has started, the operator must follow the corresponding procedures and perform the required in process inspections (measurements) to the product being manufactured, see Figure 3 for general process flow. For the product manufactured in this medical device industry, the features that are needed to be inspected are defined by design engineering or during the qualification process when it is observed that any other characteristic can be adjusted by the end user of the CNC machine.
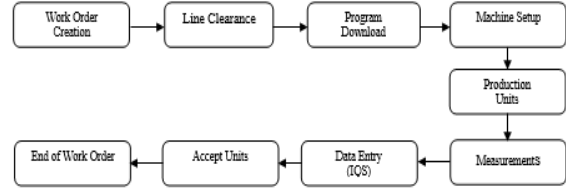

Figure 3
General Production Process Flow

To perform the required measurements the operator must use specific tools or equipment to collect the required number of samples as established by the product qualification. The data collection system must control the product specification limits or flag the operator if the product does not met the specifications. These specification limits controls and equipment traceability records is performed by IQS, but as described in the Problem Statement, this system does not communicate directly with the MES making human dependent to collect the correct number of samples, verify that the gages or equipment being used are within calibration and control or inform any type of product out of specification.

The Importance of the Inspection Process

As previously discussed, Regulation Code Part 820, establishes that every manufacturer is responsible of ensuring and maintaining the quality of the products using the appropriate control within the manufacturing process. For these reasons, it is important for every medical device manufacturing industry to develop the required inspection methods or test to distinguish between good or bad units and secure the product design. These defined acceptance activities will be the responsible of determining product conformance or non-conformance to the specification [2]. For the majority of the medical device industries the frequency and the inspection methods are defined during the qualification process of each product.

Mainly, the inspection methods for the product critical features are defined during the discovery process known as the process characterization. The process characterization activity is a type of experiment where all the requirements needed to manufacture any good are defined and it is the first step to discover the behavior of the proposed manufacturing process. When the requirements have been discovered and established during the process characterization, operational and performance qualification runs are performed to determine the frequency of inspection required to assure the quality of the products to a certain level of statistical confidence. These operational and qualification runs need to be representative of a future normal manufacturing process as the units manufactured will be used as samples to perform the qualification statistical studies [2]. In addition, during this process, it is established by objective evidence that the process is capable of consistently operate between established limits and tolerance with the required predefined acceptance criteria. Many manufacturing industries have their own specific procedures when qualifying new product or processes to define the frequency and the number of samples required to assure quality of the products to a certain confidence level [2]. As for example, the medical device industry where this improvement project will take place uses a 95/95% of confidence level and a minimum process capability of Cpk of 1.33. This Cpk value of 1.33 is used as it statistically guarantees that for a feature that has two sided specification limits (lower and an upper limit), approximately an average of 75 out of specification parts per million will be observed [3] [4] [5] [6]. With all features statistically analyzed it will be needed to determine the frequency and number of units to be inspected by product lot or sampling plan. This sampling plan will be related to the process performance (Cpk) and constrained by the feature that shows the lowest value since the lower the Cpk the higher the amount of out specification parts per million. Also, based on the feature criticality, it will take in consideration the highest severity assigned by design engineering, the

Acceptable Quality Level (AQL) and the Lot Tolerance Percent Defective (LTPD). The AQL level which is the worst tolerable process quality level and the LTPD or level of quality that the sampling plan accepts will depend of the establish policies and procedures of the specific manufacturing industry [2]. When all these values are defined, they are compared to summarized tables that will give the number of samples (n) needed to assure the required quality of the product. The above-mentioned procedures demonstrate the reasons and how a sampling plan for each product manufactured in a medical device industry is established.

Comparison between Platforms

The IQS platform has its limitations when performing direct interfaces with MES systems as the one qualified in this medical device industry. Moreover, it does not provide specific controls to flag/replace out of specification samples and accounting number of samples taken by the manufacturing operator. This lack of controls risks the manufacturing operation of this medical device industry from the quality and compliance perspective. To document samples in the IQS platform, the manufacturing operator needs to open a new inspection lot, enter the required gages, begin its documentation process, complete the sampling plan and close the inspection lot. If during this process an out of specification is found, it is operator dependent to replace this sample and solve any related issue. All the nonconformities generated are detected at a subsequent inspection point and a new investigation is generated every time a fail sampling plan nonconformity is detected. These investigations impact negatively the product yield, supply, quality, compliance and resources allocation. The new data collector (AIDT) main design objective is to work as an add-hoc platform to the MES system. This platform will replace the data collection functionality of the IQS platform and will take decision of the current status of the manufacturing process. AIDT will be configured in such a way that once the operators

opens the manufacturing lot in the MES system, the next step will automatically open an AIDT window that will not let further processing until all the required inspections are performed and found within specification. For this to happen, the AIDT will be a configurable platform that will receive the inputs of the qualification activities such as the sampling plan, gages, equipment, and features for each specific product. In terms of the process controls, if any unit is found out of specification the AIDT platform will signal the MES system to stop or hold the process and the out of specification sample unit will need to be invalidated by a quality representative to reinforce the adequate impact mitigation.

Methodology Background

This improvement project will be developed using the DMAIC methodology. This methodology is widely used in many manufacturing industries to comprise the major phases of a process improvement projects and in solving problems. The DMAIC acronym stands for each project phase; Define, Measure, Analyze, Improve and Control [7]. The Define stage of an improvement project is where the problem statement, scope, goals, customer needs and many other requirements are established. During this phase is where the importance to develop or solve the problem is defined [7]. After defining the project, it is required to Measure the current state to determine a baseline that will be compared against future results. At the Measure phase, many tools can be used to define the major offenders by the defined or required combinations. When the data is collected it is Analyzed to determine the real root cause of the business inefficiencies. This analysis of data reflects where the implementation changes can reflect better outcomes. Once the specifics details of the improvement process are analyzed all the opportunities found can be Improved with the purpose of mitigating the ineffective process. Finally, a Control stage is monitored to keep track of the improvements observed and to have an ongoing and adaptive strategy to the process

changes [7]. This DMAIC approach will be used during the development of this improvement project helping to provide the required visibility and importance of the proposed change to the upper management levels of this medical device manufacturing industry.

PROJECT METHODOLOGY

The implementation of this new inspection process platform will depend on a combination of what product families or part numbers are identified as high runners and which ones are the top offenders of nonconforming issues related to the fail sampling plan reject code. This project methodology chapter will define the tools and approach that will be used to define the project scope, schedule and required resources, among others. The success of this project will be determined by the ability to understand or manage project management and DMAIC skills.

DMAIC Approach

This DMAIC methodology will serve to maintain an open communication channel between the project manager, project champion and management in order to provide the required resources or to remove roadblocks during the execution phases. The DMAIC tool that will be used for this informational and project development process will be a Project Charter. This Project Charter will enclose brief information of what is the problem statement, which is the project Y, resources, strategic alignment, project goal, scope, business impact benefits and the relevant information related to the project plan. Most of the information for the Define phase of this improvement project has been developed on the Problem Statement and Literature Review section. These chapters have developed and answered questions such as: (i) What is the pain?, (ii) Which is the main goal?, (iii) How it is defined to a business strategy? and (iv) Which outputs will be improved once the AIDT migration is implemented?, among others. The next step to

conduct this implementation will be to determine which is the business overview in terms of nonconformities and how this failed sampling plan reject code is affecting the business manufacturing process. This phase will demonstrate the current status and will be known as Measure. The data needed to be gathered during this activity will be a combination between product nonconformities and the total product manufactured to see how this defect contributes to the number of opportunities per manufactured product. From this point, Pareto charts will need to be generated during the analyze phase with the nonconforming reports to identify which are the top offenders within the failed sampling plan reject code. A second level pareto will be the first tool to establish which is the manufacturing step at this value stream exhibits the most rejects by this nonconformity. Taking the result of this previous assessment in consideration, a third level pareto will identify which are the top offender part numbers for the failed sampling plan nonconformity helping to prioritize based on the demand forecast quantities. During the Improve phase, a prediction of the future state and the positive impact of the part numbers when configured in the AIDT platform will need to be determined. In addition, the key measures for a successful implementation need to be defined in order to be efficient during the implementation process. It is at this phase where the planning process will need to be defined and aligned to the business priorities. To conclude with the DMAIC methodology it will be needed to be demonstrated that this platform decreases the nonconforming issues related to the sampling process defects of this medical device industry by monitoring the following normal production months.

Project Management Approach

The project management perspective will be used to give a detailed description of the project, establish the schedule, determine resources needed and break down the project structure. The IQS to AIDT migration project needs to be completed by the third quarter of FY16 for the scope of part numbers defined during the Measure/Analyze phase of the DMAIC process. Once the part numbers are identified, major milestones need to be determined based on the number of configurations needed to meet the proposed project completion. With these milestones defined, the required resource allocation needs to be notified to each major stakeholder that manages a key member. These stakeholders will need to be periodically informed of the project to be aware of any risk situation that could harm the project completion. The major milestones of this improvement project will need to be visually tracked using a Gant Charts or other similar tools used to track step completion within a project. In addition, each configuration should have a defined work break down structure and the project manager should be able to identify the execution paths with less waste of time between tasks.

RESULTS AND DISCUSSION

This chapter demonstrates how the DMAIC methodology was applied to the development of this project in order to meet with the required deliverables and achieve the established goal of the failed sampling plan reject code reduction within the manufacturing line of this medical device industry.

Define Phase

The main tool used for the define phase was a project charter, see Figure 4. This served as a visual aid for the project development and appraisal while being exposed in front of management representatives. This tool helped to provide visibility for the required resources, remove roadblocks and state the benefit or level of criticality that this improvement represents to the business. The main questions answered for this phase of the project were the following:

- Who is the Customer?
  Medical Device Business Unit Products.
- What's currently affecting the Customer?
  High reject rate of Failed Sampling Plan.

- Why this Failure Mode is important to reduce to the Customer?

  Impacts Yield, Cycle time and compliance. Creates a burden for Manufacturing (customer) and Quality/Engineering Team (support).

Measure Phase

During the measure phase, many data was addressed to determine the behavior of the process. However, the major opportunities were identified in defining the current business state. In this manufacturing line, the inspection process takes place at the machining step where the rod of raw material is transformed into the plastic or metal component. Gathering data for the total rejects accounted under the Product Investigation (PI). In FY2015, 40,503 units were rejected at the following step due to Failed Sampling Plan reject code which represents a total of 20% for the overall rejects by product defects. Pareto Chart of PI Defects, see Figure 5, shows that the three (3) Major offenders of the manufacturing process are:

- Quantity Discrepancy
- **Failed Sampling Plan**
- Dimensional Out of Specification
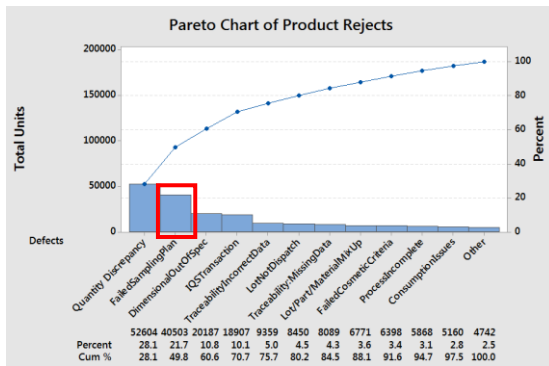
Figure 5
Pareto Chart of PI Defects

Currently for this Medical Device industry there are projects assigned to Quantity Discrepancy and Dimensional OOS based on Quality Risk priority. In FY2015, 40,503 units were rejected due to Failed Sampling Plan (20% of overall defect). From this data, an initial capability was calculated to determine which percentage of defects per opportunities. The initial Capability for this Defect for FY2015 is at a reject rate level of 0.74%, see Figure 6.
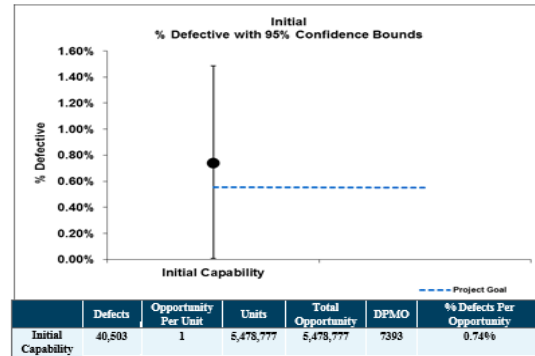
Figure 6
Initial Capability

Analyze Phase

At the Analyze phase it was important to establish which was the manufacturing step that was detecting the majority of the nonconformity to gather the data that established the family of part numbers that are being most affected. For the abovementioned purposes, a Pareto Chart, see Figure 7, of the manufacturing steps where the reject code was observed was generated. It was found that the step with the highest index of failed sampling plan nonconformity is Product Verification step (step subsequent to machining) with a total of 30,313 units rejected representing a 74.8% incidence of the reject code.
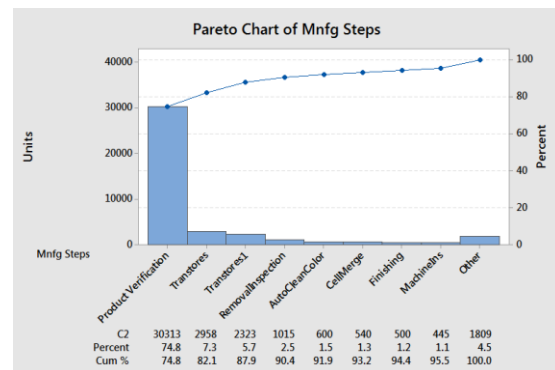

Figure 7
Pareto Chart of Manufacturing Steps

After detecting which is the major offender step, another Pareto was generated to determine which are the major product families P/N's impacted by the failed sampling plan reject code,

Figure 4
Project Charter

see Figure 8. With the information recovered from the MES system it was observed from the Pareto analysis that the two major offenders familes are the Bone Screws, Breakables and Sub-Assembly components.
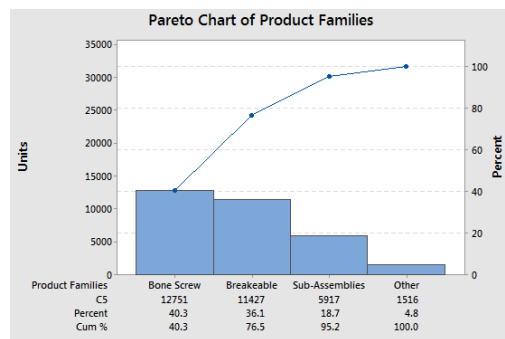

Figure 8
Pareto Chart of Product Families

These families of P/N's represented a 95.2 percentage of the total rejects by the failed sampling plan reject code. This discovery was important to determine which was the root cause of this problem that caused delays and quality issues for this medical device industry. For these purpouses a Lean 5 Why's tools was used and it resulted in the following summary of the root cause;

- The samples are documented in a separate application from MES, called IQS.
- Counting the Samples is 100% human dependent.
- IQS does not have the capability of counting samples and alerting if a sample is missing.

- MES have the capability to have an interface and/or Equipment Controller for Sampling Collection.

During the investigation and analyze process for this phase additional benefits where found to be applicable by generating an improvement of the documentation and sampling process. These opportunities were;

- Further analysis of the data reflected that the average days that takes to work a product nonconformance investigation due to Failed Sampling Plan is 9 days. This could affect the On Time Delivery metric, Overtime metric and consume resources to resolve the investigations.
- Also, transactional rejects such as IQS transactions errors, calibration of gages and incorrect gages used can be also added to the new system/enhancement to be developed by the IT Department. Doing so, additional failures and rejects affecting Yield and other Metrics were mitigated. From the initial Pareto, when adding these rejects the total Reject Rate goes from 20% (from FSP only) to 31% of the overall rejects.

Improve Phase

Once the major offenders for the failed sampling plan reject code where identified, it was important to generate an action plan to improve the inspection data collection of this medical device

industry. There are several levels of improvements based on how the defined problem is addressed. Within these levels, by lean manufacturing definitions, the best practices are to make the process Poke Yoke and to define Standard Works. Figure 9 below defines how better controls can be reached by implementing more robust improvement activities.
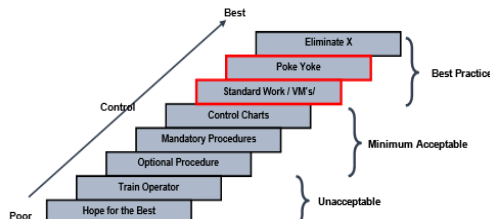

Figure 9
Improvement Approach

For this improvement project, the Action Plan was defined as follows;

- The scope was only to be the Machining steps since, by empirical data, the 78.1% of the rejects due to Failed Sampling Plan nonconformity were in that area.
- IT Department needed to develop the User Requirement Specification for the creation of an interface that could gather samples and keep counting as per sampling plan of lot being manufactured; creating a systematic Poke Yoke.
- With this successful development, this system required to be validated to be used in MES.
- General Work Instructions for the operators and engineers to learn how to use the new developed software and to configure the inspection process at this interface, were required respectively.
- At last it was required coordination with the IT Department for the installation of new interface in MES to all the computers used at the Machining step for the site.

Then, this action plan was followed by an implementation plan of this new interface with the MES platform. The implementation plan was divided by steps that needed to be completed to proceed and the specific owners for these tasks. These tasks were managed by following a critical path and using a Gant Chart striving to complete the project with the at least time possible.

With the implementation plan completed, the main work instructions for the usage of the AIDT was referenced and connected to all the machining step operation procedures. Furthermore, the following Work Instructions were generated as part of the implementation plan to reach an appropriate standardization & control:

- Operational Software Security Procedure
- Software Backup and Restore Procedure
- AIDT Equipment Controller Procedure
- Change Management Configuration Procedure
- Engineering Configuration Process Procedure

With all these requirements completed this new system was released to the manufacturing floor.

Control Phase

During the Control Phase, the most important activity was to confirm that the defined problem was resolved and that there are the appropriate controls to reduce or eliminate the root cause. For the Failed Sampling Plan reject code, it is important to assure that the incidence of this reject code was decreased overtime. Figure 10 reveals what was the result of this implementation process.
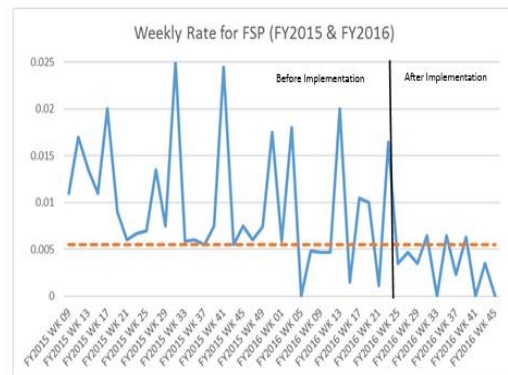

Figure 10
Rate Decrease Graph

The graph from Figure 10 shows that the reject code was decreased after the implementation by more than half of the incidence. In addition, a final capability was calculated to show the performance difference for the previous established. This final

capability, see Figure 11, shows a percentage reduction around 0.45% of the defective units by the Failed Sampling Plan reject code. With the results and the implemented systematic controls, it is expected that this reject code is not part of the major offenders for the nonconformities at this medical device manufacturing site.
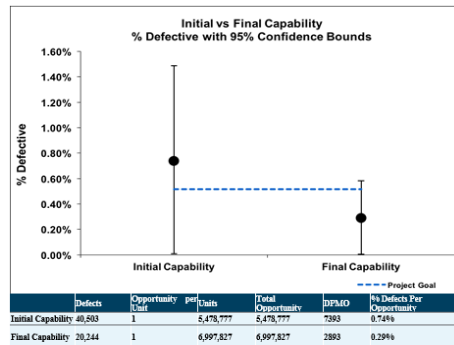

Figure 11
Final vs Initial Capability

CONCLUSIONS

The major goal of this improvement project was to reduce the pain caused to the manufacturing process due to the high amount of rejects with the Fail Sampling Plan nonconformity condition. This problem was a risk for the integrity, compliance and revenue of the company by generating nonconformities regulated by the standards of the federal agencies. In addition, each of these investigations represented a negative effect into the resource allocation and lead time of the manufacturing process adding cost to the manufacturing line. With the implemented systematic Poke Yoke System and the Standardized Work Instruction several benefits will be reached and are summarized as follows;

- Manufacturing operator does not have to count the number of samples. This quantity and its requirements are embedded to the system as initially configured from the qualification process of the product. This means that no Fail Sampling Plan reject will be reported for the configured product.
- There is a standardized work instruction that gives the operator the main instructions for the

use of this new interface in communication with the MES system. Furthermore, the configuration process of the interface is part of the training matrix for all the engineer positions.

- This failure mode capability was reduced by 0.45%, which means that the will be less defects per number of units manufactured. Capability reduction from 0.74% defects per opportunity to 0.29% defects per opportunity.
- An overall weekly rate of rejects due to the Fail Sampling Plan nonconformities was reduced from a proportion of 0.0250 to 0.0055 of total units manufactured. This represents a 78% of reduction.
- Further work is required to migrate all the existing part numbers from the IQS inspection process to this new data transfer interface. The latest will promote to eliminate the Fail Sampling Plan nonconformity from the manufacturing line of this medical device industry.

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