Steel Sutures Finished Good Test Sampling Optimization Initiative

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Abstract *— Regulated organizations have the challenge to reduce cost and increase value while complying with regulatory mandates. Quality history, process capability, and life cycle of a given suture produce for a medical device company was used to build a business case to eliminate Finished Good Level testing which will result in waste reduction and cost saving. The level of managerial interactions at internal and corporate level requires a change management strategy that portrays the need of the organization evolution and risk mitigation plans.*

Key Terms *— Change management, Finished Good Test, life cycle management, process capability, sampling plan, sutures.*

INTRODUCTION TO THE STEEL FINISHED GOOD TEST OPTIMIZATION INITIATIVE

As part of the quality systems of a medical device organization, there has been a validated requirement to perform various non-destructive and destructive testing to representative samples of each lot of finished devices manufactured in the sutures manufacturing processes. This test is part for the release process of each manufactured lot of product in the site (i.e., release to distribution center for market distribution). The Finished Good (FG) tests performed to each lot of Steel Sutures requires that at least 10 samples per lot are destroyed. This is the same for each other product family of sutures which accounts for an overall yearly volume of approximately 126,837,144 units manufactured.

Some of the product families of sutures are considered legacy products, i.e., the products have been manufactured for 20 years or more. Steel Sutures family is a legacy product.

Steel Sutures family is a low volume product with a yearly volume of approximately 1,144,248 units. It has shown a good historical quality trend in terms of customer experience (e.g., complaints), non-conformances (e.g., NCR), major issues (e.g., CAPA, Audits), and process capability (tensile strength and pull strength Ppk [4]).

In order to improve product flow and cycle time, reduce process waste, and increase Quality Assurance (QA) and human resources availability, the *Steel Suture FG Test Sampling Optimization Initiative* is strategically designed to serve as a baseline, not only to attain the aforementioned goals, but also to drive opportunities regarding product/process control and monitoring early in the manufacturing process instead of after the fact inspection and testing for product release.

Per business plan on 2014, approximately 13,500 units were destroyed annually for Finished Goods physical test purposes, while the number of finished good test related failures is zero (0).

The project consisted on preparing a business case by analyzing available and historical quality data from a product family and developing a business case to support the objectives. Results of the analysis and discussion of the interactions with key stakeholders will portray a path of undiscovered interactions of managerial levels.

REVIEW OF SAMPLING PLAN OPTIMIZATION AND COST LITERATURE

In Acceptance Sampling Plans for Percentiles Based on the Inverse Rayleigh Distribution the authors Rao et al. concluded that a sampling plan developed based on Rayleigh models showed that the minimum sample sizes are smaller than the 10th percentile of both binomial and Poisson approximations [1]. The most significant aspects of this study is the statements the authors made regarding data distribution symmetry and how stress when the quality of a specified low percentile is concerned, the acceptance sampling plans based on the population mean could pass a lot which has the low percentile below the required standard of consumers [1]. Furthermore the mean life may not be adequate to describe the central tendency of the distribution since it reduces the feasibility of acceptance sampling plans if developed based on the mean life of products [1]. Rao et al. stated that, percentiles provide more information regarding a life distribution than the mean life does [1]. Because of these assumptions, and the conclusion of the study the Steel Suture Sampling Optimization Initiative overcome a road block concerning data analysis and statistics of capability. Tensile strength testing results are in pound-force (lbf), and data sets often shows non-symmetric distribution; because of this symmetric distribution capability analysis may not be performed in the data sets available for the project to support such assessment; therefore based on the study by Rao et al. and the concept of Equivalent Capability (which is also based on the comparison of normal probabilities with percentile ranges) by Bothe [2], there is alternate ways to assess Finished Good (FG) testing process capability.

The project for Steel Sutures FG Sampling Optimization promotes cost savings and cost avoidance within cost centers of operations and quality functions within the organization. Even though the modern organization innovates to drive customer satisfaction, enhance customer experience while sustaining quality and compliance, the change within the organizational arcs may not be as resilient to managers and key stakeholders. From the beginning, this initiative has caused numerous questions in regards to compliance and risks. The use of soft skills and sensitive communication it's important for attaining the goals of the project, but also benchmark of the concept is needed to see how a cost effective sampling will not only help drive cost reduction/avoidance but also keep processes stable and compliant. Ridley and MacQueen state the strategy to follow a cost effective sampling CES strategy using a methodology that considers data trend and variation to adjust sampling to a time based tool for decision making [3]. The use of CES not only propose a cost saving strategy but promote the use of data to help management to accurately and quickly respond to trends as well as keeping compliance and informed with regulatory agencies [3]. As part of the change management strategy for the key stakeholders it is imperative to encompass not only cost savings and waste reduction within the project but to underline what are the risk mitigation plan, control plan, and compliance plan for the product family as the changes take place forward.

Analysis and Development of Local Sampling Optimization Business Case and Methodology

In order to construct a business case that portrays the value proposition behind the project, a DMAIIC methodology was used to segregate project tasks in a manner that it is understandable across the organization since DMAIIC methodology is generally used for internal projects.

Define

For the Define phase, a project charter was generated to portray the purpose of the initiative and to get agreement from the site internal management, and communicate intent to other stakeholders at the corporate level such as Worldwide Quality (WWQ), Life Cycle Management (LCM), and Research and Development (R&D) group. The milestone for the Define phase was to get approval or agreement on the business case by the key stakeholders previously mentioned.

Measure

For the measure phase, the focus was to get a capacity analysis and evaluate historical data. Based on historical quality data, a positive trend behavior was detected and serves as evidence of good product and process capability. See Tables 1, 2, and 3 for summary of NC, Complaints, and CAPA/PRE/Audit indicators.

Table 1
Analysis of product behavior from a Customer Perspective

Complaints	Total Complaints	Total Qty. Involved	Total Qty. Transferred (EA)	Defect per Millions (DPM)	Process Sigma
Reported	22	27	231K	116	5.17

Table 2
Analysis of product behavior from a Manufacturing Perspective

Total NC's	Finished Good Related	Complaint Related	Other
11	0	8	3

Table 3
Analysis of product behavior from a Vigilance Perspective

Total CAPA's	Total PRE's	Total Audit Findings
0	0	0

ANALYZE AND INNOVATION

Discussion of Change Management, Stakeholders, and Dynamic of Managerial Levels

Since the FG sampling optimization initiative challenges the status quo of the organization, it was expected to a level of disagreement or reluctance to implementation from a managerial perspective, especially from corporate level management that does not have immediate detail on the operation. Customer impact was found to be low as well as market risk due to product life cycle maturity. The major risk presented during discussion with WWQ and LCM management was from a regulatory perspective. Regulatory agencies are important stakeholders and may not react as receiving with the proposed changes. During project execution, there was a high degree of meetings and iterations with key stakeholders from the WWQ (design quality) and LCM groups to discuss the details of the project and the statistical analysis done. The innovative phase focused on a change management strategy that considered the scales of managerial levels and explore until what levels of the organizational decision making was inherent by different groups. It was found that the LCM council was found to be the front end of the initiative since it has participants from WWQ, LCM, and R&D which gather as a group to discuss the risks, the impact, and the importance of process changes such as removing or optimizing FG sampling plan for Steel Suture family.

For the Analyze phase, the data was narrowed down to Steel USP size 2 sub-family. This was the request of the LCM council in order to minimize the risk of failure after implementation and control phase of the project. Data from size 2 USP was gathered and probability analysis was completed. Figure 1 shows the normality test for the size 2 USP data set and since the P-value of 0.286 is greater than the significance level of 0.05, there is sufficient evidence to claim that the data set follows a normal distribution fit. Therefore it is recommended further control and capability analysis.

A process control and process capability analysis was performed. The I Chart, as seen in Figure 2, shows a stable process that is in control; from samples 37 to 43, it was found a positive trend, but there is no additional information on how to reproduce this positive behavior. Figure 3 shows that the process has a capability of Ppk = 1.20 or it is using 83% of the specification band. This means that a process drastic change may produce units out of specifications with only 17% of process shift span. As seen in Figure 4, the histogram of the Steel USP size 2 sutures has the shape of a normal curve and the data is away from the lower specification limit (LSL) by 17%. Comparing process capability and process control a 2 lbf difference is identified when the lower control limit (LCL = 11.7 lbf) from Figure 2 is subtracted from the LSL = 9.7 lbf from Figure 4.

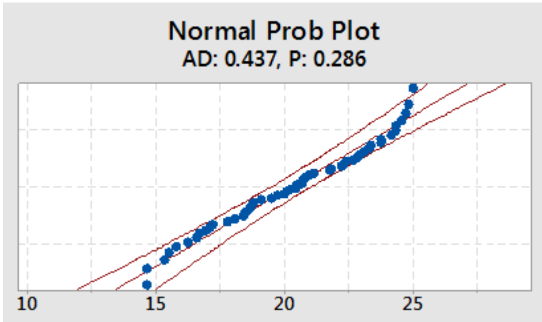

Figure 1
Normality Test for Size 2 USP Needle Pull Data

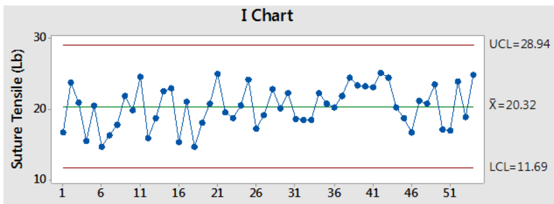

Figure 2
Control Evaluation for Size 2 USP Needle Pull Data

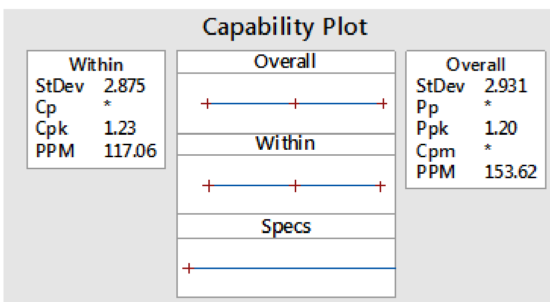

Figure 3
Process Capability Analysis Results for Size 2 USP Needle Pull Data

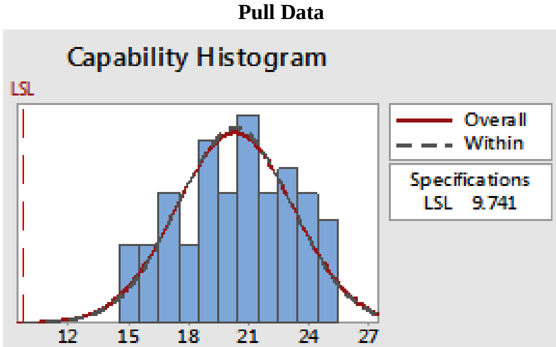

Figure 4
Histogram and Specification of Size 2 USP Needle Pull Data

Improve and Control

Because of the exploratory curve from a stakeholder management perspective during the Analyze and Innovation phases, project implementation plan as part of the Improve phase, the implementation dates were shifted forward and the scope of the project was narrowed to one size of the product family. Because of those changes, the Continuous Improvement Quality group generated offset plans for cost savings initiatives to deliver cost commitments at the site level while continue to work on the implementation and stakeholder management at all levels of the organization.

The Control phase strategy consists of generating product/process specific work instruction to monitor product trend quarterly to ensure risks has been mitigated or reduced, and because of the removal of FG testing, increase in the key performance indicators mentioned during the Measure phase are not negatively affected.

Conclusion: Steel Product Lifecycle Management and Maturity

In the path to eliminate and/or reduce Finished Good (FG) testing requirement for the regulated industry a strategy was explored to design a methodology that accounts for all measures and indicators of product life cycle maturity and assessment of such maturity from process capability, and quality trend history.

For the specifics of the subject organization it was found that key stakeholders were 3, considering two internal and one external. The internal key stakeholders are the site (or plant) middle management, and the corporate level LCM council, comprised of WWQ, LCM, and R&D representatives. To demonstrate product life cycle maturity of any product within the organization, these two stakeholders will serve as sponsors and facilitators for the final decision. The third stakeholder is the external regulatory agencies; these have to be considered since drastic changes come to question during organizational audits and strong rationale for design and process changes will have to be explained to each agency.

After business case generation and further analysis of the product family it is concluded that the Steel Size 2 USP Sutures sub-family has a good trend behavior and strong capability within product life cycle. The initiative sets the baseline of acknowledging a products life cycle maturity and rely on process controls, improvements, and enhancements instead of single lot testing. Managerial implications will appear throughout the execution of sampling optimization projects, and as part of the methodology it is recommended to generate a change management strategy that considers the aforementioned stakeholders.

Organizations invest long sums of money into improvement and controls, but do not necessarily rethink control processes. By understanding the risks associated with product and processes, and studying the life cycle maturity of the product, a different reasoning can be used to increase value and assure product performance at a customer level.

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