Finished Goods Failure Reduction in a Wound Closure Medical Device Product Family

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Abstract *— A corrective action and preventive action plan was developed to address the increase of Finished Goods failures in a wound closure medical device product family. Following a Define-Measure-Analyze-Improve-Control Six Sigma approach, process failure modes were successfully identified and mitigated. Results show Finished Goods nonconformances decreased by 93 percent during the first four months of the action plan effectiveness period increasing the process sigma level from 5.51 to 6.35.*

Key Terms *— Corrective Action, Failure Investigation, Root Cause, Six Sigma.*

INTRODUCTION

This project was performed in a medical devices company located in San Lorenzo, Puerto Rico that specializes in wound closure. It was focused on developing an action plan to address the increase of Finished Goods failures rate in a product family.

Product family A is a wound closure medical device that consists of a synthetic suture attached to drilled needles on one or both ends, as shown in Figure 1.

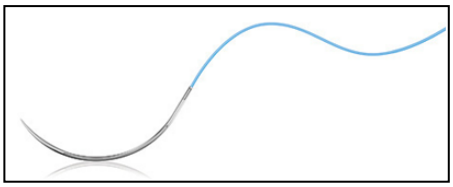

Figure 1
Wound Closure Medical Device Product Family A

The manufacturing of product family A wound closure medical device is a manual process where operators insert the synthetic non-absorbable suture in the needle hole. Then, the operator completes the attaching process by swaging the needle with the use of dies on a pneumatic press.

As part of the Finished Goods release criteria for product family A, the needle/suture joint is tested to confirm it meets minimum pull force requirements prior to detaching. Should this test fail, the product is classified as nonconforming.

There was an increase of 9% in Finished Goods (FG) failures for a wound closure medical device product family A from 3.21 events or 19.88 defects per million (dpm) in the 2010 through 2011 timeframe to a total of 3.5 events (25.38 dpm) in 2012.

The objectives of the project were to conduct failure investigation in order to identify failure modes related to the Finished Goods of wound closure medical device product family A and to develop an action plan to reduce the occurrence of non conformance events by 40%.

LITERATURE REVIEW

The literature review for this study was focused on the Code of Federal Regulations title 21 for Medical Devices (CFR 21) of the Federal Drug Administration (FDA), the Quality Management Standard 13485 of the International Standards Organization (ISO), the Introduction to Statistical Quality Control textbook of Douglas Montgomery, 2005, and the Rath and Strong's Six Sigma Pocket Book, 2005.

Nonconforming Product

The Wound Closure Medical Devices company procedures define nonconforming product as a device that does not fulfill specified customer requirements. This definition is aligned with the Food and Drug Administration (FDA, 21 CFR 820) and International Organization for Standards (ISO) definitions. Both established that a failure to comply with the requirements, expectation, or

obligation of the manufacturing process of a device turn it to a nonconforming product. Requirement is a need, expectation, or obligation. It can be stated or implied by an organization, its customers, or other interested parties [1]. Specification means any requirement with which a product, process, service, or other activity must conform [2]. Increase on nonconformance events drive management to take action to address the conditions that are impacting negatively the manufacturing process of the device. Management responsibility is clearly described in 820.20 section of the 21 CFR. Based on the regulation requirements and the internal process specifications a Corrective Action Preventive Action (CAPA) project was initiated to address the Finished Goods failure condition of the product family A. CAPA is defined by the regulated agencies (FDA and ISO) and the Wound Closure Medical Devices company procedures as a Corrective action and Preventive action project that the intended is to eliminate, reduce or prevent failures modes that can cause a nonconforming product.

Define, Measure, Analyze, Improve, and Control Approach (DMAIC)

The Define, Measure, Analyze, Improve, and Control Approach (DMAIC) Six-Sigma approach was used to identify the failures modes of the Finished Goods product family A. Douglas Montgomery established in his book, Introduction to Statistical Quality Control, 2005, that a six sigma approach looks for the variability reduction of the key product or process characteristics to the level at which failure or defect are extremely unlikely. Douglas Montgomery also defined in his book, Introduction to Statistical Quality Control 2005 the DMAIC methodology five phases, Define, Measure, Analyze, Improve and Control, as follows [3]:

- **Phase I – Define:** Define the problem, the customer expectation and their Critical to Quality (CTQ's). Establish the project boundaries and goals based on the knowledge of the organization, costumer and the process.
- **Phase II – Measure:** Collect relevant data from the process to determine the types of the defects, failures and metrics that impact the performance of the process. The data collection enabler the identification of the location of source of the problem and narrow the range of potential causes that need to be investigated and analyzed.
- **Phase III – Analyze:** Review the data and verify the cause and effect relationships to identify the source of variation. This phase allow the identification of the gaps between the actual performance and the process requirements or business goals.
- **Phase III – Improve:** Implement process improvement using techniques such as error proofing tools and standard work in pilot area to reduce the failures and establish the process capability.
- **Phase III – Control:** Deploy the improvement in all impacted areas, monitor the results and create a sustainable structure for the correction to void that the process goes back to the old way.

Using DMAIC, the variability of the process or product can be reduced to achieve at least the minimum value of 1.33 for the process capability index Cpk [3]. This index provides a numerical value of how centered is the actual process mean versus the requirements as per Douglas Montgomery book, Introduction to Statistical Quality Control, 2005. A process with a Cpk of 1.33 will produce 63 defects per million opportunities (DPMOs) [3].

The sigma level (σ) is defined as a measuring method used to measure the capability of a process. The aim is to achieve a sigma level of at least six, which equates to less than 3.4 Defects Per Million Opportunities (DPMOs) [4]. The Sigma level is calculated using the normal distribution. The idea is that the span between the upper and lower specification limits should be at least 12 standard deviations (six standard deviations on each side). Because it is not usually practical to set the

processes mean exactly on target, and the mean of most processes is subject to drift, a 1.5 standard deviation offset is assumed in converting between DPMO and Sigma Level.

METHODOLOGY

The methodology for this project is based on the DMAIC approach, as the backbone of Six Sigma and where the term "defect" goes beyond the common definition of a product defect to include any event that results in a failure to meet customer expectations.

Using the DMAIC approach, the problem was defined in the first phase of the approach, baseline metrics were measured on the second phase, and the potential sources of variation were identified by means of a failure investigation in the analyze phase. Improvements were achieved through the implementation of an aggressive action plan as part of the fourth phase of the project.

This proposed action plan was measured for effectiveness in the control phase, where the implementation needed to be proved sustainable.

RESULTS

The results for the Measure, Analyze, Improve, and Control Phases of the DMAIC Methodology follow.

Measure

The Non Conformance Report (NCR) System of the Medical Devices Company was used as source of data collection. NCR system queries were ran from January 2010 to June 2012 to obtain the data.

The overall Finished Goods Nonconformance trend was analyzed from January 2011 to June 2012. As it can be seen in Figure 2, there has been an increase of 9% in Finished Goods failures for a Wound Closure Medical Device product family A from 3.21 events (19.88 dpm) in the 2010 through 2011 timeframe to a total of 3.5 events (25.38 dpm) in 2012.

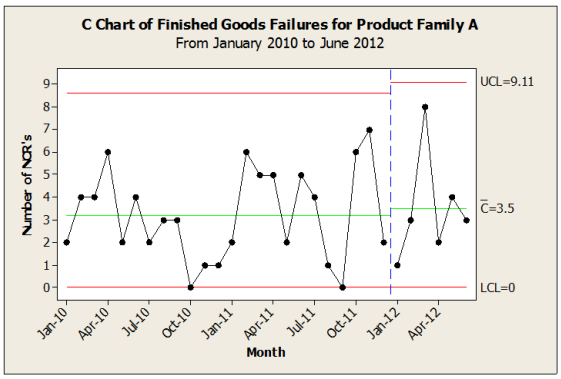

Figure 2
C Chart of Finished Goods Failures for Product Family A

The sigma level (σ) for the product family A attaching process was determined taking into consideration 21 events reported in Nonconformance Report (NCR) System as Finished Goods failures out of the total volume of 773,866 units produced from January 1, 2012 to May, 2012.

This value was determined to be 5.51 according to Table 1 below. Using the normal probability distribution, this value can be calculated as the two sided Z-value that corresponds to the percentage of defects per opportunities of a process. Since the Finished Goods testing for product family A is destructive, the number of defect opportunities per unit is equal to 1. Therefore, the defects per opportunity for the product family A swaging process is equal to 0.0028616 percent (21 defects/773,866 units).

The two sided Z-value that corresponds to this percentage of defects is the sigma level for the swaging process (5.51). This value can be extracted from a normal probability distribution table (Z-value table). It can also be extracted from either a yield to sigma or defects per million to sigma conversion tables that have been developed to facilitate this calculation.

Table 1
Product Family A Sigma Level

Number of defect opportunities per unit	O =	1
Number of unit processed	N =	733866
Total number of defects made (include defects made and later fixed)	D =	21
Calculate Defects per Opportunity	DPO = D/(NxO)	2.8616E-05
Calculate Yield	Yield = (1-	99.997138

	DPO)* 100 =	4
Sigma Level as per Process Sigma Table	σ =	5.51

The major offender of the Total Plant Finished Goods Nonconformance was related to product family A with a 77.6 percent of total number of nonconformances, as showed in the Pareto Chart presented in Figure 3.

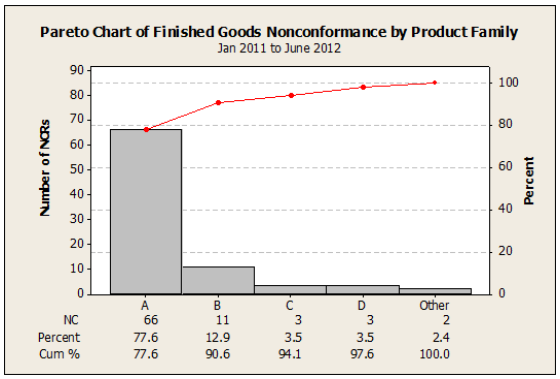

Figure 3
Pareto Chart of Finished Goods Failures by Product Family

Figure 4 shows the baseline Pareto Chart for product family A Finished Goods nonconformance (NC) by assignable cause. As it can be seen, three different potential assignable causes were identified: tooling compatibility with needle/suture product combination, insertion issues, and incorrect machine setup. The chart also shows that the major offender with 77.3% is related to tooling compatibility on the manufacturing process.

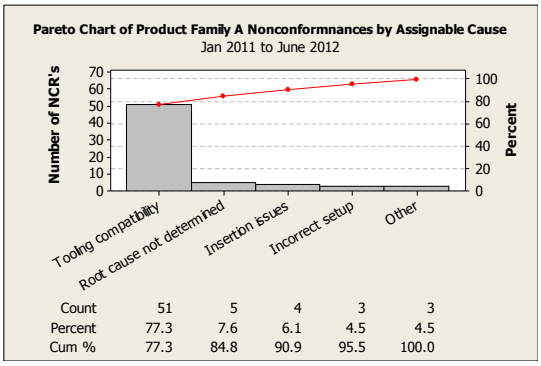

Figure 4
Pareto Chart of Product Family A Finished Goods NC by Assignable Cause

Based on the data collected for Finished Goods Nonconformances and potential assignable causes for product family A, the tooling compatibility, as major offender, shall be the area of focus on the Analyze Phase.

Analyze

Analysis tools such as Cause and Effects diagram Pareto Charts, and the Machine, Man, Material, Method, Mother Nature tool, also known as 5M were used to better understand how the tooling compatibility correlates to the Finished Goods failure for product family A.

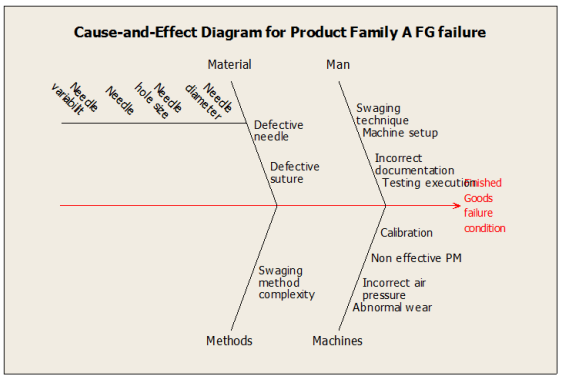

Figure 5
Cause and Effects diagram for Product Family A FG Failures

The cause and effect diagram showed in Figure 5 above, presents the main potential causes for the Finished Goods failure of product family A.

5M Analysis of Finished Goods failure for Product Family A

These main potential causes were evaluated using the 5M analysis tool. This tool focuses on determining assignable or root causes by assessing these five potential categories.

- *Machine* – Failed samples of Finished Goods evaluation confirm there is no machine issue since associates manually perform the machine setup and insert the suture on the needle at the swaging machine to complete the attaching process per the company's swaging applicable procedure. Therefore, no machine conditions can be identified that can cause this nonconformance.
- *Man* – Associates involved in the Finished Goods failures are trained in the Medical Device Company's applicable swaging

procedure specifications, which provide a detailed instruction in how to perform the machine's set up, swaging process and inspection for product family A. No swaging anomalies were found after attachment assessments of samples of each FG failure. Finished Goods inspection and in process inspection results of failed batches were analyzed and was found that FG values were below in-process statistical control requirements and some of them did not meet current target requirements. Most probable root cause for the low pull values can be related to incorrect machine set up and inspections performed by swaging associates that cause loose swaging press, low air pressure, loose suture guide, and incorrect swaging dwell time. Therefore, associates machine set up and inspection technique can cause the FG failures.

- *Material* – During attachment assessment performed in each FG failure the failed samples were evaluated and no raw material conditions were identified that can cause the nonconformance.
- *Method* – Product family A swaging method is detailed in the company's process specifications in order to ensure that the product complies with all the quality requirements. The attachment of the synthetic non absorbable suture with drilled needles is performed under the company's drill swaging process procedure. Associates manually insert and attach the suture in the needle and perform the corresponding die set up and inspections for the each unit of movements.

During data and sample analysis it was found that in most of the samples the swaging die mark end was in the same position than the needle hole depth end. More than 40 % of the failures are non absorbable synthetic suture size 0 combined with 26, 27, 29 and 33 mil needles as evidenced in the Pareto Charts of Finished Goods Nonconformances by Suture Size (Figure 6) and by Needle Size (Figure 7).

The Medical Devices Company uses the United States Pharmacopeia (USP) designation for suture sizes (7-0, 6-0, 5-0, 4-0, 2-0, 0, 1), where 7-0 is the thinnest and 0 is the thickest.

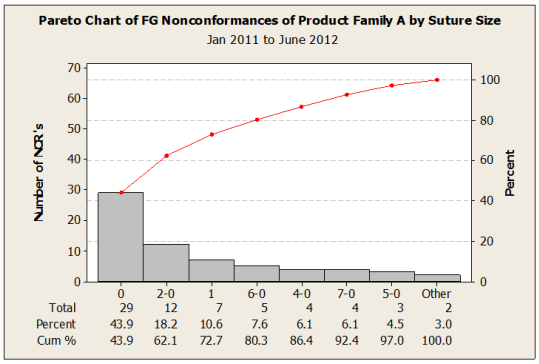

Figure 6
Pareto Chart of FG Nonconformance of Product Family A by Suture Size

Needle sizes are usually measured in mils which equals one thousand of an inch.

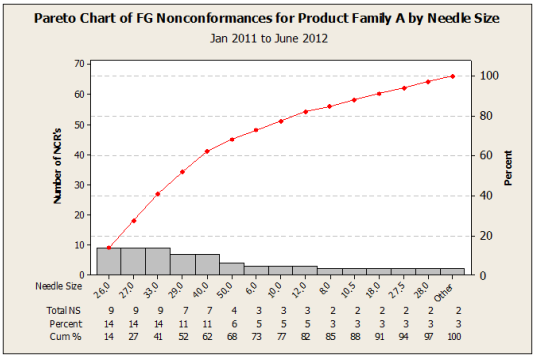

Figure 7
Pareto Chart of FG Nonconformance of Product Family A by Needle Size

The size 0 with 26, 27, 29 and 33 mils needles combinations have in common drill swage dies X of size 0.057" as per company's specification. If the needles hole depth is in the lower limit of the specification, it can cause an incomplete compression during the swaging process since the dies hit the solid needle wire. Therefore, method was identified as potential roots cause for the FG failures in the product family A swaging process.

- *Mother Nature (Environment)* – Batches were processed under normal condition in the Medical Devices manufacturing facility. There were no anticipated environmental conditions

that could have caused the product family A Finished Goods failures.

Based on the analysis it can be concluded that the root cause for the Finished Goods failures is related to Method due to tooling compatibility with the needle/suture product combination. The effect of this tooling compatibility condition on FG failures can be increased by incorrect machine setup and product testing execution (inspection) that the operator performs.

The improve phase was focused on developing and implementing an action plan to address the Man and Method conditions previously identified.

Improve

After concluding that the potential for the Finished Goods Failures in the product family A was related to the swaging die of size 0.057", it was decided to change the swaging die series from X (depth length 0.057") to Y (depth length 0.035") series to produce a better compression in the swaging process as part of a mitigation plan.

This plan helped decrease the mean Finished Goods failures from 3.5 to 3 events per month during the July to December 2012 timeframe for a 14.3% reduction as shown in the C chart presented in Figure 8 below.

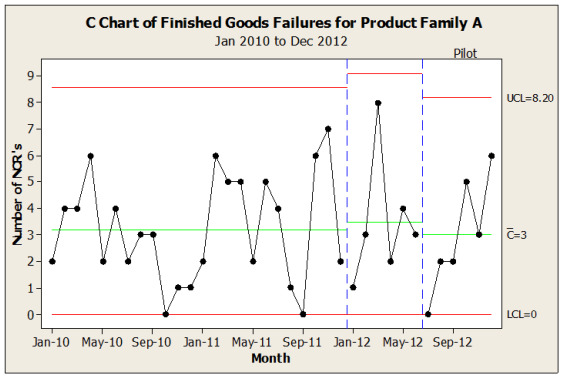

Figure 8
C Chart of FG failures for Product family A – Pilot

The following actions were pursued to address the increase in the Finished Goods Failures related to product family A related to Man and Method:

- Re-training on product family A machine set up, and product inspection were completed with the swaging associates.
- Product family A swaging process improvements by revising the process specification to change drill square swaging dies from X to X1, size 0.046".

This die change to X1 allowed for an improved compression in the swaging processes that minimizes the rate of occurrence of the Finished Goods failure for product family A that will be monitored for effectiveness in the control phase.

Control

After implementing the corrective action plan to address the rate of occurrence of Finished Goods failures for product family A, the CAPA project was monitored for effectiveness starting on January 2013. As it is shown in the C chart presented in Figure 9, a reduction of 3.5 baseline events per month to 0.25 events per month was achieved during the January 2013 to April 2013 timeframe for a 93% decrease.

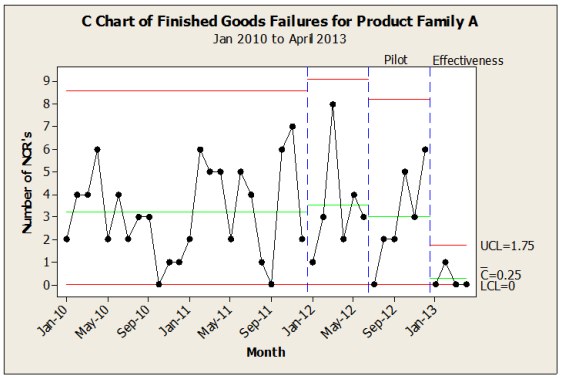

Figure 9
C Chart of FG failures for Product Family A after CAPA

Using the same approach that was used to calculate the baseline metric in the Measure Phase, the sigma level was recalculated to show improvements in terms of defects per million reduction. Table 2 shows the calculation of the new sigma level after the implementation of the corrective action plan. Only one event has been reported out of a total of 1,614,505 processed units since the implementation for a total defects per

opportunity of 0.000061938 percent (1 defect/1,614,505 units). This equals a total defects per million opportunities of 0.61938, which translates into a sigma level of 6.35.

Table 2
Sigma Level Analysis after CAPA

Number of defect opportunities per unit	O =	1
Number of unit processed	N =	1614505
Total number of defects made (include defects made and later fixed)	D =	1
Calculate Defects per Opportunity	DPO = D/(NxO)	6.1938E-07
Calculate Yield	Yield = (1-DPO)* 100 =	99.99993806
Sigma Level as per Process Sigma Table	σ =	6.35

It can be concluded that the corrective action plan has proven to be effective during the first quarter of 2013.

CONCLUSION

Based on the results of the implementation of the corrective action plan to address the Finished Goods nonconformances trend for product family A, it can be concluded that:

- The analysis tools such as Pareto charts, Cause and Effects diagram and 5M method proved to be successful in helping achieve one of the projects objectives by identifying the root causes of the Finished Goods failures.
- The CAPA project immediate actions (mitigation plan) helped decrease the current FG failure rate by 14.3%
- The corrective action plan helped increase the sigma level of the swaging process for product family A from 5.51 to 6.35 for a 93% decrease in FG nonconformances during the first quarter of 2013 exceeding the other project objective.

In light of the analysis conducted as part of the CAPA project to address FG failures for product family A and improvement observed during the first quarter, it can be recommended to use the same investigative DMAIC approach through CAPA system structure to address trends observed on other product family codes.

REFERENCES

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