MRB Disposition Process Improvement to Reduce High Inventory Level and Aging at a Medical Device Company using DMAIC Methodology

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Abstract *— Quality is an important aspect of the Medical Devices industry. The medical device manufacturing sector has become more regulated everyday in which significant quality systems and product requirements must be satisfied. In a challenging business environment is fundamental for the company to comply with the regulatory requirements and establish systematic processes to maintain the quality of the product. Currently the Material Review Board Disposition Process is being affected by the inputs of the process resulting in High Inventory Level and Aging. Lean Six Sigma methodology is focused on business and process improvements based on reducing process variation, waste elimination and customer satisfaction. This project has been developed under the Lean Six Sigma principles and using DMAIC methodology in order to identify opportunities to enable the company to reduce Material Review Board Inventory Level and Inventory Aging at the External Pumps Area at a Medical Device Company.*

Key Terms *— DMAIC, Inventory, Material Review Board, Supplier Quality Engineering*

INTRODUCTION

Many companies have a Material Review Board (MRB) for the disposition of material/components that do not conform to specifications. The Material Review Board is one of the biggest reasons for large inventory investments. [1] Several of the possible dispositions include rework, scrap, use as is and return to vendor. The amount of work done by the Supplier Quality Engineer (SQE) and the time elapsed until a disposition is made is one of the major causes for the high inventory level and aging in MRB.

This project is important for the Risk Management of the user or patient, the financial impact for the company and for compliance with regulatory requirements. The company will benefit reducing regulatory inspection and audits findings, saving inventory dollars and avoiding the cost of poor quality. The project focuses on the process improvement for the disposition of nonconformance material by the SQE, finding the root causes of the problem by implementing Lean Six Sigma methodologies to help address the waste and variability in the process and supply chain system.

BACKGROUND

Medical device manufacturers are always working to balance the demands of meeting government regulations and containing production costs, in an effort to produce the most reliable and safest medical devices. The regulatory requirements are intended to ensure that manufacturers consistently design, produce, and place into the market, medical devices that are safe and fit for their intended purpose. This means that it will get harder to manage the quality of medical devices operations as they are forced to comply with more regulations everyday.

The process of quality control includes all of the measures that are needed to verify and control the quality of the product or service that is being offered to the customer. Quality control has to be in place in order to ensure that the final product is the highest quality possible. Creating a high quality product is important to the benefit of the user or patient.

Quality control is a must during the manufacturing process, and managing the quality of incoming raw materials can greatly improve

operational performance, produce better quality goods, and increase profitability.

PROBLEM STATEMENT

The Food and Drug Administration (FDA) CFR 21 Part 820.90 indicates that each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented. In order to comply with this requirement the Material Review Board Disposition Process for nonconformance material or potential nonconformance material should be systematic, standardized and reliable. This business is a major offender across the medical device company for Material Review Board Inventory Aging and Dollars. This impacted our quality, our ability to supply and our cost performance.

PROJECT METHODOLOGY

The Lean Six Sigma Methodology DMAIC, see figure 1, will be used in this project in order to improve the Material Review Board disposition process.

Figure 1
DMAIC Methodology

DMAIC is an approach to problem solving and a tool for improving an existing process. A team kickoff meeting was performed in order to discuss the phases of the project.

- **Define:** In this phase the project leaders are responsible for clarifying the purpose and scope of the project, for getting a basic understanding of the process to be improved, and for determining the customers' perceptions and expectations for quality. A goal setting and Measurements are discussed to define the problem, the project's objective and scope. A project charter will be presented for the basic description and expectations and a SIPOC diagram will define the process input and outputs.
  a. Project Charter: The project charter is an agreement between management and the team about project goals, deliverables and expectations. Therefore is very important that leaders and teams of the Supplier Quality Engineer Department discussed about the project goals and their expectations.
  b. SIPOC Diagram: A SIPOC diagram is a high-level view of a process helps to define project boundaries (starting and ending points) and focuses the team on where to collect data. The SIPOC is useful to keep a clear scope of the project, highlight areas for improvement and ensure focus on the customer.
- **Measure:** In the measure phase the objective is to provide a clear focus on the improvement effort by collecting information and relevant data on the current situation. The goal is to obtain data collection that leads to problem location or occurrence, comprehensive baseline data and a detailed and focused problem statement. In this phase Pareto charts will be presented.
  a. Pareto Charts: Pareto Charts show which factors contribute the most to a given problem. Identifying and focusing on these critical factors will maximize results,

oftentimes with far less effort than would be required if all factors were treated equally.

- **Analyze:** The purpose of the analyze phase is to allow the project team to target improvement opportunities by taking a closer look at the data to determine the root causes of the process problems and inefficiencies. This involves discovering the reasons of defects generated (identified in the previous measure phase) that are most likely to cause process variation. Statistical analysis is a key component of this phase and used to demonstrate and confirm these relationships. By the end of Analyze, the sponsor will know which causes will be focused on in the innovative improvement step by describing which potential causes were identified, potential causes decided to investigate and the data collected to verify those causes and what the data showed. This phase include statistical tools as pareto charts and fishbone diagram.
  a. Fishbone diagram: fishbone diagram is a tool for analyzing process dispersion. The main goal of the fishbone diagram is to illustrate in a graphical way the relationship between a given outcome and all the factors that influence this outcome.
  b. 5-Whys: The 5-Whys is a simple brainstorming tool that can help the team identify the root cause(s) of a problem. Once a general problem has been recognized (using the Fishbone Diagram), ask "why" questions to drill down to the root causes. Asking the 5-Whys allows the team to move beyond obvious answers and reflect on less obvious explanations or causes.
- **Improve:** This phase focuses on fully understanding the top causes identified in the analyze phase, with the intent of either controlling or eliminating those causes to achieve breakthrough performance. The goal is to develop, pilot and implement solutions that address root causes. The key steps in this phase are:
  a. To develop potential solutions.
  b. Evaluate, select and optimize best solutions.
  c. Develop and implement pilot solution.
  d. Confirm attainment of project goals.
- **Control:** This phase ensure that the gains obtained during improve are maintained long after the project has ended. To that end, it is necessary to standardize and document procedures, make sure all employees are trained and communicate the project's results. In addition, the project team needs to create a plan for ongoing monitoring of the process and for reacting to any problems that arise. The key components in the control phase are the training, document and standardize. The first step of the Control phase is to document and standardize the improvements that were rolled out during Improve phase. The monitoring plan clarifies how the process performance will be continuously monitored, who will be notified if there is a problem and how that will happen and what response is required. The goal is to use data to evaluate both solution and plans, validate that all changes adhere to compliance requirements and maintain the gains by standardizing processes.

During the project the team used guidelines, see table 1, in meetings for the discussion of the DMAIC methodology phases.

Table 1
DMAIC Methodology Phases

DEFINE	MEASURE	ANALYZE	IMPROVE	CONTROL
What is the problem?	What data is available?	What are the roots causes of the problem?	Do we have the right solutions?	What do we recommend?
What is the scope?	Is the data accurate?	Have the root causes been verified?	How will we verify the solutions work?	Is there support for our suggestions?
What key metric is important?	How should we stratify the data?	Where should we focus our efforts?	Have the solutions been piloted?	What is our plan to implement?
Who are the stakeholders?	What graphs should we make?	What clues have we uncovered?	Have we reduced variation?	Are results sustainable?

RESULTS AND DISCUSSION

This section discusses all the implementation activities for the research project using the DMAIC methodology.

In the **Define phase** a Project Charter, see figure 2, was developed to discuss the project description, objectives, scope, benefits to the customer and the support required. The project objective is to develop an effective MRB System to reduce MRB inventory level and MRB aging at the right level of quality, service/delivery and cost to our internal and external customers. Project goals were established to reduce the current metric of the MRB inventory. The current MRB inventory is 1,211 lots and the average aging is 61 days. The goal is to reduce 15% each quarter in order to achieve the ultimate goal. Current inventory dollars is $367,346. The project charter was presented and approved by upper management. The Supplier Quality Engineering team participated and supported the MRB of External Pumps area in order to achieve goals.

Product/Service Impacted	*Material Review Board*	*Project Leader*	*Ninoska V. Rodriguez*
Business Unit	*External Pumps Diabetes Division*	*Project Sponsor*	*Aida L. Lopez*

Element	Description	Specifications			
1. Process	Name of process to be improved.	Disposition of Nonconformance Material in the Diabetes External Pumps Area.			
2. Project Description	What practical problem will be solved? What is project's purpose?	MRB Disposition Process Improvement to reduce high inventory level and aging for External Pumps in the Diabetes Division.			
3. Objective	What metrics will be improved, what is the current performance for those metrics and how much improvement is targeted? Provide specifics on how metrics are computed.	Metrics	Current	GOAL	% Improve
		Inventory (lots)	1,211	1,029	15
		Average Aging (days)	61	52	15
4. Process Scope	Which process steps will be considered in this project? What is the first step and what is the last step?	From when a material is found with a nonconformance or potential nonconformance to determined material disposition for material PRR closure.			
5. Business Case	Justification for this project. Why is it important? Why is it critical to business success?	This project is important for the Risk Management of the user or patient. The financial impact for inventory aging. For compliance with FDA regulations section 820.90 for nonconforming product.			
6. Benefit to Internal and External Customers	How will internal or external customers benefit from this project? How does improvement in the metrics that you have selected help them improve their performance?	Reduce regulatory inspection and audits findings. Save inventory dollars and avoid the cost of poor quality (SCRAP).			
7. Support Required	What resources, people,	Incoming Inspection and Manufacturing Area.			

Figure 2
Project Charter

The SIPOC diagram, see figure 3, describes the process in such a manner that helps define the project boundaries. The SIPOC includes key elements as suppliers that provide input to the process. Inputs that define the MRB disposition process of the Supplier Quality Engineer, which is the material that fail to conform to engineering drawing specifications, material that fails to conform to purchase orders and material that fail to conform to quality/workmanship standards. The output is the nonconformance material is dispositioned for our customers, the leaders of the Incoming Inspection and Manufacturing Department. A graphical description of the system helps to visualize the steps the process needs to take in order to get the desired results.

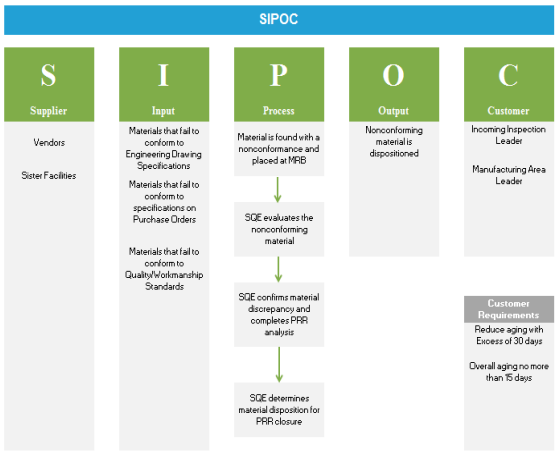

Figure 3
SIPOC Diagram

In the **Measure phase** data was collected for a timeframe of six months (October thru April). The data is represented in Pareto and Pie charts in order to identify the current situation and the major offenders in MRB of the External Pumps Area. The Pareto Chart, see figure 4, shows that the major offender is the aging with excess of 30 days.

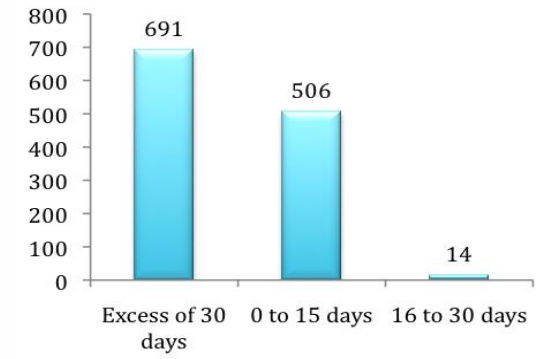

Figure 4
MRB Inventory Distribution by Aging Type

The Pareto Chart, see figure 5, shows that the manufacturing area of External Pump production

line have more material with nonconformance in than the Incoming Inspection area.

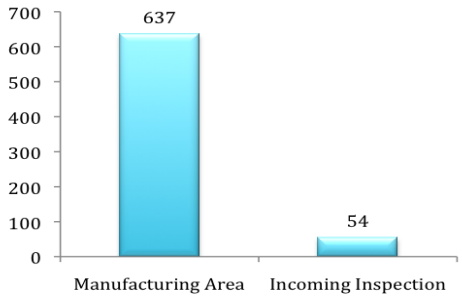

Figure 5
MRB Inventory Distribution by Area

The Pie Chart, see figure 6, sows that the 89% of the material with nonconformance in MRB is dispositioned as scrap showing the cost of poor quality.

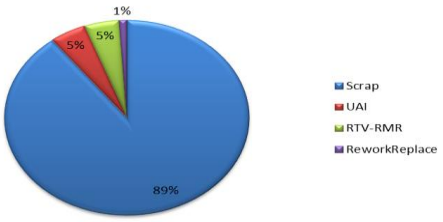

Figure 6
MRB Disposition Distribution

In the **Analyze phase** a closer look to the data was executed through Pareto Charts in order to identify the top root causes. Pareto Chart, figure 7, shows that cosmetic defect is the major offender in MRB inventory with excess of 30 days from the External Pumps Manufacturing Area.

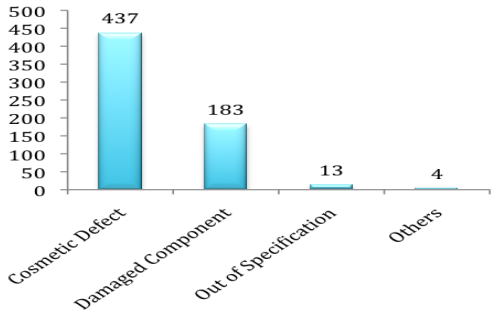

Figure 7
MRB Inventory with Excess of 30 days of Manufacturing Area by Defect

The Pareto Chart in Figure 8 shows that the Material A is the major offender in the MRB inventory with excess of 30 days.

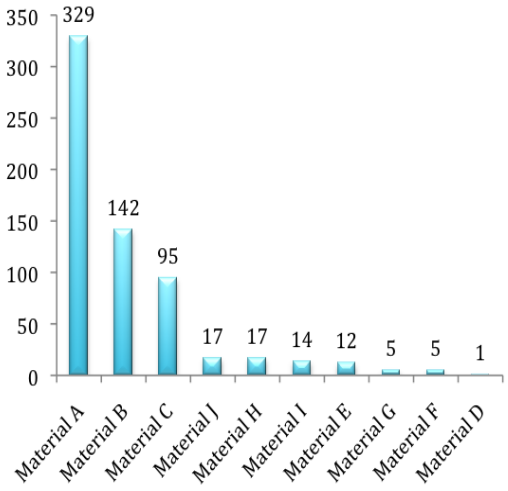

Figure 8
MRB Inventory with Excess of 30 days of Manufacturing Area by Material

The Pareto Chart in Figure 9 shows that the material A is the major offender with cosmetic defect in the MRB Inevntory wth excess of 30 days.

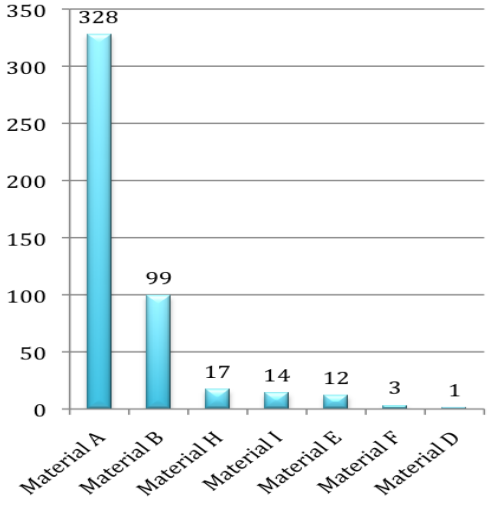

Figure 9
MRB Inventory with Cosmetic Defect by Material

The fishbone diagram, see figure 10, is intended to identify the root causes by brainstorming the major categories (method, machine, people, material, measurement and environment) of causes of the problem. Causes identified that contribute to the problem were:

- Lack of MRB Inventory Segregation Management System
- Lack of SQE Standard Work for Day to Day
- Lack of formal RACI for disposition process
- Cosmetic criteria misalignment
- Lack of Segregation and Accesability
- Acceptance criteria missalignment on the MPROC downstream processess
- Lack of Data availability for SQE disposition prioritization
- Large volume of potential nonconforming material
- Lack of Gage RnR on Legacy Components
- Lack of material specification knowledge
- Poor Planning

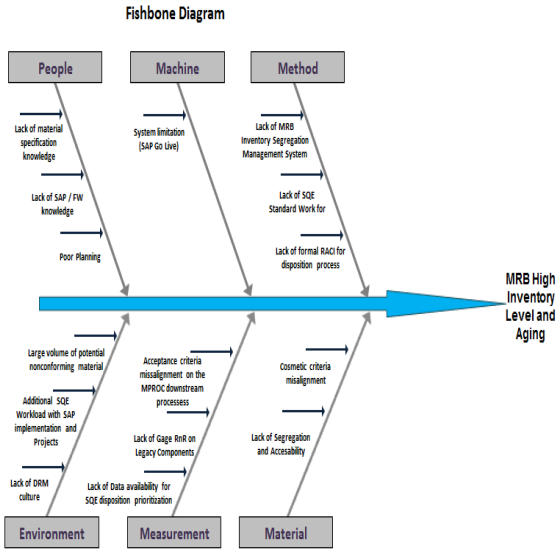

Figure 10
Fishbone Diagram of MRB High inventoy Level and Aging

After the team analyze the root causes a 5-Whys, see figure 11, was executed to explore the cause and effect relationships to a particular problem. The root cause identified for the inventory high level and aging is that the report does not provide clear reject codes to identify the material nonconformance nor the location in system, therefore physical location of the nonconformance material is unknown.

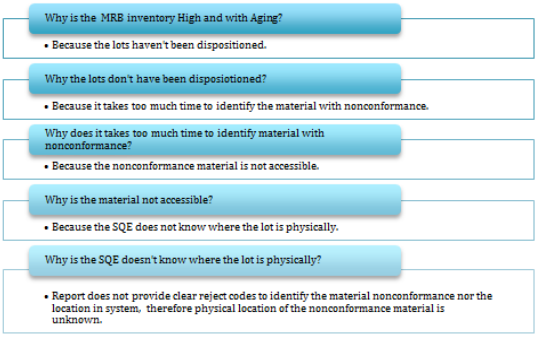

Figure 11
5-Whys

In the **Improve phase** action items, see figure 12, were developed for the team in order to address the root causes identify in the analyze phase. The action items are:

- Weekly forum lead by manager to discuss MRB issues
- Report standardization and customization
- Standardize the reject codes in system
- Monior Aging on a daily basis
- MRB Inventory Segragation Management System Implementation (5S)
- Standardize the SQE day to day work
- Develop RACI for disposition process

TEAM ACTION ITEMS								
ACTION ITEM No.	DATE OPENED	DESCRIPTION	PRIORITY	RESPONSIBLE PARTY	DUE DATE	COMPLETION DATE	NOTES	STATUS
1	4/14/2014	Weekly forum lead by manager to discuss MRB issues	H	Manager	4/21/2014	4/21/2014	N/A	Closed
2	4/14/2014	Report standardization and customization	H	SQE	5/30/2014	TBA	In Progress	Open
3	4/14/2014	Standardize the reject codes in system	M	SQE	5/5/2014	TBA	In Progress	Open
4	4/14/2014	Monior Aging on a daily basis	M	SQE	5/28/2014	TBA	In Progress	Open
5	4/14/2014	MRB Inventory Segragation Management System Implementation (5S)	H	SQE	6/9/2014	TBA	In Progress	Open
6	4/14/2014	Standardize the SQE day to day work	M	SQE	5/7/2014	TBA	In Progress	Open
7	4/14/2014	Develop RACI for disposition process	H	SQE	6/10/2014	TBA	In Progress	Open
8	4/14/2014	Job tools improvement	M	SQE	6/30/2014	TBA	In Progress	Open

Figure 12
Team Action Items Worksheet

The team action items planning worksheet is one of the most important documents, as it is utilised as a tool to drive completion of tasks throughout the entire project. The team leader ensures that someone is assigned to complete the task and follow up during the weekly forum with the team.

In the **Control phase** the inventory level and aging is monitored in order to verified that process improvements sustain results. Figure 13 shows a reduction in the major offender aging of excess of 30 days therefore a reduction in inventory level. The actual inventory level is 458 lots and the actual inventory dollars are $185,503. The team will continue to implement process improvements in the MRB disposition process and achieve the ultimate goal of no more than 15 days of aging in the inventory.

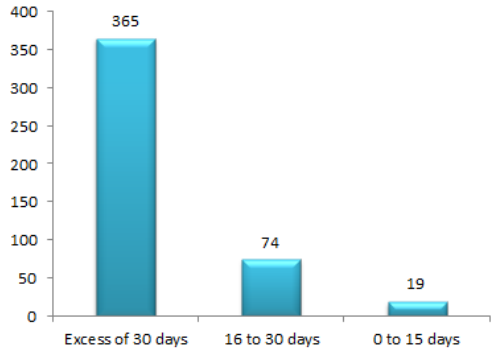

Figure 13
MRB Inventory Distribution by Aging Type

As part of the continuous improvement, management addressed key metrics to be monitored:

- Risk Management
- Inventory Management
- Inventory Cost vs. Quality

CONCLUSION

This project validates that the DMAIC methodology approach helped successful completion of the project with clearly defining the project road map. The project brought out the importance of process standarization and inventory segregation by the supplier quality engineering team and defining the material issues importance in terms of quality. The project was successful with more than 15% reduction on inventory level and aging. The company has to focus on continuos improvement for further reduction on inventory level and aging in order to meet the final goal of no more than 15 days of aging which will also result in a reduction of inventory level.

Finally, is established that the supplier quality engineering department is key to the Incoming Inspection department and the manufacturing process. The quality control of the nonconformance material can greatly improve the quality of finished good devices and increase company profitability. Based on these results, the DMAIC methodology can greatly contribute in the challenging business of medical devices.

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