Product Mix Analysis in Manufacturing Line

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Abstract —*This research project was focused on the Product Mix Analysis of a Medical Device manufacturing line due to a customer complaint. A product mix is a manufacturing defect and is defined as a mix of components/ assembly products in a batch or a mix of different batches of the same component/ assembly product. DMAIC methodology was used in order to find a root cause and implement a corrective action for the product mix defect. DMAIC is a five-step method for improving existing process problems with unknown causes [1]. The phases or stages of DMAIC include Define, Measure, Analyze, Improve and Control. In this case eliminating the product mix defect in the manufacturing line will increase the yield, eliminate customers complaints for product mix defect and reduce rework. This research seeks to eliminate product mix defects. The importance of eliminating this defect will reduce rework, customer complaints, increase the customer satisfaction and maintain product compliance.*

Key Terms — *Compliance**,** Customer Complaint, Manufacturing Line, Product Mix Defect.*

INTRODUCTION

Medical device manufacturers contribute to human welfare by applying biomedical engineering in the research, design, manufacture, and sale of instruments or appliances that alleviate pain, restore health, and extend life.

Focusing on the Quality to comply with requirements and customers satisfaction, there are a lot of challenges in the manufacturing line. One of the challenges is the customer complaints received about Reservoir product. The Reservoirs are disposable single use medication container intended for use with the external infusion pump. The reservoir system consists of a hollow barrel and movable stopper. A removable plunger rod is attached to the stopper in order to fill the reservoir. The reservoir is placed in an external infusion pump and attaches to an infusion set by means of a proprietary tubing connector instead of a standard Lure connector.

Customer complaints are the customer's way of expressing their dissatisfaction towards your product, service, or any other business aspect.

This research project will be focused on eliminating and implementing preventive and corrective actions of the product mix defect on the Reservoirs manufacturing line to reduce or eliminate customer complaints.

PROBLEM STATEMENT

During a complaint verification of a product mix of reservoir product, additional evaluation was requested since reported complaint could potentially be originated at the manufacturing process. Customer reported receiving a box of X size of reservoir product with one of ten Y size of reservoir product in the box. The customer was unable to fit the reservoir inside the X size pump's compartment.

There are 2 sizes (X and Y) of reservoirs product on the manufacturing line. The manufacturing process of the reservoir product requires a constant change over of these 2 sizes due to the receiving demand. With a decrease or elimination of product mix defect, customers complaints for this defect will reduce or eliminate. In the next investigation, will be implemented the DMAIC methodology to achieve the goal of eliminate product mix defect to avoid customer complaints.

Research Description

This project will seek to reduce or eliminate product mix defect and implement preventive and corrective actions to avoid future complaints. This will result in customer satisfaction, reduction of rework and scrap and delivered products in compliance.

Research Objectives

In the manufacturing process the operator must follow the Standard Operating Procedure (SOP). The procedure must have described the defects that could be found and the inspections or controls to avoid them. The goal of this project is to reduce and/or eliminate product mix defect in the reservoir manufacturing process that could be reflected as 0 complaints for this defect.

Research Contributions

The investigation of this project will reduce or eliminate the number of complaints received for product mix defect. Also, will reduce the cost associated with rework, investigations, and scrap created by the complaints. In addition to contributing to the good quality practices of the company and regulatory agencies.

Literature Review

Medical device manufacturing is one of the most regulated sectors in which significant quality systems and product requirements must be satisfied. The regulatory requirements are intended to ensure that manufacturers consistently design, produce and place onto the market medical devices that are safe and fit for their intended purpose [2]. Regulatory requirements are increasingly stringent throughout every step of a product's life cycle, including service and delivery. Increasingly, organizations in the industry are expected to demonstrate their quality management processes and ensure best practice in everything they do. This internationally agreed standard sets out the requirements for a quality management system specific to the medical devices industry.

ISO 13485 is the medical device industry's quality management system (QMS) standard; written to specify requirements for an organization to design and implement a quality management system to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Patient safety is at the very heart of ISO 13485, with its main purpose being to ensure the consistent design, development, production, storage and distribution, installation or servicing and disposal of medical devices. ISO 13485 requires organizations to implement these processes in accordance with identified applicable regulatory requirements for the markets they intend to operate in [3].

An organization establishes a quality management system to achieve high levels of customer satisfaction and continuous improvement by focusing on common requirements and reducing waste and variation. Customer satisfaction is a measure of how well a company's products, services, and overall customer experience meet customer expectations. It reflects your business' health by showing how well your products or services resonate with buyers.

DMAIC Methodology

In a competitive world like the one we have; every organization needs to achieve the highest level. To sustain this competitiveness, every organization needs to produce and deliver a defect-free product in the time required. In order to make this possible, organizations follow different types of business strategies, one of the most popular being the Six Sigma strategy. Six Sigma is one of the best strategies that involves existing product organizations, free of defects. Through the DMAIC methodology which is a five-phase process that helps focus a team to have an objective and a vision of the problem, and to define the controls and designs that are required to avoid continuing to have the problem we will explain these five phases.

The DMAIC Problem Solving Approach is a process improvement methodology based on the Six Sigma approach that helps to improve business

processes and products. It is used to identify, analyze, and solve existing processes that are inefficient or ineffective. The approach breaks down into five phases: Define, Measure, Analyze, Improve and Control (See Figure 1). Each phase builds upon the previous one to identify potential solutions for the problem at hand. With this method, organizations can focus on eliminating waste and defects while improving customer satisfaction and profitability.

Figure 1
DMAIC Methodology

Define

The purpose of the Define phase is ultimately to describe the problems that need to be solved and for the key business decision-makers to be aligned on the goal of the project [4]. At the beginning, you might not even have identified what problem to work on. You'll often use DMAIC tools like Pareto analysis and Supplier-Input-Process-Output-Customer (SIPOC) diagrams to help understand which problems are leading.

Measure

The Measure phase is about creating and developing a data collection plan for the process. Feedback from people who make products, feedback from customers who use the products, and how the product is processed are ways to collect data to determine how defects are created. The team also looks at business growth strategies. In this phase, the problem statement and project contract are frequently refined as a result of establishing an accurate baseline for the metrics being targeted. This is also known as the data collection step. All relevant data, important for the product, and the processes followed to manufacture the product are collected at this step.

Analyze

It is the analysis of the data collected in the previous phase. It is important to analyze the feedback given by customers, as they are the end users of the product and for what the product needs to meet their needs. At this stage, the root cause of the problem is identified. A process chart, here, helps the team understand where the product's manufacturing process has gone wrong. Gaps between present performance and desired performance are discovered in this phase, along with sources of variation and possibilities for improvement.

Improve

During the analyze phase, your understanding of the process will have solidified so that you know what changes to make to improve the process. During the improvement phase, you'll make sure to deliver those improvements to the full process. Innovative solutions are developed during the Improve phase in order to establish and implement the strategy.

Control

The Control phase seeks to maintain and sustain what was implemented. It's critical that make the improvements part of the standard operating procedure for the process. A control plan will be developed that describes the new process, and the implementation of a monitoring plan that lets you verify that the improvements are stable.

PROJECT METHODOLOGY

Methodology in a project is a set of practices, techniques, procedures and rules that guide and manage the project. It provides a framework for planning. Executing, and controlling the project and helps to ensure that it is delivered on time, within budget, and to the required quality standards. Since the purpose of the project is to find a root cause and

eliminate the product mix defect on the reservoir manufacturing line, the DMAIC tools will be used.

In order to guide the project, the following tools will be used:

Project Charter

Project charter is a short document that outlines the entirety of a project, including its goals, tasks, timelines, and stakeholders [5]. The project charter authorizes the existence of a project and gives authority to the manager to use organizational resources for achieving the project objectives. When preparing the project charter, utilize the SMART method. Be Specific, ensure your goals are Measurable, Attainable, Relevant to the project, and Timely.

SIPOC

The acronym SIPOC stands for Suppliers, Inputs, Process, Outputs, and Customers. It is a tool for mapping and improving a business process by summarizing the information from these five areas in a table or a diagram. The diagram is utilized as a high-level view of the process. The SIPOC diagram helps to understand which are the supplier and customers of the process, the input and output variables of the process, and finally the process steps. It is used in quality management programs like Six Sigma, lean manufacturing, and business process management.

Voice of the Customer

Voice of customer (VOC) is a Six Sigma tool that helps business identify and align offerings with the needs, wants, and requirements of their customers. The voice of the customer can be used for product development, process improvement, and customer satisfaction measurement. VOC can be collected through various methods, such as surveys and interviews. Focus groups. Observation and field groups.

Results and Discussion

This section will discuss all stages of the MAIC Methodology to go into process and capture all the variables used in the Six Sigma Manufacturing Principles. The results obtained through the five phases of the DMAIC methodology follows:

Define

In order to determine the problem statement, the goal of the project, benefits and the metrics that will be defined, Project Charter tool was performed as part of the Define phase. See Table 1.

Table 1
Project Charter

Project Charter
Project Name: Product Mix Analysis in Manufacturing Line
Process Impacted: Reservoir's Assembly Process
Problem Statement: Various complaints were received for product mix defects for reservoir assembly product. These complaints cause a negative impact on the customer satisfaction. Also, product mix defect increases the cost of manufacturing due to rework, investigation and scrap of the product.
Goal: Mitigate and eliminate the product mix defect in the reservoir manufacturing line.
Benefits: Eliminate future customer complaints, reduce rework, scrap, and labor cost.
Metric Definition: Product Mix Defect

Development of the Problem

The reservoir assembly process is manufactured in the following steps/processes:

- The manufacturing process starts with Pad Printing and Transfer Guard Assembly. Pad Printing Process prints the graduations on the Reservoir Barrels. Transfer Guard Assembly process assembles a plastic connector, transfer guard hub, with a needle.
- After these two processes, the remaining components and these two subassemblies are assembled by the assembly machines. The machine takes the printed Barrel and the Transfer Guard Assembly, adds a Plunger rod, stopper, two O-rings, Septum, and Snap-Cap to complete the assembly.
- Then the packaging process for X size model and Y size model consists primarily of a form, fill, seal machine where reservoirs are placed in flexible blister trays and heat sealed with paper lid. The secondary packaging is an automatic

process for packaging the blister in customer boxes, then the customer boxes are packaging into shipper cases to complete packaging process.

These processes were evaluated in order to find a root cause of the problem. Due to the amount of product handled during shifts and change overs of the 2 sizes of reservoirs, product mix defect is possible to be generated.

Measure

In order to determine customers' needs and inputs and outputs of the process, Voice of Customers tool and SIPOC tool was performed as part of the Measure phase.

Nonconformities of the process are documented in the Device History Record (DHR) of the batch. All nonconformities were validated, and manufacturing personnel were trained in the process that are executing.

In Table 2 and Figure 2 below, Voice of Customers and SIPOC results are showed.

Table 2
VOC

Voice of Customer	Customer issues	Customer Requirement
What are the customers saying?	What do the customers need?	What is required to fulfill the customers need?
The Reservoir is a different size than my insulin pump	Customers need a reservoir of the same size of the insulin pump	- Training - Clarify instructions on procedures - Reduce the quantity of changeovers - Improve quality controls
The reservoirs are from different size than packaging batch identification.	Customers need that the reservoirs come from the same batch	
Reservoirs are from two different batch numbers.		

The voice of customers shows us what are the needs of the customers. The concerns or complaints about the product is that in some cases they are not receiving the product as requested or described in the packaging box. There are various opportunities in the manufacturing process that could help with the customers' requirements. These improvements will be very beneficial not only for the projects but also to increase the satisfaction of the customer.

Suppliers	Inputs	Processes	Outputs	Customers
Who supplies the process inputs?	What inputs are required?	What are the major steps in the process?	What are the process outputs?	Who receives the outputs?
Vendors (raw materials suppliers)	Raw materials	Subassemblies process	Reservoir model X Reservoir model Y	Customers (patients)
		Main assembly process		Medics
		Packaging process		Pharmacies

Figure 2
SIPOC

From the SIPOC analysis it can be determined that the customers want the specific reservoir model from the manufacturing. Also, avoid any nonconformity. The customer wants to receive the product without defects.

Complying with customers' requirements and needs will be achieve a better customer satisfaction and maintain the customers with the company.

Analyze Phase

A report of defects was executed with the intention of obtaining an indicator of which process step of the reservoir manufacturing process is causing the product mix defects during the assembly (See Figure 3). This reports along with the customer complaints, will help to identify those requirements that are causing problem and will help to identified which sub-process needs to be worked in order to achieve the goal of zero (0) product mix defect or complaints for reservoir assembly process.

It is observed that the product mix defect was originated from the packaging process. Customer complaints were evaluated, and it could be inferred that the cause of the defect was created as found in the report.

In order to reduce defects a 6M Fishbone Analysis (Manpower, Methods, Mother of Nature, Measurements, Materials, Machine) or cause-and-effect diagram was generated to determine the potential contributors to reduce product mix defect (See Figure 4). The 6M/6M's is a mnemonic tool that helps to find the root causes of a problem or an event. It is usually seen in brainstorming about problem-solving and decision-making. To uncover the root cause of a problem or variation, 6M analysis helps to evaluate all the possible process inputs and assess them properly. Since there are other offenders in the report collected and related to customers', cause and effects diagram was created and will be focused only on product mix defect to determine which contributors are affecting the assembly process.

LOTID	LOT_ORIGINATIONSTE	LOT_DISPO	PRODU	PRB_ST	PRB_REJECT_CODE	PRB_COMMEN	AGING	PRRNUI	QTY
HG3XXQ0H56	MMR_Inspection2_RAM	Accept after C	7005317JC	Closed	MMR:TransferGuardTight	Transfer guard ap	7	1	18000
HG3XXQ0H58	MMR_Inspection1_RAM	Accept after C	7005317JC	Closed	MMR:TransferGuardTight	Transfer guard ap	7	1	12000
HG3YAH1H10	MMR_Inspection1_PAD	Accept after C	7005290JC	Closed	MMR:FailVolumetricTest	Volumetrica alta.	9	1	6000
HG3YAH1H11	MMR_Inspection1_PAD	Accept after C	7005290JC	Closed	MMR:FailVolumetricTest	Volumetrica alta.	9	1	6000
HG3YAH1H12	MMR_Curing_PAD	Accept after C	7005290JC	Closed	MMR:FailVolumetricTest	Volumetrica alta.	9	1	6000
HG3YAH1H13	MMR_Curing_PAD	Accept after C	7005290JC	Closed	MMR:FailVolumetricTest	Volumetrica alta.	9	1	6000
HG3YAH1H14	MMR_Inspection1_PAD	Accept after C	7005290JC	Closed	MMR:FailVolumetricTest	Volumetrica alta.	9	1	6000
HG3YAH1H16	MMR_Inspection1_PAD	Accept after C	7005290JC	Closed	MMR:FailVolumetricTest	Volumetrica alta.	9	1	4700
HG3YBS7H03	InvMMRFFS1Machine	Accept after C	7005316JC	Closed	MMR:ProductMix	UNKNOWN	2	1	12240
HG3YD7AH06	MMR_Inspection1_FFS	UNKNOWN	7005566JE	Open	MMR:BentNeedle	Se encontro aguja	11	1	1728
HG3YAH1H32	MMR_Inspection1_PAD	UNKNOWN	7005290JC	Open	MMR:Miscellaneous	Dent dentro del ba	11	1	6000
HG3YAH1H33	MMR_Inspection1_PAD	UNKNOWN	7005290JC	Open	MMR:Miscellaneous	Dent dentro del ba	11	1	6000
HG3YDDPH03	MMR_Inspection1_FFS	UNKNOWN	7005566JE	Open	MMR:BentNeedle	UNKNOWN	10	1	1728
HG3YBS7H11	InvMMRFFS	Accept after C	7005316JC	Closed	MMR:ImproperPrint	UNKNOWN	1	1	18000
HG3XXQ0H52	MMR_Inspection1_RAM	Accept after C	7005317JC	Closed	MMR:ExcessiveAdhesive	Ajuntando lote co	1	1	18000
HG3YEJ1H06	MMR_Inspection1_RAM	Accept after C	7005316JC	Closed	MMR:ExcessiveAdhesive	Ajuntando lote co	1	1	12000
HG3YEK5H03	MMR_Inspection1_FFS	Accept after C	7005566JE	Closed	MMR:IncorrectPrint	Fallo prueba shipp	1	1	1728
HG3YG63H05	MMR_Inspection1_FFS	Accept after C	7005566JE	Closed	MMR:Seal<50%	During G2 test QC	0	1	1728
HG3YG63H06	MMR_Inspection1_FFS	Accept after C	7005566JE	Closed	MMR:Seal<50%	During G2 test QC	0	1	288
HG3YEK5H08	MMR_Inspection1_FFS	Accept after C	7005566JE	Closed	MMR:BentNeedle	Transfer Guard we	1	1	1728

Figure 3
Reservoirs Defects by Process

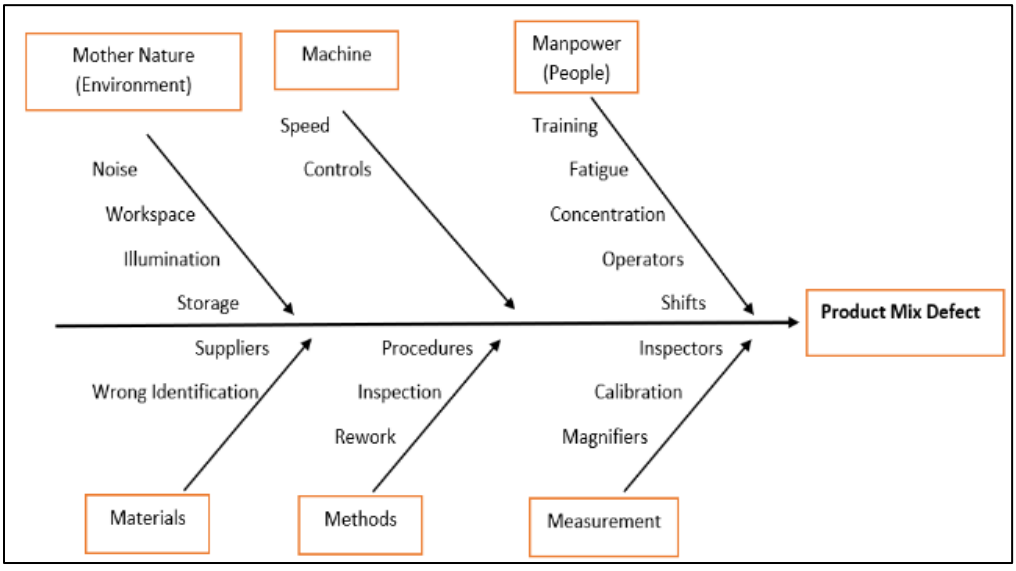

Figure 4
Cause and Effect Diagram (Fish Bone Diagram)

From the Cause-and-effect diagram it was determine that the most potential contributors that could create or avoid shipping of the product mix defects are as following:

Material: This category is ruled out since no component of the top assembly showed no defects and is not related to this event.

Mother Nature: Subassemblies are assembled by the main assembly machines. Once reservoirs are assembled, go automatically into a bin. Additionally, a print label per bin is generated and attached with adhesive tape. Once bins are full, are put aside until are taken into the inventory area next to the packaging lines. The fact that inventory areas of Model X and Model Y are next to each other and there is time where both reservoirs use the same color bins. This may prone for mix up. This category is considered a contributor to this event.

Measurements: This category is ruled out since the inspections are to verify and functionality and are not related to this event.

Method: The following process/procedures are related to the end step manufacture of top assembly reservoirs, and it is where product mix could occur or re-process.

Bolus and Basal Cavity Segregation Process - After Sterilization Process, Bolus and basal Testing is performed to release the sterilized lot located at the sterilization facility while a representative sample is received. Lot implicated in this event was manufactured through this reclaim process. The fact that lack of instructions regarding physically material segregation, storage, and print label bin identification shows a gap in the reclaim process. This lack of instructions from the reclaim process shows a potential to induce models to be mixed during the bin consolidation or merging lots. Moreover, there are no instructions related to verification of the product sorting during reclaiming. Hence there is no further verification prior to transferring the product into the feeder bowl of the packaging lines. These gaps are ruled in as a possible root cause for this event.

Packaging lines - Packaging lines 1 and 2 are used to pack models X and Y reservoirs. Even though reservoir models are different in size both use the same flexible blister trays with a rectangular shape. During the packaging process several inspections are performed. At this point of the manufacture process, product models are challenged using visual inspections. Although a 100% visual inspection is performed still a human dependent process. The fact that a product mix was reported by a customer suggests that these inspections are not capable of detecting this type of defect. Moreover, the procedure lacks instruction regarding product mix inspection showing a gap in the process. Thus, this step is considered a contributor to this event.

Product Review Board Rework process - This procedure describes the process for handling non-conforming product occurrences associated with the manufacture of Reservoirs products. It provides responsibilities of all the parties that intervene in nonconforming product handling. Although a 100% visual inspection was performed still a human dependent process. The fact that a product mix was reported by a customer suggests that these inspections and AQL were not capable of detecting 100% mix Model X with the Model Y. Moreover, the Product Review Board procedures above lacks instruction regarding specific handling product mix inspection showing a gap in the process. Thus, this step is considered a contributor to this event.

Machine: The machines from subassembly processes are ruled out as a possible contributor for this event due to models are differenced by barrel size only.

Reservoir Assembly Machines - These machines assemble two models of reservoirs (Model X and Model Y). These models only differ by the barrel size, whereas subassembly parts and blisters are the same. Per design, Reservoir Assembly Machine 1 is dedicated to produce model Model X, Reservoir Assembly Machine 2 is dedicated to produce model Model Y, and Reservoir Assembly Machine 3 produces both models. The fact that each barrel has its own specifications it is not possible to mix barrels between Reservoir Assembly Machines. Parameter settings in each Reservoir Assembly Machine prevents that product mix occurs.

Manpower: Manufacturing personnel are properly trained and certified before they can perform any task. This means that the operator must be certified in the procedure and / or machine in which operator is executing. The batch involved in the complaint, was created with merge lots of units from Bolus and Basal reclaim process. These units

to be claimed are identified with printed barcode labels, placed in bins and placed in the corresponding inventory area to eventually be used again. It is in this process of re-using and packing that the operator realized when placing the units in the feeder bowl of the packaging machine that there was product mix (Model X with Model Y). This batch was sent to the Product Review Board to be segregated. As part of the analysis was determined that this product was incorrectly identified in a form, meaning that bins were already a mixture of models. As part of the rework process, these units were segregated to contain Model Y. Despite a 100% visual inspection followed with an AQL, a customer received one (1) reservoir of Model Y model in the ten (10) pack costumer box of Model X. Thus, this category is ruled in as a possible contributor for this event.

The analysis of the data collected shows that the training, lack of instructions on procedures, machine controls, storage, reworks and inspections are the major contributors.

Improve Phase

According to the contributors, the following updates and implementation of controls were pursued in the reservoir manufacturing process in order to eliminate or avoid product mix defects.

- Eliminate reclaim process from Bolus and Basal test.
- Improve sorting activity for Product Mix defect adding another 100% visual inspection (200% visual inspection).
- Clarify visual inspection of reservoirs inside of blister packs to detect Product Mix.
- Replace stainless steel guard by Lexan (transparent) to facility Line Clearance Procedure on packaging lines. Include instructions to perform inspection of this area.
- Modify Kanban area to separate Model X from Model Y.
- Include visual aid (images) of the areas where Line Clearance (Change Over) is performed.

Control Phase

The main goal of this phase is to establish and implement effective controls to ensure that the identified causes are effectively implemented. Improvements mentioned above will be controlled as follows:

- Instruction was included as part of the change over process to verify through Lexan if a reservoir is remaining in the line.
- Visual aid was included in the Kanban area (storage) to separate assembly (side by side) from each other.
- Instruction included to procedure to perform 200% visual inspection and a signature in system is required after inspection.
- Refresh training on affected procedures will be required every 6 months.

CONCLUSION

The Reservoir assembly process has been improved using the DMAIC tools. The goals of the project were eliminated product mix defects from reservoir assembly line in order to avoid customer complaints and comply to regulatory requirements. The results of this project were satisfactory, 2 months of effectiveness was monitored to verify if a product mix defect was detected on the manufacturing process and if a customer complaint for this defect was received. Both goals were worked on, and the results will be beneficial for both the customer and manufacturing process.

Through the result of Six Sigma with the DMAIC methodology we could notice that our process was not robust and that we needed to implement measures to be effective.

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