

Reduction of Cosmetic Defects Due to Criteria Misalignment at a Medical Device Manufacturing Line Using DMAIC Methodology

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Abstract — *For the last few years, the economy of Puerto Rico has been negatively affected, increasing the operational cost of the industries in the Island. The Pharma / Medical Device industry is not excluded of this situation. In addition, regulatory agencies have been increasing their requirements and conditions that enforce activities to ensure that the products or devices being manufactured meets or exceeds the expectations of clients and regulatory agencies across the world and to protect the public health. In this challenging business environment is essential for the industry to invest in new equipment and technologies to address the required corrective and preventive actions to ensure the quality and efficacy of the goods to be manufactured. All this factors makes Pharma and Medical Devices companies to reduce and/or eliminate their unnecessary scrap to maintain competitive costs. Companies focus on production efficiencies and often drive attention to inefficiencies due to scrap or reworks that are performed during the manufacturing process. Lean Six Sigma Methodology is focused on business and process improvements based on decrease of process variation, waste elimination, process improvement and customer satisfaction. This project has been developed under the Lean Six Sigma principles and using DMAIC five-step approach, in order to identify opportunities to enable the company to reduce cosmetic defects at the neuromodulation manufacturing line at MPROC Juncos.*

Key Terms — *Cosmetic Defects, DMAIC, Lean Six Sigma, Medical Devices.*

PROJECT STATEMENT

Through the years, rejects due to cosmetic defects have been increasing among the manufacturing process. This can be reflected in dents, scratches, marks or any other cosmetic defect that could be caused prior or during the manufacturing process of an Infusion Pump from MPROC site. This issue is related to cosmetic defects that detract from a blemish free shield provided to the physician. Devices are not affected in terms to form, fit, function, or reliability of the product. The parts are 100% inspected for cosmetic defects, and when observed by the manufacturing area, is cause for rejection. Therefore this issue is related to the physical appearance of the shield, and becomes a financial hit to MPROC when a shield is rejected for this condition.

As an operational excellence medical device manufacturing company, costs is always a variable that is seen in detail to become highly competitive among different industry competitors.

Research Description

This project has been outlined with the purpose of analyzing and evaluating the current inspection standards and calibrates them within our manufacturing associates and suppliers to make it consistent, while maintaining quality and compliance. Primarily to evaluate the actual procedures and criteria for the rejection of product due to cosmetic defects and align them across the affected areas to minimize false rejections impact.

Research Objectives

The objectives for this project are:

- Cost reduction due to rejecting good devices as bad devices;
- Maintain compliance and the reliability of the system;
- Never compromise quality in the pursuit of cost reduction;
- Improve manufacturing efficiency;
- Decrease inventory due to devices pending engineering evaluation;
- Decrease lead time on device manufacturing.

Research Contributions

With the project implementation, the Synchroned II infusion pump manufacturing line will breakthrough cost savings and gain efficiencies by eliminating redundant inspections, unnecessary engineering evaluations and implementation of process improvements. This assessment may extend other business units, eventually impacting all MPROC manufacturing sites that use titanium components through the island and creating a direct impact in the manufacturing efficiencies.

LITERATURE REVIEW

To guarantee the quality of a product and service, it's necessary to ensure the accuracy and validity of process equipment, delivering reliable processes within a degree of acceptance. Around the world, people are living longer, more active lives thanks to continuing advancements in medical technology. This evolution in technology stems from the development of metals and alloys that are finding new uses in internal and external medical applications. From improvements in diagnostic guide wires to new alloys for permanent implants in the body, metals continue to find new uses. The metals industry has a long history of innovation, development, and processing of metals and alloys, in step with medical device development. This has allowed development of new devices ranging from tiny screws for the smallest implants to complex surgical tools operated robotically.

Titanium is one of the most versatile metals used in internal applications. It resists corrosion and connects to human bone when properly treated, with fewer negative reactions than other metals. Osseointegration is a unique phenomenon where the body's natural bone and tissue bond to the titanium implant, which firmly anchors the implant in place. Titanium is also now a staple in the medical field for uses such as shields for implanted devices that control heart function; products that dispense medicine and perform various neurostimulation; and orthopedic rods, pins, and plates. Titanium is a standard shield material in such implanted medical devices as pacemaker and defibrillator cases due to its resistance to attack by body fluids, high strength, and low modulus.

In addition to its use inside the body, titanium is an ideal choice for surgical instruments, such as drills, forceps, retractors, scissors, needle holders, and Lasik eyesurgery equipment. The metal is also compatible with Magnetic Resonance Images (MRIs) or Computer Tomography (CT) scans.

One key feature in terms of process is measurement of quality. The manufacturer's products must meet all of the relevant essential requirements contained in the relevant annex of the appropriate directive. Depending on the device, this may include:

- Biological safety,
- Clinical data,
- Electrical safety,
- Electromagnetic compatibility,
- Labeling and instructions,
- Risk management,
- Sterilization.

Quality reflects the process integrity and process design which results primarily in the intended of the device and product efficacy. For this purposes a set of user requirements are established during the design process. The user requirements are established with the intention of complying with all regulations applicable including cosmetic specifications.

Synchromed II infusion pump, refer to Figure 1, manufacturing procedures provides the Manufacturing Associates provides the instructions to perform the tasks to end in a complete device. At each station, the manufacturing associate must confirm through some type of inspection (visual, measurement or poka-yoke) that the task was executed as intended.



Figure 1
Synchromed Infusion Pump

As part of the visual inspections (refer to Figure 2 - 4), there are several Total Quality Checkpoints (TQC) where the device must be inspected for cosmetic defects at the end of the manufacturing phase of the product. If a device doesn't meet the established criteria it should be sent to the Product Review Board (PRB) for engineering evaluation.


8.1 Descripción de la Operación del Proceso / Description of the Process Operation	
#	Descripción / Ilustración - Description Illustration
15	<p>PROCESS</p> <p>Inspeccione para rajaduras, decoloración de soldadura, mellas, huecos y salpicadura. Inspect for cracks, discoloration of welds, pits, holes and splatter.</p> <p>⚠️ Refiérase al POD000567 - Criterio de Inspección de la Soldadura Láser. Refer to POD000567 - Laser Welding Inspection Criteria.</p> 

Figure 2
Laser Welding Inspection - A

An opportunity has been seen after analyzing several manufacturing procedures since several of them have inspections of the tasks that were performed, but the only cosmetic criteria that is mentioned is for laser non-conformances. During these inspections manufacturing associates proactively inspect the complete device, most of the times under a calibrated microscope, and if they found any cosmetic defect they send it to the PRB area.


26	<p>PROCESS</p> <p>Inspeccione la soldadura del "inner shield" al "bulkhead". Inspect inner shield to bulkhead weld.</p> <p>⚠️ Una desigualdad (debe ser máxima de 0.004") tiene que ser medida por el Ingeniero o Técnico de Procesos. Mismatch (maximum is .004") must be measured by the Process Technician or Engineer.</p> <p>⚠️ Inspeccione si hay grietas, decoloración de la soldadura, hoyos, huecos y salpicaduras. Inspect for cracks, discoloration of welds, pits, holes and splatter.</p> <p>⚠️ Utilice como referencia el POD000567. Reference document POD000567.</p> 
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Figure 3
Laser Welding Inspection - B

At the same time at the end of the manufacturing process, a final inspection and cleaning area is established to capture any cosmetic defect or potential nonconformance that the unit may have (missing parts, laser defects, incorrect labeling) as per POD 000586: "Final inspection and Cleaning."

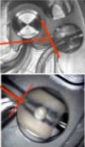
8.3 Ensamblaje del outlet fitting / Outlet fitting assembly	
#	Descripción / Ilustración - Description Illustration
5	<p>⚠️ Retirarse del "fitting" e inspeccione la pieza. Remove from fixture and inspect.</p> <p>⚠️ Ningún tipo de daño o pedazos del "O-ring" pueden ser visibles dentro del hueco del "fitting" del "bulkhead". No damage or O-ring pieces can be visible inside the outlet fitting hole in the bulkhead.</p> <p>⚠️ Si el "fitting" se extiende más allá del límite de moldeado al presionar la pieza, el ensamblaje tendrá que ser enviado a PRB. Outlet fittings extended beyond the over molding of the pump tube assembly must be sent to PRB.</p>  <p>⚠️ El "fitting" no puede extenderse más allá del límite de moldeado al realizar el presado. Control fit pressed beyond.</p> 

Figure 4
Assembly Visual Inspection

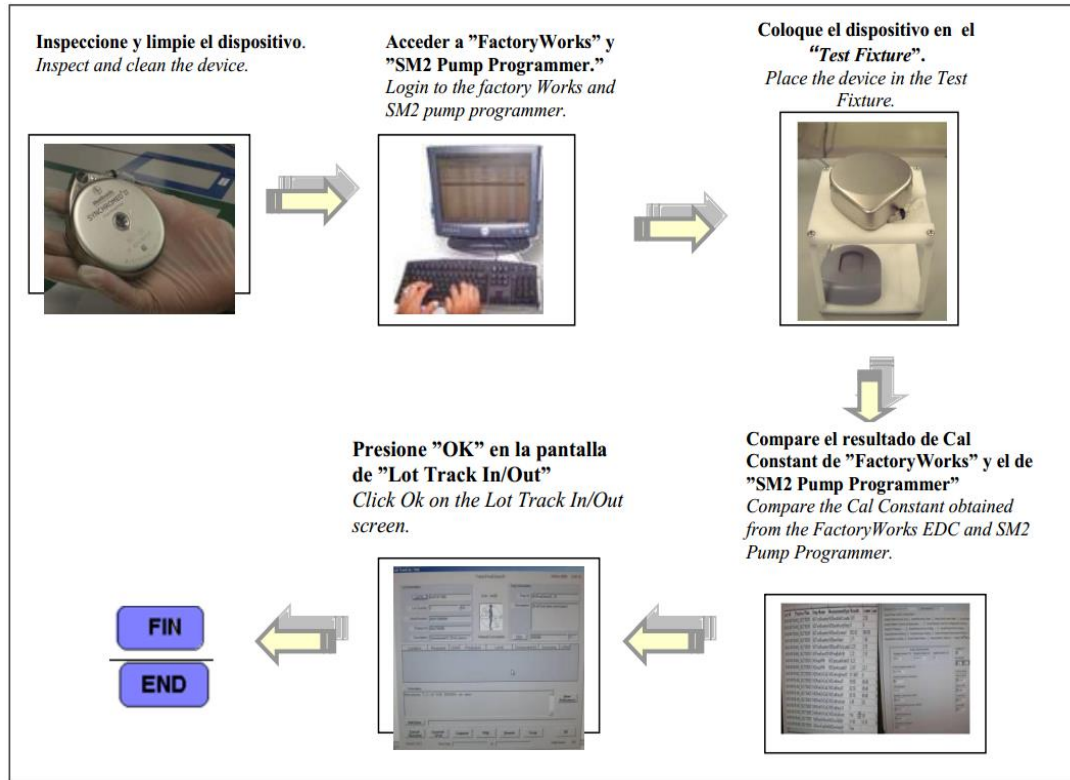


Figure 5
POD000586 Process Flow

The final inspection and cleaning process as per Process Operational Description (POD)000586 is, refer to Figure 5, the only manufacturing procedure where a vague criteria is established in terms of visual inspections and cosmetic criteria. This procedure is not referenced in other manufacturing areas where the device can be inspected for this type of criteria, detecting any possible nonconformance at an earlier manufacturing phase.

This POD has been reviewed and analyzed and it doesn't contain the necessary images and/or criteria to reject devices due to cosmetic defects. To reduce or decrease the rejection frequency (possible scrap) for those devices an analysis must be performed evidencing with historical data that acceptable cosmetic defects area allowed among customers and that they aren't reflected in field complaints. This will confirm that a complete master criteria document should be implemented to reduce the scrap impact and false rejects among the manufacturing process. The evaluations should be

conducted by collecting the necessary data, evaluate, analyze and catalog all defects, source history and details. Once the processes data is gathered, it must be validated, before the execution of any change in manufacturing documents to ensure process and system compliance to make the change effective. These changes could reduce the scrap and inventory impact and shall be completed with the required MPROC change documentation to prevent any remark by regulatory agencies.

In order to meet the proposed objectives, Lean Six Sigma methodology will be used to accomplish the reduction target. Lean Six Sigma is set of techniques focused on business and process improvement. Lean Six Sigma is based on the combination of the concepts of Lean Manufacturing and Six Sigma principles, using DMAIC strategy [1]. Lean Manufacturing is a philosophy derived from Toyota Production System that maintains a continuous flow of product, eliminate waste and improve customer satisfaction. There are seven types of waste which are in between these:

overproduction, excess inventory, waiting, transportation, unnecessary motion, over-processing and defects.

As a complement to the philosophy of Lean Manufacturing, Six Sigma pursues the decrease in variation and process improvement. This methodology began in the manufacturing industry and has expanded to other industries such as service, health care and banking [1]. Six Sigma was developed by Motorola in the mid-80 and known to the world in 1995 by Jack Welch, as it was used as a business strategy for the company GE. Six Sigma used as strategy of process improvement the DMAIC project methodology, which is divided into five main processes:

- **Define:** Identify the requirements and problem statement;
- **Measure:** Identify and document the process;
- **Analyze:** Collect data to determine cause;
- **Improve:** Select the best solution in order to improve;
- **Control:** Revised process to hold the gains.

Each of the previous stages involve and promote the use of tools for process improvement, reduction in variation and customer satisfaction [2].

METHODOLOGY

In order to achieve the proposed objectives, this section provides an overview of procedure and methodology that will be applied in the design project. The project methodology to be used is DMAIC improvement strategy coming from Six Sigma principles [3]. DMAIC is an acronym that has five phases: Define, Measure, Analyze, Improvement and Control.

- **Define Phase:** This phase consists in defining the scope, goals and project statement. As part of this phase a project charter will be presented in order to describe the process and identify the possible opportunities of improvement.
- **Measure Phase:** The objective of this phase is the collection of the key aspects of current process and relevant data. As well as the identification of potential factors that may

affect the process. It will use data collection and detailed process flow diagram. The tools to be used to present visual representations of the current state are graphs, charts and flowcharts.

- **Analyze Phase:** This phase consists on identifying deep causes with the objective of validate them with relevant data. The key components of this phase include cause-effect, root cause and value- non value added analysis.
- **Improvement Phase:** The objective of this phase is optimizing the current process based on data analysis. The key components for this phase include lean manufacturing tools, optimized process parameter settings and standardized work.
- **Control Phase:** This phase includes designing and documenting the new controls and procedures, in order to hold the gains. Key components to this phase are visual workplaces, periodic audit exercises and training process to monitor the success.

RESULTS AND DISCUSSION

This section presents the problem analysis and improvement results using the Lean Six Sigma Methodology and DMAIC tool.

Define Phase

The amounts of scrap due to rejects in cosmetic defects have been increasing through the year. As per analysis and interviews with the manufacturing associates, this is due to not having enough criteria to discern among bad / good units and instead of sending them for engineering evaluation; they scrap it as “scrap on-line”. This happened across the line since the “quality inspection point” is at the end of the line, but manufacturing associates, trying to major scrap decided to inspect the units prior finishing the device where the cost is higher.

The project goal pursues to reduce the amount of rejects and the increase of engineering evaluations as needed in order to avoid scrap devices.

The project team members include the supervisor, quality technicians, quality engineers, compliance representative and area coordinator. The role of the team members consists in recurrent problem discussion, progress meetings and the collection of information related to cosmetic defects, possible root causes, standards, historical data, fixtures, handling process and manufacturing procedures revision. All these activities will be completed as part of the DMAIC measure phase. The measure phase has an expected duration of one week. As a guide for team members and managers to see whether the project is conducted in the right direction as proposed and the goals has been reached in time, a Project Charter was performed.

Measure Phase

In order to identify the relation between the manufacturing associates, quality technicians, engineers and support staff a Flow Chart Diagram was created. To serve as a visual aid in the analysis process.

The manufacturing process is divided in different stages: Bulkhead, Resweld, Resfill, Motors, Electrical and Final Clean. At each station operators perform different tasks and as per procedures they have to perform a visual inspection or a test to ensure the functionality of the device. Furthermore in most of the cases, manufacturing associates perform visual inspections with the use of microscope and scrap the device if this presents any type of cosmetic defect. Depending of the criticality of the defect they contact the support staff for further evaluation. Figures 8 through Figure 11, shows the cosmetic defect incidents that have been encountered by cell area and by type, this data has been collected to identify potential trends or patterns across the manufacturing area.

Analyzed Phase

The focus in this phase is about finding opportunities for improvement within the current calibration process. The first step is to analyze all measured data. Then understand all feasible causes

that affect PRB Rejects and scrap costs by steps and set priorities among the discovered causes.

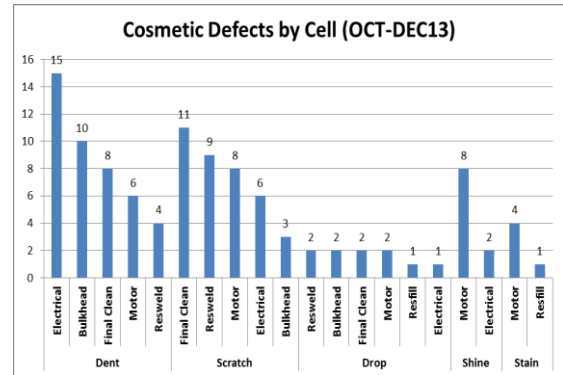


Figure 8
Cosmetic Defects by Cell – October to December 2013

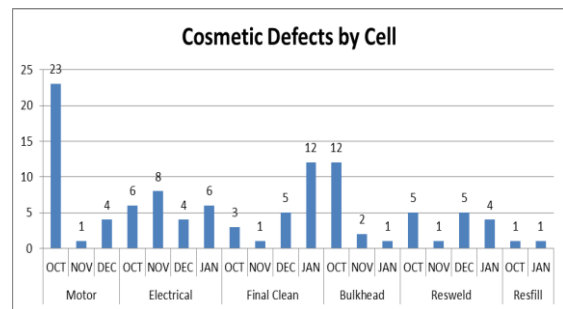


Figure 9
Cosmetic Defects by Cell – Process Stage Category

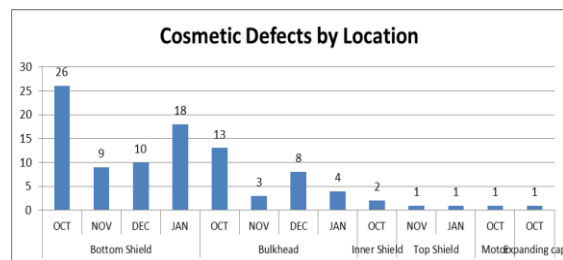


Figure 10
Cosmetic Defects by Location

As presented in the measure phase, a increase in scratches and dents have been consistent in the electrical and final clean areas. This is since the device is 75% and 100% assembled at these stages respectively. Additionally in these stages, an extra handling occurs since at the electrical phase there is several manual welding processes which creates a higher potential of dropping the units to the floor or being scratched by any fixture across the manufacturing process. At the Final Cleaning manufacturing cells, different testing are performed

to the device and an extra handling is performed due to cleaning (buffing) and packaging of the device which also creates a higher potential of scratches and drops.

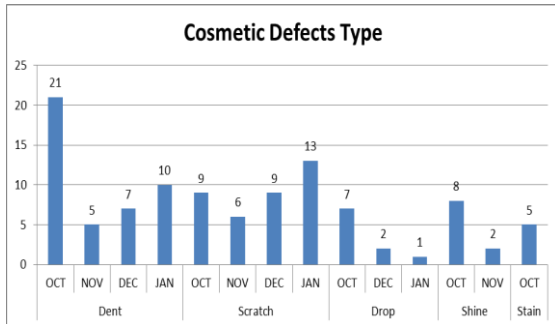


Figure 11
Cosmetic Defects by Cell

According to historical complaints in the field data for the past three years, no field complaints have been registered due to a scratch in the device which shows that a minimum or no impact is a very low level cosmetic defect in the device.

After discussing with the team members, there were several aspects selected and categorized as root causes for the rejection of devices. The primary focus was that device specifications allow cosmetic scratches if they aren't visible with an un-aid eye at 18 in. for three seconds. This has been the industry standard since it has been proven that the different sterilization techniques used for creating a sterile device, are capable of eliminating any potential microorganism flora that could reside in any area of the device. As part of the packaging process the format used for shipping the device is a clear sealed tray where the end user has the opportunity to inspect the device prior opening it and they can reject them if any discrepancy or anomaly is showed. Complaints records and field marketing reps were reviewed and interviewed and none of them showed any type of feedback for this project purposes.

Improvement Phase

As part of process improvements, a cosmetic defects template was created to be generated for each unit that is sent to the PRB area for engineering evaluation. The primary purpose of

this sheet is to serve as a data collection template where the PRB coordinator will describe the event, where it was found and the affected area of the device. Additionally a disposition is performed after evaluation and a space for any potential comments was also in place.

During the improvement phase, a Cosmetics Defects Board was appointed, this to discuss at the end of day all cosmetic reject devices and as a board discuss the findings and determine if the reject is acceptable or not. The Cosmetics Defects Board will consist in area owner Manufacturing Engineer, Quality Engineer and the PRB Coordinator who is responsible for gathering the PRB data and sharing it to the support staff.

An attribute agreement analysis, was performed among quality technician, quality engineer and area coordinator to determine if the leaders in the different manufacturing areas acknowledge the difference between good and bad devices due to cosmetic defects. For this purposes, a table was generated with different cosmetic defect that could be encountered or generated as part of the manufacturing process. Training was performed to all manufacturing associates, quality technicians, quality inspectors and other support staff to align the criteria and eliminate any potential doubts.

After all actions were implemented, Cosmetics Defects Board – Defects Criteria – PRB Coordinator Guidance – Cosmetics Defects Template, a reduction in cosmetics defects have been achieved during the last two weeks of January and a increase in Use as Is (UAI) devices has been since as result of an aligned cosmetic criteria among the support staff (refer to Figure 12).

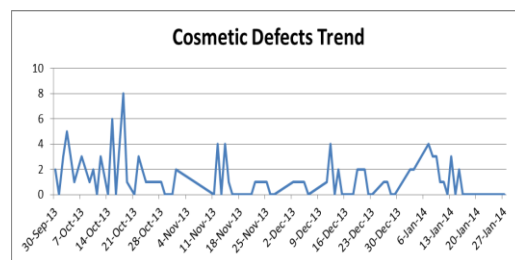


Figure 12
Cosmetic Defect Trends

Control Phase

The purpose of DMAIC control phase is to provide a control plan to prevent the counter measures and solutions in place that can be controlled to prevent future problems and provide a sustainable financial benefit. As mention in the improve phase, the team designed the Cosmetic Defects Density Chart. It was created with the objective of gather data and mitigates any potential issue. The Cosmetic Defects Density Chart allows the Cosmetic Defects Board perform a continuously evaluation of the affected devices. This form will be part of the existing quality forms.

Also a master presentation was created using the table of definition / acceptance criteria to train all manufacturing associates during the Quarterly Quality Meeting in order to transfer the knowledge from the Area Leaders to the manufacturing process.

This table contains brief information about the different potential defects that could be seen in titanium shields and that could be created due to the handling process. Finally, all collected data will be included in different managerial levels meetings to expose results and resources to be dedicated to mitigate any root causes that could be found as generating these cosmetic defects. Tier 1 will be gathered to present on a daily basis the results to the manufacturing associates, Tier 2 for support staff and Tier 3 for management.

CONCLUSION AND RECOMMENDATIONS

From start to finish, DMAIC tool provides a structured way for business improvement with a road map for solutions. This technique allowed the identification, evaluation and categorization of opportunities under their impact and difficulty. After a deep analysis performed, the Use as Is of devices on terms of dollar costs increased in 55%. It shows that a potential of \$9k could be scrap in the past 3 months if the cosmetic defects criteria wasn't established or aligned among the support

staff that are responsible in evaluating these defects.

In addition, the implementation of the different action items achieves the reduction of scrap and an increase in available devices to the manufacturing process. The standard work created doesn't compromise the quality or compliance of the manufacturing process.

In order to make a standardize work plan, the team designed the Cosmetic Defects Density Chart and the Definition / Acceptance criteria table. The implementation of these form allows the continuously flow of information in a simplified way to recognize any potential defect or doubts that manufacturing associates may have in terms of cosmetic acceptance criteria.

Due to a successful project implementation, this achievement will extend to other manufacturing areas that use titanium shields and may have this issue, serving as a quality project to be adapted in their manufacturing areas.

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