Scrap Reduction due to Mechanical Failures in Heart Failure Medical Devices

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Abstract

This research addresses the critical issue of reducing scrap in the manufacturing line of medical devices for heart care in Puerto Rico. Currently, manual assembly processes pose risks of mechanical failures, leading to significant financial losses and potential harm to patients. The project aims to identify root causes of mechanical defects, quantify associated costs, and implement measures to reduce scrap by 50% and improve manufacturing line yield by 10%. Employing the DMAIC methodology, the study involves data collection, analysis, and targeted interventions. Key improvements include implementing standardized work procedures, optimizing welding parameters, and enhancing maintenance protocols. Statistical analysis demonstrates significant enhancements in process capability, with notable reductions in rework instances and associated costs. These interventions result in tangible economic benefits and improved product quality, underscoring the effectiveness of continuous improvement initiatives in achieving sustainable manufacturing excellence.

Introduction

In recent years, Puerto Rico has emerged as a significant player in the manufacturing of medical devices, particularly those related to heart care. Despite this progress, the manual assembly of these devices presents substantial risks, including mechanical failures during production. These defects not only cause significant financial losses due to damaged components and scrap but also pose severe health risks if defective devices reach patients. This project aims to mitigate these issues by reducing mechanical failures in the manufacturing line of heart medical devices. Through rigorous data collection, analysis, and process optimization, this research strives to enhance product quality and ensure the financial stability of the industry in Puerto Rico.

Background

The medical device manufacturing industry in Puerto Rico has seen substantial growth, especially in the production of heart care devices like pacemakers and defibrillators. Despite this advancement, a significant portion of the manufacturing process remains manual, leading to high risks of mechanical failures. These defects can result in severe financial losses for companies due to damaged components and increased scrap rates. Furthermore, undetected defects pose critical health risks to patients if faulty devices are implanted. The high incidence of manual assembly errors has led to millions of dollars in annual losses and threatens the sustainability of manufacturing operations.

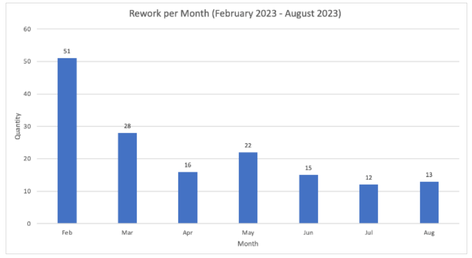

Figure 1
Mechanical Rework per month since startup of Manufacturing Line in February 2023 until August 2023 (each rework cost: $650.00/each)

To address these issues, this project focuses on identifying and reducing mechanical failures in the production line. By analyzing data from various manufacturing stages, the project aims to pinpoint the root causes of defects and implement strategies to reduce scrap and rework costs, thereby enhancing product quality and ensuring the industry's economic stability in Puerto Rico.

Problem

During the last years, Puerto Rico has seen progress in the manufacturing of medical devices of different types, but specifically in heart care. Most of these devices are manufactured 100% manually, which means there are risks of different failures at the time of device assembly. These failures cause manufacturing companies to lose millions of dollars a year in component damaged or scrap, which leads to the product leaving the market and the possible closure of these multinational companies. At the same time, due to the assembly and inspection of these devices are 100% manual, there is a risk that one of these devices will escape to the market if existing failure is not detected and could be implanted in a patient, which could cause serious consequences in the patient's health. For this reason, this project will focus at reducing scrap on a manufacturing line due to mechanical problems in heart medical devices.

Methodology

The methodology used for this project was the DMAIC concept (Define, Measure, Analyze, Improve and Control) which will help achieve the objectives of the scrap reduction project due to mechanical failures in a medical device manufacturing line for the heart failures.

The first step was Define in which the problem, the opportunity for improvement, the goals and objectives of the project, and the scope of the project were already defined. In this Define stage, a Critical-to-Quality (CTQ) Tree will be developed, which will seek to analyze what the client's critical needs are and how these needs will be satisfied. Similarly, at this stage a process map will be developed which will help to have a visual representation of the manufacturing processes and the possible scenarios where mechanical failures are created in the device.

The Measure phase will continue with which it will seek to see the scope of the problem with data that supports the problem, thus being able to understand the current performance of the manufacturing line in terms of scrap and subsequently being able to control it. In the measure phase, a data collection plan will be developed to later collect the data and analyze it and data analysis technique will also be defined to establish the different controls that must be done to reach the scrap goal.

In the Analyze phase, the data collected in the Measure phase will be used to find the root cause of the different problems. In this phase, brainstorming, the 5 why method and the fishbone method will be carried out, which will help find the root cause more quickly and efficiently. Once the root cause or causes of the problem are identified, statistical analysis will be carried out, including validations in order to enter the improvement phase with data that supports the entire investigation.

After the analyze phase, the Improve phase will continue, which will seek to identify and execute different solutions proposed from the data analysis to reduce scrap. In this phase, changes to processes, new processes, training, new equipment, or software may be made that help detect possible mechanical failures in the devices and result in scrap. The goal for this phase is to make only the necessary adjustments since it must be taken into consideration that many changes can help reduce scrap but could increase operational costs or impact business productivity.

For the control phase, the new characteristics of the process will be measured and how this resulted in the improvement of scrap at the manufacturing line level. In parallel, a control plan will be worked on to ensure that the improvements made were implemented.

Results and Discussion

After defining the problem represented by rework on the manufacturing line, the data on the various reworks and the manufacturing processes of the biggest offenders were analyzed. Among the biggest offenders were Can Damaged, Casting Anomaly, nonconforming resistance welding, and damaged components.

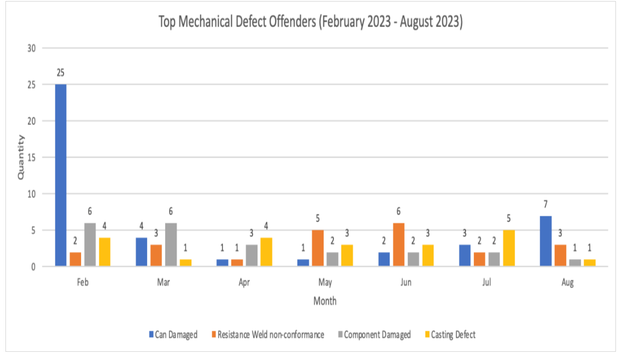

Figure 2
Mechanical defect top offenders since startup of Manufacturing Line in February 2023 until August 2023

In Figure 2, shows that in the first month of manufacturing, there was a high incidence of mechanical rework, costing $24,050 for the biggest offenders. For the subsequent months from March to August, there were a cumulative 71 defects among the biggest offenders, amounting to $46,150 over a 6-month period. Following the DMAIC methodology, a Cause-and-Effect diagram shown in Figure 3 (or fishbone diagram) was created to identify the most critical areas of opportunity. It was found that for the manufacture of pacemakers, the headers and cans are the most critical materials. As a result of the Cause-and-Effect diagram, improvements were made to equipment, fixtures, and preventive maintenance processes to avoid rework.

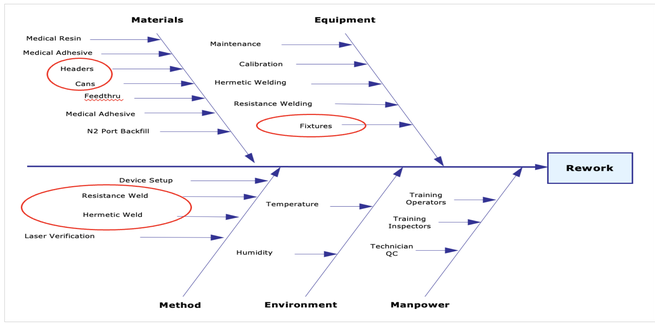

Figure 3
Mechanical defect Cause and Effect Diagram

These improvements included:

- Implemented weekly and monthly fixture cleaning and inspection by engineer/technician.
- Implemented Lase weld fixture modification.
- Resistance and Hermetic weld parameter improvements.
- Implementation for standard work for Resistance Welding process
- Cleaning workstation daily with compressed air and wipes with 99% alcohol.
- Update Manufacturing Operation procedure to add new inspection point in devices Assembly Operation to evaluate any component damaged.

To improve the hermetic welding process, it was necessary to go through a validation process to ensure that the new parameters were identified to avoid crack weld, incomplete fusion in weld and hermetic weld non-conformance. To analyze the validations, statistical analysis was carried out with the Minitab Software where a Cpk (Capability Process Index) of 2.40, 1.42 and 1.80 was obtained for runs 1, 2 and 3 respectively for the hermetic welding process. These values obtained exceed the standard established by the industry of a Cpk of 1.33. Figures 4, 5 and 6 show the statistical results obtained with the Minitab Software.

In the case of resistance welding, 3 validation runs were made to observe the performance of new welding parameters to avoid crack weld, smashed weld and blown weld. Figures 7, 8 and 9 show the statistical results for the validation of the resistance welding process. For the resistance welding process, a value of Cpk 6.56, 7.40 and 6.36 for runs 1, 2 and 3. These values obtained exceed the standard established by the industry of a Cpk of 1.33. These Cpk values indicate the capacity that the process achieves regardless of whether the average is centered between the specification limits.

For the resistance welding process, a standard work was developed to create a generic process in resistance welding processes to create a work process that was the same for each of the operators who execute that resistance welding process. It also reinforces and improves training processes by certifying personnel in this operation. Table 1 shows the standard work created for the resistance welding operation.

Table 1
Standard Work for Resistance Welding Process

Potential Cause	Action/ Activity
• Smashed Weld • Crack Welds • Incorrect Targeting • Contamination • Blown Weld	• Align header and wire parallel to weld electrodes • Align weld wire with ribbons in all unit models. • Clean weld electrodes for each unit welded • Evaluate ribbons and feedthrough wire for visible damage. • Before operator certification, training must perform using scrap components. • Perform go-no go test in electrodes for each unit welded

Figure 4 shows a significant impact on the scrap and yield metrics since the number of reworks in the manufacturing line decreased from a total of 142 for the months of February to July where the implementation of the different types of control began. After implementation of control variables, a cumulative amount of 42 reworks for the months of August 2023 to January 2024 were observed. This represents an economic impact of $65,000 in a period of 6 months after the implementation of all the changes made using the DMAIC methodology. In the case of rolled throughput yield, an improvement of 7.2% was seen for mechanical defects based on a production volume of 1500 devices per month.

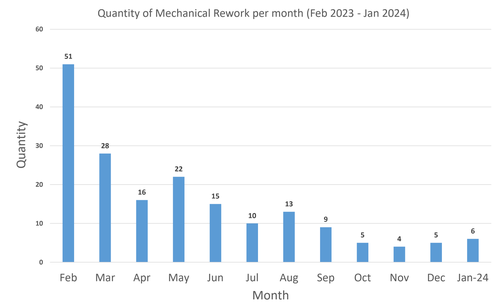

Figure 4

Quantity of Mechanical Rework per month from February 2023 to January 2024

Conclusions

The investigation into manufacturing rework, particularly focusing on the major contributors such as Component Damaged, Can Damaged, Casting Anomaly, and nonconforming resistance welding defects, provided valuable insights into the root causes and potential solutions. Through rigorous data analysis and the application of DMAIC (Define, Measure, Analyze, Improve, Control) methodologies, critical areas of improvement within the manufacturing processes were identified.

Statistical analysis using Minitab software revealed significant improvements in process capability, with Cpk values surpassing industry standards, indicating enhanced process stability and performance. Moreover, the adoption of standardized work procedures facilitated consistency across operators, fostering a culture of quality and efficiency.

The culmination of these efforts resulted in tangible economic benefits, with a reduction of $65,000 in rework costs over a six-month period following the implementation of improvements. Additionally, a notable improvement of 7.2% in rolled throughput yield for mechanical defects was observed, reflecting enhanced overall process efficiency and product quality.

Future Work

To maintain control of scrap in the manufacturing line of heart failure medical devices, several avenues for exploration emerge, each with the potential to enhance the project's impact and contribute to long-term success. One crucial aspect of future work involves the periodic verification and refinement of scrap metrics to ensure ongoing effectiveness in monitoring and managing manufacturing processes. By establishing a structured framework for the regular assessment of scrap metrics, including key performance indicators such as defect rates, and rework costs, manufacturers can proactively identify emerging trends or areas of concern and implement corrective actions in a timely manner. This iterative approach to scrap management fosters a culture of continuous improvement and enables organizations to adapt to evolving production challenge.

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