Design Project for the Manufacturing of Electrode Ring Monolithic Controlled Released Devices

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Abstract

Medtronic Rice Creek Pharmaceutical Operations at Fridley, Minnesota currently build the Electrode Ring, Monolithic Controlled Released Device (MCRD) assembly which is sent to Medtronic Villalba Campus (MVC). At MVC, the Electrode Ring MCRDs go through a various of manufacturing process to untimely build the final product which is a Pacemaker Lead cable. This project was developed as part of a process improvement initiative to reduce cost in the manufacturing process of the Electrode Ring MCRD. The project was developed following the problem-solving methodology know as DMAIC which stand for Define, Measure, Analyze, Improve and Control. The intention of using this methodology is to profoundly analyze the current manufacturing procedure for the Electrode Ring MCRDs to identify potential areas of improvement.

Introduction

This project has been outlined to provide a basic overview about the heart physiology, pacemakers, defibrillators or cardiac resynchronization devices. Subsequently, the manufacturing procedure of the assembly containing the drug component of the steroid-eluting lead will be address with the purpose of improving the current process at Medtronic Rice Creek Pharmaceutical Operations at Fridley, Minnesota. The intention of providing an overview of the pacemakers in general before focusing on the manufacturing of a specific assembly is to highlight why it is important to be robust in the implementation of a process improvement project since the life of patients depend on these devices.

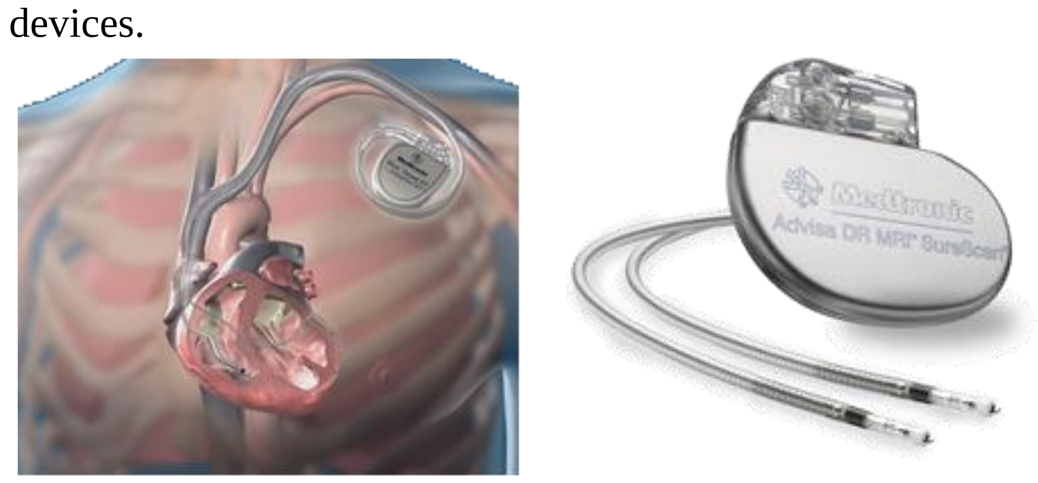

Figure 1 – Example of a Medtronic Pacemaker Device

Background

The objective of this research is to decrease the Labor, Burden and Material (LBM) cost for the Electrode Ring MCRD manufacturing process from a yearly cost of proximally $1,500,000 to $650,000 per year. This cost down yearly savings will be achieve addressing the following areas: High scrap (99%) of raw material; high cost of testing/material, units count discrepancy and line balancing. The theorical yield percentage will also be required to not be harmed during any improvement implementation.

Problem

Currently Medtronic Rice Creek Pharmaceutical Operations at Fridley mixes 250 grams of Dexamethasone Acetate (DXAC) and Silicone Rubber which is then molded to form 960 units of MCRDs Rings. Only 0.24 grams is used to manufacture the 960 units and the remaining 249.76 grams is scrapped and considered as waste.

Methodology

The purpose of this research was to identify and implement a solution that would decrease the Labor, Burden and Material (LBM) cost to the Electrode Ring MCRD manufacturing. The problem-solving methodology tool used for this research was DMAIC which stands for Define, Measure, Analyze, Improve and Control.

Define
- For the define phase the project team created a project charter using Microsoft Project and developed a high-level map of the Electrode Ring MCRD manufacturing process.

Measure
- For the measure phase the project team developed a Fishbone Diagram and collected all the necessary data to statistically calculate the baseline of the current manufacturing process for the Electrode Ring MCRD

Analyz e
- For the analyze phase the project team based on the potential root causes identified during the measure phase determined the actual root cause.

Improve
- For the improve phase the project team conducted several experiments to identify possible fixes to the root cause of the problem and implement a standardized solution.

Control
- For the control phase the project team implemented the actual changes, updated the procedures and work instructions and re-certified all the operators in each individual operation that the Electrode Ring MCRD manufacturing process goes though.

Results and Discussion

Rout Cause	Why?	Implemented Solution	Solution Results
Waste in Material Utilization	During the molding procedure 0.24 grams is used to manufacture the 960 units and the remaining 249.76 grams is scrapped and considered as waste.	The 32-Cavity Mold qualification and implementation.	32 Cavity mold creates 2,000 parts from 250g of material, a 100% increase in material usage. Reduction of lots from 110 to 55 reduces cost of testing
Unit Count Discrepancy	Every single unit is counted and inspected throughout the manufacturing process for Electrode Ring MCRDs. The highest indicator for lot production hold is "Units Miss Counts".	The 500 Cavity Peek Tray Implementation qualification and implementation.	50% reduction in scrap related to count discrepancies.
Pharmaceutical Testing	The amount of testing release per lot has a significant cost per year.	Double the number of units per Lot shipped.	Decrease in burden cost (total cost of testing) from $466K to $234K (50% reduction).

Fiscal Year 2020 Material, Burden and Material Total Cost

Labor					Burden		Materials	
Process	Lot Quantity	MTMS	Hours	Day	Testing Cost per lot	$2,631	DXAC Standard Qty (g)	0.112
Lot Mixing	1	2	28	3.50	# of lots in FY20	110	Silicone Standard Qty (g)	0.453
Lot Milling/Prep	1	1.5	18	2.25	Total cost for testing in FY20	$289,410	DXAC Cost for Standard Qty ($)	$1.89
Lot Molding	1	1	24	3			Silicone Cost for Standard Qty ($)	$0.23
					# of parts scrapped for testing and Retains/lot	63		
# of lots/year in FY20	110				# of parts scrapped for testing Retains/year	6930	DXAC Cost per gram ($/g)	16.88
					Cost of 1 MCRD	$ 25.86	Silicone Cost per gram ($/g)	0.50
# of hours mixing/year	3080				Total cost in test/retain samples in FY20	$ 179,209.80		
# of hours milling/year	1980						DXAC grams/lot (g/lot)	336
# of hours molding/year	2640						Silicone grams/lot (g/lot)	784
Labor Cost/Hour	$47						DXAC cost per lot ($/lot)	5670.00
							Silicone cost per lot ($/lot)	389.40
Mixing Cost/Year	$144,760							
Milling Cost/Year	$93,060				Total Burden Cost in FY20	$468,620	# of lots in FY20	110
Molding Cost/Year	$124,080							
							DXAC Cost in FY20 Silicone Cost in FY20	$623,700.00 $42,834.00
Total Labor Cost for Mixing, Milling, Molding/Year	$361,900						Total Material Cost	$666,534.44
Total Labor, Burden and Material Cost						$1,495,384		

Conclusion

In conclusion as part of the implementation of this Design Project for the Manufacturing of Electrode Ring – Monolithic Controlled Released Devices (MCRDs) the company will be benefits consist of the following:

- High scrap (99%) of raw material/high cost of testing - 32 Cavity mold creates 2,000 parts from 250g of material, a 100% increase in material usage. Reduction of lots from 110 to 55 reduces cost of testing
- Units Count Discrepancy - New handling trays allow placement of 1 part in 1 well, easing counting activities and reducing monthly count discrepancy by 50%.
- Line not Balanced – After decreasing child lot size from ~950 to ~480 space in the WIP shelves and manufacturing stations was increased providing more flexibility for operators to support each other and reduce lead time.
- The Theorical Yield Percentage – will not be harmed as part of any of the improvement implementations. In addition, during testing runs the yield percentage was higher than the current yield percentage in the production line.

Overall savings for Medtronic Rice Creek Operations at Fridley as part of this design project are the following:

Current vs. Future State LBM Savings

	Current State	Future State	Delta
Labor	$ 360,000.00	$ 90,000.00	$ 270,000.00
Burden	$ 466,000.00	$ 234,000.00	$ 232,000.00
Material	$ 666,000.00	$ 333,000.00	$ 333,000.00

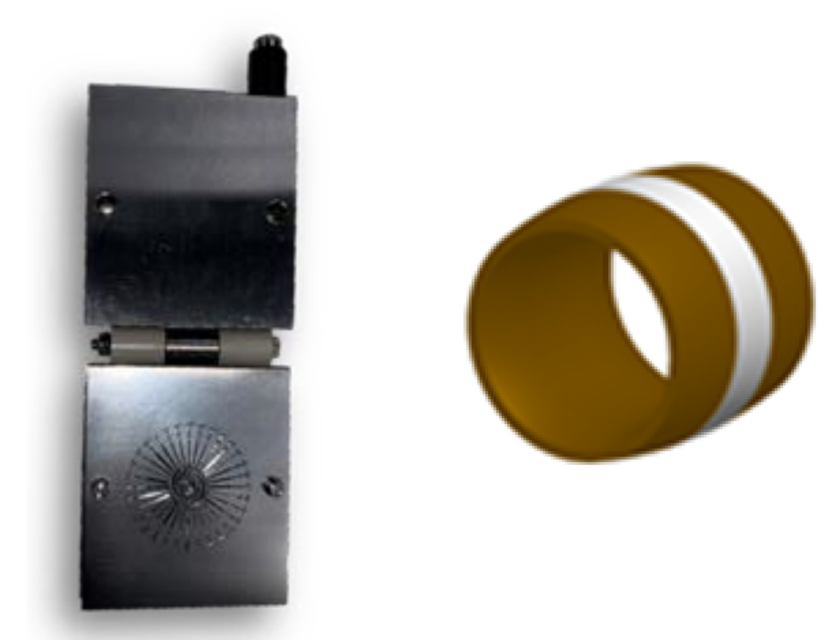

Figure 2 – 32 Cavity Mold Tool (Left) and Electrode Ring MCRD (Right)

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