Radio Frequency Identification Tags (RFID) Configuration Application for Medical Device Industry Supply Chain using DMAIC Methodology

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Manufacturing Competitiveness

Abstract

To align data control and maintains process compliance at inner cell an RFID Configuration Application was developed following the DMAIC methodology with the intend to eliminate lost traceability issues. The project guaranteed to record the 100% of traceability information systematically, eliminated 48s of changeover time (total available time of 80 min per day), reduced wastes as motion, overprocessing and defects (Non-conformances due to "Lost Traceability" that resulted on scrap). This project helped to reach a labor cost avoidance of $2,558.88 and to increase 51% of the workstation capacity per day (creating a surge capacity of 63 units per day required for an upcoming project. Furthermore, improved the operators (customer) satisfaction, as well as the support team.

Introduction

Build in Quality is focused on Risk Identification, Evaluate the Risk, Mitigate Risk, Monitor and Control and sustain the performance. A Global Project named Workstations Vulnerability Assessment (WSVA) is being deployed to make use of lean tools to evaluate people, method, material, measurement, equipment and environment. This project has the intention to identify opportunity areas and develop projects that can help the quality of the product and the yield of the lines.

In the manufacturing line, the Traceability Data (i.e. Component ID, Batch No., Operator, Date, etc) is collected through Radio Frequency Tags (RFID) and recorded electronically in Manufacturing Execution System (MES). "Aurora" line manufactures two different products: Product A several years ago, and Product B which was validated at the end of 2019. A data control opportunity in Workstation 2 due to lost traceability issues was found for Product B after a WSVA was performed in 2020.

Background

RFID is a technology that uses radio waves to transfer data from an electronic tag, called RFID tag or label, attached to an object (tray or fixture), through a reader for the purpose of identifying and tracking the object [5]. There are two types of RFID: active and passive. Active RFID tags needs a battery because are commonly used as "beacons" to accurately track the real-time location, while Passive RFIDs tags are used for many applications as smart labels, access control, file tracking, supply chain management, among other processes. This technology promises more control and larger savings to companies that handle high volume of products [6]. The data collection method based on RFID technology is very convenient because allow the companies to be agile, reduced manpower, saved time, improved data accuracy, and helped to automate the manufacturing process.

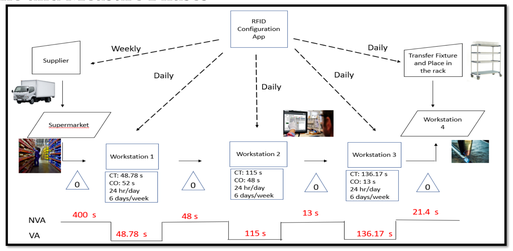
Problem

Product Identification and traceability issue in workstation 2 detected as part of WSVA.. The issue will be addressed to guarantee recording the data systematically, maintains the process in compliance, and to facilitate changeover activities. This project will improve the product Identification and traceability of workstation 2 by 100% using passive RFID Technology, will reduce changeover time of 48s, and will help to increase the daily output for about 32 additional units.

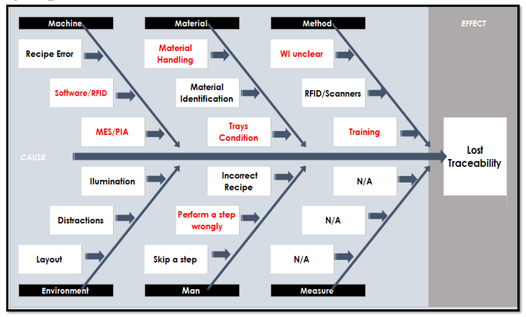
Methodology

The Quality Management System (QMS) approach comes from the Integration of Lean Six Sigma Principles. Lean Six Sigma Methodology basic approach consist DMAIC, which means Define, Measure, Analyze, Improve and Control, and each of them are considered a phase.

Define and Measure Phases



Analyze phase

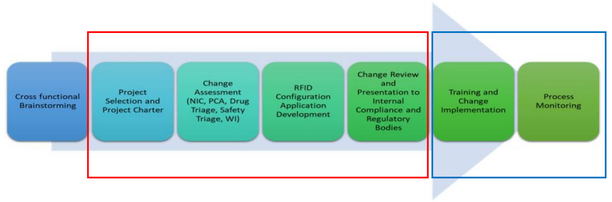


No.	Cause	Actions	Effect on Project?	Possible Solution
1	Software /Configuration RFID	RFID Function Capability was tested to understand its functionality. It was found that RFID port are fixed. Its configuration is being monitored by PIA.	YES	Creates different RFID configurations files.
3	MES / PIA	MES/PIA configuration for this process was verified and it was found to be correctly. However, it was found that PIA controls the recipe parameters (which include the RFID port set up). In this case, if product builders try to change the RFID configuration manually in PIA files, watch dog will trigger an alarm, and the process will automatically stop. The process can't be re-initiated without technical support intervention/investigation.	YES	N/A. PIA is performing its intended work
4	Material Handling	A walk up through supermarket to understand the storage process. The workstation material handling was observed in several shifts to understand the product behavior when handling the material.	NO	Material Handling should be addressed through operators
5	Material Identificati on	The Material Identification it's supposed to be recorded through the RFID tag. Operators are currently printing the labels.	NO	Don't allow to use the MES printer
6	Trays Physical Condition	The Trays inventory was inspected to see if shows physical damages that might be interfering in the tray loading position in the workstation.	NO	Perform and inventory verification
7	Work Instruction (WI)	The work instruction was reviewed in detail and it was found that the process can't be executed as stated in the document.	YES	Modify the steps
8	Training	Because the work instructions have opportunity areas will be necessary to perform a re-training once updated the work instructions.	YES	Re-training the staff
14	Perform a step wrongly	Operators are printing labels because the process can't be performed as currently stated in the work instructions	YES	Correct the Product Builders

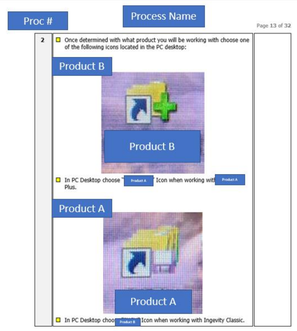
Improve and Control Phases

The **solution** was to enable a PIA data base per product. That allows to create files with distinct RFID configurations according with the product requirements. These two RFIDs configurations files can be accessed through executable shortcuts in the HMI. The executable shortcut must be selected before starting the regular "log in" process.

Results and Discussion



WI updated to instruct how to run the RFID Configuration application in the HMI



Process Cycle Time

Product B		
Lecture	Process CT (sec.)	
	Before	After
1	114	85
2	115	77
3	114	73
4	117	80
5	114	76
6	113	78
7	114	73
8	115	76
9	113	81
10	115	72
11	118	76
12	114	76
13	116	70
14	115	77
15	120	74
Average	115	76
Max	120	85
Min	113	70

Capacity Increase per day for about 51%

Workstation 3	Product B Cycle Time	Equip Qty.	Uptime	Shifts	Yield	Capacity / Day
Before	115	3	100%	1210	1.50%	1866
After	76	3	100%	1210	1.50%	2823
						957

Changeover Labor Cost per Year for about $5,117.76

Frequency/ Shift	Shift per day	Time CO (sec.)	Total CO (min.)	Labor Cost	Days per month	CO Labor Cost per Day	CO Labor Cost per Year
50	2	48	80.00	17.77	9	$213.24	$2,558.88

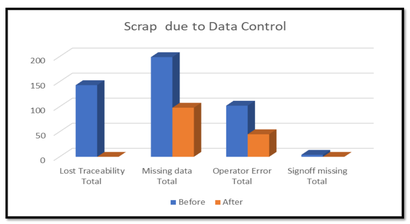
Surge Capacity of 63 units

Area	Process / Station	Process CT (sec.)	Frequency/Shift	Shift per day	Time/CO (sec.)	Total CO/Day	Process Efficiency	Potential Units
Inner	Workstation 2	76	50	2	48	80.00	95%	63

Waste Reduction (MES Label printing)

Inner Cell Daily Output (2 shift)	1200
Product B Production days/month	9
Labels/package	1000
Label Package cost	$ 20.00
MES Printer Label Cost ($)	$ 216.00
Annual Cost Avoidance ($)	$ 2,592.00

Waste Reduction (Non-Conformance due to "Lost Traceability"



Conclusions

RFID Configuration Application was developed and implemented successfully after a "Data Control" opportunity was identified during a Workstation Vulnerability Assessment. DMAIC methodology was used as guidance to define and solve the problem. This application improved the RFID ports configuration when product changeovers has to be performed allowing to maintain the product traceability as required by the regulatory bodies as Food Drug Administration (FDA), Medical Device Single Audit Program (MDSAP) and the European Union (EU). This project contributes satisfactory to decrease the changeover time (from 48s to 0s), a labor cost avoidance of $2,558.88, reduce waste (Overprocessing [MES labels: $2,592] , defects [100% of non-conformances due to lost traceability], motion [ask for support]), and staff investigations. Furthermore, helped to increase the daily output (A surge capacity of 63 additional sub-assemblies at inner cell). This project promoted to maintains the line flow and to increase the product builder's satisfaction.

Future Work

- Finish to document the Project Value Improvement (VIP) Process through the company system
- Develop a project using Lean Six Sigma approach to reduce missing data and operator error.
- Share the improvement with other lines/sites that might be facing the same issues.

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