Incidences of Incorrect Serial Number Labels

Maria de los A. Rodriguez Rivera
Engineering Management
Dr. Héctor J. Cruzado
Engineering Department
Polytechnic University of Puerto Rico

Abstract *— Since May thru July 2017, there were reported four instances of units shipped with incorrect serial numbers. It caused impact to quality metrics at local manufacturing site. Nevertheless, a local project was initiated to pursue a reduction of these shipped defects. DMAIC methodology was applied for this project, and the problem statement was the first step completed for the define phase. Then, the current state of the manufacturing process was evaluated as part of the measure phase. During the analyze phase, key inputs contributing to these defects were confirmed which allowed to start identifying improvements of the process. Finally, improvement process is taking place and controls such as the use of magnifiers, equipment controllers, integrated vision systems and reporting tools solutions were developed and some of them implemented on the corresponding process steps. Further, control phase will be monitoring the improved process to demonstrate the effectiveness of the improvements.*

Key Terms *— DMAIC, equipment controller (EC), fixture, vision system.*

INTRODUCTION

A project was initiated to pursue labeling process improvements at a local industry site dedicated to the manufacturer of medical devices. Since May 2017 to July 2017 there were reported four instances where units were shipped with incorrect serial number labels from the local manufacturing site. Two out for four instances were related to serial number labels of the units not matching the sterile tray serial number label; one instance was related to duplicated serial number labels and one instance related to serial number in the PTO label that did not match the serial number on the sterile tray label. It resulted in shipped defects which impacted quality performance. Then, the need to pursue a reduction of these defects related to incorrect serial numbers labels was identified, and accordingly, a project was developed. Six Sigma DMAIC methodology was followed for this project. It allowed an easy identification of the root cause related to these labeling failures, then to bring solutions to eliminate the problem and therefore, to improve the process.

LITERATURE REVIEW

Since, this manufacturer site is producing medical devices, then regulations in terms of the labeling, identification and traceability were assessed to assure that any potential change to the process will continue meeting any regulatory requirements. FDA regulations establish that medical devices manufacturers for US territories shall provide procedures that assure the product identification during all stages of the process and, to assure the identification of each unit, lot and components with a control number [1]. FDA has a UDI (Unique Device Identification) rule that requires a numeric or alphanumeric identifier to be placed on the label of most medical devices (Class 3 and Class 2), as well as on their device packages [2]-[3]. UDI should appear both in a text format and in automatic identification and data capture format (most typically, a machine-readable barcode). Accordingly, the UDI consists of a device identifier and a production identifier [2]-[3]. In addition, EU Commission also defined same traceability and labels of medical devices UDI requirements for European territories. Nevertheless, these UDI regulations requirements applicable to medical devices are being met by this local site, thus any further solutions for reported label defects shall remain in compliance. A data matrix technology could address the situations related to

incorrect serial numbers labels. In this case, the standard for data contents the product to be identified and, allows additional attributes to be carried in the same technology, such as the batch number and expiration date and, if required, unique serial numbers for the item [4]. Then, the data matrix technology represents a benefit within production organizations which require traceability of their manufacture items while, effectively enabling shipments and distribution of the product in a compliance and safety way. Accordingly, the product reliability and process yield performance are the leading indicators that shows that improvements are effective. It is also important to remark that implementation activities involve the establishment and understanding of user and business requirements, defining software and infrastructure, modules selection, and trainings to assure a smooth process and the expected outcome of the system [5].

ANALYSIS

Six Sigma DMAIC methodology was followed to perform project. This methodology provides several phases such as define, measure, analyze, improve and control which permitted a full mapping of the process [6].

The define phase was the first one completed for the project. Accordingly, a problem statement stated a situation where several units were shipped with incorrect serial numbers from a local manufacturing site. It resulted in shipped defects and therefore, quality performance of the site was affected.

A reduction of 50% of non-conforming product related to this defect of incorrect serial number label is being pursued as part of the goal established in this project. The scope of this project will include local manufacturing site at PR, while other external manufacturing sites were out of the scope.

The current state of the process and performance of the line were evaluated as part of the measure phase, and lack of detection controls for some steps of the process were observed.

Two operation steps associated to these defects were assessed and Figure 1 presents some related pictures. First process step is the serial number label generation and it was noticed the following opportunities:

- Serial number entry in manual form/manual traceability
- No verifications of the labels installed in the lead vs. the serial number documented in the manual form

Second process step assessed was the sterile pack operation, as follows:

- Serial number is manually entered system
- No verifications lead label vs. sterile pack label
- Line clearance has opportunities

Figure 1
Pictures Showing Examples of Lack of Processes Controls

After evaluating the current performance of the line, it was also noticed an increased trending of these label defects as presented in Figure 2.

Figure 2
Incorrect Serial Number Labels Defect Rate

Root Cause Analysis

Cause and Effect Diagram methodology (Fish Bone Tool) was used to identify likely suspected factors (X's). There were three inputs associated to man factor and three inputs associated to method factor as presented in Figure 3.

Key inputs affecting the process were identified and confirmed as part of the analyze

phase. Table 1 presents a summary of key inputs with their corresponding evidences.

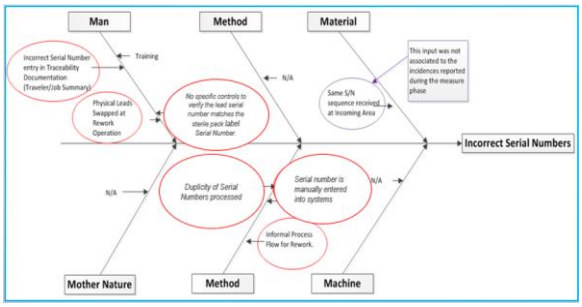

Figure 3
Fish Bone Analysis for Identified Factors (X's)

Table 1
Key Inputs Affecting the Process

Input	Evidence	Key Input
Incorrect Serial Number entry in Traceability Documentation	The operator documents the serial numbers in a job summary form.	Yes
Duplicity of serial numbers processed	Two different systems at the label generation step process and sterile pack process that do not share the serial number information.	Yes
No specific controls for verifying that lead serial numbers match the sterile pack label serial number	Labels verification just to assure that serial number labels are legible	Yes
Serial number is manually entered for generation step and sterile pack step.	After serial numbers are entered there are no verification to assure correct entries	Yes
Physical Leads Swapped at Rework Operation	Traceability errors, no controls	Yes
Informal Process Flow for Rework	Traceability errors, no controls	Yes

RESULTS

Identification of Solutions and Controls

Solutions and controls were identified to address the key inputs that were confirmed as part of the root cause analysis. Serial number generation step improvement controls already implemented were, as follows:

- Equipment controller for entering serial numbers
- Printing serial number report from the system and remove manual form
- Implement a verification between serial number label installed in the lead and serial number report
- Implement the use of magnifiers

This equipment controller (EC) provides a user interface to automate the assignment of serial numbers to job during the labeling operation of lead manufacturing. Operator input errors were eliminated because the input of data is directly performed to system which serial number is searching into a database to assure that serial number entered belongs to the sequence assigned to the lot being processed and to detect any duplication issue of serial number. In addition, a serial number report is being generated directly from the system to verify that serial numbers entered in the system match the installed serial number labels on the lead. This inspection is performed by using a magnifier which was also added as a tool for the process improvement. Moreover, manual form used to manually document serial numbers was removed. Figure 4 presents pictures of improvements elements at serial number label generation step.

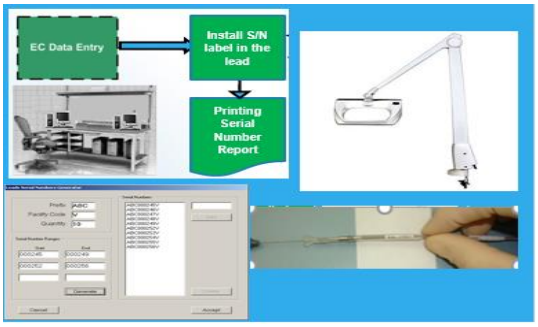

Figure 4
Improvements at Serial Number Label at Generation Step

Sterile pack process improvements are being implemented, as follows:

- Implementation of integrated vision system EC with fixture
- Implement a verification between serial number label installed in the lead and serial number label of the sterile pack
- Implement the use of magnifiers

MES integrated vision system EC includes the sterile Pack vision application and equipment controller fixture that will interface with sterile pack vision application. This system will aid operators to print automatically sterile pack product identification labels once the camera as part of the vision system has read the serial number installed in the lead. Accordingly, operator input errors were eliminated because the input is automatically performed by a reading device which is a camera. EC will control the lot workflow, including the vision application execution, validation and verification of the scanning labels. Accordingly, EC won't allow to work on more than one lot at the same time, which added controls for the line clearance process.

Therefore, this EC handles a vision application of optical character recognition that will now facilitate the operator task of printing correct labels and to complete the required traceability aspects in our Manufacturing Execution System. Figure 5 shows pictures of improvements at sterile pack process step.

Figure 5
Pictures of Improvements at Serial Number Label at Generation Step

DISCUSSION

So far, improvements to assure process sustainability were implemented and/or being implemented, as follows:

- Magnifiers
- Manufacturing procedures changes that added verifications controls
- EC implementation for the serial number label generation step
- Serial Number report which eliminated the Job Summary Form
- MES integrated vision system EC includes the sterile Pack vision application and equipment controller fixture (Poke Yoke solution)

It is important to remark that improvements will be monitored throughout the process performance by making use of defect rate Pareto charts and control charts to can demonstrate the effectiveness of the implemented actions.

CONCLUSIONS

In this case, the main objective of the project selected was to pursue a 50% reduction of defects related to incorrect serial numbers labels installed in the devices and placed in the sterile pack as well. The reason for that is because this local manufacturing site dedicated to the production of manufacturing devices was facing a quality product issue related to labeling issues. Which represented a regulatory issue since labeling requirements were under compliance risk. Accordingly, an initiative was conducted to look for process improvements. DMAIC methodology was followed and in this way problem statement was properly defined while process performance was assed and opportunities were defined. Then, solutions were identified and almost all of them have been implemented to enable an improvement process that assure the effective addressing of this labeling situation.

So far, there is just pending one action to be implemented out of six ones, however, these improvements show effectiveness since it has not

been reported new labeling issues related to incorrect serial numbers at this moment.

REFERENCES

[1] FDA. (2017, April 1). *Code of Federal Regulations Title 21, Part 820 Quality System Regulation, Subpart F – Identification and Traceability* [Internet]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=820.65

[2] FDA. (2013). *Unique Device Identification–UDI* [Internet]. Available:https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm

[3] Tautan, A.M. (2017, May 29). EU UDI - *New Requirements on Medical Device Traceability* [Internet]. Available: http://www.qservegroup.com/i71/eu-udi---new-requirements-on-medical-device-traceability

[4] Morrison, Martin. 2010. Data Matrix barcodes: print quality and popularity on the up Pharmaceutical Technology Europe. pp. 25-26.

[5] Johns, Chip. 2017. Improving operations with ERP. www.adhesivesmag.com. pp. 39-41.

[6] George, M. L., et al. 2005. *The Lean Six Sigma Pocket Toolbook*, pp. 1-19.