Labeling and Packaging Process Improvement using DMAIC

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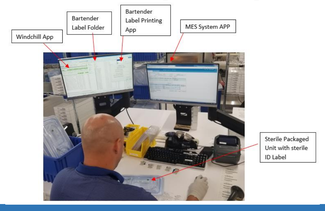
Abstract

Medical Device Companies must ensure that each unit of product has a unique identification and that it is labeled correctly. Labeling requirements include having the appropriate data in the label, not having misleading information in any of the labels, labeling content and configuration should be appropriate and, the label should remain legible through the expected usage of the device. Manual labeling and inspection processes are time consuming, fully dependent on humans, sometimes inconsistent and the potential of rework or scrap is higher; whereas automated processes bring consistency, help reduce cycle time, bring reproducibility, improve inspection process, and reduce human dependency. As part of this design project, the labeling and packaging process of the Neuromodulation Division of the Medical Device Company was assessed using the DMAIC methodology. This structured methodology facilitated the identification of robust solutions, integrating automation to the label print and inspection processes, reducing defects, and achieving process improvement.

Introduction

Medical Device companies have labeling requirements that they need to comply with, as required by regulations (e.g. FDA and EUMDR). Neuromodulation (NMD) Final Packaging process is performed in four separate workstations (WS). The process is fully dependent on human interactions with systems such as Windchill (Documentation System), MES System (Traceability System), and Bartender Application (Labeling System). Incidents have been reported involving the label printing and inspection process for Neuromodulation (NMD) units. Units were found with traceability errors in final pack labels. These errors are related to duplicated final pack labeling (two units labeled with same traceability information), incorrect Use by Date (Expiration Date), and incorrect artwork.

Figure 1: Workstation Setup Before Implementation



Background

One of the most important processes within a Medical Device company is the labeling and packaging process of the finished device. It is in this process where the final pack process is completed, and the units becomes labeled with its unique identification. Label accuracy is imperative in the medical device industry, as any incorrect information can lead to fines, recalls, and a reduction in consumer confidence [1]. The label inspection process is a critical step within the labeling and packaging process. For processes that are not automated, this requires attempting to inspect label quality manually via 200% visual inspection [1]. According to Juran, inspectors find about 80% of the defects present in the product and miss the remaining 20% [2]. Manual processes are time consuming, fully dependent on humans, sometimes inconsistent and the potential of rework or scrap is higher; whereas an automated process brings consistency, help reduce cycle time, bring reproducibility, improve inspection process, and reduce human dependency.

Problem

The objectives of this design project are the following:

- Improve the labeling process to reduce human dependency and facilitate the labeling and packaging process through the implementation of an automated system.
- Reduce label printing issues and ensure labeling requirements are met.
- Reduce manufacturing escapes related to labeling issues associated to current manual labeling process.
- Improve inspection process to avoid having escapes from human visual inspections.

Methodology

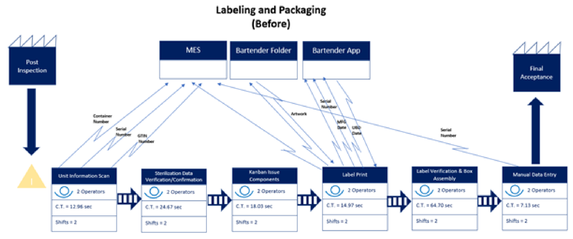
DMAIC Methodology (Define, Measure, Analyze, Improve and Control) was used for this Design Project to identify the sources of variation on the manual execution of the labeling and Packaging process of the Medical Device Company, that are contributing to the labeling errors in the Neuromodulation Division.

Results and Discussion

Define

Go See, Value Steam Map (VSM) and SIPOC tools were used to define the problem statement. Through the VSM (shown in Figure 2), it was established that the Product Builders had many manual interactions and during several times, with MES System, Bartender Folder and Bartender App during the whole labeling process. the cycle time to process a unit up to the label verification and box assembly is 64.70 seconds per PB per unit.

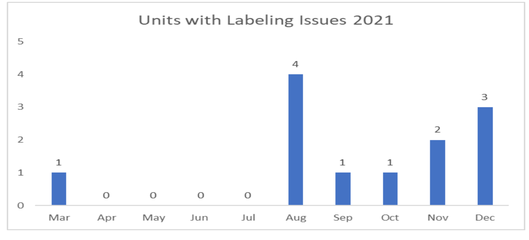
Figure 2: VSM before Implementation



Method

An evaluation of the events reported and documented through the Medical Device Company investigations platform was performed. Four investigation records were found involving NMD units with labeling defects for a total of 12 units impacted. Most of the units were processed between Aug to Dec 2021 (Figure 3).

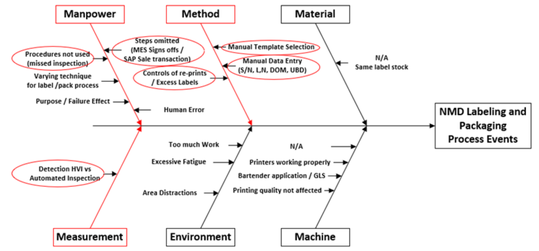
Figure 3: Units with Labeling Issues



Analyze

A Cause-and-Effect Diagram (Figure 4) was completed to identify the inputs that were potentially related to any nonconforming outputs. The Cause-and-Effect Diagram was completed performing problem solving sessions with Subject Matter Experts, Quality and Manufacturing area personnel. Manpower, Method and Measurement were the ones identified as contributing to the events reported, it was concluded that even though procedures and controls existed to prevent labeling issues, they were mostly dependent on product builder behavior and adherence to procedural requirements. There was opportunity for error due to the different process complexities.

Figure 4: Cause and Effect Diagram



Improve

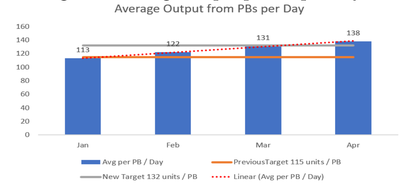
A custom label print and inspection application was developed and implemented, using the CRM Division label printing process, which is automated, as a baseline. Brainstorming sessions were conducted to define the user requirements for this custom application with representation from all functional areas. The application was validated to ensure reproducibility, sustainability and that it performs as intended. The Improve phase was implemented in two phases as follows:

- Phase I: Implemented an automated Label Printing Process (LPS) capable to interphase with MES System and Bartender to retrieve required variable data information (Use by Date, Manufacturing Date, Serial Number and Artwork number) and artwork file.
- Phase II: Added an Automated Vision System to LPS to ensure correct labels with correct variable data are applied to final back box (top and lateral labels). This vision system replaced previous unaided human visual inspections for label content accuracy and eliminated the need of a redundant inspection at the next workstation (Final Acceptance).

Through a new VSM, it was confirmed that after the implementation, the Product Builders have fewer manual interactions with systems, human dependency was reduced and, the cycle time of the process was reduced to 57.14 seconds per PB per unit from the previous 67.14 seconds per PB per unit. This in turn, helped improving capacity, since by reducing the cycle time, each PB will be capable to produce 17 additional units per shift at the completion of the learning curve.

In addition, it was proved that over time and while overcoming the learning phase, the PBs have been able to exceed the previous target of 115 units per PB per shift and in some cases exceed the new target of 132 units per PB per shift (Figure 5).

Figure 5: Average Output per PB per Day



Conclusions

The implementation of a validated automated label print process minimizes the potential of having mislabeled units. It facilitates labeling and packaging processes and provides the benefit of reducing human dependency. Human interactions and manual entries can be eliminated with a labeling application that communicates and interacts with other systems such as MES (Figure 6). Process complexity is also simplified. The inspection process is also improved implementing a validated automated vision system, capable of comparing the variable data from the label with the data provided by MES System. The weight of the labeling critical inspections relies in the system and not in the human. Thus, allowing the elimination of redundant human visual inspections.

Implementing an automated label print process contributed to reducing the process cycle time from 64.70 secs to 57.14 seconds per PB per unit. This resulted in a capacity increase (additional 17 units can be processed by PB per shift) and a calculated cost saving of $17,688 in a year. The elimination of WS Final Acceptance resulted in an overhead reduction of 2 PBs, which represents a cash saving of $83,994.

Figure 6: LPS Automated System

Future Work

The labeling and inspection system was customized for NMD Division based in CRM Division label print process. Harmonization between both divisions labeling processes should be pursuit in the future.

Acknowledgements

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