Labeling and Packaging Process Improvement Using DMAIC Methodology

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Abstract *— Medical Device Companies must ensure that each unit of product has unique identification and that it is labeled correctly. Labeling requirements include having the appropriate data on the label, not having misleading information on 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 facilitates the identification of robust solutions, integrating automation to the label print and inspection processes, reducing defects, and achieving process improvement.*

Key Terms *— automation, DMAIC, labeling, visual inspection*

PROBLEM STATEMENT

Pharmaceutical and Medical Device companies have labeling requirements that they need to comply with, as required by regulations. For Medical Devices, regulations such as 21 CFR Part 801 (US Code of Federal Regulations – Medical Device Labeling) and 2017/745 (European Medical Device Regulation) apply. Medical Device Companies must ensure that each unit of product has unique identification and that it is labeled correctly. Labeling requirements include having the appropriate data on the label, not having contradicting or misleading information on any of the labels accompanying the product, labeling content and configuration should be appropriate for the product, and the label should remain legible through the expected usage of the device.

NMD Final Packaging process is performed in four separate workstations (WS): WS Post Inspection, WS Labeling and Packaging, WS Final Acceptance, and WS Shrink Wrap. Each part of the process is performed by independent Product Builders (PB) per 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), which is prone to human errors.

Research Description

Incidents have been reported involving the label printing and inspection process for Neuromodulation (NMD) units. NMD Units were found with traceability errors in final pack labels. Errors found are related to duplicated final pack labeling (two units labeled with same traceability information) or incorrect use-by date (Expiration Date), and incorrect artwork. Some of these labeling defects were identified on units within the Company control. However, others were already past their manufacturing detection points.

Based in the preliminary investigation performed for the events, it was concluded that these were caused by a combination of Manpower and Method. Even though procedures and controls existed to prevent any of these issues, they were mostly dependent on product builder behavior and adherence to procedural requirements. Opportunities existed to evaluate current defined methods and identify areas of improvement to facilitate product builder work and reduce the possibility of human error.

Research Objectives

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.

Research Contributions

Implementation of the design project will minimize the potential of having mislabeled units and avoid having compliance issues with regulatory agencies, company policies, and procedures. In addition, implementing an automated label print process will contribute to reduce process cycle time at least 10%, which will represent cost savings of around $17,000 per year. Adding a systematic visual inspection will support the elimination of the Final Acceptance Workstation, in which a redundant human visual inspection is performed to confirm label quality and accuracy of label content to 100% of the units. This will represent cost savings of around $80,000 due to potential overhead reduction. Other benefits are capacity improvements and rework reduction associated to labeling errors.

LITERATURE REVIEW

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 product in its final packaging becomes labeled with its unique identification. Labels and labeling are two very different concepts [1]. If it is on the device, attached to the unit, it is a label. Label accuracy is imperative in the medical device industry, as any incorrect information can lead to fines, recalls, and a reduction in consumer confidence [2]. The label content should easily help the customer identify the product and all labels attached to the final packaging should have the same information. Important content information on the label are material, model, serial number, use-by date, manufacturing date, UDI (Unique Device Identification), GTIN (Global Trade Item Number), manufacturing plant, sterilization method, and handling/storage requirements, among others. Also, it is important to use the correct label template or artwork for the finished device being processed.

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 [2]. This means that, in some cases, such as in the Neuromodulation Division of the Medical Device Company, two independent product builders are needed to inspect for label accuracy. According to [2], inspectors find about 80% of the defects actually present in the product and miss the remaining 20%. Human factors such as visual acuity or sight can contribute to inspection errors. When a human inspector is involved, human judgement and perception have influence on the quality assessment of the process [3]. There are different types of inspection errors (e. g., error in technique, inadvertent errors, and conscious errors) that could be minimized or even eliminated adding automation (e. g. vision systems) to the inspection process.

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, helps reduce cycle time, brings reproducibility, improves inspection processes, and reduces human dependency. As part of this design project, the labeling and packaging process of the Neuromodulation Division of the Medical Device Company will be assessed using the DMAIC methodology. The intent is to understand the current process, identify where waste is being produced, and eliminate or reduce this waste by pursuing an automated process.

DMAIC stands for Define, Measure, Analyze, Improve, and Control. It is a data-driven quality strategy used to improve processes [4], a structured problem-solving methodology introduced by Motorola in 1986. The DMAIC methodology breaks

down an identified problem to identify sustainable solutions to reduce defects in processes.

The first step of the methodology (Define) involves understanding clearly what are the problem and the scope. A SIPOC (Supplier, Input, Process, Output, and Customer) can be used to create a high-level view of the process. This can be supplemented by a Value Stream Map (VSM), which is used to identify the areas where the problem originates. It is also important to create a project charter at this phase.

The purpose of the Measure phase is to gather baseline information about the process that has been identified as needing improvement [5]. As part of this phase, the current process to be improved is evaluated to understand what exactly is happening, where are the defects being generated, and to what extent. Tools like Pareto charts, capability analysis, histograms, complaints, and FTR (First Time Right) metrics can be used for the data collection process.

In the Analyze phase, the gaps between the current process performance and the intended performance are determined. This phase involves performing the root cause analysis to determine the process inputs that are affecting the outputs. Cause-and-effect diagrams can help identify all the potential causes.

The Improve phase is when the solutions to the root causes identified are implemented [6]. The solutions must address all potential causes identified in the Analyze phase. An implementation plan should be developed with all associated tasks to make sure the solutions are implemented in a timely manner and with all the resources needed.

The last phase of the DMAIC methodology is the Control phase. In this phase, a monitoring plan should be developed to track the success of the improved process and make sure the actions are sustained. Once the control phase documentation is completed, the process is handed to the process owner.

METHODOLOGY

The design project will use the DMAIC methodology 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. The activities to be performed as part of the different phases of the methodology are the following.

Define Phase

In this phase, we will confirm the problem statement and scope with support from the functional areas (Production, Engineering, Quality, MES and Software) involved in the process through the following:

- Go See or process Walkthrough to the labeling and packaging area to understand the current process.
- Value Stream Map (VSM) of the current process to understand the interaction of the product builders with the different systems needed to produce the labels and the cycle time.
- A SIPOC diagram will be created to develop a high-level diagram of the process and understand the inputs and outputs.

Measure Phase

In this phase, data collection will be performed to better understand the extent of the problem.

- Histograms and Pareto charts will be used to understand the timeline when the defects have been reported, the quantity of labeling defects, and where it has been detected.
- A detailed process flow will be completed for the labeling and packaging process.
- The current manual label print system and human visual inspections will be evaluated to understand configuration opportunities among all systems used during the process.

Analyze Phase

A root cause analysis will be performed to identify the potential causes contributing to the labeling and inspection errors.

- The data obtained from previous phases will be analyzed.
- A cause-and-effect diagram will be created to define the causes contributing to the defects.
- Identify solutions to the potential causes identified as contributing to the incidence of

events associated to labeling defects and missing inspections, and define an implementation plan.

Improve and Control Phases

The solutions will be implemented in this phase and a control mechanism will be used to ensure sustainability of the improvements.

- Develop and implement an automated solution for the label printing and label inspection processes.
- Validate the performance of the automated system to ensure reproducibility and consistency in the labeling process.
- Update documents procedures and training package with the new automated process requirements.
- Transfer process to the process owner and complete financial analysis of cost savings.

RESULTS AND DISCUSSION

These are the results obtained by implementing the five phases of the DMAIC methodology.

Define Phase

A walkthrough (Go See) was performed to the labeling and packaging area by representatives from manufacturing, engineering, and quality to understand the process and identify areas of opportunity. The Go See focused on the workstations where the labels are printed and inspected. These were the most important observations.

- **Workstation Labeling and Packaging (Procedure Labeling and Packaging)**
  - As part of the process, PB was required to log into MES system, open applicable reference procedures, and required applications (Windchill and Bartender). In addition, the PB interacts with Bartender Label Folder to select the applicable artwork (figure 1).
  - The PB manually inputs the required variable data either by scanning from a source or typing the information in the bartender screen.

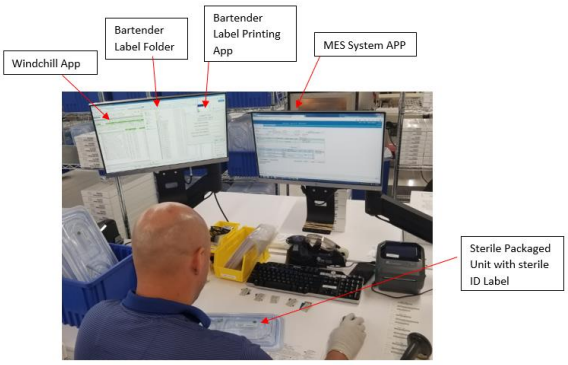

Figure 1
Workstation set-up before implementation

  - A visual inspection was performed for variable data matching (e. g serial number), printing defects and label content.
  - Labels were applied to the box and Tyvek of the unit. Then, to confirm match between unit (serial number scanned previously) and labels applied to the box, the batch number (serial number) from the label was manually typed to MES.
  - Another visual verification was performed per procedure by same operator for label content. If label content is not correct, an NC is created in MES.

- **WS Final Acceptance (Procedure Packaging Final Acceptance Master)**
  - Final pack labels were inspected per applicable drawings and BOM.
  - As a redundant inspection, the closed box packaging and the labels were visually inspected for packaging damages and label content (including serial number, date of manufactured and use-by date).
  - Once correctness was confirmed and package inspection was satisfactory, MES Task List was signed off in the system.

Through a VSM (figure 2), it was established that the Product Builders had many manual interactions and on several times with MES System, Bartender Folder, and Bartender App during the whole labeling process. This process is fully dependent on Product Builder behavior and adherence to procedure requirements. In addition, the cycle time to process a

unit up to the label verification and box assembly is 64.70 seconds per PB per unit.

A SIPOC diagram (figure 3) was prepared to summarize the inputs and outputs of the Labeling and Packaging Process. Among the inputs identified for the final packaging and labeling of the units are the product builder performing the process, labels, application and other systems (MES, Windchill, etc.). The output of the process is the conforming Neuromodulation Finished Good units with the correct traceability, correct packaging, and label configuration meeting all quality standards.

Based on the Define Phase evaluation, the scope of the design project was confirmed. The labeling and packaging process for Neuromodulation products required many manual interactions with several systems at the same time that do not interphase between them.

Measure Phase

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, with a total of 12 units affected. Most of the units were processed between Aug to Dec 2021 (figure 4). At the time of the events, the controls available, visual inspections in WS Labeling and Packaging, and redundant visual inspection in WS

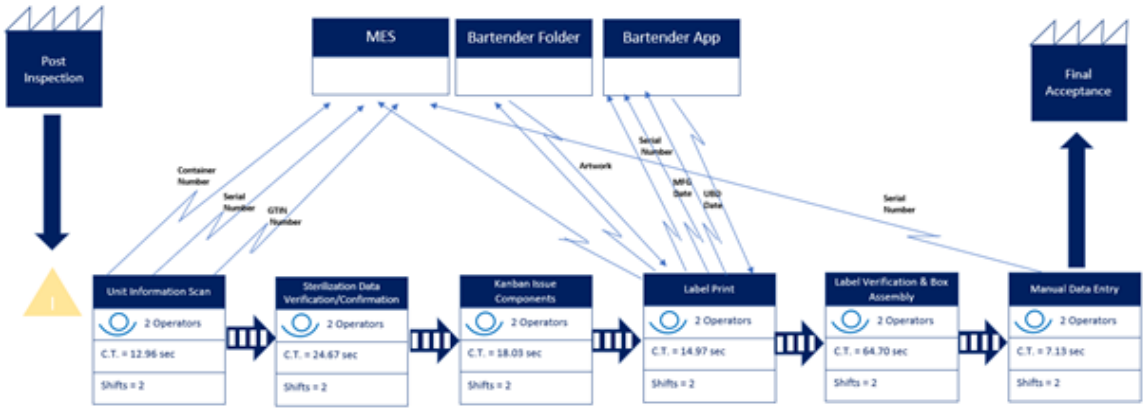

Figure 2
VSM of process before change

Suppliers Inputs Process Outputs Customers (SIPOC)

Process Name: NMD Labeling and Packaging
Process Owner: Final Pack Core Team

Suppliers	Inputs	Process	Outputs	Customers
Providers of Resources	Resources Required	Process Description (4-6 key steps)	Process Deliverables	Stakeholders
Main Line - Lead Unit	Final Pack Box	Post Inspection	Finished Good final packed in	Distribution Centers
Material Suppliers	Labels		correct packaging	Product Division
	Literature Package		configuration, labeling and	Sales Representatives
	Workstation	⇩	traceability	Physicians
	MES Traceability System	Labeling and Packaging		Pacient
	Bartender Folder			
	Bartender App			
	Windchill	⇩		
	Lead Unit	Final Acceptance		
	Product Builder			
	Final Pack Area			
	Printer	⇩		
	Shrink Wrap Equipment	Shrink Wrap		

Figure 3
SIPOC diagram; process areas in green were the focus of this project

Final Acceptance by a different Product Builder were not capable of detecting the discrepancies. The labeling defects were captured by one of the customers of the process (Distribution Centers). None of the units were beyond this point or at patient level.

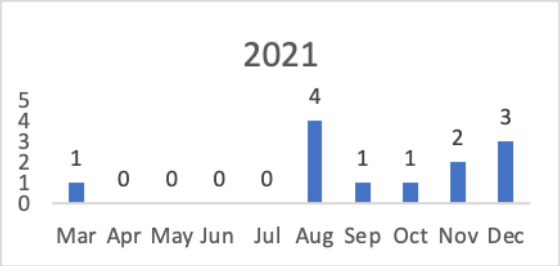

Figure 4
Units with labeling issues

The investigations performed as part of these events concluded that the labeling errors were produced by different product builders (regardless of their experience within the process) on different days and different shifts. No tendency among the PBs was identified. The potential causes identified included Bartender Manual Entry Method, Human Visual Inspection Inadequate, Duplicated/Incorrect Label Applied, Omitted Process Step – Final Acceptance Visual Inspection, and Unauthorized Label Re-print.

Through a detailed process flow (figure 3), it was confirmed that the labeling and packaging process is complex due to all the manual interactions with systems and the manual process to assembly the box, labels, literature and finally inspecting the unit.

Analyze Phase

A cause-and-effect diagram was completed to identify the inputs that could be potentially related to any non-conforming outputs. The cause-and-effect diagram was completed during a problem-solving session with Subject Matter Experts, Quality and Manufacturing area personnel based on the facts documented in previous sections. The ideas generated during the brainstorming were clarified and organized in the different cause-and-effect categories (Environment, Man, Material, Method, Measurement, and Machine). The causes in red in figure 6 (Manpower, Method, and Measurement) were the ones identified as contributing to the events reported as follows.

The label printing process was performed manually. PBs were required to use different application as part of the process (Windchill, Bartender Labels Folders, Bartender Printing Application, and MES System).

- **Method:** This was considered the root cause for the events. The label printing process was performed manually and there were multiple opportunities for the PBs to make mistakes.
  - The manual selection of the artwork templates can contribute to selecting an incorrect label for the unit.
  - The DOM and UBD were manually typed in the Bartender Application (figure 3). This could lead to transcription errors and, therefore, incorrect UBDs printed in the labels.
  - Instead of printing one label at a time (one-piece flow), the PBs printed all the labels from the group of units available for processing in the workstation at the same time. Then, while processing each unit individually, the PBs picked the applicable label for the unit being processed from all the labels printed. This practice could lead to an incorrect matching between the unit in the tray and the label picked.
  - Bartender Labeling Application also evaluated did not limit the quantity of label re-prints. Thus, there was no control to ensure that the PBs followed the right process for non-conforming units.
- **Manpower:** Product Builder performance was considered part of the research. The applicable procedures for the process were evaluated and found to have specific steps for the manual printing of labels and human visual inspection process. Nevertheless, it was concluded that the product builders failed to detect the discrepancies on the labels at WS Labeling and Packaging and further in WS Final Acceptance.

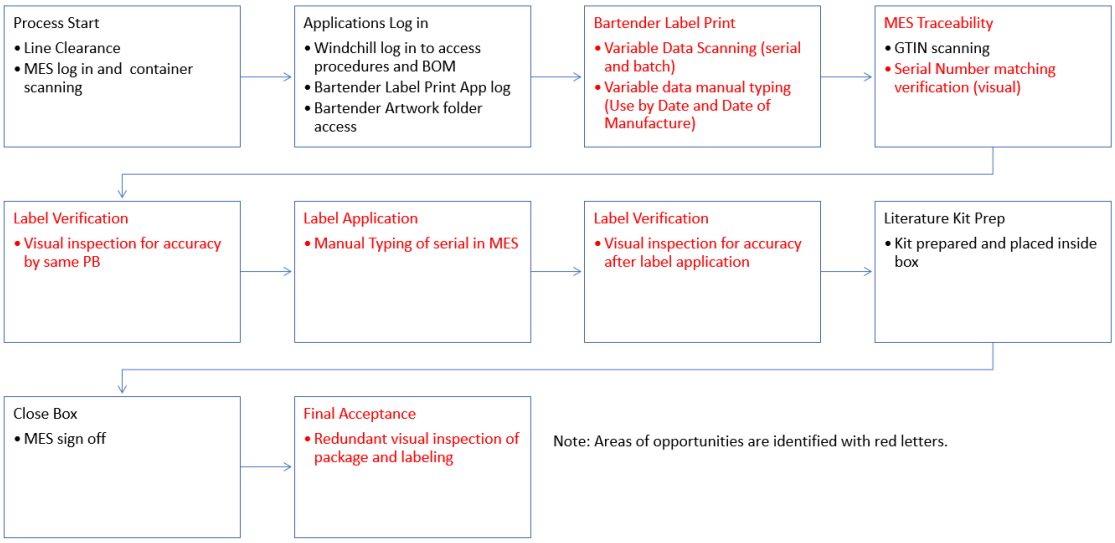

Figure 5
NMD labeling process flow

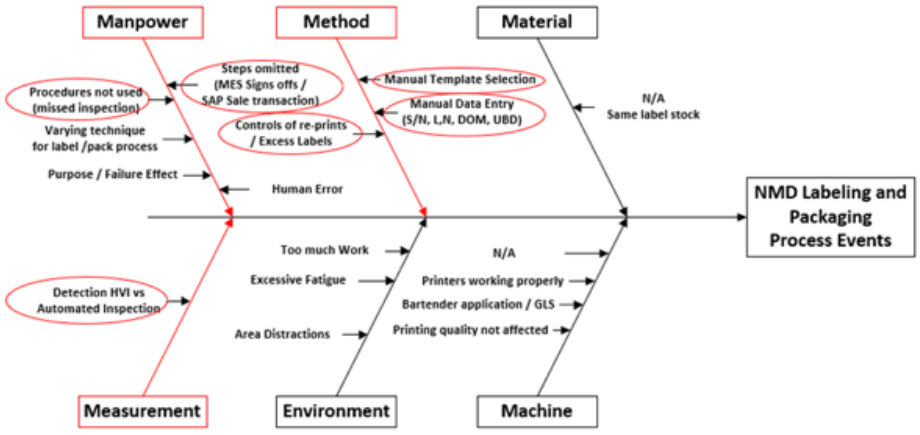

Figure 6
Cause-and-effect diagram

Per the Device History Records evaluated from the affected units, it was found that, at the time of the events, the PBs were trained in the applicable procedures and certifications. However, inadequate inspection was found as root cause for all the events. Multiple systems (MES, Bartender, Windchill) and work instructions are used to perform these steps. This complexity could contribute to product builder errors when verifying labeling information between product and system.

- **Measurement:** The label inspection process was compared to the label inspection process from another division within the Medical Device Company. The inspection process for this division involves auto-scanning the labels during the printing process and performing barcode verifications prior to closing the unit's box to confirm that information on all labels match (final packaging, outer tray label, and MES System). This inspection process is less people-dependent than the inspection process for NMD units. Therefore, not having a similar inspection process/control for labeling content correctness for Neuromodulation units can be considered a contributing factor for the event.

As a result of this analysis, 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.

Improve and Control Phases

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 and taking in consideration the user (PB) inputs. The application was validated to ensure reproducibility, sustainability, and that it performs as intended. The Improve phase was implemented in two phases:

- **Phase I:** Implemented an automated Label Printing Process (LPS) capable of interphasing with MES System and Bartender to retrieve required variable data information (use-by date, manufacturing date, serial number, and artwork number) and artwork file. The application also added controls for label re-prints. With this implementation, the potential of labeling a unit with incorrect information and artwork was eliminated. The PB does not need to manually collect traceability data in MES System, since the application is able to communicate directly with MES and perform all required sign-offs. Also, the potential of selecting an incorrect artwork is eliminated since the PB does not need to access and pick artwork from the bartender label folder, as the application does it automatically (figure 5).
- **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) (figure 7). The PB collects images of the required label areas into the application and compares each image to confirm variable information matching with MES System data. Then, the result of the inspection is sent directly to MES System. Thus, dependency of humans as part of the inspection process and their potential to not detect a non-conformity related to mismatches in variable data (date of manufacture, material number, serial, and expiration date) was reduced. The PB inspected only for label and box damages.

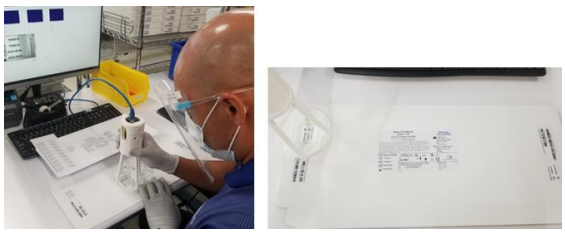

Figure 7
LPS automated vision system

Once the new process was implemented, a detailed process flow was created. The new process flow (figure 6) shows that the complexity of the previous process and its vulnerabilities were eliminated when compared to the previous process flow (figure 3).

Through a new VSM, it was confirmed that 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, down from 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.

The output of the new labeling and packaging process was monitored to verify the effectiveness of the new system. Through a Pareto histogram, 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 9).

The Device History Records and Investigations platform was verified. Non-conformities related to labeling errors (Incorrect UBD, duplicated label, and different artwork) reported previously and that triggered the implementation of the new labeling process have not been reported.

CONCLUSIONS

The implementation of a validated automated label print process minimizes the potential of mislabeled units and avoid compliance issues with regulatory agencies, company policies, and procedures. It facilitates labeling and packaging processes and provides the benefit of reducing human dependency. Human interactions and manual entries can be reduced or eliminated with a labeling application that communicates and interacts with other systems, such as MES System. Process complexity is also simplified and the Product Builder can focus on the critical tasks that cannot be performed by the systems (e. g. box assembly, labeling application, inspections for damages, etc.).

Human visual inspections can be replaced by automated inspections. The inspection process is also improved through the implementation of a validated automated vision system capable of comparing the variable data from the label to the data provided by MES System. The weight of the labeling critical inspections relies on the system and not on humans, thus allowing the elimination of redundant human visual inspections.

Most Important Findings

- The DMAIC methodology provided was effective to understand the problems caused by the manual labeling process and determine

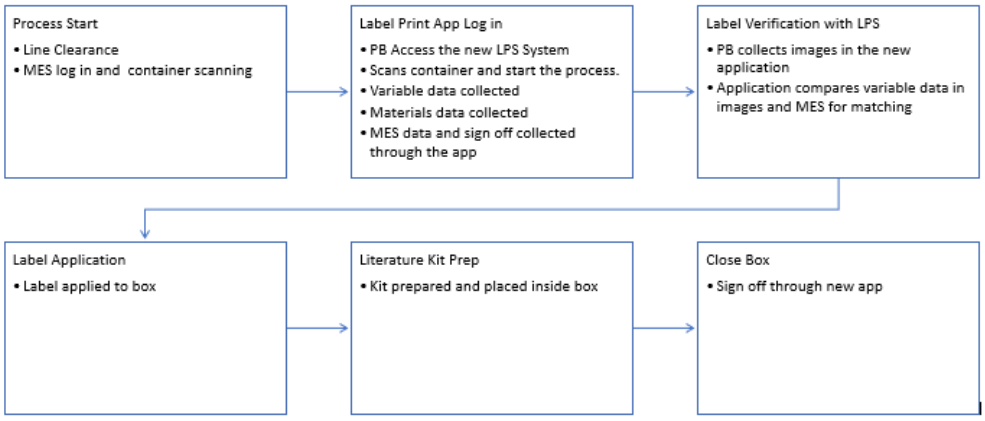

Figure 8
New process flow

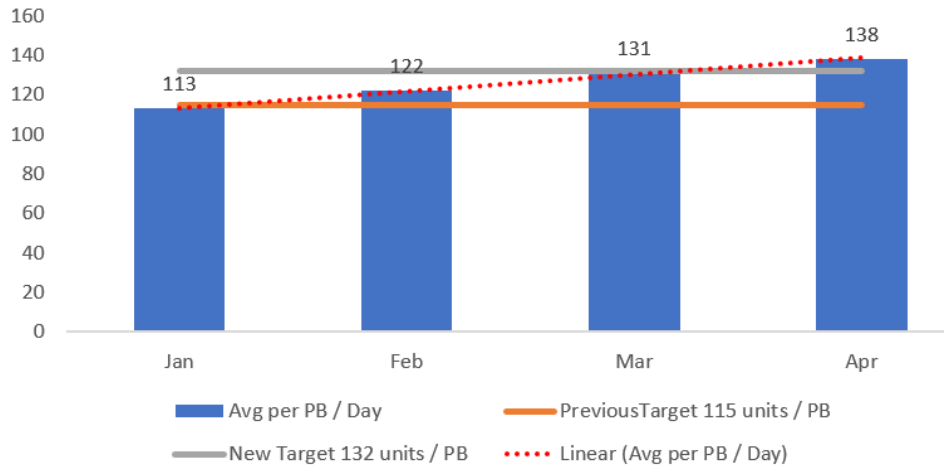

Figure 9
Average output per Pb per day

adequate solutions to avoid recurrence of the events reported previously, which gave reason for this design project.

- The implementation of both the automated label print and visual inspection application helped reduce human error associated to the manual processing and inspections at the label and packaging workstation.

Limitations

- Due to the MES Configuration inherent to NMD Division products, some of the functionalities of the new labeling application needed performing live testing through a Special Work Order (SWO) instead of a MES business simulation, to confirm the software was configured as intended. This was not foreseen at the beginning of the project and required scrapping "good units" as part of the validation effort.
- Not all labeling components are barcoded. Therefore, a barcode verification to confirm that the correct components were used and placed inside the box during the label and packaging process could not be configured. This was not part of the initial scope of the design project. However, it was an additional vulnerability identified during the user requirements definition.
- The NMD Returns re-processing required programming a separate configuration to address the vulnerabilities of this process. This re-processing does not follow the normal manufacturing process and requires additional controls to ensure label adequacy. Due to this, the labeling application has two different buttons to initiate the process. Additional controls had to be put in place to ensure the PB selects the correct button during processing.
- The COVID-19 pandemic added some limitations at the time of execution.

Summary of Contributions

Implementing an automated label print process contributed to reducing the process cycle time from 67.14 seconds to 57.14 seconds per PB per unit. This resulted in a capacity increase (an additional 17 units can be processed by PB per shift) and a calculated cost savings of $17,688 per year. The elimination of WS Final Acceptance resulted in an overhead reduction of two PBs, which represents a cost savings of $83,994. This project was recognized with an Honorific Mention Award as part of the company's Value Improve Process (VIP) program.

Future Research

The labeling and inspection system was customized for the NMD Division based in the CRM Division label printing process. Harmonization between both divisions' labeling processes should be a future pursuit. Although the implementation was successful and all objectives were met, the CRM labeling process still provides additional controls such as a label inspection performed simultaneously as the label comes out of the printer and a Barcode Verify feature to prevent labeling and inspection errors. Future research should be focused on identifying alternatives to improve the new labeling application to harmonize the process in the CRM Division.

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