How to Reduce the Confirmation Period of Possible Critical Defects Detected During the Quality Assurance Acceptance Sampling Plan for Inspected Drug Product

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Abstract

An Acceptance Sampling Plan, or ASP, is a Quality attributes assessment performed during the manual inspection of Drug Products. After inspection, the inspected product then becomes an Inspected Drug Product, or IDP. During the ASP, if any critical defect is identified during inspection, it is segregated for further On the Floor Testing (OFFT) or Process Development (PD) evaluation for additional confirmation. This project focused on how to reduce this confirmation period by implementing portion segregation during the inspection process and sending the defective unit(s) for further evaluation as soon as the portion is completed, instead of waiting for the culmination of the batch inspection process. This implemented modification in current standard operating procedures, reduces the wait period by performing the defect confirmation parallel to the on-line inspection process, thus avoiding delays in the product's final disposition.

Key Terms *—Acceptance Sampling Plan, Critical Defect, On the Floor Forensic Testing, Process Development.*

Introduction

Quality is a set of distinctive, defect-free characteristics that separates a product from the rest [1]. During the in-process inspection of a DP (Drug Product), certified Manufacturing associates perform a visual inspection for possible defects. All possible defects are discarded by these associates and QA performs a sampling, in order to confirm the units are defect free[6].

Background

Critical defects are those that are considered threatening to the patient's safety and must be avoided at all costs. Major A defects have the potential to affect the product's quality, Major B defects have the potential to affects the product's functionality, and Minor defects affect cosmetic attributes [1]. The Quality Assurance department performs an Acceptance Sampling Plan or ASP, to units that have been previously accepted by inspection operators. Either a Normal Sampling Plan or a Tightened Sampling Plan is performed, depending on product requisites and whether or not a re-inspection is being executed. Initial inspections are normal, while re-inspections go through a more rigorous inspection, better known as tightened inspections [2].

Problem

-Follow an established procedure when a possible critical defect is identified.
-Reduce the time it takes to perform the corresponding identification by performing on-the-floor testing and timely delivery when on the floor is not available.
-Take action when re-inspection is required due to a critical defect being identified in order to comply with quality standards and patient safety.

Methodology

Figure 1: Gantt chart

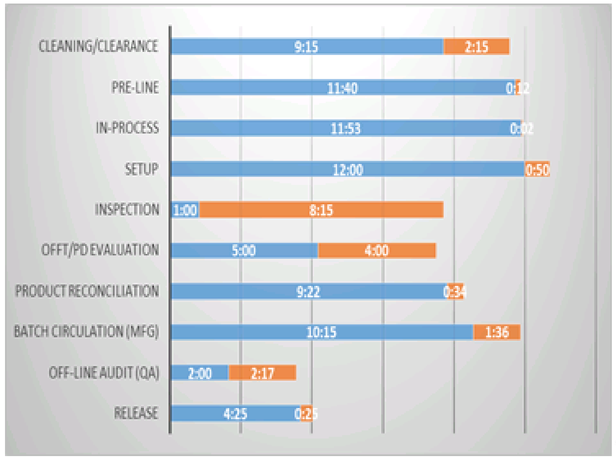
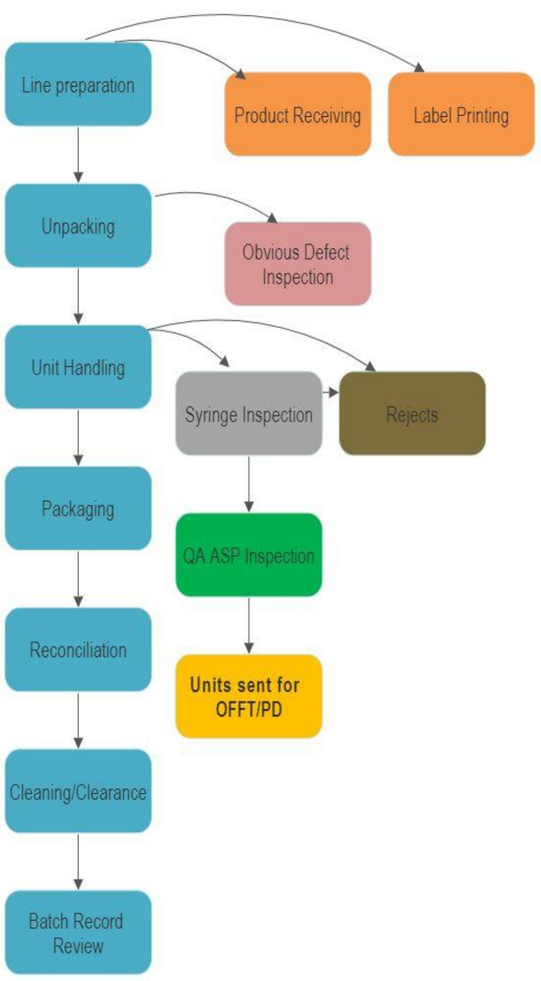
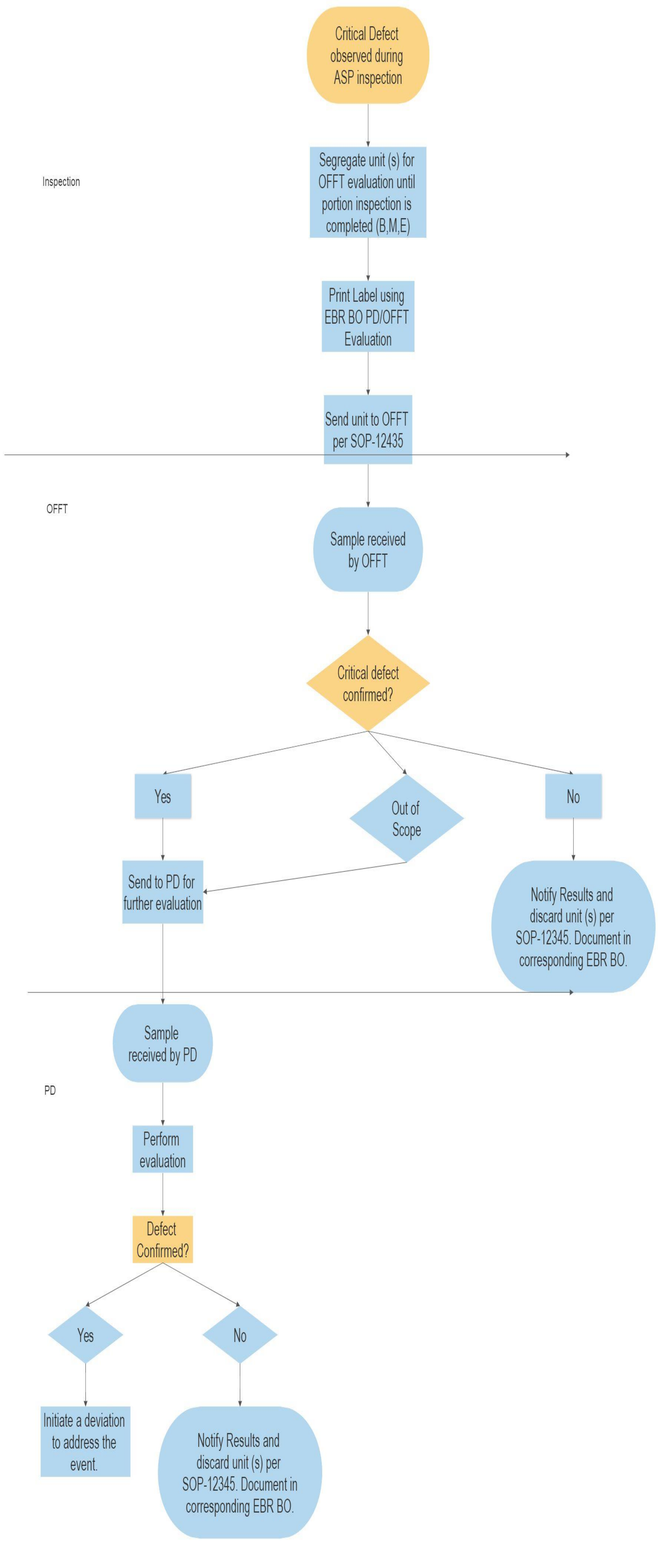


Figure 2: Inspection Flowchart



Results and Discussion

Figure 3: Implemented Flowchart



Conclusions

Throughout the implementation of product segregation during the inspection process, the time needed in order to confirm any critical defect is reduced, avoiding Overtime and delayed product disposition. Through the continuous improvement of manufacturing, inspection, product review and final disposition processes, a company can produce consistent quality over time.

Future Work

I would suggest the creation of standards containing the most common critical defects observed, this would allow us to "pre-screen" the sample and avoid sending false defects. I would also recommend that Process Development shifts be more similar to our Inspection shifts, since Inspection lines work 24/7, this would help with the timely release of PD results and would unquestionably help with the product's on time release, especially those pertaining to critical inventory.

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