Reduction of Human Errors Investigations Related to Documentation in Manufacturing Areas

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Abstract *– The human error has become an issue in the pharmaceutical companies. The biggest challenges throughout times have been detection and prevention of the human errors. An example of this situation occurred in BMS, Manati plant. BMS is a site where parenteral and oral products are manufactured. Since January to October of 2019, it was observed an increase of human error investigations related to documentation of manufacturing processes. A comprehensive study was performed to evaluate variables for the human error in order to provide alternatives to simplify the documentation and identify actions to reduce the documentation errors. The analysis for this study was quantitative using root cause analysis as methodology. The thesis was based on the perception that the human is a most contributing factor of errors. The investigations' increase was attributed to the changes in policies related of when is required an investigation. In order to mitigate documentation events, an annual cGMP training with emphasis to good manufacturing practices was provided to the population. It was observed a reduction of investigations after implementation and monitoring of multiple effective preventive and/or corrective actions.*

Key Terms *— Corrective and Preventive Actions, Human Error, Manufacturing investigations, Root Cause Analysis.*

INTRODUCTION

An increase on investigations of human errors related to documentation in manufacturing areas in Sterile Department is observed during the period of January 2019 to October 2019 in BMS, Manati. BMS, Manatí, is a manufacturing site where parenteral Drug Product (DP), Oral Solid dosage (OSD) and parenteral packaging operations are performed. Manufacturing Areas in the Sterile Department are: Parenteral Lyophilization Area (PLA), Parenteral Syringe Area (PSA) Parenteral Vial Area 1 (PVA1), and Parenteral Area 2 (PVA2). Additional investigators have had to be hired in order to support the increase of investigations. In addition, the releases of lot could be impacted based on the duration of investigation process.

Objectives

The objectives of these project are:

- Obtain an 15 % of reduction in human error investigations during November 2019 to Feb 2020.
- Evaluation of variables for the human error in order to provide alternatives to simplify the documentation in manufacturing areas
- Identification of actions to reduce the documentation errors.

This paper challenges the investigation process, human errors and corrective and/or preventive actions.

Thesis of the paper

The perception that the human is a most contributing factor of errors & the effectiveness of implemented corrective and preventive action could minimize errors.

BRIEF REVIEW OF LITERATURE

In order to minimize the events and prevent reoccurrence of human error events books and or topics about science behind the human error and the investigation process were studied. In addition, the perception that the human is a most contributing factor of errors and the effectiveness of

implemented corrective and preventive action were evaluated.

Topic A - Human Error Reduction in Manufacturing.

"Companies are abusing human error as a simplistic explanation for faulty quality systems. This is a not a book on human reliability, buy any professional working with process improvement investigation and CAPA systems must become familiar with these concepts. It is essential that we stop using human error (or any of its variations as root cause of our quality problems)" [1].

As mentioned above the investigation process in BMS, Manati uses human error as a category for root cause, however behind this classification always is a system failure

Topic B - Investigation and effective CAPA System

"Lack of attention plays a significant role in all categories of human error. Recognition errors, slips, lapses and mistakes are all more common when situational factors (fatigue, workload, multitasking and boredom) divert our attention. In the manufacturing industries, these factors should be negligible; we should not be relying on memory for procedures and instructions" [2].

The secondary categorization for human error in the closed investigation of manufacturing areas in BMS, Manati is lack of attention and part of the corrective actions an awareness is offered to personnel. This some time is very simplistic, and the investigation process needs to be focused in the situational factors that promotes the lack of attention

Topic C - Behind Human Error

"Human error" is cited over and over again as a major contributing factor or "cause" of incidents. Most people accept the term human error as one category of potential causes for unsatisfactory activities or outcomes. Human error as a cause of bad outcomes is used in engineering approaches to the reliability of complex systems (probabilistic risk assessment) and is widely cited as a basic category in incident reporting systems in a variety of industries" [3].

Human factor has been considered for decades the major contributing factor nevertheless, it is important the reasons and causes incidents behind the human error.

ANALYSIS/ METHOD APPROACH

The analysis for this study be quantitative. This document is limited to the evaluation of BMS-Manatí closed investigations related to documentation errors from Jan 2019 to October 2019. A query in the investigation system of BMS, (Trackwise) [4] was performed in order to determine the quantity of human error investigations related to documentation generated from January 2019 to October 2019. A total of 52 investigations in Sterile Operations related to documentation error were opened during this period.

RESULTS

The investigations identified as part of the TrackWise query specified in Section four (4) were evaluated. The TrackWise query showed that most of the investigations (48 out of 52) were opened during the second and third quarter of 2019. The increase number of investigations is attributed to the changes in policies related to definition of "what is" and "what is not" an investigation. Starting on May 2019, most of the documentation errors are being managed using the site deviation management quality system instead of corrections in the documents. Table 1 summarizes the results.

An analysis was performed using the closed investigations to evaluate the major offenders per area. The figure 1 demonstrates that the Parenteral Vial Area 2 (PVA 2) is the major offender for investigations related to omission in electronic batch record.

Another analysis was performed using the closed investigations to evaluate the major offenders per Root Cause Category documented in

TrackWise. Table 2 summarizes the root cause categories, major offenders, and percentages.

Table 1
Summary of Investigations from TrackWise Query

Parameter	Total Number of Investigations
Total Investigations	52
On-going Investigations	1
Closed Investigations	51
Investigations Opened during Q1'2019	1
Investigations Opened during Q2'2019	21
Investigations Opened during Q3'2019	27
Investigations Opened during October 2019	3

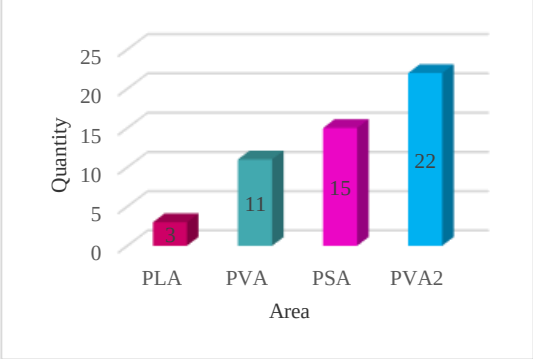

Figure 1
Opened Investigation from January 2019 to October 2019.

Table 2
The root cause categories, major offenders, and percentages

Root Cause Categories	Major Offender	Quantity	Percentage
Primary root cause	Manpower	26	50%
Secondary root cause	Method	23	44%
Third root cause	Multiple	1	2%
Forth root cause	Machine	1	2%
To be determine	Open investigation	1	2%

DISCUSSION / ARGUMENT IN SUPPORT THESIS

The perception that the human is a most contributing factor of errors

A human error is an action not intended by a human. Nonetheless, human error is the most contributing factor of incidents, deviations of manufacturing processes. Exists many variables that contribute to human error such as: poor design of planta and equipment, inadequate procedures, ineffective training, wrong supervision, ineffective communication, and incorrect handling of resources. Usually, after an event of human error the corrective action is an awareness without investigation of sources for failure. In BMS, an awareness to affected personnel is the most correction action used in order to close the investigation. Due to the investigations increase in the manufacturing areas, the evaluation of root cause was robust. To prevent re-occurrence of events, the corrective and preventive actions were developed based on improvement process design, simply accessible procedures and attention to employee concerns.

The effectiveness of the implemented corrective and preventive actions (CAPAs)

The CAPA system in a company is the most important part of an effective investigation process. The corrective and/or preventive actions of deviations or event should evaluate factor and variables for the human error. To robust outline of CAPA plan and evaluate all the contributing factor it is important to use risk analysis tools like FMEA, Fish bone, 5 Why's, etc. These tools will be effective to determine the causal factor and mitigate events. In addition, after implementation of CAPAs it is important to monitor the effectiveness of the implemented actions. As results of deviations in manufacturing processes and to avoid re-occurrence of events, BMS has had to incorporate effectiveness monitoring not only to CAPAs but also to change controls.

CONCLUSIONS

After implementation of effective corrective and /or preventive actions, it was observed a reduction of investigations since November 2019 to February 2020. Eight investigations related to documentation were generated during this period. The average per month is reduced in a 42%. This exceed the objective of the project 15% of reduction in human error investigations during November 2019 to February 2020. The implementation of corrective and preventive actions was focused on documentation simplification in manufacturing areas and identification of actions to reduce the documentation errors. The investigations system/ process is extensive in the BMS. The increase number of investigations is attributed to the changes in policies related to definition of "what is" and "what is not" an investigation. Starting on May 2019, most of the documentation errors are being managed using the site deviation management quality system instead of corrections in the documents. Based on the evaluation performed, the area where most of the events was PVA2. Most of the events (19 out of 22) were related to discrepancy opportunities in the electronic batch record. From those events, 9 of 19 are related to documentation issues during the execution of filter integrity tests. In PSA, most of the events (6 out of 10) were related to two documents. One of them (PS-F-035) was related to method. The site recognized the increase of documentation events across the board. In order to mitigate those type of events, an annual cGMP training with emphasis to QA-S-021 was provided to the population. Monitoring of the effectiveness of corrective and preventive actions and robustness of the investigation process are essential to reduce the re-occurrence of human error events.

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