Simplify Process Events Documentation During the Manufacturing Process in a Pharmaceutical Industry

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Abstract

All events during manufacturing must be resolved in a promptly manner and documented properly. Therefore, is very important to have simple yet effective process that helps to determine the best way to resolve the events. the mayor problem in the Manufacturing Area is that the current procedures does not establishes the specific circumstances in which the form needs to be documented. For this project the methodology of Six Sigma DMADV was used. Prior to the implementation of the Project all 25 lots had the form. After the implementation of the new process only 16 lots had an Occurrence Form. This means a reduction of 36%. As per the results and after the evaluation, it can be concluded that the new process was successfully implemented.

Introduction

Every process has unplanned events, and the manufacturing process of pharmaceutical products is no different. All events during manufacturing must be resolved in a promptly manner and documented properly. If the events during a manufacturing process are not resolved and not properly documented, it may lead to some serious problems to the final product and/or the patient. Therefore, is important to establish adequate corrective actions to resolve any process occurrence. Also, is important to have robust and yet simple processes that can help the employees follow the procedures and resolve any unplanned event during the process correctly.

The company in which the project was developed is a pharmaceutical company established in Puerto Rico for over 30 years. This company is dedicated to the manufacturing and packaging of generic medications and employs over 500 employees. The current procedures in the Manufacturing Area provide a form called Process Event Occurrence Form. In this form are documented all the events that happens during the weighing, manufacturing and packaging of the product.

The situation identified is that the current procedures does not establishes the specific circumstances in which the form needs to be documented. The current practice is that a Process Event Occurrence Form is manually documented for every situation, including normal process situations like oil refill to a compressing machine. In addition, the situations are documented in other electronical systems. This cause duplicity and delays in the manufacturing process.

The importance of this project consists in the results. With this project is expected a reduction in the duplicity and the delays in the Manufacturing Process due to Occurrence Form documentation.

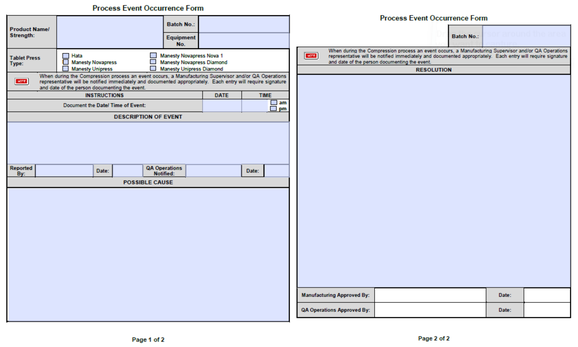


Figure 1
Current Process Event Occurrence Form

Methodology

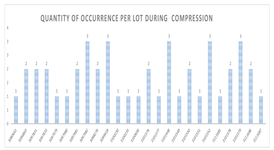
For this project the methodology of Six Sigma DMADV will be used. The Six Sigma approach is a process to measure and improve quality [1]. This method has been proven to help standardize the processes and reduce the defects. The methodology of DMADV is the acronym for the five phases in which consist the methodology. DMADV consist of: Define, Measure, Analyze, Design and Verify (Figure 2).

Figure 2
DMADV Diagram

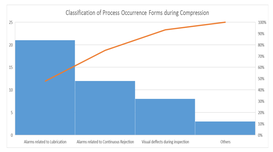
DMADV is a data-driven quality strategy that differs of the traditional DMAIC (Define, Measure, Analyze, Improve and Control). The DMADV methodology is often used when implementing new processes based in data compared with the old process. Like DMAIC, DMADV is an integral part of the Six Sigma quality initiative [2].

Define Phase - As part of the project it was identified that the documentation process of Process Occurrence is not clearly defined nor established. Currently all situations must be documented and approved by the Quality Assurance (QA) Department prior the restart of the process. The average Process Occurrence Documentation is between 3 to 4 hours. In addition, the incidents are also required to be documented in other electronical systems like LIMS, which also requires the QA approval. This cause duplicity and delays in the manufacturing process.

Measure Phase - The second part of the project was to collect the data and record the specifications. A total of 25 batches manufactured were used to measure the quantity of Process Occurrence during the Compression Stage. Refer to Graph 1. All the batch gathered had a Process Occurrence form on the Compression Stage. The Average was two (2) Process Occurrence Forms per Lot.



Graph 1
Quantity of Occurrence Documented per Lot during Compression



Graph 2
Classification of Process Occurrence Forms during Compression

Analyze Phase - The result of the data gathered showed that all the lots manufactured had an event during the manufacturing process. Furthermore, in some cases, one batch had up to three (3) Process Occurrence Forms for different reasons. The data was analyzed, the largest amount of cases the Process Occurrence were due to alarms during the compression. A Root Cause Analysis (RCA) was used to determine the reason of the alarms. After the evaluation it was determined that the major cause was due to the Alarms related to Lubrication. Refer to Graph 2. This alarm is considered to be a normal process alarm and does not affect the quality of the product.

Results

Design Phase - As part of the steps to resolve the two major offenders identified in the previous phase, it was decided to revise the current Compressing Procedures and to create a new Standard Operating Procedure for the Process Events Occurrence.

The Compressing Procedure was revised to include a table of the most common alarms. The Table 1 contains the alarm summary and the action to be performed when the alarm is triggered. This table was included in the Compressing Procedure as a guidance on what to do for the Manufacturing Operators. However, a Note was added in the procedure that if any other alarm not listed in Table 1 was triggered during the Compressing Process the Supervisor or Designee most be informed for evaluation.

ALARM DESCRIPTION	ACTION
LOWER GUARD OPENED	Close the Back Lower Door
PPER GUARD OPENED	Close the Back Upper Door
LOWER GUARD OPENED	Close the Front Lower Door
UPPER GUARD OPENED	Close the Front Upper Door
OWER GUARD OPENED	Close the Left Lower Door
PPER GUARD OPENED	Close the Left Upper Door
LOWER GUARD OPENED	Close the Right Lower Door
UPPER GUARD OPENED	Close the Right Upper Door
OAD TONAGE LOW WARNING	Contact the Supervisor or Designee to generate a Work Order. Document the Work Order Number on LIMS System
%MP PRESSURE FAULT	Contact the Supervisor or Designee to generate a Work Order. Document the Work Order Number on LIMS System
%MP OIL LEVEL LOW	Refill Lube Pump Oil, Document a comment on the LIMS System
T MOTOR NOT RUNNING	Contact the Supervisor or Designee to generate a Work Order. Document the Work Order Number on LIMS System
R EMPTY DURING RUN	Contact the Supervisor or Designee and Quality Assurance Representative to start a LIMS Investigation
%OUS REJECTION	Contact the Supervisor or Designee and Quality Assurance Representative to start a LIMS Investigation
R OF STATION MISMATCH	Contact the Supervisor or Designee and Quality Assurance Representative to start a LIMS Investigation
IUM REJECTS PER SINGLE	Contact the Supervisor or Designee to generate a Process Event Occurrence.
IUM REJECTS PER TURRET LTION	Contact the Supervisor or Designee to generate a Process Event Occurrence.
IUM CONSECUTIVE REJECTS	Contact the Supervisor or Designee to generate a Process Event Occurrence.
OAD TONAGE HIGH WARNING	Contact the Supervisor or Designee to generate a Process Event Occurrence.
OAD TONAGE HIGH FAULT	Contact the Supervisor or Designee to generate a Process Event Occurrence.
OAD TONAGE LOW FAULT	Contact the Supervisor or Designee to generate a Process Event Occurrence.
'OMPRESSION OVERLOAD	Contact the Supervisor or Designee to generate a Process Event Occurrence.
R EMPTY FAULT	Contact the Supervisor or Designee to generate a Process Event Occurrence.
PROUS FAULT	Contact the Supervisor or Designee to generate a Process Event Occurrence.

Table 1
List of Common Alarms Summary and Action to perform included in the Compressing Procedure

In addition, the Process Event Occurrence Form of the Compressing Procedure (Figure 1) was removed. This form was replaced with a new procedure that specifies how to document the new Process Events Occurrence Form. The new procedure for the Process Events Occurrence was created to provide a specific instruction to the Manufacturing Supervisor and Designees of how to document the form. The procedure was created in Spanish with the purpose of better understanding for the responsible of performing the documentation. On the other hand, the form was created dual language (Spanish and English). The form was created in dual language with the purpose that the responsible documenting the form can choose the language in which he feels most comfortable and can document the best.

After the procedures were approved by the Manufacturing Management and the Department of Quality Assurance the impacted personnel were trained. Then, as stablished in the current training procedure, after all the personnel impacted with the changes were trained and informed of the changes the new Process Events Occurrence Procedure and the Compressing Procedures were made effective. Refer to Figure 3.

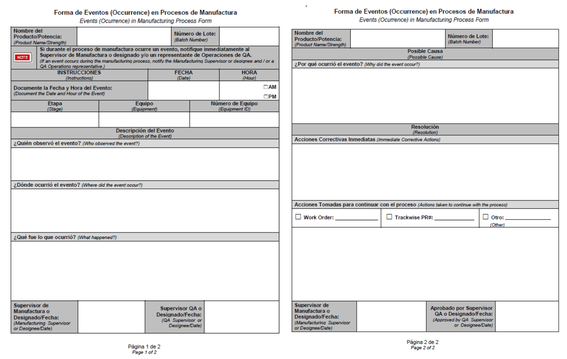
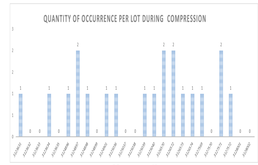


Figure 3
New Process Events Occurrence Form

Results

Verify Phase - Once the new procedure was ongoing it was verified the effectiveness of the implementation. Metrics are further developed to keep track of ongoing customer feedback on the product or service. For these purpose another 25 lots were gathered to evaluate the Compression Stage and to determine if further changes were required. Due to reasons of shortage of time the lots evaluated were chosen in campaigns (several batches of the same product).



Graph 3
Quantity of Occurrence per Lot During Compression after Implementation

As seen on Graph 3 a total of 25 lots were evaluated. The lots evaluated, nine (9) lots did not have any Process Event Occurrence Form on the Compression Stage. Prior to the implementation of the Project all 25 lots had the form. This means a reduction of 36%. On the other hand of the 16 lots with Occurrence Form the total sum of the Process Event Occurrence Forms found were 20. The 20 forms found on the lots were also evaluated. In these lots the mayor contributors were problems with the Hopper and the Feeder. These alarms and/or situations were part of the alarms listed on Table 1, which complies with the process established.

Another aspect which was evaluated was the feedback from the Manufacturing Personnel. In the shift change it was asked for the feedback of the new process. Most of the personnel were satisfied with the changes. They considered that the new form was easier to follow, and also, they preferred to document the Events Occurrence in Spanish.

Conclusion

In summary this project was created to simplify the Process Occurrence Documentation and to determine the instances in which the form needed to be documented. Accordingly, the project was implemented. The table with the alarms listed was created and placed in the Compacting Procedure. A new Standard Operating Procedure was created with the instruction of how to document the new form. After implementation the verification of the process was executed. As per the results it can be considered that the new process was successfully implemented.

Recommendations

The scope of this project was to create a general procedure for the documentation of the process events during the manufacturing. Further evaluation is recommended to include other alarms in the Alarm List with the action to perform. Since this project was also applied to Compression Stage it is recommended to extend the project to all manufacturing stages.

References

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Acknowledgments

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