Reduction of Review and Approval Process for Manufacturing Procedures

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Abstract

Long waiting times for the review and approval process in the Manufacturing Department affects the batch. The main causes of this problem are the missing signature, dates, comments, steps not executed properly, and formula calculation. A new system was introduced to eliminate manual manufacturing procedures and to eliminate manual formula execution. The system will automatically record the date, time and signature as each step is executed. Categorization of critical process parameters and critical quality parameters reduce the amount of time each designee is reviewing and approving each manufacturing order.

Key Terms *— Manufacturing Procedures; Electronic Manufacturing Procedures; Review and Approval Process; Batch.*

Introduction

The manufacturing department of a Pharmaceutical Industry is one of the most important departments in the organization. It faces daily tasks to produce top quality product for customer, but what happens during the execution of manufacturing procedures is the key to determine when a batch is in compliance to proceed with the next step. Good manufacturing practices in a Pharmaceutical Industry are one of the most important aspects to provide efficient documents that comply with the Federal Food & Drug Administration (FDA) regulations. The manufacturing department personnel have to be efficient documenting every action, value, comments or corrections needed for the manufacturing procedure. The reduction in time for the review and approval process with new system implementation will help reduce commons errors while documenting and also the time each batch is release to the next phase in the manufacturing process.

Objective

The main objective is to reduce revision and approval process for manufacturing procedures.

Background

There is a variety of challenges presented every day in a manufacturing department. One of them is human error during documentation and execution. A lot of companies have standards to follow through an avoid errors. Human error can be reduced with the right set of skills per person. The performance level on which an individual works depends on the tasks being performed and the individual's knowledge [1]. Manual entry of signatures, date, comments, and times is a candidate to reduce errors and lower risks [2]. Today, new systems can reduce the amount of paper documentation and also reduce entry to be more efficient [3]. The roles of a Manufacturing Execution System (MES) and an electronic batch-record (EBR) system could play in an FDA regulated, batch-oriented, make-to-stock manufacturing company [4]. There are always new ways to improve current methods and take advantage of a single sourcing information content-management system that can streamline processes, increase control, and reduce costs. The benefits of having Mater Batch Records (MBRs) are that they can be created, modified, and approved in a fraction of the time required [5].

Methodology

Define Phase

The manufacturing department faces every day with the review and approval process for each batch. The department needs the process to be more efficient. The personnel leaves manufacturing procedures steps without documenting actions; it contains missing signatures, missing dates and times. These actions affect the review and approval process compromising each batch. The main goal is to reduce the revision and approval process of manufacturing procedures. To reduce and prevent manual entries, a new system will help in the configuration and execution of the electronic procedures. The system will show step by step according to the operational process, each instruction in order.

Measure Phase

The review and approval process monitoring is necessary to determine the amount of time each batch is under the approval process. For each process, a monitoring of the review and approval process took place in order to determine the amount of time each manufacturing procedure was under the review and approval process. For each process a sample size of 10 batches were monitored. Table 1 represents the monitoring for Process1 – Process 4. Table 2 shows the amount of manual entries, formulas, steps part of standard operation procedures (SOP), critical process parameters (CPP), and critical quality parameters (CQA) per process.

Table 1
Monitoring Review and Approval for Process 1 – Process 4

	Process 1	*Process 2*	*Process 3*	*Process 4*
Batch	***Time (days)***	***Time (days)***	***Time (days)***	***Time (days)***
1	2.00	3.45	2.30	3.00
2	3.00	5.65	2.75	3.45
3	3.25	3.35	2.90	3.50
4	4.00	4.85	3.60	4.00
5	4.75	2.90	4.50	4.32
6	3.30	2.00	5.00	3.78
7	4.15	4.50	3.85	3.35
8	2.90	4.00	3.10	3.75
9	3.50	3.55	4.15	3.75
10	2.90	3.45	3.90	5.00
Average	3.38	3.77	3.61	3.79

Table 2
Actual Steps, Entries in System, Amount of CPP and CQA per Process

Process	*Step*	*SOP*	*Formula Conf.*	*System Entries*	*CPP*	*CQA*
1	354	84	115	155	11	0
2	367	24	147	196	11	18
3	699	33	299	367	7	14
4	655	53	182	420	20	23
Total	2075	194	743	1138	49	55

Figure 1 shows the amount of entries per process. For example, for Process 1 the amount of entries in the manufacturing procedure was 354. With the new electronic procedure for Process 1 and taking into consideration Table 5, the amount was reduced from 354 to 155 entries an operator performs during the manufacturing order. This also applies for Process 2, having an amount of 367 entries reduced to 196 entries, for Process 3 having an amount of 699 entries reduced to 82, and for Process 4 containing 655 entries reduced to 45 entries.

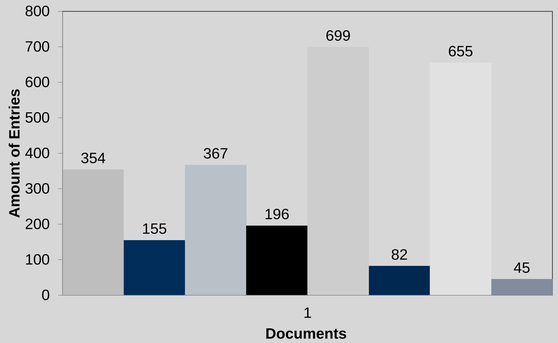

Figure 1
Actual Manufacturing Procedures Steps and Entries in System

Analyze Phase

The potential causes that impact the review and approval process corresponds to missing dates, comments, signatures and formula calculations. These factors affect the process and therefore compromised the batch from moving to one process to the other. The importance of having the system implementation is that will prevent the operator from skipping steps and also the system permits formula configuration, which helps, since the operators don't have to do it manually.

Improve Phase

The manufacturing procedures (MP) were created as electronic manufacturing procedures (EMP). The amounts of manufacturing procedures created are four. The system has the functionality that permits the creation of parameter value lists (PVL). PVL is a type of list were material number, critical process parameter (CPP), critical quality parameters (CQA) are identified per process and solid dosage giving an advantage to only have four electronic manufacturing procedures. The manufacturing procedures reduced from 16 to 4.

Control Phase

For each process to be efficient and effective in the department, four standard operation procedures (SOP) were created in accordance with the electronic manufacturing procedures and process procedure, for the use of operators to guide them through the process and let them know when is necessary to document in the electronic manufacturing procedure. Training is an important factor, and each month the department needs to be re-evaluated as part of the control in terms of the execution for the personnel.

Results and Discussion

The monitoring for electronic manufacturing procedures was performed. With the new procedures, each process was analyzed with 8 batches. Table 3 represents the monitoring for Process 1 – Process 4. The average time for Process 1 is 2.41 days which corresponds to 57.93 hours. The time reduced is 0.97 days, almost a day reduction in the process. This means the new procedure for the review and approval process is more effective and efficient for the manufacturing department. The average time for Process 2, Process 3, and Process 4 is 2.99, 2.86, 3.11 days, respectively. Process 2, Process 3, and Process 4 reduced about 0.78, 0.75, and 0.68 days, respectively. Each process average time based on the sample monitored was reduced to more than 15 hours. The reduction of events is evident since the review and approval process is more easily achieved. In the manufacturing department every minute counts; with this in mind the implementation of the system is necessary since it brings the revision and approval process more rapidly and the amount of events is reduced.

Table 3
Monitoring Review and Approval of Electronic Manufacturing Procedure Process 1 – Process 4

	Process 1	*Process 2*	*Process 3*	*Process 4*
Batch	***Time (days)***	***Time (days)***	***Time (days)***	***Time (days)***
1	1.50	3.00	2.75	2.60
2	2.45	3.65	3.00	3.00
3	2.45	2.35	2.53	3.10
4	1.90	2.50	2.30	3.45
5	2.30	3.25	3.70	3.60
6	3.00	2.78	2.60	3.10
7	2.56	3.85	3.20	2.90
8	3.15	2.55	2.80	3.15
Average	2.41	2.99	2.86	3.11

Conclusions

The review and approval process of the manufacturing department that contains four processes was studied and monitored. The time the manufacturing orders to be reviewed and approved for Process 1, Process 2, Process3, and Process 4 was found to be 3.38, 3.70, 3.61, and 3.79 days, respectively. The implementation of new system to configure manufacturing procedures to electronic manufacturing procedures was successful. The electronic manufacturing procedures review and approval process was monitored. The time for Process 1, Process 2, Process 3, and Process 4 for the review and approval process was found to be 2.41, 2.99, 2.86, and 3.11 days, respectively. With this study is evident the reduction in time for the review and approval process completion.

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