Implementation Plan of Electronic Batch Record System for Code X manufactured in Cell Y Using a Project Management Technique

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Abstract — *This research project was focused to develop a plan for electronic batch record implementation using a project management technique for machine JB in a cell of a Medical Device Company. The implementation should be in the shortest time possible. In order to create an implementation plan a Gantt chart was used as a project management tool. This is an effective tool for smaller and simpler projects. The Gantt chart shows bar's drawn on time scale for each operation showing graphical representation of work vs. time. Therefore, it brings structure to solve the problem, which is to effectively implement an electronic batch record machine in a medical device industry. This research seeks to provide Management an idea or baseline of the completion time of the project and key tasks. The main focus is to be more predictable in the project completion date. With this information management can allocate adequate resources in critical tasks in order to meet the expectations of the implementation completion time and can be used for future projects. This project provides the Staff Management of a manufacturing plant the information necessary to support integration of Electronic Batch record.*

Key Terms — *Electronic Batch Record, Gantt chart, Manufacturing Plant, Project Management*.

PROBLEM STATEMENT

This project is developed to improve the documentation process of code M manufactured on Machine JB at a Medical Device Industry in Puerto Rico. Currently, the manufacturing unit performs the documentation of code M manually, but due to management decision it is required to implement an electronic batch record system for this code. Most of the time the original due dates of implementations are not met, causing loss of time and money to the company. An implementation plan for electronic batch record system needs to be established to determine the expected finish time and required resources to complete the implementation. A project management tool needs to be selected to provide the Staff Management of the manufacturing plant the information necessary to complete the implementation of electronic batch record in the most effective way.

RESEARCH DESCRIPTION

Today's economy along with the advances in technology and science had created a big challenge in industries all around the world. The result is that all manufacturers need to continue looking for new initiatives to reduce their costs maintaining and improving their ability to satisfy the compliance requirements of the United States Food and Drug Administration (FDA) regulations. Budget, time and labor optimization to comply with regulations play a big role in today's economy and certainly is a huge challenge. The manufacturing process requires many assembly steps and testing that need to be recorded to assure quality and effectiveness of the product resulting in a group of documents together. Working with paper batch records instead of using an electronic batch record system can be a paper nightmare and takes too long to trace a component. Besides that, manual documentation process could result in many documentation errors that have a negative impact in the product release. Thus, paperless oriented initiatives play an important role in the Manufacturing Operations and

provide many advantages that will be presented in this project.

RESEARCH OBJECTIVES

The main objective of this project is to develop a plan for electronic batch record implementation using project management techniques. The implementation should be in the shortest time possible because management requires reduction of manual documentation as part of the strategy to increase competitiveness. The main focus is to be more predictable in the project completion date. Currently, plant resources are working several projects and priorities at the same time. Therefore, it is very critical to have clear expectations in order to accomplish the task. Basically, the intent is to plan the implementation of electronic batch record in a production floor.

RESEARCH CONTRIBUTIONS

Machine JB is working three shifts during week days and two shifts during weekends, representing at least 19 batches per week. Since code M is manufactured on a daily basis it represents a lot of paper work and potential loss of documentation. Constantly machine operators have difficulties filling all the forms resulting in a delay in product release and service level.

Additionally, manual documentation has the following wastes: Slow traceability response time (Regulatory Compliance); Material supply cost (Financial); Space due to documentation storage (Financial) and Time required for handling the documents thru the process flow (Financial & Customer Focus).

Thus, some of the advantages of electronic batch record implementation include: Reduced release time of product (Customer); Faster traceability response time (Regulatory and Customer); No supply cost (paper and pens) (Financial); No physical storage required for documents (Financial) and No missing documents which is a potential regulatory risk (Regulatory and Customer).

Other benefits for the Company of using Project Management for electronic batch record implementation are: Establish a completion date; Adequate resources allocation (Budget); Reduce implementation time (Customer and Budget); Increase number of machines using electronic batch record (Customer) and have a written project plan for other departments and plants.

LITERATURE REVIEW

The electronic batch record is to be implemented in a regulated environment. Therefore, it is important to outline the requirements that should be met in order to be in compliance with the regulatory agency Food and Drug Administration (FDA).

As mentioned in the book "Mastering and Managing the FDA Maze" [1], the FDA is one federal agency under the direction and control of the Department of Health and Human Services. The FDA is mandated by the federal government to enforce Title 21 of the United States Code. The FDA consists of a variety of departments with oversight of specific activities, including among others medical devices. The specific FDA Regulations that apply to Medical Device Manufacturers are the Code of Federal Regulations (CFR), Title 21, Part 7, Part 11 and Parts 800-1299.

The Code of Federal Regulations Title 21 – Food and Drugs establishes in Part 820 the Quality System Regulation that must be followed in order to manufacture Medical Products. The following definitions relevant to project scope are established in Code of Federal Regulations, Title 21, Volume 8 revised in April 1, 2013.

1. Component means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.
2. Lot or batch - means one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially

the same conditions and that are intended to have uniform characteristics and quality within specified limits.

3. Management with executive responsibility means those senior employees of a manufacturer who have the authority to establish or make changes to the manufacturer's quality policy and quality system.
4. Manufacturer means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.
5. Manufacturing material means any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a byproduct constituent produced during the manufacturing process, which is present in or on the finished device as a residue or impurity not by design or intent of the manufacturer.
6. Product means components, manufacturing materials, in-process devices, finished devices, and returned devices.
7. Section 820.5, Quality System, establishes that each manufacturer shall maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part. Section 820.20 states that each manufacturer shall provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, to meet the requirements of this part and also ensure that quality system requirements are effectively established and effectively maintained in accordance with this part. As mentioned before one of the advantages of electronic batch record implementation is faster product traceability. Product traceability is a requirement of section 820.65.

The Code of Federal Regulations establishes in Part 11 the Electronic Records; Electronic Signatures requirements in Title 21, Volume 1 revised in April 1, 2013. The following definition is applicable to project scope:

Closed system means an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.

Electronic record means any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

Section 11.10 establishes the following requirements that should be taken in accountability for electronic record implementation. Persons who use closed systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, when appropriate, the confidentiality of electronic records, and to ensure that the signer cannot readily repudiate the signed record as not genuine. Such procedures and controls should include the following:

a. Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.
b. The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.
c. Protection of records to enable their accurate and ready retrieval throughout the records retention period.
d. Limiting system access to authorized individuals.

e. Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.
f. Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.
g. Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.
h. Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.
i. Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.
j. The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.
k. Use of appropriate controls over systems documentation including:
    1. Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.
    2. Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.

In this project a project management technique is going to be selected, thus project management should be understood. To understand project management, it is important to know what a project is. A project is a goal that has a definable objective, consumes resources, and operates under time, cost, and quality constraints [2]. In definition, project management is the planning, scheduling, and controlling of a series of tasks such that the objectives of the project are achieved successfully. The challenge is to manage effectively activities that never been attempted and may never be repeated. To be effective in project management extensive planning and coordination is required. In the book Advanced Project Management [2] it is stated that work flow and project coordination must be managed horizontally, not vertically as in traditional management. In vertical management, workers are organized along top down areas. In horizontal management, work is organized across the various functional groups that work with each other improving the coordination among employees and managers. In modern project management multiple reporting relationships, time management, leadership, conflict resolution, negotiation, team building, motivation, and basic management areas such as planning and controlling are taken in accountability. In advanced project management, the scope is scheduling techniques and software packages used for planning and controlling projects.

As part of project management typical problems should be discussed. In the book Project Management [3], a project is defined as a collective effort of number of people coming together for a common goal. Based on this definition it is important to be inclusive, knowing each person is unique. Working together in a multi-functional group could lead to conflict due to behavior and work styles. Some of the situations you can face as a project manager are the following: Organizational/behavioral, Financial, Legal, Engineering, Construction/installation, Site evacuation / development, Labor unrest / unavailability, Non-availability of resources, Weather conditions among others.

In project management, different techniques are used to accomplish project goals as an aid to management. Some examples of these techniques

are Gantt Chart, Program Evaluation and Review Techniques (PERT) and Critical Path Method (CPM) that will be discussed.

Let's start with one of the most common tool known as Gantt Chart. Dragan Z. Milosevic mentioned in his book Project Management Tool Box [4] that the Gantt Chart is an effective tool for smaller and simpler projects. In the book Operation Research, PERT, CPM & Cost Analysis [5] describes that the origin of the Gantt Chart took place prior to World War-I, when the U.S. Army Ordinance Bureau indicated the need for a technique of planning and controlling the production of ordinance material. In order to satisfy that need the consultant Henry L. Gantt designed a chart that is known as Gantt Chart.

The Gantt Chart shows bar's drawn on time scale for each operation showing graphical representation of work vs. time.

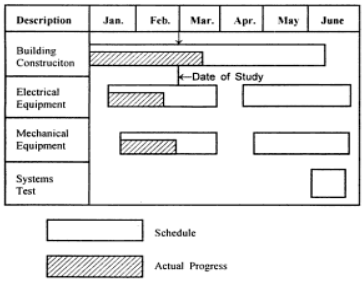


Figure 1
Gantt Chart

In Figure 1, [5] shows an example of a Gantt Chart displaying the schedule for a building project of a small industry. The time taken by an activity is represented by a horizontal line, the length of which being proportional to the duration of activity. The shaded bar indicates the progress made in the project. As mentioned in the book Project Management Tool box [4] having a Gantt Chart helps ensure everyone understands the timetable for project activities. Then, project participants will have the necessary time allocated on their calendars and be available to perform their activities.

Critical Path Metohd (CPM) is the second tool that will be discussed. CPM was developed in 1967 by Morgan R. Walker of the Engineering Services Division of DuPont and James E. Kelley of Remington Rand [5]. The objective was to provide a technique for control of the maintenance of chemical plant. It works for optimum balancing between schedule time and cost of the project and mostly used for projects involving activities of repetitive nature. At present, CPM is employed widely in different areas of industrial activities, particularly in construction industry.(Sharma, 2006).

CPM (Figure 2) is a network analysis technique used to predict project duration by analizing which sequence of activities has the least amount of schedule flexibility (float). CPM calculates a single, deterministic early and late start and finished date for each activity based on specify, sequential network, logic and an single duration estimate [6].

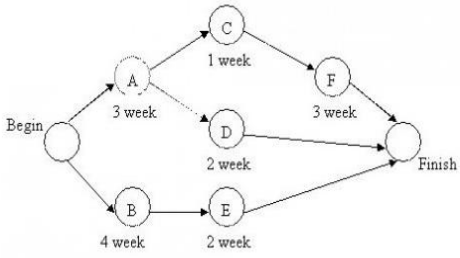


Figure 2
CPM Diagram

The third technique or tool is PERT (Figure 3) developed in 1958 by U.S. Navy and a team of Management Consultants (Boose Allen and Hamilton) for scheduling the research and development activities for the Polaris Missile Program [5]. PERT uses sequential network, logic and a weighed average duration estimate to calculate project duration [6]. PERT assumes a probability distribution for the duration of each activity given on the completion of a task rather than the activities required to be performed to reach a particular event or task. It is used for activities which may never have been performed before helping in identifying critical areas in a project in order to do adjustment to meet schedule completion date [5].

Based on the discusion of the Project Managements tools: Gantt Chart, CPM and PERT, the selected for this project is Gantt Chart. Gantt

Chart is the appropriate tool since the Electronic Batch Record implementation in Machine JB is basically a small and simpler project. A Gantt Chart will be developed with the required activities in order to provide a graphical illustration of a schedule, to assign resources and allocate time.

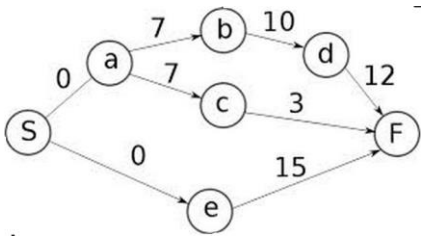


Figure 3
Pert Diagram

PROJECT METHODOLOGY

This chapter discusses the use of methodology for Electronic Batch Record implementation in JB machine. As previously discussed in Chapter 2 there are different and essentials project management tools for successfully completing the project. Examples are Gantt chart, CPM and PERT to name previously discussed. All of them have advantages and disadvantages but based on this project scope the Gantt chart was selected to present the project plan. The main tasks and sequence of the implementation are presented in a Gantt chart with the estimated time. Microsoft Project Software is available in the plant and will be use to develop the Gantt chart for the implementation of the EBR. Gantt chart was selected because is one of the most popular and easier tool. Besides that, it is visual and simple tool that helps the Project Team to track the progress of every task and is ideal for small and simpler project. A Gantt chart will be developed with the main tasks and estimated time to implement Electronic Batch record in machine JB.

There are certain critical variables that need take in consideration during the realization and management of any project in order to be successful. Just to name a few, the expertise in the topic along the availability of the team members to participate in the project. Other aspects are the Project Leader Expertise and people skills, budget limitations or constraints such as Equipment, Labor and Computer Aid (Software).

The following steps were developed for this project:

Table 1
Steps for Project Development

Item number	Task or activity
	Project Scope and Team Selection
1	Establish the Project Context at high level (Scope, Schedule, Resource Target)
2	Appoint Responsible Leaders (Sponsor , Team Leader)
3	Incorporate the Core Team
4	Create a Multifunctional Team to work in the implementation of EBR on selected product
5	Define Project Scope
6	Identify Potential areas to start implementation
7	Select a machine and product as a pilot plan for EBR implementation
8	Perform an assessment to selected area
9	Clarify Roles and Responsibilities
10	Assign responsibilities for every team member (Quality, Manufacturing and IT Specialist)
11	Develop Schedule
12	Optimize Schedule
13	Validate with Sponsor
14	Define frequency of the meetings, agenda and participants.
15	Perform a Regulatory Assessment
16	Perform a Gap Analysis (System vs Manufacturing)
17	Hands on training for core Team Members
18	Benchmarking with similar facilities within the company
19	System Configuration
20	System Validation (Setup, wrote protocol and SOP)
	Procedure, Data gathering and population
21	Review SOPs and forms used to document inspection results, parameters and batch information that may apply to identify if change is required.
22	Submit changes to SOP and forms if required
23	Training in SOP changes to affected personnel
24	Post SOPs and forms with new revision
25	Database entry in test environment and menu configuration
26	Product Challenge in test environment and perform changes if needed
27	Communicate results to users
28	Populate fields and data requirements of selected machine and product
29	Review and compare populate data populated in system
30	Make corrections and certify data in system
31	Data validation
32	Data migration to live environment
33	Identify Lessons Learn
	Equipment
34	Identify equipment quantity for selected machine and product.
35	Provide equipment for selected machine and product
	Training Phase
36	Prepare training plan
37	Prepare training material
38	Provide a Machine Operator a work station with computer for on the job training
39	Electronic signature training
40	EBR training
41	On the job training
42	Material Review
43	Exam and users certification
44	Create users accounts
	Implementation Phase in production floor
45	Determine First of code requirements
46	Determine First of code date and shift
47	First of Code Meeting
48	Execute First of Code
49	Evaluate First of Code
	Metrics
50	Develop metrics for Electronic Batch Record
51	Communicate metrics and results of EBR uptime

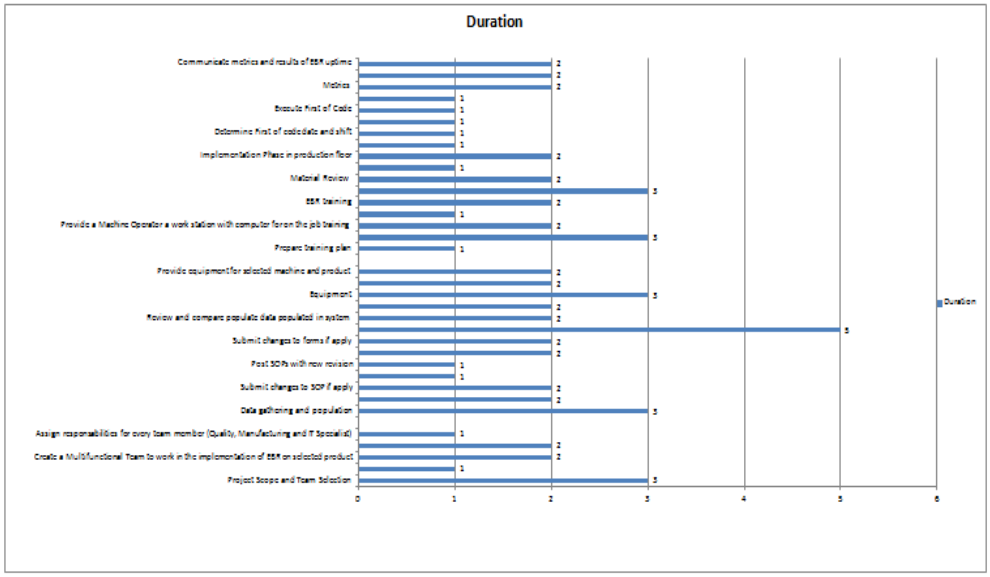
Table 2

Project Gantt Chart

Description	Reponsible	WK 1	WK 2	WK 3	WK 4	WK 5	WK 6	WK 7	WK 8	WK 9	WK 10	WK 11	WK 12	WK 13	WK 14	Description	Duration
Project Scope and Team Selection																**Project Scope and Team Selection**	3
Select a machine and product as a pilot plan for EBR implementation	Core Team															Select a machine and product as a pilot plan for EBR implementation	1
Create a Multifunctional Team to work in the implementation of EBR on selected product	Core Team															Create a Multifunctional Team to work in the implementation of EBR on selected product	2
Define frequency of the meetings, agenda and	Implementation Team															Define frequency of the meetings, agenda and	2
Assign responsabilities for every team member (Quality, Manufacturing and IT Specialist)	Project Leader															Assign responsabilities for every team member (Quality, Manufacturing and IT Specialist)	1
Kick of meeting	Core Team and Implementation Team															Kick of meeting	
Data gathering and population																**Data gathering and population**	3
Review SOPs that may apply	Implementation Team															Review SOPs that may apply	2
Submit changes to SOP if apply	Quality Enginner															Submit changes to SOP if apply	2
Training in SOP changes	Training Leader															Training in SOP changes	1
Post SOPs with new revision	Doc Center Representative															Post SOPs with new revision	1
Review and evaluate forms used to document inspection results, parameters and batch	Implementation Team															Review and evaluate forms used to document inspection results, parameters and batch	2
Submit changes to forms if apply	Quality Enginner															Submit changes to forms if apply	2
Populate fields and data requierements of elected machine and product	IT Specialist															Populate fields and data requierements of elected machine and product	5
Review and compare populate data populated in	Quality Tech															Review and compare populate data populated in	2
Make corrections and certify data in system	IT Specialist and Quality Tech															Make corrections and certify data in system	2
Equipment																**Equipment**	3
Identify equipment quantity for selected machine	Implementation Team															Identify equipment quantity for selected machine	2
Provide equipment for selected machine and	IT Manager															Provide equipment for selected machine and	2
Training Phase																**Training Phase**	
Prepare training plan	Core Team															Prepare training plan	1
Prepare training material	Training Leader and Quality Engineer															Prepare training material	3
Provide a Machine Operator a work station with computer for on the job training	IT Specialist															Provide a Machine Operator a work station with computer for on the job training	2
Electronic signature training	Training Leader and users															Electronic signature training	1
EBR training	Training Leader and Quality Technicisn															EBR training	2
On the job training	Training Leader, Quality Technician and MO															On the job training	3
Material Review	Training Leader, Quality Technician and MO															Material Review	2
Exam and users certification	Training Leaders and MO															Exam and users certification	1
Implementation Phase in production																**Implementation Phase in production**	2
Determine First of code requirements	Core Team															Determine First of code requirements	1
Determine First of code date and shift	Core Team															Determine First of code date and shift	1
First of Code Meeting	Core Team															First of Code Meeting	1
Execute First of Code	Process Engineer															Execute First of Code	1
Evaluate First of Code	Process Engineer															Evaluate First of Code	1
Metrics																**Metrics**	2
Develop metrics for Electronic Batch Record	Core Team															Develop metrics for Electronic Batch Record	2
Communicate metrics and results of EBR uptime	IT Specialist															Communicate metrics and results of EBR uptime	2

Table 3

Project Duration



A multifunctional team will be assembled in order to have representation from each of the following support area: Quality, Manufacturing, Information Systems and Process Engineering. At least one resource will be selected from each support area and assign to the project. Project Team members will be responsible for the implementation of EBR in machine JB.

RESULTS AND DISCUSSION

This chapter discusses the results of a Gantt chart for Electronic Batch Record Implementation in JB machine. Microsoft Project Software was used to develop the Gantt chart for the implementation of the EBR. There are certain critical variables that need take in consideration during the realization and management of any

project in order to be successful. Just to name a few, the expertise in the topic along the availability of the team members to participate in the project. Other aspects are the Project Leader Expertise and people skills, Budget limitations or constraints such as Equipment, Labor and Computer Aid (Software).

Key steps developed for this project:

1. Establish the Project Context at high level (Scope, Schedule and Resource Target).
2. Appoint Responsible Leaders (Sponsor, Team Leader).
3. Incorporate the Core Team
4. Create a Multifunctional Team to work in the implementation of EBR on selected product .Select a Multifunctional Team to work in the implementation of EBR.
    a. A multifunctional team will be assembled in order to have representation from each of the following support area: Quality, Manufacturing, Information Systems and Process Engineering. At least one resource will be selected from each support area and assign to the project. Project Team members will be responsible for the implementation of EBR in machine JB. Manufacturing Supervisor, Manufacturing Operator, Quality Engineer, Quality Engineer, Information System Manager, Information System Specialist.
5. Define Project Scope
6. Identify Potential areas to start implementation.
7. Select a machine and product as a pilot plan for EBR implementation.
    a. Machine JB was selected as a pilot plan for EBR.
    b. Key characteristics of machine JB: High activity and demand with an operation of are 7 days /24 hours working three shifts during week days of eight hours and two shifts during weekends of 12 hours. This represents at least 19 batches per week generating multiple documents and handling that could be missing or potentially loss. Constantly machine operators have difficulties documenting data and testing results that delay product release and affect service level.
8. Perform an assessment to selected area to gather information such as:
    a. Number of operators, products, SOP's that are impacted.
9. Clarify roles and responsibilities for each Staff member and core team members s
10. Assign responsibilities for every team member (Quality, Manufacturing and IT Specialist)
11. Develop Schedule
12. Optimize Schedule
13. Validate schedule with Sponsor
14. Define frequency of the meetings, agenda and participants.
    a. This is a project that impacts one of the key elements of plant strategy that provides certain benefits to the operation. Based on that is it highly recommended to schedule certain meeting with different work groups.
        i. Plant Staff - every two weeks in order to present project progress and status. An agenda need to be developing to assure that Plant Staff receive critical information such as project and task status, progress, threats, resources constraints and other activities that could affect the project schedule and completion.
        ii. Core Team – at least every week each core team member need to attend a weekly meeting to present status and develop strategies and changes.
15. Perform a Regulatory Assessment
16. Perform a Gap Analysis (System vs. Manufacturing)
17. Hands on training for core Team Members
18. Benchmarking with similar facilities within the company
19. System Configuration
20. System Validation (Set up , write protocol and SOP

21. Define responsibilities and assign task for every team member such as:
    a. SOP revision and changes, training development, training session, equipment.
22. Review SOPs and forms used to document inspection results, parameters and batch information that may apply to identify if change is required.
23. Submit changes to SOP and forms if required
24. Training in SOP changes to affected personnel
25. Post SOPs and forms with new revision
26. Training in SOP changes to affected personnel
27. Post SOPs and forms with new revision
28. Identify implementation steps or tasks.
    a. Task each team member with the required activities.
29. Establish the sequence of each task.
    a. It is important to establish the sequence of the tasks in the Gantt chart. It will help to visualize and to develop the most efficient way to accomplish the implementation. This is where you can see the correlation of each task.
30. Estimate completion time for each task.
    a. Estimate completion time will be calculate based on input from each team member using the Time Estimated formula:

$$TE = (a+4m+b)/6 \quad (1)$$

Where;
a=Optimistic Time
m = Likely Time
b = Pessimistic time

For example to calculate the task of Establish the Project Context at high level based on the times provided by the team members we use the formula: TE= (a+4m+b)/6 where TE= (a=5 days, m=10 days and b=15 days).

TE = 10 days

31. Develop metrics for the EBR uptime
    a. Metrics are really important tool in many aspects. For instance in order to maintain visibility of the use of the new EBR System in Machine JB the following charts and metrics were developed.
        i. POMS Uptime (%) – (Number of batch or lots manufactured using EBR / Number of all batches or lots manufactured) * 100.

Example using EBR in one shift:

Shift A, B and C = 5 shifts / week total 15 shifts / week.

Shift D and E = 2 shifts / week total 4 shifts / week.

Total shifts /week = A + B + C + D + E = 19 shifts

Total Shifts A = 5 / week

Machine JB EBR uptime = (5 shifts/ 19 shifts) * 100% = 26%

32. Estimate equipment quantity for selected machine and product.
    a. Consider project budget and lead time.
33. Provide equipment for selected machine and product.
    a. Based on manufacturer lead time.
34. Prepare training plan.
    a. Machines Operators (production floor users)
    b. TIQ – Total inspectors quality
    c. Group Leaders
    d. Supervisors (Quality and Manufacturing)
    e. Quality Technicians
35. Prepare training material.
36. Provide a computer work station to Machine Operator for on the job training.
37. Electronic signature training.
    a. Security issues cover during this training.
38. EBR training
39. On the job training
    a. Brings confidence to the user practicing in a test environment. Allow operator to dominate the program and answer questions before running in a live environment.
40. Users certification

a. On the job training, Material Review, Electronic signature training, Exam and Create users accounts.

41. EBR system
    a. Populate fields and data requirements of selected machine and product.
    b. Review and compare populate data populated in system.
    c. Communicate results to users for feedback.
    d. Make corrections and certify data in system.
    e. Data validation
    f. Data migration to live environment.
42. Identify Lessons Learn

CONCLUSION

This project validated the use of one project management technique. A Gantt chart was used as a tool to implement EBR in machine X in a medical device industry. Key tasks were included into the Gantt chart with estimated completion time.

Management will have an idea of the completion time of the project and key tasks. With this information management can allocate adequate resources in critical tasks in order to meet the expectations of the implementation completion time. Besides that, management can increase resources in the key activities in order to reduce the implementation time in each machine increasing the number of machines using EBR in the company.

In a Regulatory perspective it helps to reduce the chance of losing important documents and reduce the time in traceability. This type of project also contributes in a positive way to the environment using less paper moving the company to an environmental friendly operation.

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