Manufacturing Traceability System Replacement to Maintain Business Continuity in a Medical Device Company

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***Abstract* —** *This project was focused in the Manufacturing Traceability System Replacement in a Medical Device Company. The existing Manufacturing Traceability System is obsoleted, therefore, a new Traceability system is being implemented in order to maintain Business Continuity. The system to be implemented, Manufacturing Execution System (MES), is the current standard in the industry.*

Project Management Planning methodology was used to develop an appropriate implementation plan that consisted in the evaluation of Requirements, Development, Test, Implement, and Sustain. During the implementation phase, several items were identified and incorporated to the initial plan. Requirements were evaluated on a line to line basis, in order to create a comprehensive plan, flexible enough to accommodate to the needs associated of each line. MES was implemented successfully in the first two manufacturing areas. Project plan was updated per lessons learned from initial implementation in order to achieve implementation goals in future lines.

Key Terms— *Manufacturing Execution System (MES), Project Management, Project Plan, Traceability System*

PROBLEM STATEMENT

Food and Drug Administration (FDA) CFR 21 Part 820.6 establish that each manufacturer shall establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation to prevent mix-up. Therefore, it is key to maintain a system that is suitable, robust and reliable in order to comply with this requirement.

RESEARCH DESCRIPTION

The current Manufacturing Traceability System (MATT) was identified to have a technical risk, since no support for system maintenance is available. The new Manufacturing Execution System (MES) will replace the current Manufacturing Automated Traceability Tracking system, which has been deem by a Business case to have a technical risk that will potentially negatively impact the Manufacturing Processes at the Puerto Rico Site.

RESEARCH OBJECTIVES

Implement new Manufacturing Execution System in the Puerto Rico Site for the selected Phase I lines, which include IROX Laboratory and Drug Collars Manufacturing Area.

RESEARCH CONTRIBUTIONS

Comply with regulatory requirements, Maintain Business Continuity and provide future opportunity for Value Improvement Project. MES will provide reporting and calculations capacity that were not available in current system.

LITERATURE REVIEW

In medical devices and pharmaceutical industry different systems are used for tracking and traceability of manufacturing processes and components. These goes from paper traceability, custom built software, and off-the-shelf systems as MES.

Complaints associated to current or previously used computer or paper systems:

- Information out-of-date
- Reports too large
- Documentation practices errors
- System maintenance
- Record retention
- Systems integration
- Multiple sites integration
- Equipment integration

Manufacturing Execution Systems

Manufacturing Execution Systems are software solutions that ensure that quality and efficiency are built into the manufacturing process and are systematically enforced.

Manufacturing Execution Systems connect multiple plants, sites and vendors' live production information, and integrate easily with equipment, controllers and business applications. The result is complete visibility, control and manufacturing optimization of production and processes across the enterprise.

Manufacturing Execution Systems monitor and synchronize manufacturing activities across plants; and link them in real-time to the enterprise for optimal performance. MES tracks product and order details on the plant floor, collects transactions for reporting to financial and planning systems, and electronically dispatches orders and manufacturing instructions to shop floor personnel.

MES is an on-line extension of the planning system with an emphasis on execution or carrying out the plan.

Execution means:

- Making products
- Turning machines on and off
- Making and measuring parts
- Moving inventory to and from Work Stations
- Changing order priorities
- Setting and reading measuring controls
- Assigning and reassigning personnel
- Changing order priorities
- Assigning and reassigning inventory
- Scheduling and rescheduling equipment

Benefits of implementing MES

The implementation of MES in a production line will provide the following benefits:

- Reduces manufacturing cycle time
- Reduces or eliminates data entry time
- Reduces work-in-process inventory
- Reduces lead times
- Reduces paperwork between shifts
- Improves product quality
- Eliminates lost paperwork/blueprints
- Empowers plant operations people
- Improves customer service
- Responds to unanticipated events

The potential gain by implementing MES addresses the need for immediate, current, on-line information that allows users or the MES computer system to make the best informed decisions regarding the application of inventory, plant resources, and people.

MES eliminates human error in manufacturing by providing real-time quality data checks, yield monitoring, automatic enforcement of specifications and business rules, and as-manufactured lot, batch, device or unit traceability – all resulting in improved product and process quality, and higher productivity. Paperless manufacturing with MES helps to reduce scrap and eliminates paperwork errors and redundant checks. MES provides the flexibility to model and change complex processes and enforce them immediately. Manufacturing Execution also provides the real-time feedback needed to quickly identify and resolve issues for continuous product and process improvement and optimization of manufacturing processes [1].

Software selection

In order to align Business Units, the software selected was Camstar®. This has being used by other Corporation sites during several years, usually for batch type operations. An upgraded version of the software will be installed in Puerto Rico site, which is also aligned with other sites that are implementing MES as part of the same project.

The version to be implemented (Version 4.5) is an upgrade to the version implemented in other sites [2].

The selected version of MES provides the following improvements:

- Expanded capabilities for global manufacturers with multiple locations or outsourced operations.
- Capability to support even the most complex manufacturing processes that span discrete, batch or hybrid operations.
- Augmented Platform configurability and usability to allow users to quickly adopt the solution with minimal training – and realize benefits earlier.

PROJECT METHODOLOGY

In order to achieve the goal of the MES implementation Project Management Planning methodology developed by Project Management Institute [3] will be used to complete the project objectives.

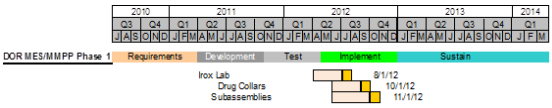

Figure 1
Project **Timeline**

Five main milestones/deliverables are defined for the MES project (See Figure 1):

- Requirements
- Development
- Test
- Implement
- Sustain

This research is focused on the Implementation phase for Puerto Rico site Batch Production areas. Change Notice Implementation was defined as the second item of the critical path of the project and is the main scope of this project. See Figure 2.

Critical Path
Testing Phase → Change Notice →Line Readiness → Go-Live

Figure 2
Project Critical Path

Project Management Methodology

The project management methodology is divided in different stages describe in detail below (See Figure 3).

Initiation

All projects start with an idea for a product, service, or other desirable outcome. The initiation process group determines the nature and scope of the project. If this stage is not performed well, it is unlikely the project will be successful in meeting the business needs. The key project controls needed, are an understanding of the business environment and making sure all necessary controls are incorporated into the project. Any deficiencies should be reported and a recommendation made to fix those [4].

The first project document is the project charter, which includes:

- Business case
- Scope and deliverables
- Objectives
- Resources needed
- Milestone plan and timeline
- Cost estimate
- Risks and issues
- Dependencies

Planning and Design

After initiation, the project is planned to an appropriate level of detail. The main purpose is to plan time, cost and resources adequately to estimate the work needed and to manage risk effectively during project execution. This is recorded in the project management plan. As with the initiation process group, a failure to plan adequately lessens the project's chances of success.

Project planning includes:

- Developing the scope statement

- Developing the schedule (Gantt chart)
- Developing the budget
- Selecting the team
- Creating a work breakdown structure
- Identifying deliverables
- Risk planning
- Communication planning

This information forms the project contract, used to gain formal approval to begin work [5].

Execution

Execution consists of the processes used to complete the work defined in the project management plan, to accomplish the project's objectives. The execution process involves coordinating people and resources, as well as integrating and performing the activities of the project. The deliverables are produced as outputs from the processes performed as defined in the project management plan.

Monitoring and Controlling

The monitoring and controlling process group involves managing and tracking the project, so potential problems can be identified quickly and corrective action taken. To do this the project management plan is used. Monitoring and controlling includes:

- Measuring the ongoing project activities
- Monitoring the project variables (cost, effort, scope) against the project management plan and the project baseline
- Identifying corrective actions to address risks and issues
- Managing changes using our change control process

The monitoring and controlling process group ends once the project has achieved its goals and objectives as detailed in the project contract. A project may be stopped before completion for various reasons, including changes in the business, lack of resources or higher priorities.

Closing

Closing a project means finishing all activities across all process groups, splitting up the project team, and signing off the project with the customer.

At this point it is important to know how well the project has performed. This is done using the project closure report. It communicates how well the project has performed against its original business case, quality measures, cost, duration and tolerances. This is used to pass on valuable learning that can be applied to future projects [6].

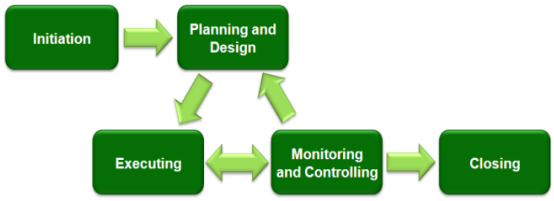

Figure 3
Project Management Methodology

RESULTS AND DISCUSSION

MES was implemented per plan in IROX laboratory. The following advantages were identified during and after the implementation phase:

- System is web based, therefore is accessible from any computer and no major installation is required. This makes it more flexible since current hardware can be used during and after implementation.
- Screens are configurable according to role responsibilities. System was configured so that all functions required for product builders are available within the same screen. See options on left side of Figure 4.
- An additional improvement that MES provides is that specifications and other traceable information are shown in the Build Product screen. Refer to Figure 4.

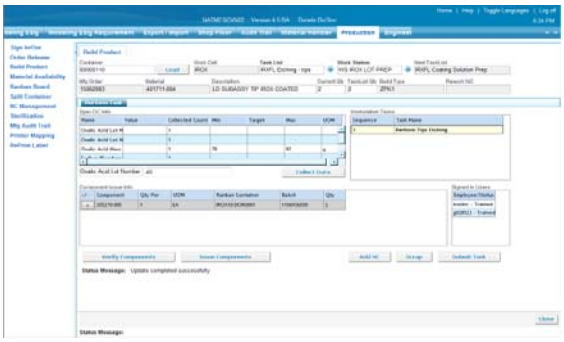

Figure 4
Build Product Screen

- MES minimizes the need of adding training comments, since builders in training are shown in the build product screen, as well as any builder logged in the station. Refer to Figure 4.
- The current Manufacturing Traceability Tracking System documentation ties several documents during the process of a change to the configuration. MES provides more flexibility to engineers and process owners when implementing changes to the current configuration. The initial configuration of MES requires the creation of multiple documents (Verified Resources, Product Settings, Task Lists-one per step, and Workflow) that are currently contain within only two documents (Process sequence and Tracesheet- one per Manufacturing Instruction). The creation of these documents allows that changes going forward to impact only affected step of the process.
- Initial project plan included a Change Notice to create Routers (used for SAP) for each part number. The need for this change was further understood during implementation phase of IROX manufacturing. This change notice was not required; therefore it was removed from the Change Notice plan in further phases of implementation.

Disadvantages

After implementation in IROX laboratory and during implementation in Drug manufacturing area some disadvantages were encountered, as well as required actions that were not included in original plan were identified.

- During implementation of MES in the Drug manufacturing area it was identified that an additional Change Notice is required when several instances of the same BOM item are required as part of the build process in order to allow SAP to perform this transaction. This required further evaluation of the project plan in order to add this change for all part numbers impacted. This unplanned event was managed concurrently with other change Notice in order to meet implementation date. Refer to Figure 5

BOM Information for Assembly Number: 401380-102
Description: COLLAR CARRIER DRUG
Revision: E **Effective Date:** 07-OCT-2012 **Change Order:** 85942
** = No data is available in MOL at this time

ITEM #	DESCRIPTION	PART #	USAGE	QTY	UOM	COMMENT
1	RBR CMPD SLCN LIQ	500268-003 PRIMARY 0		LB		
2	DRUG DEXAMETHASONE ACETATE	500568-002 PRIMARY 0		G		
1001	RBR CMPD SLCN LIQ	500268-003 PRIMARY 0		LB		Item exists for MES and SAP configuration only

Figure 5
BOM Resulting from MES implementation

- During the entire Implementation phase of the project, both the current manufacturing system and MES will be maintained. This triggers changes to manufacturing documents to be implemented in two systems until phase out of current system.
- Manual Verification of MES configuration is required as part of the Business Simulation in order to confirm that data is transferred correctly. This time consuming task for the manufacturing line subject matter experts is required for the review process.
- During the implementation of MES in IROX laboratory, MES configuration resulting from the Manual Verification was not uploaded to the production environment as configured in the Business simulation environment. This triggered additional Change Notices in order to fix the errors. This was taken as a lesson learned, and a data loader tool was implemented for further phases of MES implementation in order to minimize errors.

- During MES implementation in the IROX laboratory an opportunity was identified, since the Manufacturing Instructions numbers/documents are not tied to any MES document or screen. For the implementation in the Drug manufacturing area a "display only" data point was added to the configuration in order to show the Manufacturing Instructions Document required for every task list. The need for this prompt will be eliminated in a future state of the project, since the system will provide the ability to add a link to the applicable document.
- MES have a several constraints identified as part of the implementation in the Drug Manufacturing area. Calculations, currently performed by the current traceability system, are required as part of the build process. MES does not contain capacity for the required calculations. Therefore, a strategy managed concurrently to Change Notice implementation plan was developed in order to meet line needs. This included a spreadsheet validation and installation of required printers and changes to downstream process (since MES will not communicate to the current traceability system). Refer to Figure 6.

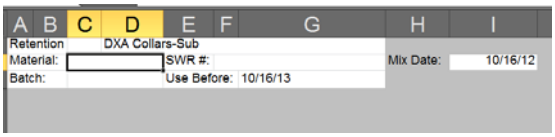

Figure 6.
Spreadsheet for Calculations

- The Change Notice Implementation plan was develop using a "pre-approval" strategy. This facilitated and allowed for quick expedite of changes associated to MES implementation. The findings mentioned before, created a disruption to this strategy, generating the need of additional documentation and approval processes.

CONCLUSION

Initial implementation of MES in IROX laboratory and Drug manufacturing area was completed successfully. Below is a summary of actions completed and conclusions of the project.

- 11 part numbers were transferred to MES as part of implementation in the IROX laboratory per Project plan. This required the creation of 68 new documents and updates to 44 existing documents.
- 13 part numbers are ready to be transferred to MES (Change Notices completed) as part of implementation in the Drug manufacturing line. This implementation included the addition of an unplanned part number and the fixes to the details mentioned in the previous section. This required an adjustment in the project plan in order to fulfill business requirements. As part of this implementation 208 new documents were created and 61 existing documents were updated.
- Schedule was updated based on the lessons learned from implementation in IROX laboratory and Drug Manufacturing Line.
- Project Plan Methodology is a live technique that must be maintained during the entire life cycle of the implementation project in order to cover for any adjustments required.
- Requirements of the implementation must be evaluated on a line to line basis in order to create a comprehensive plan that is flexible enough to accommodate to the needs associated to each line.
- Project plan was updated per lessons learned from implementation in IROX and Drug area and considering specific requirements per line.

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