

Implementation of Electronic Logbooks for the Utilities Area in a Pharmaceutical Manufacturing Facility

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ABSTRACT

Technology is an ever evolving concept, that every year incorporates new terminology appropriate to technological advances and different application domains. Industries are trying to leverage all of those new concepts to start to have major integration between their processes and their systems. One of the enablers to do this integration in the pharmaceutical industry are the Manufacturing Execution Systems. Serving as the main point for capturing manufacturing data, the Manufacturing Executions Systems can help pharmaceutical industries detect inefficiencies and problems sooner, saving time and money and support continuous business improvements. With the objective of simplifying and standardizing processes, as well as to leverage the infrastructure and systems already in place, this design project will focus in the implementation of electronic logbooks for the Utilities area, including, but not limited to the creation of requirement and design documents, development of electronic logbooks, validation and production implementation.

INTRODUCTION

With the objective of simplifying and standardizing processes, as well as to leverage the infrastructure and systems already in place, there is an initiative to implement electronic logbooks for the Utilities area. This area manages and assist with the electric system, air conditioning system, water supplies, nitrogen, condensate, cooling water as well as operate the wastewater treatment facilities. This design project will focus in the implementation of a total of 10 electronic logbooks, using a Commercial Off the Shelf Manufacturing Execution System (MES), for the Utilities area.

BACKGROUND

Industry 4.0

Industry 4.0 is the so called fourth industrial revolution. In this new industrial revolution computers and automation will come together in an entirely new way. The initial goals in Industry 4.0 are automation, manufacturing process improvement and production optimization.

Information Technology

Information technology (IT) is the area in charge of supporting all other business area in the leveraging of information management. The IT department is the one with the expertise to work with computers, networking, infrastructure and processes to create, process, store, secure and exchange all forms of electronic data.

Manufacturing Execution System

A Manufacturing Execution System (MES) is an information system that “concerns the activities that take place within manufacturing department. These include preparatory activities, such as detailed production scheduling and logbook management, but also retrospective activities, such as data collection, reporting, and analysis. [1]

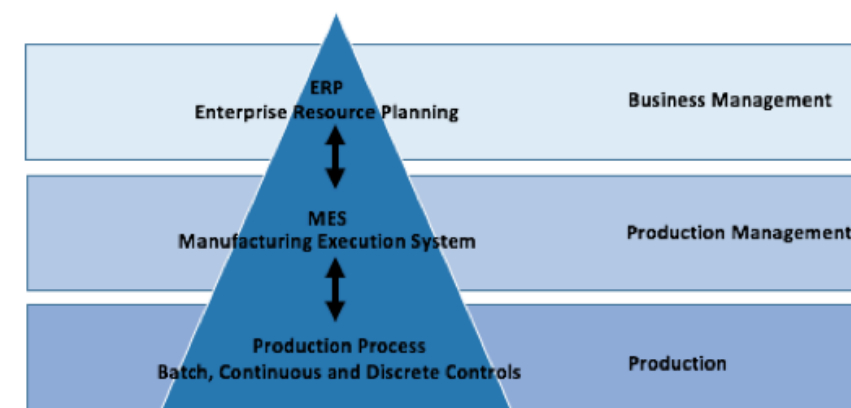


Figure 1
System Integration Model

PROBLEM

The Plant Utilities area has more than 30 paper logbooks to document, resulting on thousands of paper records, manual data entries, calculations and verifications. Paper records does not prevent documentation omissions or errors and require storage, handling and procedures to guarantee the documentation integrity and availability.

OBJECTIVES

- Create a paperless environment with an integration among the business and other systems.
- Eliminate data omission, documentation errors, second person verification and maximize resources for their process.
- Provide proactive management of situations to minimize deviations as well as rapid access to current data for management to make decisions with up to the minute information.
- Have all the data needed in a single place to enable future reporting capabilities for Environmental Agencies reports.

METHODOLOGY

Lean thinking, as well as Six Sigma approach, will be used as part of the methodology. In Six Sigma, one of the most effective process improvement technique is the DMAIC methodology (refer to Figure 2). The main purpose to select DMAIC is that this technique is focused in analyzing the process thoroughly before doing any kind of implementation. This approach is important in the conversion of paper logbooks to electronics due to all the simplification opportunities that can be identified such as data availability in other systems, activities that can be performed simultaneously, process improvements and resource allocation.

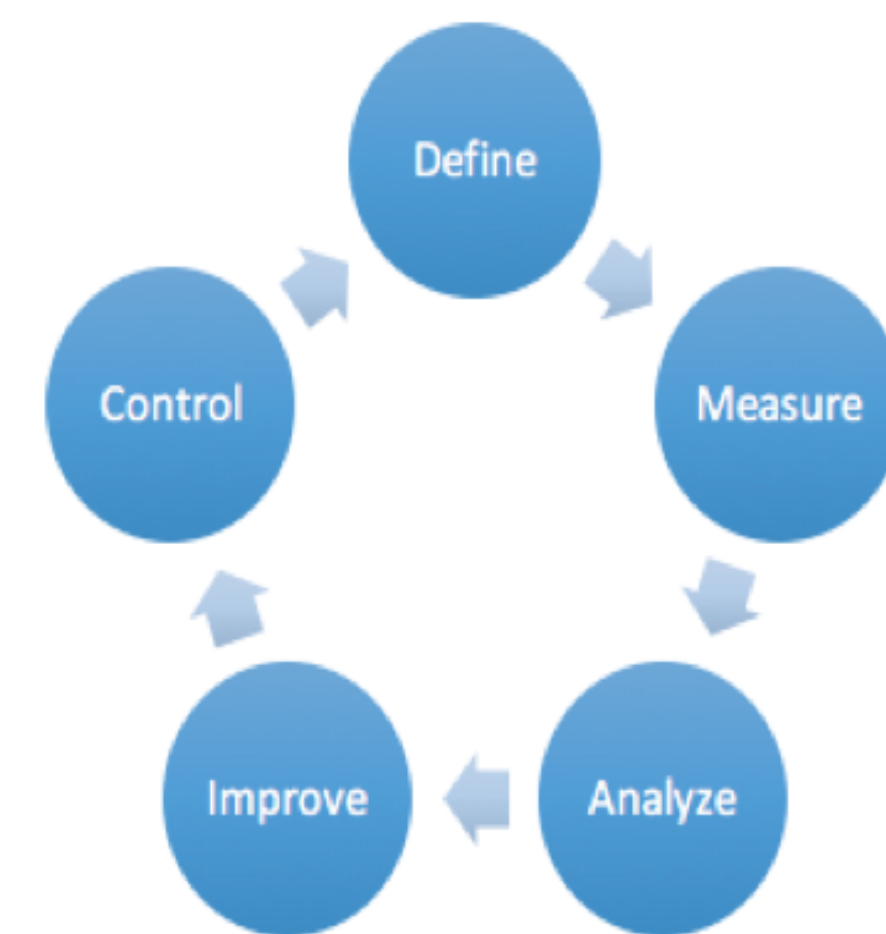


Figure 2
DMAIC Model

RESULTS AND DISCUSSION

Define: As part of this project it was defined that 10 logbooks would be converted to electronic as an initial phase. Project team was established and it included a multifunctional team with representatives from different areas. The main milestones were Project Kick-off, Utilities Process Review, Electronic Logbook Application Training and Electronic Logbooks Go Live.

Project Team:

- IT Technical Lead
- Utilities Team Leader
- Utilities Operation Representative
- L&D Representative
- Process Engineer
- Electronic Logbook Configurator
- CSV/CSQ Representative

Steering Team:

- IT Technical Leader
- IT Manager
- Utilities Manager
- L&D Manager

RESULTS AND DISCUSSION

Measure: In order to better understand the logbooks to be converted to electronic, as well as to identify opportunities for simplification and standardization, a Process review was performed. Once the process review was completed, a Voice of the Customer (VOC) was used to gather all the inputs and requirements from the customer (refer to Figure 3). “The VOC analysis gathers the customers' needs and wants as a basis for establishing objectives” [2]

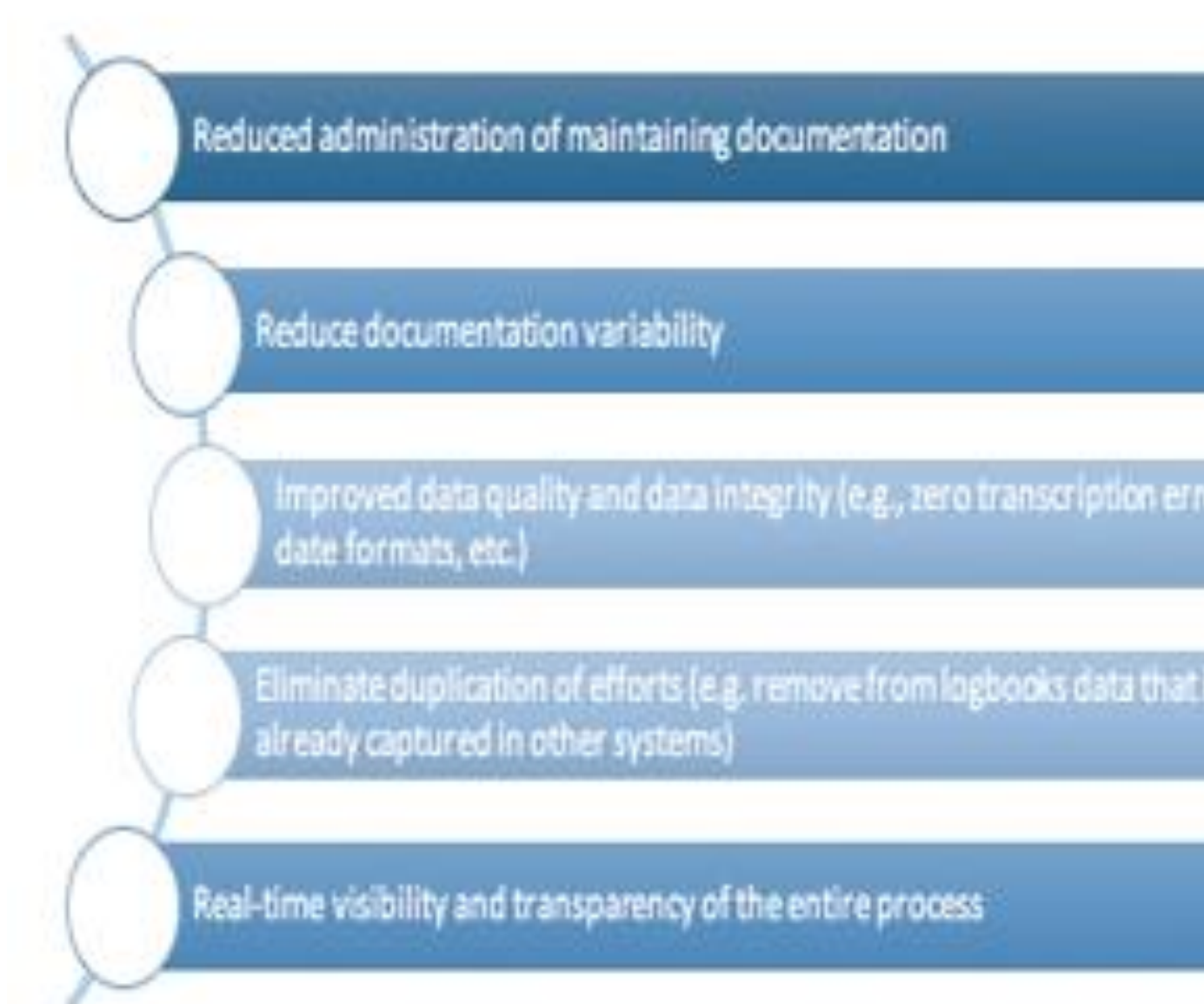


Figure 3
VOC Results

Analyze: In the Analyze phase, a detailed review of each paper logbook was performed, were several simplification opportunities were identified such as: reduced documentation frequency, reduce parameters to document due to information existing in other systems, reduce parameters due to no value added, standardize documentation methods, re-organization of inspections routes and reduce amount of second person verification needed.

Also in this phase, requirements for Environmental reporting were gathered, to ensure that data is collected in a meaningful manner to later build reporting solutions for environmental purposes.

A summary of the benefits that were analyzed and that are expected as part of this project can be view in Figure 4.

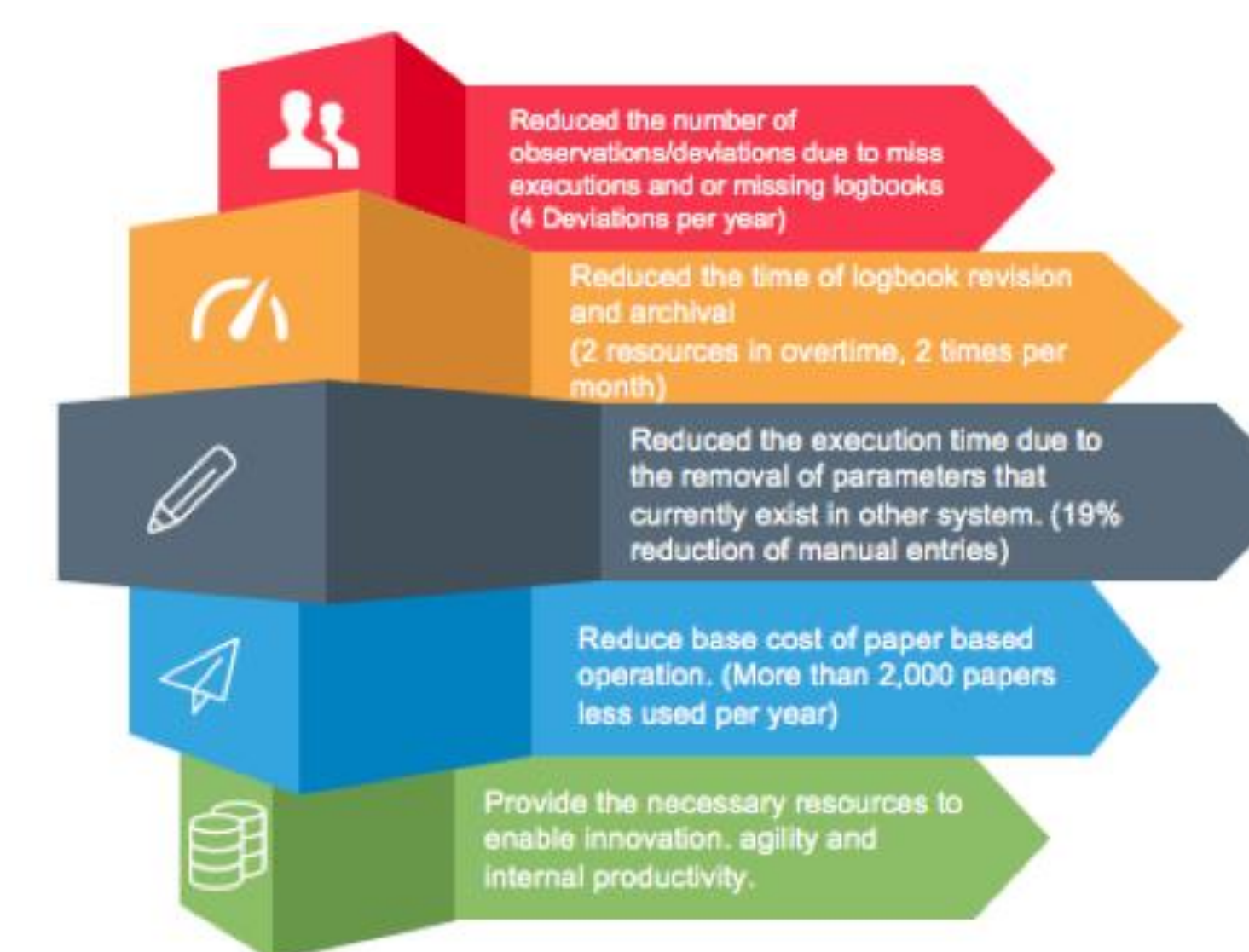


Figure 4
Implementation Benefits

RESULTS AND DISCUSSION

Improve: During the improve phase all the validation activities started. Validation of each electronic logbook developed was performed by Utilities area operators, with the intent of integrating them and made them familiar with the solution. In parallel, all the SOPs that were being revised were sent for review and approval, to ensure that documents can be effective in a timely manner.

Once all the validation activities were completed, the SOPs approved and the training was delivered, coordination with the Utilities area was performed to implement the electronic logbooks in the production environment and start Go Live activities.

Control/Support: Once the Go Live started, a stabilization period began. An information technology resource was supporting the area on-site (24 hours, 7 days a week) for the first 2 weeks. Tier 1 support was covered by the previously identified Power Users. Power users are utilities operators with additional trainings that are responsible in the identification and resolution of possible issues. Tier 2 support is performed by an Information Technology Analyst an it is typically performed on an on call basis.

In addition, the Project Team started to measure all the benefits that were established in the Analyze phase in order to compare in 6 months all the parameters and performance indicators, including deviations, resource management, documentation handling and execution time.

CONCLUSIONS

Due to the highly regulated environment that controls Company X's processes, having a process that standardizes, simplifies and facilitates the documentation of process parameters is fundamental. An MES system provides a mechanism to prevent documentation omissions or errors, eliminate paper storage and archival, and guarantee a higher degree of documentation integrity and availability.

Applying Lean Six Sigma to this project helped identified opportunities to be more efficient and simplify the process such as:

- Reduced documentation frequency
- Reduce parameters to document
 - Existing in other systems or no value added
- Standardize documentation methods
- Reorganization of inspections routes
- Reduce amount of second person verification needed.

FUTURE WORK

Part of the next steps would be to fully convert all the other paper based logbooks into electronic. In addition, once all the data resides into a single source system, specific regulatory reports can be created to facilitate Environmental agencies reporting.

REFERENCES

- [1] B. Scholten, MES guide for executives. Research Triangle Park, NC: ISA, International Society of Automation, 2009.
- [2] J. Arthur, Lean Six Sigma demystified, 2nd ed. New York u.a.: McGrawHill, 2011