Implementation of Software Tools for Paperless Processes Oriented in Lean Manufacturing Applied Specifically in the Biotechnology Industry

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Abstract *— Now days, one major cost area in companies getting scrutinized is paper-based business systems. Traditional paper-based methods for creating and delivering documents are expensive. Some of these large costs include: paper and paper-related expenses, storage, labor, capital expenses, employee productivity, and business processes. The manufacturing technical reports are an essential part for lots release. The lean industries are continuously improving processes to obtain better results throughout the different stages of the process. For this reason the FDA regulated industry is working in a Paperless/Electronic Environment. The research will be about all the requirements needed for the implementation of this electronic tool including the expectations and improvements resulting of this implementation, the qualification requirements, documentation required since the proposed improvements will reflect information that needs to follow the GMP and GDP regulatory requirements. In addition expected results will be based on the proposed changes improvements and implementation.*

Key Terms *— GDP (Good Documentation Practices), GMP (Good Manufacturing Practices), FDA (Regulated Environment), Lean Manufacturing.*

OBJECTIVE

The research topic [1] is based on the implementation of electronic tools to replace printed reports of the manufacturing process related to the automated system. The expectation regarding this topic is to identify the positive impact as part of manufacturing process, in order to reduce time and costs related to this part of the process (printing and managing records), which is an auditable process [2]. The objective is to validate the reliability of an electronic system that will comply with the intended purpose and the process. In addition to demonstrate that this changes will not impact the product. Benefits of paperless technology can be outstanding including dramatic increases in efficiency, quality, service, measurement, and knowledge protection [3].

CONTRIBUTION

Based on the proposed study a plan will be developed for the implementation of tools that will help in decreasing the use of traditional paper-based methods for creating and delivering documents, this being expensive. The research expectation is to identify the positive impact as part of manufacturing process, in order to reduce time and costs related to this part of the process (printing and managing records), which is an auditable process. Some of these large costs include: paper and paper-related expenses, storage, labor, capital expenses, employee productivity, and business processes.

By becoming a truly paperless company, manufacturers can [4]:

- Improve Visibility and Accessibility With a paperless shop floor system, all production data is maintained in a single virtual location, providing maximum visibility into real time manufacturing activities. While the information can be shared across departments, the system can also be configured easily to enhance accessibility.
- Automate Compliance Adherence Beyond paper and printing-related cost savings, paperless factories increase the overall compliance rate of the site. Unlike paper-based systems, a paperless floor helps manufacturers take training directly to the factory floor where it's needed the most. This, in turn, provides

greater accuracy in reporting, enabling organizations to remain compliant.

- Facilitate Real-Time Data Collection With a smart shop floor data collection system, manufacturers will receive real-time data about operations with up-to-the-minute dispatch lists to prioritize the most important tasks. In any paperless manufacturing environment, the push of a button on a scheduling software will fetch a realistic line-up of work at each center, with the software performing real-time analysis and sending alerts on problems as they occur.

  As part of the research findings, lean tools were used to help during the analysis development. Those lean manufacturing tools have been developed to reach an improved manufacturing environment to avoid execution errors and to improve the lot release timeline. In a lean environment, you want to minimize the amount of hunting and searching, and this includes sifting through computer directories for the most current version of work instructions.

METHODOLOGY

The manufacturing technical reports are an essential part for lots release. The lean industries are continuously improving processes to obtain better results throughout the different stages of the process. For this reason the FDA regulated industry is working in a Paperless/Electronic Environment. The paperless systems facilitate the revision of release documentation because it provides real time information by electronic source. The real-time access to production-related information facilitates the ability of employees to analyze results and take action to resolve or eliminate potential issues.

The implementation of an automated paperless operation, the same software can support to track-and-trace systems to help you meet emerging regulations regarding product quality. It can also help you conduct more efficient product recalls, shorten containment response and augment marketing efforts.

The implementation of a paperless environment need to be supported with the appropriate software technology, a comprehensive strategy involves adopting standardized processes and making the necessary cultural adjustments to pursue appropriately selected and realistic goals and targets.

The development of this kind of system required a thorough analysis of the information flow in production processes, to find out the key factors to conduct tests under accreditation requirements. The process of implementation consists basically of the following key elements:

- Qualified personnel – qualified technicians and appropriate training
- Documentation - Quality manuals, test procedures, test standards, product and/or process specifications, etc.
- Equipment – appropriate and accuracy
- Tests - Performing qualification Tests
- Reports - Creating final test reports to confirm that the system comply with the requirements.

Implementing paperless operation is a proactive step to even greater manufacturing efficiency. Paperless operation is only one component of an overall quality management solution. Additionally, electronic systems can make it easier to more quickly retrieve, integrate and process data than hard-copy filing systems, allowing access from any location at any time.

With growing cost pressures and new regulations, manufacturers and quality managers in the pharmaceutical industry are always looking for ways to improve their processes and procedures. An electronic environment system enables complete paperless manufacturing within regulated processes and helps achieve operational and manufacturing excellence from the design of the batch record to the release of the batch report, both in manual and in highly automated environments.

Considering the significant market pressures they face, pharmaceutical companies generally understand that it is important to reduce the cost of

quality and that paperless manufacturing is an important means to achieve this goal.

Making the change to a paperless manufacturing always involves changing established procedures and requires a change in the mindset of both employees and management. It is important to address the concerns and requirements of all parties involved. In pharmaceutical manufacturing, these specifically include the production staff, the quality management department, and IT. In order to fully obtain the benefits of the new system and to ensure both smooth implementation and full support and compliance, it is important to take a strategic approach to the implementation.

First, the project team needs to create a common understanding and commitment by defining the business and production objectives the company wants to achieve by going paperless. These objectives will incorporate the specific needs of the quality, production, and IT teams, such as the following:

- How will the new solution improve manufacturing quality, regulatory compliance, and review workflows?
- How will the new system support production operations and help operators make informed decisions and manage the process correctly?
- How will the new solution interface with existing systems and workflows?
- Illustrating how paperless manufacturing can make a contribution to improved performance in each of these areas will help create a mind-set that views change as an opportunity, not as a threat. This is the precondition for successful implementation.

The next step is addressing the critical aspects for implementing paperless manufacturing. Most commonly, these are as follows [4]:

- Defining goals and benchmarks – to illustrate the implications and benefits to both the operational and management levels.
- Securing management commitment – to provide the necessary resources for the project.
- Compiling user and documentation requirements – to assess the current state, to ensure a risk-free transition and to exploit added benefits (this might also include a feasibility study)
- Specifying the operational design and system requirements – to define expectations and requirements, taking into consideration the existing system and developing appropriate migration strategies and system interfaces where needed.
- Defining the appropriate technical solution – to define the system configuration and integration requirements.
- Developing the implementation approach and project time frame.
- Assigning the project team and responsibilities.
- Developing suitable key performance indicators to demonstrate the project's success.

A careful assessment of all these factors is needed to ensure that the system matches the specific requirements. For this reason testing is required as part of the project in order to ensure and demonstrate system effectiveness. The testing is design based on the requirements, where multiple testing are generated to confirm the system functionality is as expected. A plan is generated to comply with project milestones. This plan includes system configuration, deployment and final testing.

RESULTS AND DISCUSSIONS

For this step of methodology implementation, testing in development environment was performed, in order to qualify the system and confirm the Data integrity reflected as part of the reported information after water runs. Discrepancies were identified as part of the verification and were addressed accordingly to correct the findings. Once the verification and qualification was completed the system was implemented in the production environment. An additional run was performed in order to confirm that the production implementation was implemented correctly. As a result, all data was

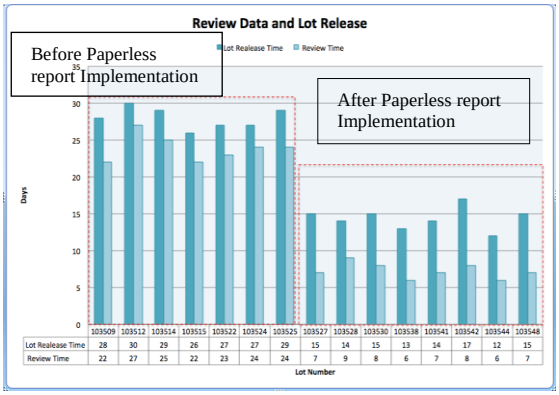
evaluated and found as expected [5]. After implementation, a manufacturing campaign was produced and evaluation was performed in terms of productivity. The following points were taken into consideration:

- The elimination of the need for paper, saving endless time and financial resources.
- Full traceability of the process in an electronic format.
- Inherently less review time, therefore reduce the lot release expected time, as can observe in Figure 1 "*Lot Release time*".
- Quick analysis and characterization of the manufacturing process.

Thus, implementation of the paperless reports process allows the operators to focus on the quality of the product and process, not on the paperwork.

Figure 1

Lot Release time



This new system eliminated a paper trail and resulted in a savings of more than $0.5 million dollars in overfill costs.

This system enables facilities to run manufacturing processes completely paperless at the highest level and to be compliant with international GMP guidelines and FDA regulations. Therefore, it helps to increase accuracy and productivity and the ability to monitor and analyze relevant data in real time, as observed in Figure 1 "Lot release time". The real-time access to production-related information facilitates the ability of employees to analyze results and take action to resolve or eliminate potential issues.

While the environmental impact of paperless manufacturing is obvious, removing hard-copy documentation from the production process also has a multitude of benefits: Reducing paper lessens clutter and storage space.

A clear reason for adopting digital platform is that the information can be easily, accurately and effectively collected, aggregated, distributed and used in global enterprises, which leads to operational excellence through better communication and decision-making.

CONCLUSIONS

In a rigorous regulatory environment that will only continue to tighten, the speed of actionable and available information translates directly to savings.

An important consideration over hard copies is that paperless systems facilitates, with a level of ease, sharing and collaborating.

Whereas important paper documents must be physically stored, often under lock and key, a paperless system can be stored in numerous virtual locations, and can also have tiered access to the information depending on roles and responsibilities. It can also significantly cut the cost of paper purchasing and disposal and ultimately result in a reduction in energy consumption.

We can see that a paperless environment is an important factor in increasing the speed of response to issues on the shop-floor.

In order to respond to modern manufacturing dynamics and back-to-back activities, personnel need to have access to accurate and up-to-date information to take quick and decisive actions. The immediacy and real time information provided by digital displays greatly speeds the rate of information flow between key stakeholders as the time to produce, share, and edit paper reports is eliminated.

As mentioned about the expenses with a paper based manufacturing approach, the cost on wastage can be minimized, while also ensuring that the data is available when needed; despite any occurrence of

events such as flood or fire, through regular data backup at remote servers.

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