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. My selected topic of "Implementation of software tools for paperless processes oriented in Lean manufacturing applied specifically in the biotechnology industry" is based on the implementation of electronic tools to obtain the critical results and information, including key parameters of manufacturing process as well as critical alarms that are monitored during the process and critical information that helps for the product release.

Project Description

The project is about the requirements needed for the implementation of this electronic tools 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.

Objectives

The Objective of this project is to evaluate the requirement for the implementation of electronic tools to replace printed reports of the manufacturing process related to the automated system. In addition to measure the resulted 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. As part of the project objectives also will be to validate the reliability of an electronic system that will comply with the intended purpose and the process.
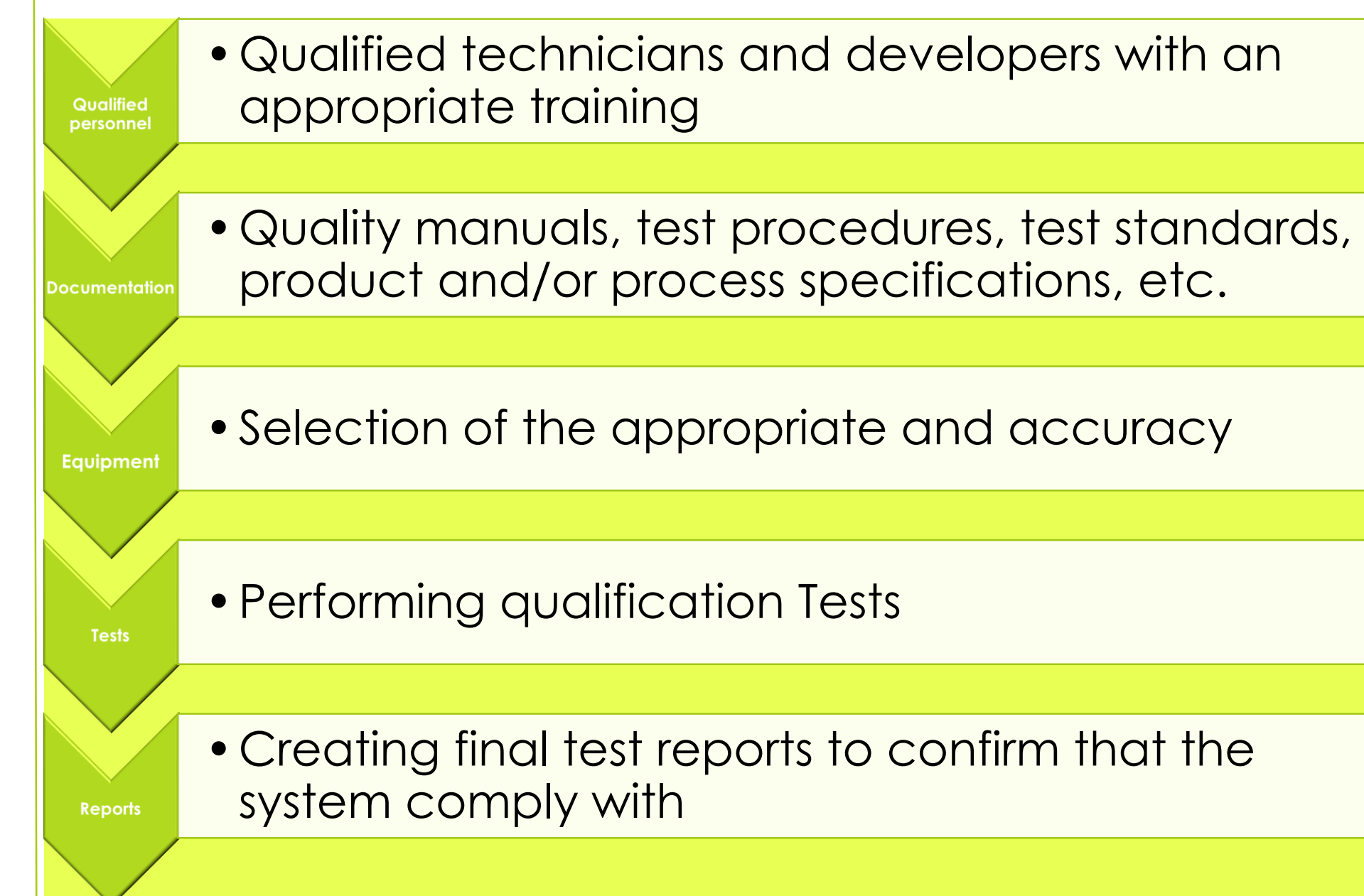
Methodology

The development of the system will require an analysis of the information flow in production processes, to find out the key factors to conduct tests under accreditation requirements.

Methodology (CONT.)

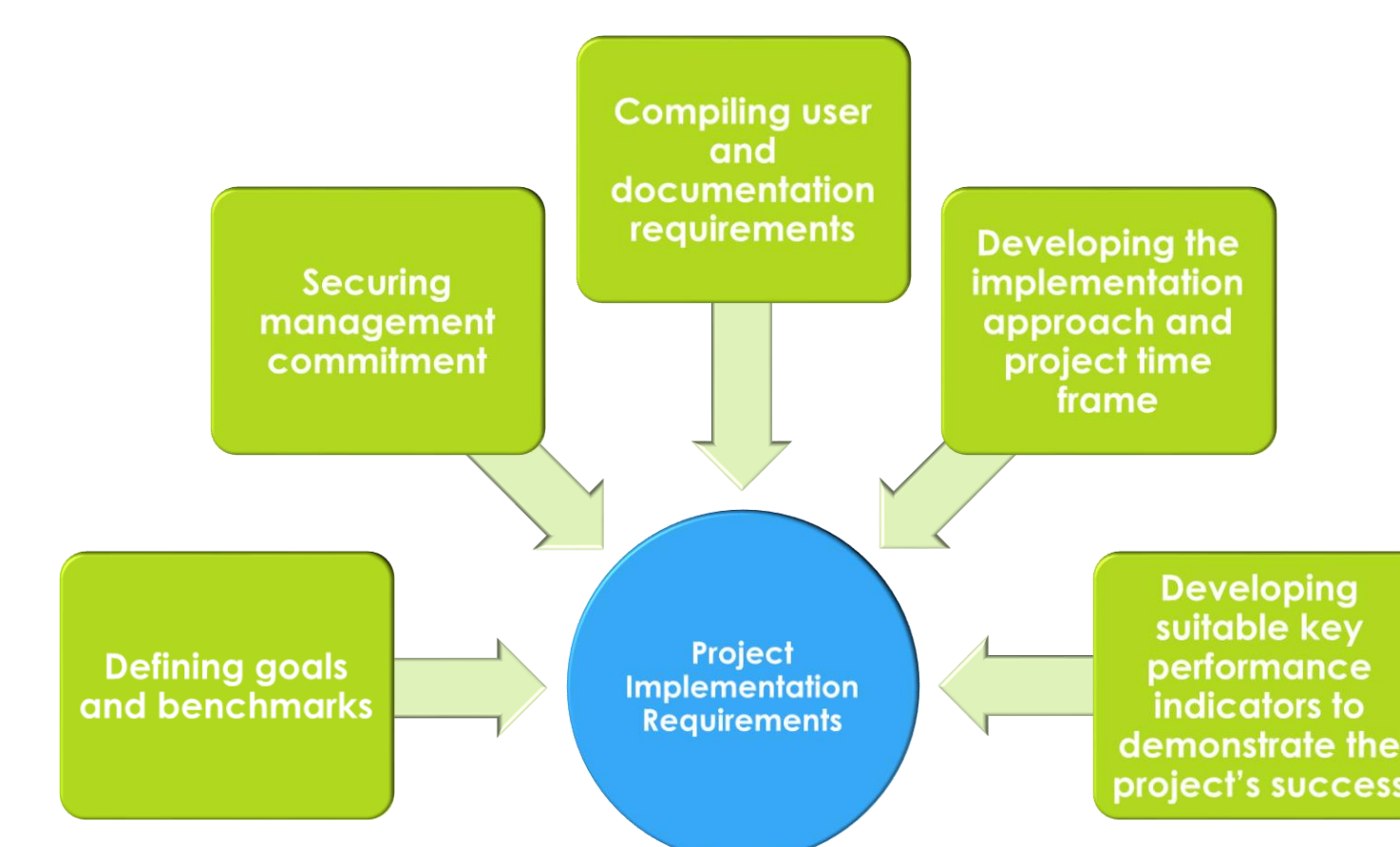The process of implementation consists basically of the following key elements:

Figure 1: Project Planning Requirements

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

The implementation of paperless as part of manufacturing will increase manufacturing efficiency. 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.

As part of the implementation the following steps needs to be addressed for the critical aspects of manufacturing paperless implementation. Most commonly, these are as follows:

Figure 2: Project Implementation Requirements

- Compiling user and documentation requirements
- Securing management commitment
- Developing the implementation approach and project time frame
- Defining goals and benchmarks
- Project Implementation Requirements
- Developing suitable key performance indicators to demonstrate the project's success

A careful assessment of all these factors was performed to ensure that the system matched the specific requirements. For this reason testing was performed 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 was generated to comply with project milestones. This plan included the system configuration, deployment and final testing.

Results and Discussion

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. 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
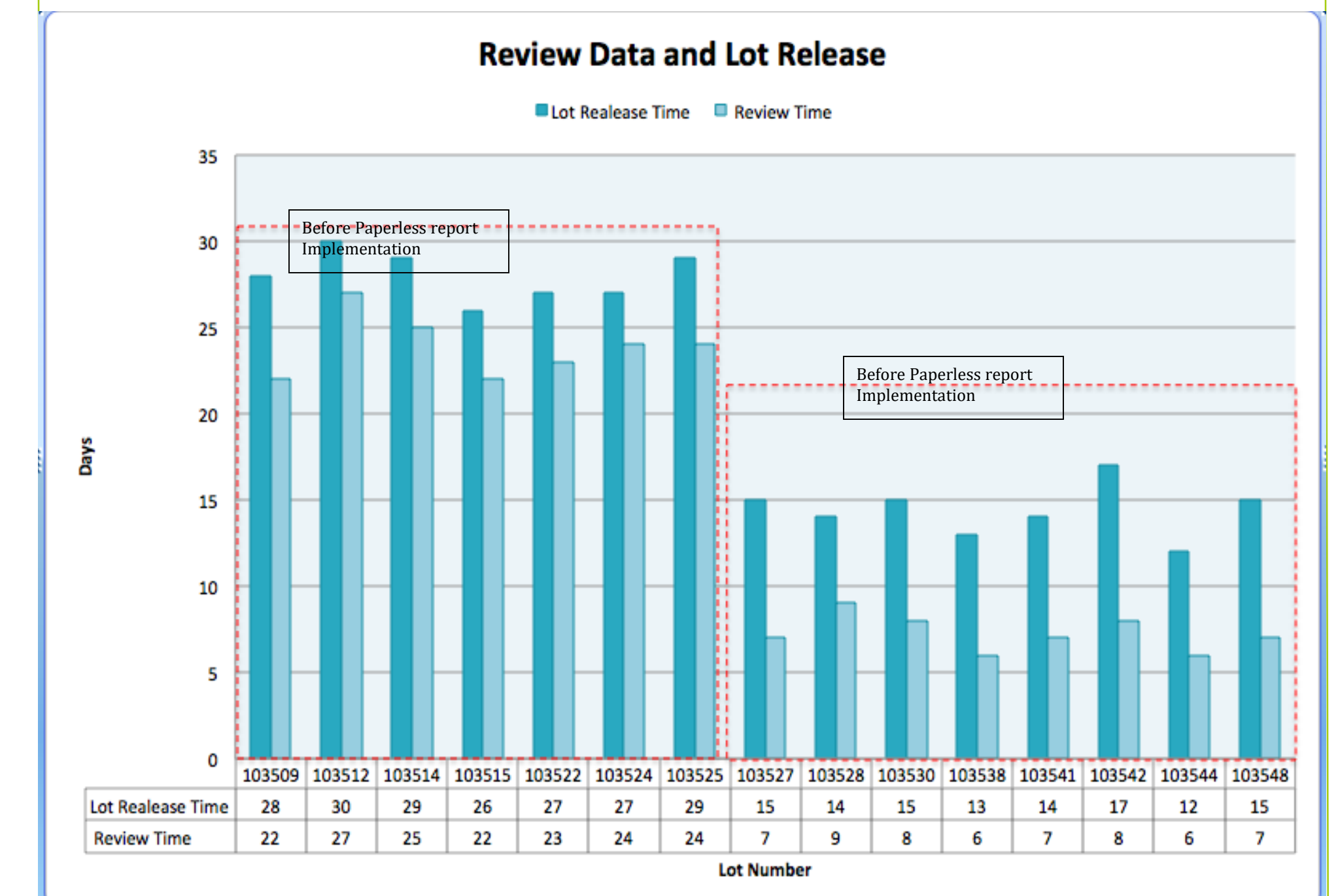- Quick analysis and characterization of the manufacturing process

Thus, implementation of the paperless reports process allows the operators to focus on the quality of the product and process, not on the paperwork. Refer to Figure 3 for analysis results of the following 15 lots, Table 1: 15 Release Time Lots Evaluation.

Table 1: 15 Release Time Lots Evaluation

Lot number	Lot Release Time	Review Time
Before Paperless Report Implantation		
103509	28	22
103512	30	27
103514	29	25
103515	26	22
103522	27	23
103524	27	24
103525	29	24
After Paperless Report Implantation		
103527	15	7
103528	14	9
103530	15	8
103538	13	6
103541	14	7
103542	17	8
103544	12	6
103548	15	7

Results and Discussion (CONT.)

Figure 3: Lot Release Time

Lot Number	103509	103512	103514	103515	103522	103524	103525	103527	103528	103530	103538	103541	103542	103544	103548
Lot Realease Time	28	30	29	26	27	27	29	15	14	15	13	14	17	12	15
Review Time	22	27	25	22	23	24	24	7	9	8	6	7	8	6	7

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. 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.

Conclusion

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

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