

Validation's Biggest Challenge

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INTRODUCTION

For many years there have been many conferences and articles discussing the many challenges in validation.

Most of these discussions are centered on issues and philosophies related to integrating commissioning and qualification, quality unit, and whether we should call it verification, qualification, testing or something else. Other challenges discussed are the value of performing qualification and the cost associated with this process.

In most of these debates what is absent is objective discussion about what truly drives cost and the inefficiencies of the paper based processes.

This article will provide discuss the challenges of paper based processes, electronic document management systems and the advantages of implementing Validation Management Systems (Paperless Validation).

THE PAPER CHALLENGES

Paper based validation processes are plagued with inefficiencies and high cost associated with managing paper based documents. The process of creating, printing, execution and scanning paper based validation documents is time consuming and yields very high inefficient cycle times. Paper based document management is very tedious and time consuming process that requires a significant amount of time from the validation and document management teams. Paper based validation executions create delays related to releasing manufacturing equipment for critical manufacturing operations.

Inspection readiness is negatively impact by paper based validation processes due to the delays created by attempting to retrieve documents from the vault. Record retention over time can be very costly due to the amount of space required to store paper based documents. Paper based validation processes require contracting a document archival company to move documents from the vault to a remote storage location which adds a significant amount of cost. The biggest impact of paper based validation processes is to resources. Utilizing validation resources to perform document management activities is not value added and one of the most demotivating factors that validation professionals face in their careers.

In summary paper based validation processes are inadequate, inefficient and very costly in the long term. Companies can benefit significantly by looking at options that eliminate paper. One option is to implement a document management system to replace paper. This option although it appears to be efficient sometimes is not due to some of the challenges related to these systems.

CHALLENGES WITH ELECTRONIC DOCUMENT MANAGEMENT SYSTEMS

Electronic document management systems have been the leading technology for automating paper based processes in the biotechnology industry. Electronic document management systems provide automation of the creation, review and approval cycle of validation documents. These systems require validation professionals to create the document in Word or Excel, route the document for review and approval using the automated workflow. Once the document is approved in the system a controlled copy is printed for the execution of the validation protocol. Once the execution is complete the document is reviewed and approved outside of the system and scanned into the electronic document management system.

Although the process is partially automated it continues to be inefficient due to the need to print the protocol for execution and scan it back in the system. The fact that executed documents are approved in paper this requires validation resources to dedicate a significant amount of time routing the document for final approval.

Documents routed in an electronic document management system require a document coordinator for each document which adds additional cycle time, delays and cost.

In summary electronic document management systems are not an adequate solution for validation documents. These systems partially automated the document lifecycle but not the entire process including the execution. Due to the inability to execute electronically document management systems lack the efficiencies provided by paperless validation systems. Unfortunately during the implementation of these systems document management procedures are created that require resources to coordinate a document that can be fully automated. The document coordination step adds unnecessary complexity and cycle time to the process.

Due to the lack of electronic executions these systems don't provide full validation lifecycle management capabilities. Electronic document management systems don't provide the ability to link all records to one system. These systems also fail to automate the discrepancy or deviation generation process and linking them to a failed step during the validation execution. Document management systems fail to provide validation metrics and to automate the generation of traceability matrix.

In addition to these challenges document management groups tend to rely on manual processes driven by procedures that require coordinators to interface with every document in the system, this add unnecessary complexity and inefficiencies. The cost of document management systems is very high and can run into millions of dollars for a global implementation. Unfortunately these systems fail to provide full validation document lifecycle automation and require resources for document coordination.

In summary electronic document management systems are not adequate to manage the validation document lifecycle. These systems provide partial automation and require a significant amount of capital investment to implement.

THE SOLUTION

Paperless validation systems have been in the market for several years. In the early years of this technology the tools available lack adequate functionality and workflows needed to automate the validation document life cycle process. Since inception these tools improved significantly and now are widely used in the industry.

Validation lifecycle management solutions are designed specifically to validate and maintain the validated status of complex systems. These tools allow organizations to reduce the validation effort and cost by approximately 50%. Validation lifecycle management solutions reduce cycle time by automating critical validation activities and eliminating the non-value added activities that are labor intensive.

These tools are web-based Validation Lifecycle Management System that manages the entire validation lifecycle process, from the Validation Plan, Risk Assessment, Project Planning, Requirements Management, Dynamic Trace Matrix generation and then moving on to test case/protocol development, Electronic Execution and completing the validation life cycle with the Decommission/Retirement process. In addition to the validation lifecycle management process some systems supports Change Management, Periodic Review and Cleaning and Usage Log management within the system.

These solutions expedite the validation process and remove the inefficiencies that plague paper-based validation processes. It provides full visibility for GxP systems, reduces the audit duration from a few days to just a few hours, improves the efficiency of the entire validation process, enhances consistency and reduces the validation cycle time and cost by approximately 50%.

In addition, these solutions enable users from different sites and/or departments to collaborate and share Validation data and documents. This eliminates redundant validation tasks across the site or organization. These tools harmonize the validation process across the entire organization.

These tools provide the following integrated functions to manage equipment and systems validation lifecycle process electronically:

Requirements Management – Paperless validation system supports the creation, review, approval and managing requirements. In this technology each requirement is treated as an object with version control.

Dynamic Trace Matrices – These tools provide a dynamic traceability matrix functions that will automatically link requirements to test cases. When there are changes to one of the requirements, the system will indicate which other objects including design specifications, and test cases that have been impacted.

Risk Manager – These tools provide the ability to conduct Risk Assessment at the system level or at the requirements level. The tools also provide the ability to create, review, approve and manage risk assessments.

Validation Plan– These tools provide the ability to define the required validation deliverables that must be completed in order for any system to be considered validated as per validation SOPs. These tools provide the ability to enforce dependencies between deliverables and systems or processes that are part of the project.

Protocol Developer –These tools provide the ability to author validation protocols using MS Word or MS Excel.

Test Executor – Paperless validation systems supports electronic, automated and manual execution processes. Through the electronic execution functionality adding screenshots or file attachments to any executed row can be achieved with a few mouse clicks.

Off-line Execution: Paperless validation systems provide offline execution functions that allow users to execute documents electronically even though they are not connected to the network.

Validation Exception and Deviation Management: Paperless validation systems provide the ability to manage validation exception/deviations occurred during the validation test execution through a controlled workflow and linked to protocol objects.

Equipment Inventory – These systems provide equipment inventory with real-time validation and cleaning status. Validation and cleaning statuses of equipment and instruments are dynamically updated.

Scheduler – Paperless validation systems allow users to create periodic review schedules that automatically alert user groups of any upcoming or delayed periodic review tasks. In this way human errors are removed from the process ensuring that users are aware in real time of the status of any periodic review.

Cleaning and Usage Log Management – Some of these systems provide a module to manage cleaning and usage logs. Cleaning and usage logs are continuously monitored and they are available with validation data with real-time status.

Decommissioning/Retirement – Paperless validation systems manage the decommissioning/retirement process. This ensures that decommissioning/retirement of GxP systems and processes are controlled and documented as per approved procedures.

BENEFITS OF IMPLEMENTING PAPERLESS VALIDATION SYSTEMS

Paper based validation processes present a significant amount of challenges to management and validation teams. Some examples of these challenges include the following:

- Inconsistent Documentation

- Review and Approval Delays
- Ineffective Tracking
- Missed periodic reviews
- Time consuming audit preparation
- Difficulty enforcing validation standards and policies
- Scanning documents and electronic management

All these challenges can be addressed by implementing paperless validation systems. Paperless validation systems eliminate completely all the inefficiencies found in paper based processes.

Paperless validation systems provide a significant amount of advantages and benefits not found in paper based processes and electronic document management systems. Some of these benefits include the following:

- Template driven development Improves consistencies
- Approvals are tracked and alerts through e-mail are sent out to approvers
- Dynamic audit trails provide real time validation status and metrics
- Automated alert notification to SMEs regarding periodic reviews
- Enforces validation standards, policies and procedures
- Web-based system allows for approvals on-line with full view of documentation
- Reduced Validation effort while increasing compliance
- Full equipment lifecycle management
- Electronic protocol execution

An additional benefit provided by this technology is since content is entered electronically the common issue of illegible handwriting is no longer a problem. Losing documents will be avoided completely. In addition, review and approval processes of executed validation protocols are accelerated, since protocols are routed to reviewers and approvers in real time regardless of geographical location.

In summary the benefits of implementing paperless validation systems are significant to the industry.

SUMMARY

One of validation biggest challenges is relying in paper based processes. Paper based validation is very costly and inefficient. Electronic document management systems sometimes appear to be an adequate solution, but they have their own challenges. Electronic document management systems only provide partial automation of the process and don't enable dynamic linking and paperless executions.

Implementing and validating global enterprise systems can be very challenging and costly. The lack of global standards and procedures can have a negative impact in the implementation of global enterprise systems. To ensure an adequate ROI governance and oversight must be established to enable full utilization of global enterprise systems.

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