Strategies for the Successful Implementation of Validation Lifecycle Management Systems
What is the risk with your current validation process?
Can the implementation of a validation lifecycle management system reduce that risk?
How to identify the risk related to a paper based validation process?
Reduce risks and learn the benefits of a paperless validation solution
Case Study: Noven Pharmaceuticals paperless validation implementation
Validation Biggest Risk & Challenge?
What is the Risk?

Look familiar?
Assessing the Status Quo?

• Points to consider:
  • 100% paper based process
  • Paper based system with some electronic repository?
  • Hybrid process paper & EDMS system?
  • Other?
Risk with Paper-Based Validation

• Compliance Risk
  • Failure to follow approved procedures
    • Difficult to enforce and follow approved validation procedures and validation master plan
  • Lack of consistency
    • Difficult to standardize and harmonize the validation process across sites
  • Documentation issues
  • Lost and misplaced records
  • Inability to collect, generate and report quality metrics
  • Regulatory observations
Risk with Paper-Based Validation

• Business Risk
  • Loss revenue
  • Higher operational cost
  • Higher expenses (document storage, archiving, retrieval, resources)
  • Inability to release manufacturing equipment
  • Delayed production schedules
Paper-Based Validation Risk & Challenges

- Paper-based validation processes are plagued with inefficiencies and risk
- High cost associated with paper-based document management
  - Creating
  - Printing
  - Executing and scanning validation
  - Inefficient cycle times
Paper-Based Validation Risk & Challenges

• Paper-based document management is very tedious and time consuming process

• Requires a significant resource commitment from the validation and document management teams

• Create delays related to releasing manufacturing equipment for critical manufacturing operations

• Paper-based validation DOES creates job security!!!!
Paper-Based Validation Risk & Challenges

- Record retention over time can be very costly and unsustainable
- The biggest impact of paper based validation processes is to resources
- Utilizing validation resources to perform document management activities is not value added and cost effective
Document Management Systems: The Solution?

- EDMS systems are inefficient due to the following:
  - Need to print protocols for execution
  - Scanning documents back in the system
  - Routing the executed document and related data for final review
  - Routing the executed document and related data for final approval

- Electronic document management systems normally require a document control coordinator for each document which adds additional cycle time, delays and cost
Document Management Systems: The Solution?

- EDMS systems are **not an adequate** solution for validation documents.
- EDMS systems **partially automate** the document lifecycle but not the entire process **including the execution**.
- EDMS systems **lack the efficiencies** provided by paperless validation systems.
- Due to the lack of electronic executions these systems **do not provide full validation lifecycle management capabilities**.
Risk with Document Management Systems

• Compliance Risk
  • Failure to follow approved procedures
  • Lack of consistency
  • Documentation issues
  • Lost and misplaced records
  • Inability to generate, collect and report quality metrics
  • Regulatory observations
Risk with Document Management Systems

• **Business Risk**
  - Loss revenue
  - Higher operational cost (document storage, archiving, retrieval, resources, license cost)
  - Inability to release manufacturing equipment
  - Delayed production schedules
Enterprise Validation Lifecycle Management Systems

• Solutions that reduce cycle time by automating critical validation activities

• Eliminates the non-value added manual activities that are labor intensive and time consuming

• Web-based systems that manages the entire validation lifecycle process including electronic execution

• Expedite the validation process and remove the inefficiencies that plague paper-based validation processes
Enterprise Validation Lifecycle Management Systems

- **Provides full visibility** for GxP systems, reduces the audit duration **from a few days to hours:**
  - Improves efficiency
  - Enhances consistency
  - Reduces cycle time approximately 50%
  - Enable cross-functional collaboration across multiple sites
Enterprise Validation Lifecycle Management Systems

• Provide the following integrated functions that enable paperless lifecycle management:
  • Requirements Management
  • Dynamic Trace Matrices
  • Risk Manager
  • Validation Plan
  • Protocol Developer
  • Test Executor
  • Off-line Execution
  • Exception and Deviation Management
  • Equipment Inventory
  • KPI’s & Quality Metrics
  • Decommissioning/Retirement
Case Study: Noven Pharmaceuticals
Paperless Validation Implementation

Validation Lifecycle Management Software Solution
Agenda

- Company Background
- Problem Statement & Business Drivers
- Vendor Selection Process
- Pre-Implementation Strategies
- Discuss potential risk prior and during implementation
- How to reduce risk to enable a successful implementation
- Results & Benefits
- Lessons Learned
Company Background

- **Noven Pharmaceuticals**
  - Founded in 1987
  - Based in Miami Florida
  - Specializes in transdermal drug delivery systems
  - Over 325 employees
  - ValGenesis implemented on April 2013
  - Currently 96 Noven employees are ValGenesis users
Problem Statement & Business Drivers

• Business compliance needs to consistently manage the development, routing, review, and approval of validation lifecycle documents across the organization
• Compliance issues
• Documentation errors
• Delays
Problem Statement & Business Drivers

• Eliminate paper in the validation lifecycle process

• Storage space for all the paper documents generated during a validation lifecycle process

• Traceability, managing and accessing validation documents generated during a validation lifecycle
Vendor Selection Process

- 3 vendors identified & assessed against Noven requirements via a formal RFP (Request for Proposal) process.
- Vendor (ValGenesis) selected based on ability to meet Noven requirements
- ValGenesis Corp. team accessibility.
Pre-Implementation Strategies

• **Points to consider:**
  • Senior management support
  • Robust organizational change management
  • Vision and common organizational goals
  • Anticipate and eliminate potential organizational obstacles
  • Robust communication plan
  • Assess inefficiencies in current paper-based process
Reducing Risk Prior and During Implementation

- Inadequate Project Timeline
- Undefined roles and responsibilities between ValGenesis Inc. and your company
- Lack of Organizational commitment
- Not assessing the current process for inefficiencies
- Poor understanding of the value proposition
Reducing Risk Prior and During Implementation

Continued

- Attempting to automate a very inefficient paper based process
  - Excessive reviewers & approvers
  - Excessive amount of unnecessary bureaucracy
  - Excessive amount of quality oversight
  - Excessive amount of attachments and print screens
Reducing Risk Prior and During Implementation

Continued

- Inadequate implementation strategy
  - Poor scope definition
  - One size fits all approach to implementation
  - Inadequate document migration strategy
  - Not understanding legacy record retention requirements
Reducing Risk for Successful Implementation

• Reducing or eliminating inefficiencies prior to implementation
  • Reduced number of reviewers and approvers
  • Eliminate unnecessary bureaucracy driven by personal preferences
  • Integrated quality oversight
  • Risk based approach to attachments and print screens
Reducing Risk for Successful Implementation

Continued

• Top-down organizational commitment

• Adequate scope definition –
  • Low lying fruits provide a quick ROI!
Results & Benefits

- Noven implementation provided a significant amount of benefits such as the following:
  - Paperless solution for their validation processes
  - Reduction in compliance issues or investigation due to the control during the execution
  - Improvement of the validation management life cycle by delivering of projects on-time or less time within budget
  - Improvement of the project resources time utilization
Results & Benefits

Continued

• Efficiencies around the development, execution and approval of validation related documents

• Support of the Go Green initiative with a paperless system

• ValGenesis is used to manage the validation lifecycle for Enterprise Software validations, Stand Alone Software validations and Equipment Qualification.

• Support of the Go Green initiative with a paperless system
Results & Benefits

Continued

• It is a centralized electronic storage for all validation deliverables
• Part 11 compliant audit trail
• Provides complete visibility of GxP validation/qualification processes,
• 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
Results & Benefits

Continued

- Enables virtual collaboration, visibility, accountability, time savings through simultaneous review and approval of validation documents
- Enables notifications and task alerts routed through email
- Electronic workflows supported by automatic audit trails and electronic signatures
Results & Benefits

Continued

• Real-time access for the authorization, execution, review, and approval of GxP assets across different departments

• No more issues deciphering handwriting

• Reduced cycle times range between 30% to 50%
Lessons Learned

• Executable tables can be corrupted if the developer does not follow the instruction provided during the training.

• If a user is no longer part of the company, every document assigned must be transferred to another user before this user becomes inactive.

• Validation deliverable templates must be revised in order to be used in ValGenesis.
Lessons Learned

• Executable tables properties must be set up as follows:
  • Allow row to break across pages
  • Repeats header row at the top of each page
  • Automatic resize to fit contents must not be selected
Summary

• During this session, we covered the following concepts:
  • Risk and inefficiencies of a paper-based validation process
  • Challenges and risk of Electronic Document Management Systems
  • Reducing risk during the implementation of a VLMS system
  • Case Study: Noven Pharmaceuticals