Considerations for the Paperless Laboratory

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1) Identify The End Goal of being Paperless
2) Identifying critical documentation areas within the laboratory
3) Classify the document groups/types
4) Common Methods for E-Doc storage
5) Examining each document class using examples of documents routinely encountered
6) Deciding on actual paperless storage method
7) Identifying actual storage formats
Define the Objective

Paperless Has a Purpose

➢ Examples of Common Needs
  • Environmentally Friendly
  • Common and Centralized Storage
  • Ability to Data Mine and Retrieve easily
  • Research and Project Organization
  • Regulatory Compliance
  • Ease of Access
Common Methods for Electronic Document Storage:

- Scientific Data Management System (SDMS)
- Laboratory Information Management System (LIMS)
- Cloud Based Structural Storage
- Local Area Network structural Storage
SDMS Method

Why SDMS?

1. Designed specifically for Scientific Electronic Document Organization
2. Routinely provides ability for collaboration and project based research and organization
3. It is sole focused

Why Not SDMS?

1. Potentially expensive for a sole task
2. One more system to maintain and interact with
Cloud Based Method

Why Cloud?

1. Documents are stored off site (Disaster Recovery)
2. Very Flexible Design
3. Access from anywhere on the web

Why Not Cloud?

1. Flexible design means you must design your own.
2. Potential Security Issues
LAN Method

Why LAN?

1. Documents are stored within Network making them secure
2. Very Flexible Design
3. Access from anywhere in the network while providing permissions controls

Why Not LAN?

1. Flexible design means you must design your own.
2. Security Controls require management from IT
LIMS Method

Why LIMS?
1. Some Modern LIMS Allow for uploading of e-docs
2. Centrally stored and accessible
3. Cloud hosting may be possible
4. Likely already in use for routine operations

Why Not LIMS?
1. LIMS may not have capacity
Once Storage Method has been decided its time to break the laboratory down into structural/functional areas where e-docs would exist

- Field Operations and Sample Collection
- Laboratory Receipt
- Laboratory Testing
- Results Submission and Reporting
1) Common Laboratory Document Types

➢ Sample Collection Information (Chain of Custody)
➢ Field Observations and On-Site Testing Results
➢ Site Imagery
➢ Sample Preparation Logs
➢ MSDS and Standard COAs
➢ Sample Analysis Logs (Bench Sheets)
➢ Instrument Outputs and Summaries
➢ Review and Approval Documents
➢ Certificates of Analyses and/or Deliverables
Knowing what to store and where to store is key.

Then consider the format for the file?

➢ Consider ability of document to be edited
  1. .pdf, .tif, or image-like format reduces likelihood of editing.

➢ Consider who will be using the file in the future
  1. Instrument files requiring specific software to view can be problematic in the future
     – Consider export to common format
Process Integration

Once the overall method has been defined, documents identified and storage formats finalized:

It’s time to consider process integration

• User Roles responsibility at specific points in work cycle
• Checks must exist to verify that critical documents have been preserved
• Document your Document Procedures
The Time Cost of Technology

- Complexity consumes time
- Creating necessary traceability can be complex
- These considerations provide justification for single system approach
Depending on the method of storage selected, recovery of electronic files needs to be considered before going live.

- Plan for Disaster Recovery Now
- If storage location is on site – determine backup frequency and off site backup storage
- If offsite (cloud or central IT), verify frequency and recovery is possible.
- Floods and Fire have the same affect on computers as they do on paper.
Final Considerations

• Evidence vs. Traceable
  – Think about whether the file has to have a signature (Chain of Custody: Relinquish vs. Receipt)
    • Is a Scan of a signature acceptable or is the actual signature on paper required
    • Electronic Signature can be enforced by a system and can be an image of a signature or digital certificate.
      – Will these signature methods meet your regulatory needs?
Keys to Success

• Prior to Beginning:
  – Identify all document classes
  – Determine file types best suited to need
  – Always consider e-sig requirements
  – Consider impact to current operations

• Once Underway:
  – Document The Process
  – Perform Routine Reviews to ensure adherence
Questions and Answers

• Q&A