Migration of Controlled Documents into Compliant SharePoint Document Management Systems

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What is This Presentation About?

- Overview of SharePoint
  - What it is, how it’s structured
  - To provide framework for this presentation
- The migration process
- How to validate migration to SharePoint
What is This Presentation *Not* About?

- How to configure SharePoint
- How to validate SharePoint
- Specific configured or customized SharePoint solutions
• SharePoint is validated
• SharePoint implementation meets some or all of the regulatory requirements for compliance document management
## Key Terms: Traditional EDMS vs. SharePoint

<table>
<thead>
<tr>
<th>Traditional EDMS</th>
<th>SharePoint</th>
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<tbody>
<tr>
<td>• Current market leaders in EDMS</td>
<td>• Microsoft EDMS, collaboration, and web site software</td>
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<tr>
<td>• Documentum solutions, QUMAS</td>
<td>• Highly configurable but not out-of-the-box dedicated compliance EDMS</td>
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<tr>
<td>DocCompliance, Pilgrim,</td>
<td>• FDA-regulated industries showing increasing interest in SharePoint</td>
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<tr>
<td>MasterControl, etc.</td>
<td>• Key Terms:</td>
</tr>
<tr>
<td>• Typically dedicated to compliance</td>
<td>• Document as multiple objects</td>
</tr>
<tr>
<td>EDMS solutions</td>
<td>• No PDF renditions</td>
</tr>
<tr>
<td>• Key Terms:</td>
<td>• Content Databases: MSSQL</td>
</tr>
<tr>
<td>• Document as a combined object</td>
<td></td>
</tr>
<tr>
<td>(content, renditions, metadata,</td>
<td></td>
</tr>
<tr>
<td>previous versions)</td>
<td></td>
</tr>
<tr>
<td>• PDF Renditions</td>
<td></td>
</tr>
<tr>
<td>• Content Databases: Oracle, MSSQL</td>
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</table>
Migrations from One Traditional EDMS to Another

Traditional EDMS → Different Traditional EDMS
Traditional EDMS Document Object

An electronic “document” consists of native content, metadata, signature data, and a dynamically generated PDF rendition.

This is represented as one document object in the system – the user sees only one entry.

Whereas in standard SharePoint systems...
SharePoint Document Objects

Document Object 1

Document Object

Native Content

Metadata

Signature Data

Document Object 2

Document Object

PDF Content

Metadata

Signature Data
**Traditional EDMS Architecture**

Custom solutions that sit directly on a database layer.

These solutions are designed to meet compliance requirements for FDA-regulated industries.

Traditional EDMS products typically have an integrated PDF render solution.
SharePoint Architecture

SharePoint is a standardized EDMS platform, that is designed to meet generic document management needs.

Customized EDMS solutions sit on top of the SharePoint platform to meet industry-specific requirements.

SharePoint *does not* provide an integrated PDF render solution.

The SharePoint API is used to interact programmatically with the SharePoint platform.
Migration As It Is Perceived

Current State

Source System

Migration

Data Migration (Easy Button)

Migration Complete

SharePoint System
Migration Process Stages

Export  Transform  Load

Compliance complexity is the greatest at the Transform stage
Exporting from an existing solution is straightforward, provided you account for the following key components:

- Document metadata
- Document content (native and renditions)
- Electronic signatures
- Change Request history
- Audit information
### Export: Risks & Mitigation

#### Documents Missed
- Proper requirements definition
- Content counts to verify source and exported documents

#### Corrupted Data
- Clean-up in the source system, if possible
- Clean-up during the Transform stage
- Customize destination system to work with available data

#### Open Change Requests
- Establish timeline to close out all open revision cycles in the source system prior to export
The work of transforming data requires the skills of:
- Subject Matter Experts
- Technical Experts

You cannot transform your data until you know what it is, and where it is going.
Transform: Planning

**Business Requirements**
- What business requirements are driving this new implementation?
- What changes would you *like to* make in the new system?

**Technical Requirements**
- What changes do you *have to* make to the data to meet new system requirements?
- What can you do in the new system that you couldn’t do before?
### Transform: Typical Business Requirements

#### Document Type Consolidation
- Streamline system configuration
- Revise design to meet current business needs

#### Custom Attribute Cleanup
- Modify existing values to meet new syntax
- Correct data inaccuracies

#### Existing Attributes
- Map existing attributes to new attributes
- Identify attributes to be brought over “as-is”
- Identify attributes to be transformed

#### New Attributes
- Determine rules for populating new attributes
- Assign SMEs to generate the new data

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**Proper planning at this stage is critical to defining the scope of the migration effort. Key compliance data must be maintained.**
### Critical Compliance Data
- Document Names/Numbers
- Document Titles
- Document relationships/references
- Signatures
- Renditions

### New Required Data
- New mandatory system attributes
- New system architecture/functions

### Data Type Matching
- Special characters
- Date/DateTime matchups
- Data cleanup

The technical team should review these key requirements and provide feedback to the business team to finalize requirements.

Not everything will match one-to-one. As a result tools, processes, and procedures must be developed to get your data technically ready to meet SharePoint requirements.
What About Electronic Signatures on Exported Content?

**PDFs Contain Signatures**
- Content may be migrated as-is
- Some banding/watermarking may need to be done during export

**PDFs Do Not Contain Signatures**
- A tool may be needed to extract metadata signatures and fuse them to the exported PDF file
- Rely on a custom SharePoint solution to replicate the functionality of the legacy system
Transform: Risks & Mitigation

Improper Data Transformation
- Proper requirements definition
- QA Verification Plan
- Automated data verification against destination system

Content Corruption/Missing Data
- Manual correction of content
- Mitigation strategy for unrecoverable documents

Production System Down/Frozen
- Make corrections in the Source System prior to export
- Automate transformation as much as possible
- Be quick!
Transform: Compliance

- Validate all tools
- Validate the process

Rules

- Document transformation rules

QA Approval

- QA sign-off on all transformed metadata
### Electronic Signatures
- How are signatures manifested in the current system?
- Are they applied to renditions on the fly, or stored in the repository?

### Rendition Management
- Do all content files have PDF renditions for controlled viewing?
- Do they need to be modified for storage in the new system?

### Metadata
- Will all attributes exist in the next system?
- How will the values for new attributes be determined?
Planning

- Importing to SharePoint requires planning for how and where you’ll store your data

Load Requirements

- Standard, base SharePoint
- Customized SharePoint solutions
- COTS EDMS SharePoint
Load: Where is Data Loaded?

- Render Solution
- Other EDMS Components
- EDMS Solution
- SharePoint
- SharePoint API
- Database Layer

Load utilities talk to SharePoint via the API.
### Load: Understanding Content Requirements

<table>
<thead>
<tr>
<th>Previous Versions</th>
<th>Native Content</th>
<th>PDF Renditions</th>
<th>Permissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Determine if previous versions are required in the compliance SharePoint EDMS</td>
<td>• Migrated content may look different than content created in the new system</td>
<td>• Understand the rendition management solution</td>
<td>• Document permissions must be set by the API during import</td>
</tr>
<tr>
<td>• Can this be stored in an archive?</td>
<td>• Metadata gets fused into document properties for all documents</td>
<td>• Ensure your migrated PDFs won’t be overwritten – they have signatures embedded!</td>
<td>• They should match library and content type settings</td>
</tr>
</tbody>
</table>
### How are Renditions Managed?
- Unlike a traditional EDMS, content objects in SharePoint will always exist independently.
- Will both the native and PDF rendition be loaded to the same library?
- How are the native and PDF rendition linked?

### Historic Electronic Signatures
- If they’re on the PDF, you need to understand the render solution.
- If they’re metadata only, how will they manifest on Effective copies?

### Are Documents Keeping Their Version Number?
- SharePoint doesn’t allow the manual setting of a version number via the API.
- To load a document as v4.0, the import tool must check a document out and in 4 times to set the version label to 4.
- This will add to the load time.

### Data Verification
- All good migration tools verify data against a configuration prior to load.
- Ensure that:
  - All required fields are completed.
  - All of the fields match the target data type.
  - Any list-driven values match the value on the list in the system.
### Load: Archiving Options

<table>
<thead>
<tr>
<th>Legacy System</th>
<th>Database</th>
<th>File Share</th>
<th>SharePoint</th>
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</table>
| • Keep system running  
• Limited number of licenses | • Metadata  
• Content files either in DB or file share  
• Accessible via report | • Spreadsheet of metadata  
• Content Files | • Simple library with “text” metadata  
• Content files are stored directly with metadata |
Quality Oriented Migration Phases

Plan
- Overall Project Planning
- Overall Technical Analysis
- Requirements Gathering

Development
- Create/Modify Utilities Based on Requirements

Validate
- Migration Utilities
- Migration Process

Migrate
- Export
- Transform
- Load
Data Migration Validation Deliverables

Plan
- Data Migration Plan
- Data Migration Requirements

Develop
- Data Migration Utilities

Validate
- Data Migration Test Protocol
  - Export
  - Transform
  - Load
  - Post-Load Verification
- Data Migration Summary Report

Migrate
- Migrated Production Data
### Key Data Migration Validation Deliverables

<table>
<thead>
<tr>
<th>Data Migration Plan</th>
<th>Data Migration Requirements</th>
<th>Data Migration Test Protocol</th>
<th>Data Migration Summary Report</th>
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<tbody>
<tr>
<td>• Outlines the approach</td>
<td>• Detailed export requirements</td>
<td>• Protocol Wrapper</td>
<td>• Documents results of Data Migration validation testing</td>
</tr>
<tr>
<td>• Explains the source and destination systems</td>
<td>• Detailed import requirements</td>
<td>• Export Test Script</td>
<td>• Prerequisite of releasing system to production</td>
</tr>
<tr>
<td>• Defines roles and responsibilities</td>
<td>• Field mapping</td>
<td>• Transformation Verification Script(s)</td>
<td>•</td>
</tr>
<tr>
<td></td>
<td>• Guides development of any custom tools</td>
<td>• Load Verification Script</td>
<td>•</td>
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<tr>
<td></td>
<td>• Provides traceability for Data Migration Test Protocol</td>
<td>• Error Handling Check</td>
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<td></td>
<td>• Post-Load Processing</td>
<td>•</td>
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<tr>
<td></td>
<td></td>
<td>• Version up</td>
<td>•</td>
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<tr>
<td></td>
<td></td>
<td>• Retire</td>
<td>•</td>
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<tr>
<td></td>
<td></td>
<td>• Periodic Review</td>
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Succeeding in Your Migration

Plan + Prepare + Process = Prosper

Drug Information Association

www.diahome.org
Conclusion
Questions

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