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Getting To and Through the FDA

Document Management For IND Stage Companies

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Melbourne Marriott

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Agenda

Document Management

- What is a document management system (DMS)?
- Why do I need one?
  - What does FDA require?
  - Are there other benefits?
- When is the best time to get a DMS?
- What might go wrong if I don’t have a DMS?
- What can go right if I have a DMS?
- How do I choose?
  - What features do I need in a DMS?
  - How much will a DMS cost?

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- What is a Document Management System (DMS)?
  - A DMS manages the creation, capture, indexing, storage, retrieval, and disposition of “records” - information assets of an organization.

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- The paper days – content storage:

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- The paper days – submission to FDA:

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- The paper days – submission archive:

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Today – content storage:

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Today – submission to FDA:

For a few special submission types:

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Today – submission archive:

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Why do I need a DMS?

- FDA requirement
  - GXP document control rules (predicate rules)
    - Nonclinical reports and data
    - Clinical reports and data
  - 21 CFR Part 11 – Electronic records and signatures
- Electronic (eCTD) submissions:
  - May 5, 2017: All NDA, ANDA, and certain BLA submissions
  - May 5, 2018: All IND submissions
  - May 5, 2019: DMFs

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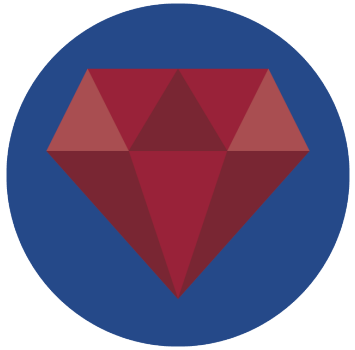
What does FDA require in a DMS?

- Controlled user access
- Version control
- Part 11 Audit trail
- System usage procedures
- System management procedures
- Cloud-based or hosted systems - encryption



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Practical benefits for a DMS

- Finding documents quickly and easily
  - McKinsey report - Employees spend 1.8 hours daily (9.3 hours weekly) searching for information
  - Interact: 19.8% of business time (1 working day per week) wasted searching for information
- Finding the right versions of documents
- Collaboration and due diligence
- Security
- Backup and recovery
- Portability

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When is the best time to get a DMS?

- When document creation begins
  - Patents
  - Initial nonclinical protocols
  - Preparing for your first IND

- Is it ever too late?
  - No!!
  - Can migrate content and reap benefits of a DMS
  - Strategic migration

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What might go wrong if I don't have a DMS?

Case study 1:

- 1 person start-up pharma company
- IND-stage
- Outsourced clinical activities to CRO who subcontracted regulatory IND preparation work
- Expected CRO to maintain and store original IND documents
- Consequence:
  - Paid CRO ~$30K+ US to recreate IND source word files from the PDF copies submitted
  - Caused 3-4 month delay to program

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What might go wrong if I don't have a DMS?

Case study 2:

- 5-person pharma company
- Conducting global clinical trial – Phase 2
- Terminated study
- Major health authority audited
- Company could not find original source documents
- Consequence:
  - Noncompliance findings in official audit report
  - ~$100K US spent over 2 years in remediation
  - Damaged company reputation

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What can go right if I have a DMS?

Case study 1:

- 5-person ex-US pharma company
- NDA-stage, new chemical entity
- Migrated content into DMS after phase 2
- Enabled 24-7 collaboration - 2 geographies and 3 time zones
- Documents organized by content area. Efficient document finalization/approval cycle
- One critical team member left the team - no loss of data!
- Prepared 2.4 GB (600+ file) NDA in less than 6 months!

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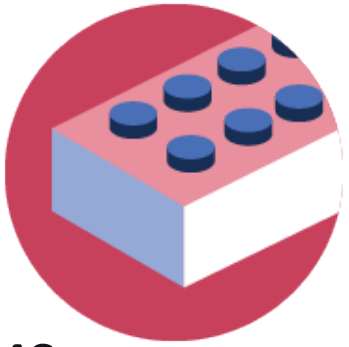
What can go right if I have a DMS?



Case study 2:

- 4-person pharma company
- IND-stage, new chemical entity
- Document security and version control issues prior to adopting DMS
- Adopted DMS to build IND
- Security restricted to a few users (and documents!)
- Version control issues resolved
- Using a DMS properly suited for cost and feature/function needs led to efficient preparation of IND without hiring more staff

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How do I choose a DMS? – Required Features

Feature	Required by FDA regulation	Optional
Controlled user access	X	
Version control	X	
Backup and recovery	X	
Part 11 Audit trail	X	
System usage procedures	X	
System management procedures	X	
Encryption	If cloud-based or hosted, X	

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How do I choose a DMS? – Optional Features

	Required by FDA regulation	Optional
Simple to use		X
Pre-set content organization		X
Workflows		X
Metadata		X
Automated messaging		X
Submission staging		X
Correspondence tracking		X

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How do I choose a DMS? – Required Feature Costs

Feature	$-$$$$
Controlled user access	$
Version control	$
Backup and recovery	$$-$$$
Part 11 Audit trail	$
System usage procedures	$-$$$$
System management procedures	$-$$$$
Cloud-based or hosted - encryption	$$$$

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How do I choose a DMS? – Optional Feature Costs

	$-$$$$
Simple to use	$
Pre-set content organization	$$-$$$$
Workflows	$$$
Metadata	$$
Automated messaging	$$-$$$$
Submission staging	NA - $

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- What can I expect to pay?
  - DMS range from ~$17K - $400K US for base software
  - + Validation fees
  - + Maintenance and storage fees
  - + Training
  - + Migration of existing documentation
- Software pricing is based on:
  - Product features
  - Number of users
  - Duration of use

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What about those “free” systems? – Required Features

	Box	Dropbox	Google Drive	OneDrive
Controlled user access	X	X	X	X
Version control	no	no	no	no
Backup and recovery	no	no	no	no
Part 11 audit trail	no	no	no	no
System usage procedures	no	no	no	no
System maintenance procedures	no	no	no	no
Encryption	no	no	no	no

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What about those “free” systems? – Optional Features

	Box	Dropbox	Google Drive	OneDrive
Simple to use	X	X	X	X
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Automated messaging	X	X	no	no
Submission staging	no	no	no	no

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So how do you decide?

- Evaluate development program and proactively plan to move to a DMS based electronic submissions to FDA
- Select from systems that meet FDA requirements
- Determine what optional features are desirable (not just available and fun) for your company's needs
- Evaluate cost vs benefit of optional features
- Don't forget "hidden costs"
- Don't forget "hidden benefits"
- Think both short- and long-term (company's overarching plans for growth, in-licensing, divesting, etc.)

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Summary

- A document management system (DMS) manages the creation, capture, indexing, storage, retrieval, and disposition of information of an organization.
- All companies who are creating documents for submission to FDA must have a DMS.
- The DMS must comply with all FDA regulations and guidances (and not all do!)
- There are practical benefits for small companies when they use a DMS.
- Choosing the right DMS involves balancing optional features, and costs.

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What's Next?

- BIO 2018 – Boston, MA
- SNMMI 2018 – Philadelphia, PA
- Future webinars:
  - Medical device regulatory development pathways
  - Expert services – Zeroing in on the best provider for you!
- Free Resources at www.facetlifesciences.com
  - Podcast
  - White Papers
  - Webinar Library

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Questions?

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