Using SharePoint 2013 for Managing Regulated Content in the Life Sciences

Presented by Paul Fenton
President and CEO, Montrium

www.montrium.com

Overview

- **Informative Webinar** that aims to provide an overview of how SharePoint can be validated for different regulated applications within **the Life Sciences**
- Slides can be distributed upon request. Details on how to request slides will be distributed to attendees following the webinar
- Feel free to ask questions in the **questions panel**
- You can also **Tweet** me at **@paulkfenton**
- Thank you for your interest!

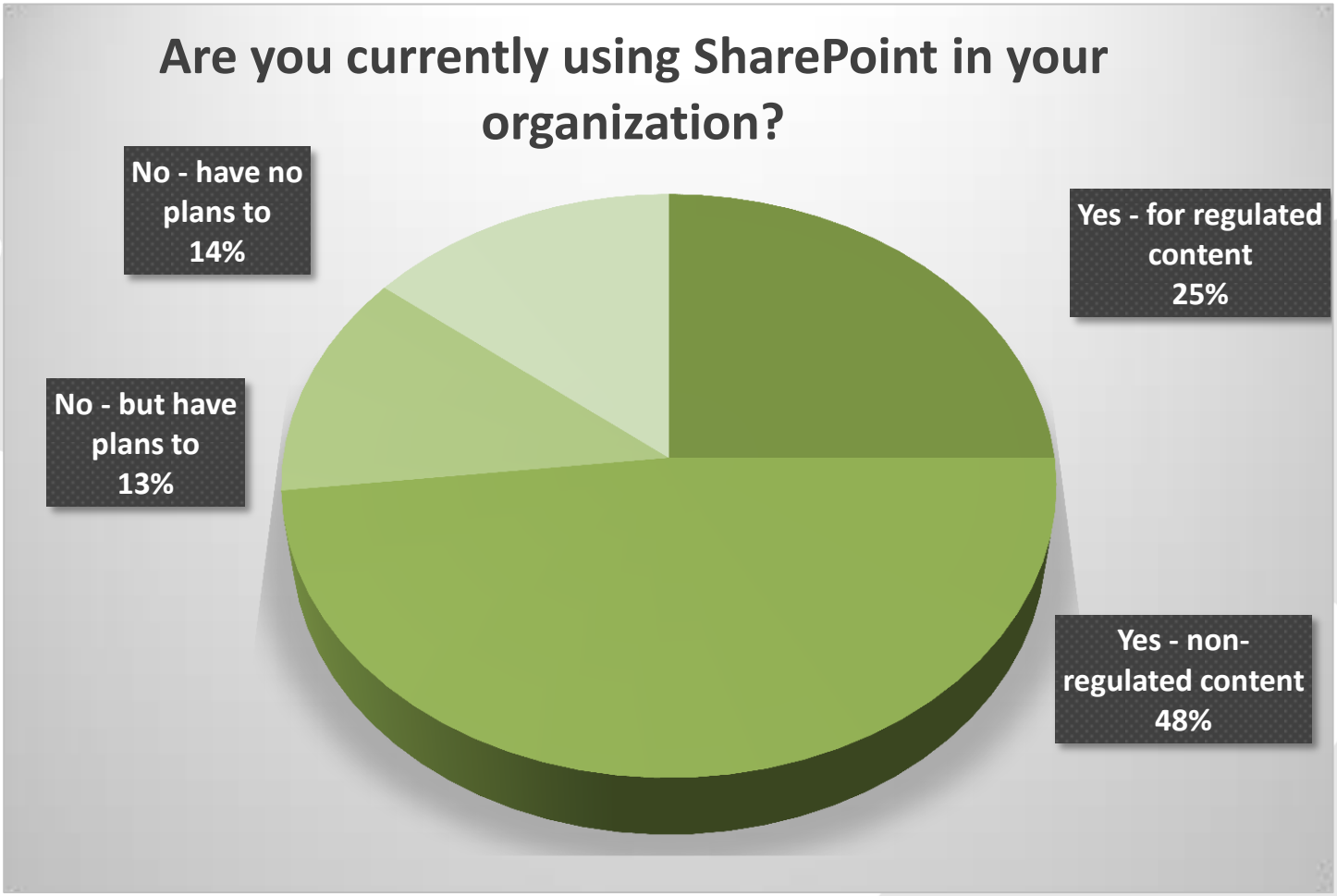
montrium
where people + processes + technology connect

Agenda

- Introduction
- What is regulated content?
- Regulatory Requirements
- How SharePoint can be configured to meet requirements
- SharePoint governance and qualification
- Deployment Options
- Advantages of SharePoint for regulated content
- Montrium's approach to providing solutions for regulated content
- Conclusion and recommendations

montrium
where people + processes + technology connect

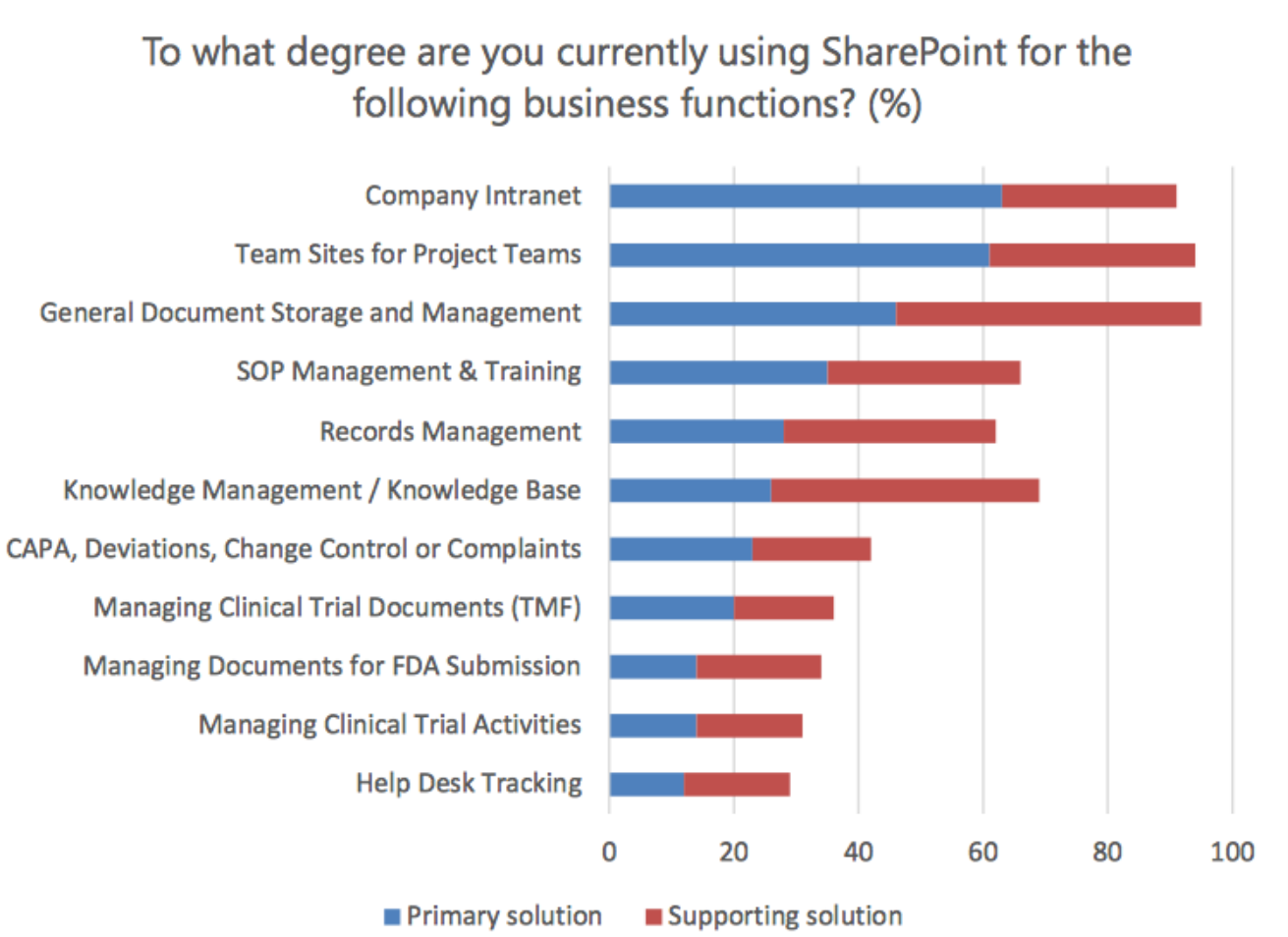
Are you using SharePoint?



Source: Webinar Registrants

montrium
where people + processes + technology connect

SharePoint Use in the Life Sciences



Source: State of SharePoint in Life Sciences in 2013

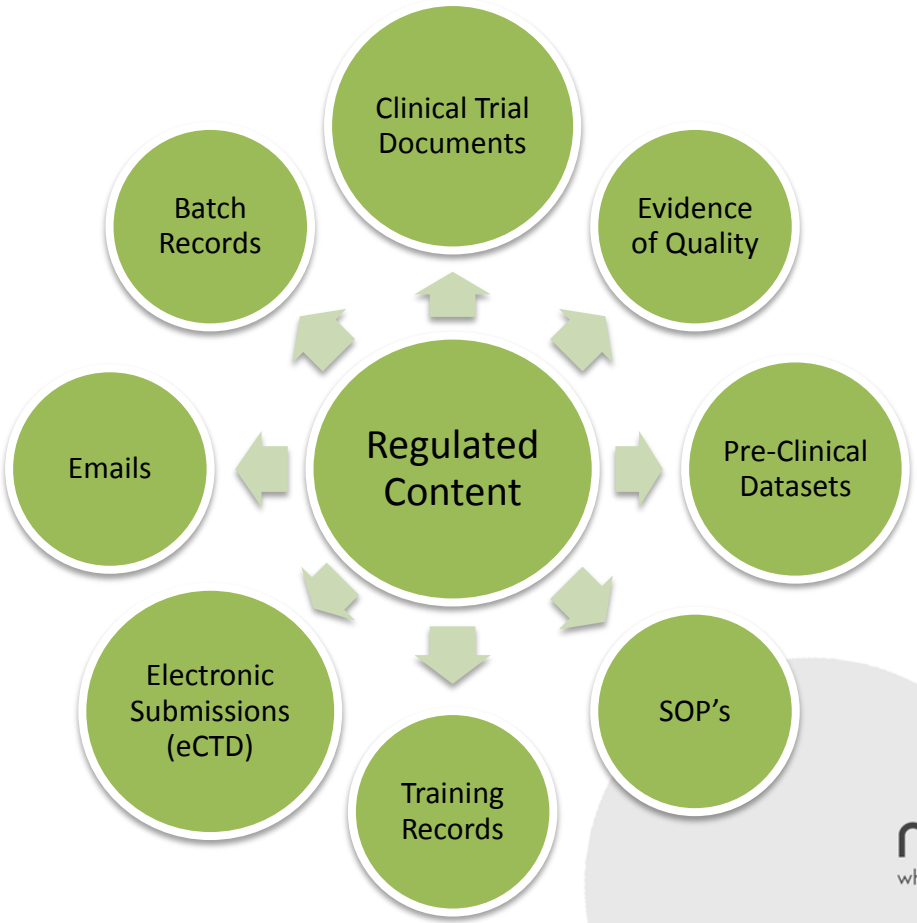
montrium
where people + processes + technology connect

Preliminary thoughts

- SharePoint is being used more and more in our industry for many **different applications**
- **Content management** is one of these
- There is sometimes a perception that SharePoint **cannot be used** for regulated content
- As with any system we need to determine if it has **regulatory relevance** and **validate / control** accordingly

What is regulated content?

- Any document, record, evidence or data that is required to be maintained by predicate rule.



montrium
where people + processes + technology connect

What isn't regulated content

- Any document or data which is not required by predicate rule.
- Even if documents are **not required** by predicate rule, **but do** support **regulated decisions,** they may need to be maintained as records.

montrium
where people + processes + technology connect

Poll

- In your organization, how is regulated content currently managed?

montrium
where people + processes + technology connect

How to identify electronic records

- **21 CFR Part 11** defines electronic records as:
  - Records that are required to be **maintained under predicate rule** requirements and that are maintained in electronic format ***in place of paper format***
  - **Records** that are required to be maintained under predicate rules, that are maintained in electronic format ***in addition*** *to paper format, and* ***that are relied on to perform regulated activities***

How to identify electronic records

- **21 CFR Part 11** defines electronic records as:
  - **Records submitted to FDA**, under predicate rules (even if such records are not specifically identified in Agency regulations) in **electronic format**
  - **Electronic signatures** that are intended to be the equivalent of handwritten signatures, initials, and other general signings **required by predicate rules**

How to identify electronic records

Does the record exist in electronic format only with no paper source?

Yes

No

Is an electronic copy of a paper record?

Yes

Does it drive regulated processes/decisions?

No

Is it required by predicate rule?

Yes

Yes

montrium
where people + processes + technology connect

Electronic Records within SharePoint

Records within the context of SharePoint could be:

- **Documents** (excluding descriptive metadata) required to be maintained by predicate rule.
- **Metadata** (Columns) used to perform regulated activities (or make regulated decisions).
- **InfoPath** forms used to document regulated activities

Electronic Records within SharePoint

- **Electronic / Digital Signatures** used to sign records required by predicate rules
- **Audit Trails** generated for electronic records being generated and/or managed in SharePoint
- **Custom Applications** deployed within SharePoint and used for regulated activities

Compliance approach

- **Goal:**
  - Ensure SharePoint can meet the **requirements** for 21 CFR Part 11 **Electronic Records**
- **How:**
  - Identify all **procedural** and **technical** controls
  - Document and verify **configuration**
  - **Maintain** under change and configuration control
  - **Deploy** regulated applications

Compliance approach

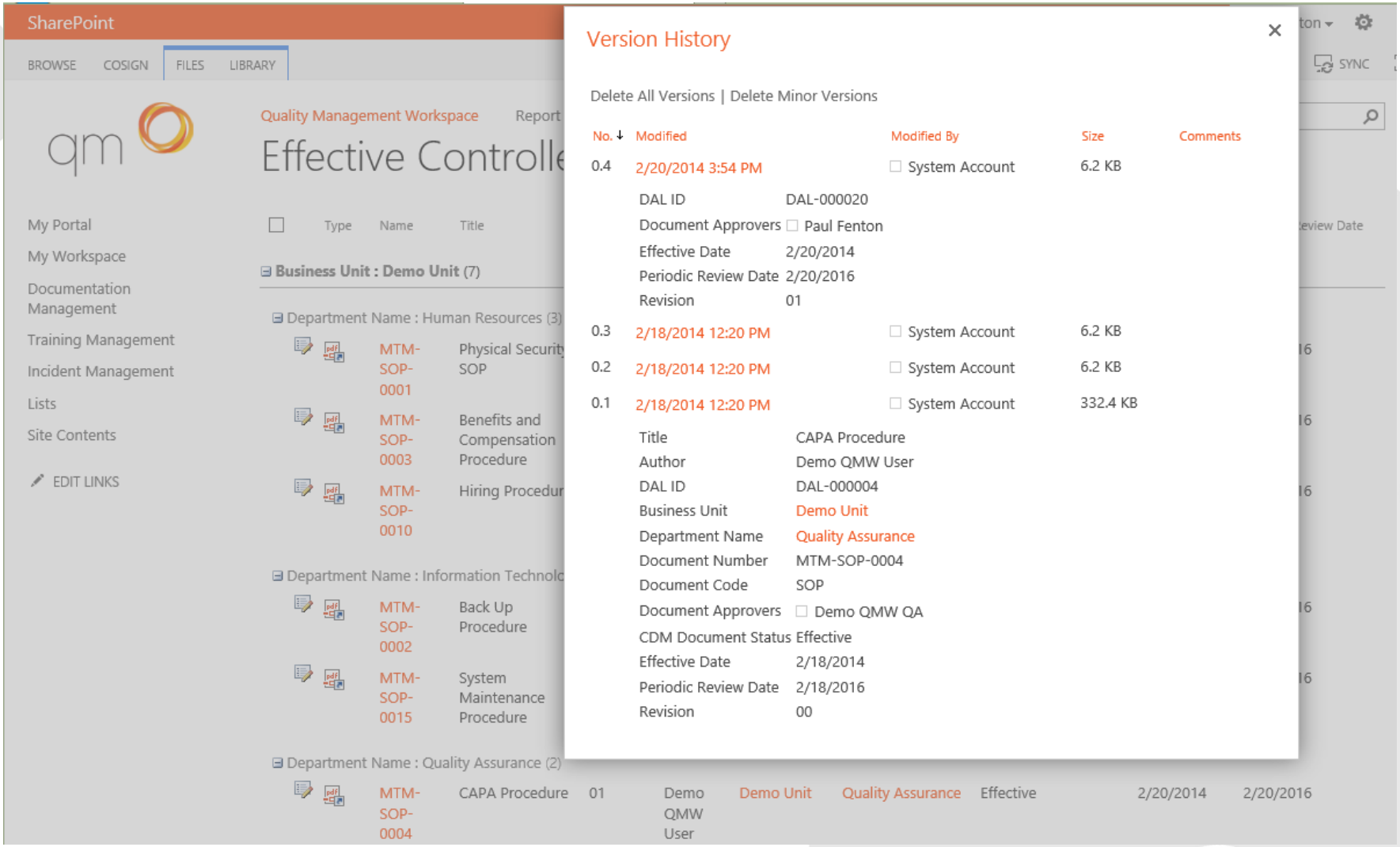
- **Out of Scope:**
  - SharePoint **does not** natively provide an **electronic signature** function
  - If implementing a **3rd party** electronic signature solution, perform a **separate** validation exercise

Regulatory Requirements – 21 CFR Part 11

- **Requirement:** **11:10(b)**: Ability to generate accurate and complete copies of records in both human readable and electronic form

- **Control:** SharePoint maintains just one copy of a record in addition to version history

Version History

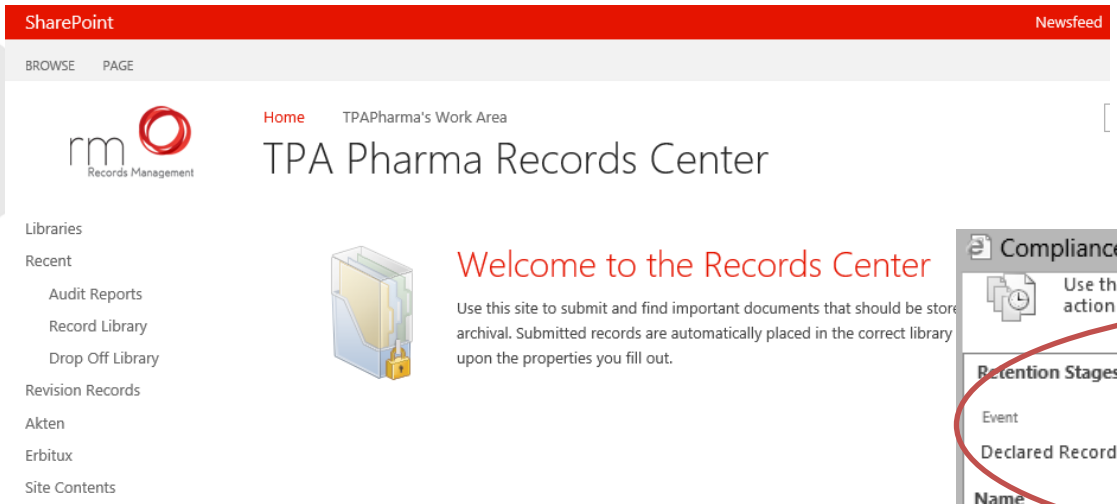


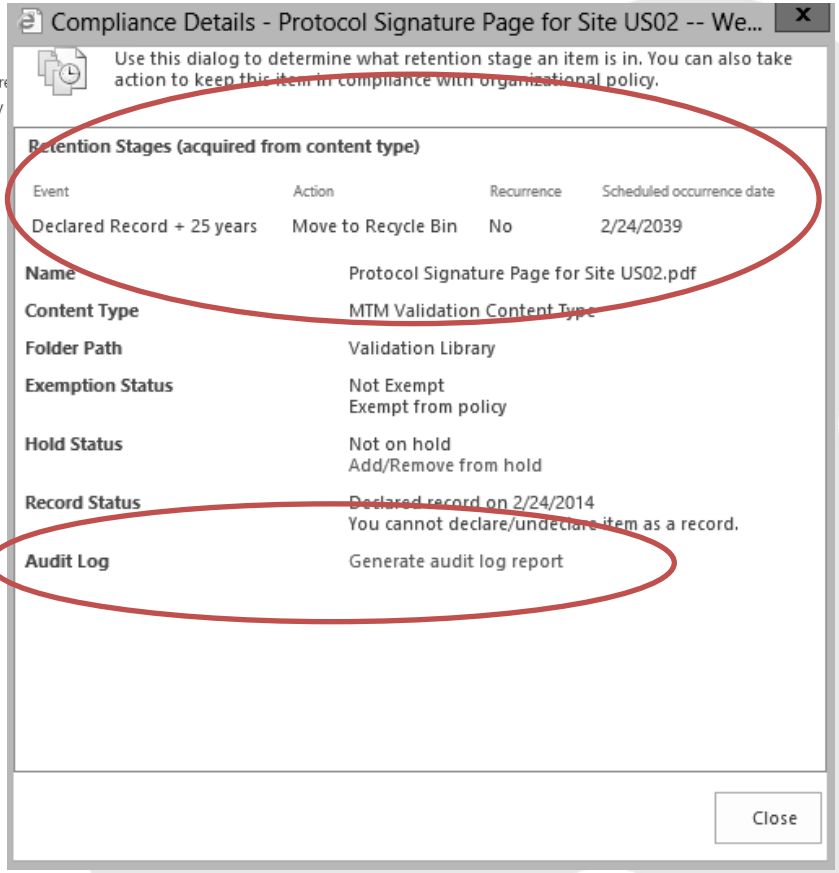
Regulatory Requirements – 21 CFR Part 11

- **Requirement: 11.10(c)**:Protection of records to enable their accurate and ready retrieval throughout the records retention period

- **Control:** SharePoint has a built-in record center which allows the retention and retrieval of records

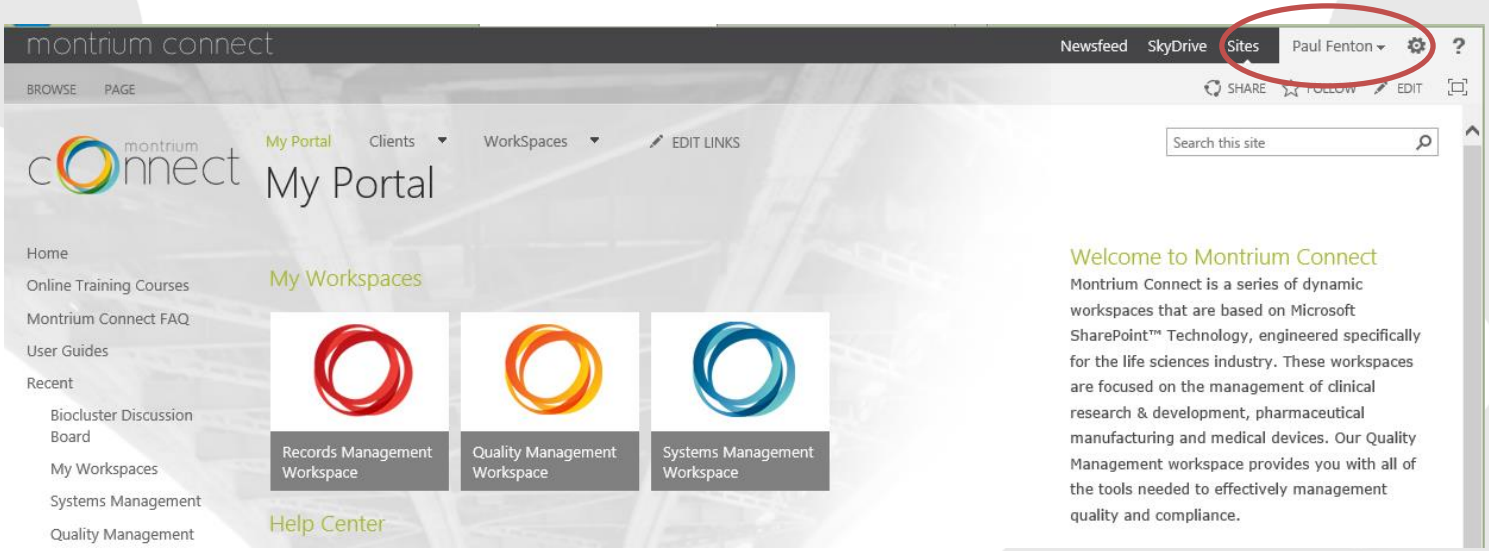
Records Center





Regulatory Requirements – 21 CFR Part 11

- **Requirement: 11.10(d)**: Limiting system access to authorized individuals
- **Control:** Windows authentication and granular security model



montrium
where people + processes + technology connect

Regulatory Requirements – 21 CFR Part 11

- **Requirement: 11:10(e)**: Use of secure, computer generated, time stamped audit trails to independently record the date and time of operator entries.

- **Control:** SharePoint auditing
  - Full auditing feature which can be enabled on all content
  - Audit trails remain linked to respective records
  - Audit trail reports can be generated in Excel

Example of Standard Audit Report

FILE | OPEN IN EXCEL | DATA | FIND

	A	B	C	D	E	F	G	I	J	K
1	Site Url	http://demo2013/sites/qmw-RC								
2										
3	Site Id	Item Id	Item Type	User Id	Document Location	Occurred (GMT)	Event	Event Source	Source Name	Event Data
4	{6dbff6e6-00d9-4d72-90f	{e043a895-e709-4a	Document	System Account <SHAREPOINT\system>	sites/qmw-RC/QA Documents/MTM-SOP-0004.pdf	2014-02-18T17:20:44	Update	SharePoint		<Version><Major>1</Major><Minor>0</Minor></Version>
5	{6dbff6e6-00d9-4d72-90f	{e043a895-e709-4a	Document	System Account <SHAREPOINT\system>	sites/qmw-RC/QA Documents/MTM-SOP-0004.pdf	2014-02-18T17:20:44	Update	SharePoint		<Version><Major>1</Major><Minor>0</Minor></Version>
6	{6dbff6e6-00d9-4d72-90f	{e043a895-e709-4a	Document	System Account <SHAREPOINT\system>	sites/qmw-RC/QA Documents/MTM-SOP-0004.pdf	2014-02-18T17:20:44	Update	SharePoint		<Version><Major>1</Major><Minor>0</Minor></Version>
7	{6dbff6e6-00d9-4d72-90f	{e043a895-e709-4a	Document	System Account <SHAREPOINT\system>	sites/qmw-RC/QA Documents/MTM-SOP-0004.pdf	2014-02-18T17:20:45	Update	SharePoint		
8	{6dbff6e6-00d9-4d72-90f	{e043a895-e709-4a	List	System Account <SHAREPOINT\system>	sites/qmw-RC/QA Documents	2014-02-18T17:20:45	Update	SharePoint		MTM-SOP-0004.pdf
9	{6dbff6e6-00d9-4d72-90f	{e043a895-e709-4a	Document	System Account <SHAREPOINT\system>	sites/qmw-RC/QA Documents/MTM-SOP-0004.pdf	2014-02-18T17:20:45	Custom	Object Model	Submission Complete	<RecordsRepositorySubmission><Properties><Property>
10	{6dbff6e6-00d9-4d72-90f	{e043a895-e709-4a	Document	System Account <SHAREPOINT\system>	sites/qmw-RC/QA Documents/MTM-SOP-0004.pdf	2014-02-18T17:20:46	Update	SharePoint		<Version><Major>1</Major><Minor>0</Minor></Version>
11	{6dbff6e6-00d9-4d72-90f	{e043a895-e709-4a	Document	SP_CRAWL <i:0#.w|eclinica\sp_crawl>	sites/qmw-RC/QA Documents/MTM-SOP-0004.pdf	2014-02-18T18:56:04	View	SharePoint		<Version><Major>1</Major><Minor>0</Minor></Version>
12	{6dbff6e6-00d9-4d72-90f	{e043a895-e709-4a	Document	SP_CRAWL <i:0#.w|eclinica\sp_crawl>	sites/qmw-RC/QA Documents/MTM-SOP-0004.pdf	2014-02-19T04:56:39	View	SharePoint		<Version><Major>1</Major><Minor>0</Minor></Version>
13	{6dbff6e6-00d9-4d72-90f	{e043a895-e709-4a	Document	SP_CRAWL <i:0#.w|eclinica\sp_crawl>	sites/qmw-RC/QA Documents/MTM-SOP-0004.pdf	2014-02-20T04:56:29	View	SharePoint		<Version><Major>1</Major><Minor>0</Minor></Version>
14	{6dbff6e6-00d9-4d72-90f	{e043a895-e709-4a	Document	Scott McGrail <i:0#.w|eclinica\smcgrail>	sites/qmw-RC/QA Documents/MTM-SOP-0004.pdf	2014-02-20T18:43:17	View	SharePoint		<Version><Major>1</Major><Minor>0</Minor></Version>
15	{6dbff6e6-00d9-4d72-90f	{e043a895-e709-4a	Document	System Account <SHAREPOINT\system>	sites/qmw-RC/QA Documents/MTM-SOP-0004.pdf	2014-02-20T20:53:58	Update	SharePoint		<Version><Major>2</Major><Minor>0</Minor></Version>
16	{6dbff6e6-00d9-4d72-90f	{e043a895-e709-4a	Document	System Account <SHAREPOINT\system>	sites/qmw-RC/QA Documents/MTM-SOP-0004.pdf	2014-02-20T20:53:58	Update	SharePoint		<Version><Major>2</Major><Minor>0</Minor></Version>
17	{6dbff6e6-00d9-4d72-90f	{e043a895-e709-4a	Document	System Account <SHAREPOINT\system>	sites/qmw-RC/QA Documents/MTM-SOP-0004.pdf	2014-02-20T20:53:58	Update	SharePoint		<Version><Major>2</Major><Minor>0</Minor></Version>
18	{6dbff6e6-00d9-4d72-90f	{e043a895-e709-4a	Document	System Account <SHAREPOINT\system>	sites/qmw-RC/QA Documents/MTM-SOP-0004.pdf	2014-02-20T20:53:58	Custom	Object Model	Submission Complete	<RecordsRepositorySubmission><Properties><Property>
19	{6dbff6e6-00d9-4d72-90f	{e043a895-e709-4a	Document	System Account <SHAREPOINT\system>	sites/qmw-RC/QA Documents/MTM-SOP-0004.pdf	2014-02-20T20:54:00	Update	SharePoint		<Version><Major>2</Major><Minor>0</Minor></Version>
20	{6dbff6e6-00d9-4d72-90f	{e043a895-e709-4a	Document	SP_CRAWL <i:0#.w|eclinica\sp_crawl>	sites/qmw-RC/QA Documents/MTM-SOP-0004.pdf	2014-02-20T20:55:34	View	SharePoint		<Version><Major>2</Major><Minor>0</Minor></Version>
21	{6dbff6e6-00d9-4d72-90f	{e043a895-e709-4a	Document	SP_CRAWL <i:0#.w|eclinica\sp_crawl>	sites/qmw-RC/QA Documents/MTM-SOP-0004.pdf	2014-02-21T04:56:05	View	SharePoint		<Version><Major>2</Major><Minor>0</Minor></Version>
22	{6dbff6e6-00d9-4d72-90f	{e043a895-e709-4a	Document	SP_CRAWL <i:0#.w|eclinica\sp_crawl>	sites/qmw-RC/QA Documents/MTM-SOP-0004.pdf	2014-02-22T04:56:18	View	SharePoint		<Version><Major>2</Major><Minor>0</Minor></Version>
23	{6dbff6e6-00d9-4d72-90f	{e043a895-e709-4a	Document	SP_CRAWL <i:0#.w|eclinica\sp_crawl>	sites/qmw-RC/QA Documents/MTM-SOP-0004.pdf	2014-02-23T04:55:58	View	SharePoint		<Version><Major>2</Major><Minor>0</Minor></Version>
24	{6dbff6e6-00d9-4d72-90f	{e043a895-e709-4a	Document	SP_CRAWL <i:0#.w|eclinica\sp_crawl>	sites/qmw-RC/QA Documents/MTM-SOP-0004.pdf	2014-02-24T04:56:09	View	SharePoint		<Version><Major>2</Major><Minor>0</Minor></Version>
25										

Item Id	User Id	Occurred (GMT)	Event	Event Data
{e043a895-e709-4a	Scott McGrail <i:0#.w|eclinica\smcgrail>	2014-02-20T20:54:00	Update	<Version><Major>2</Major><Minor>0</Minor></Version>

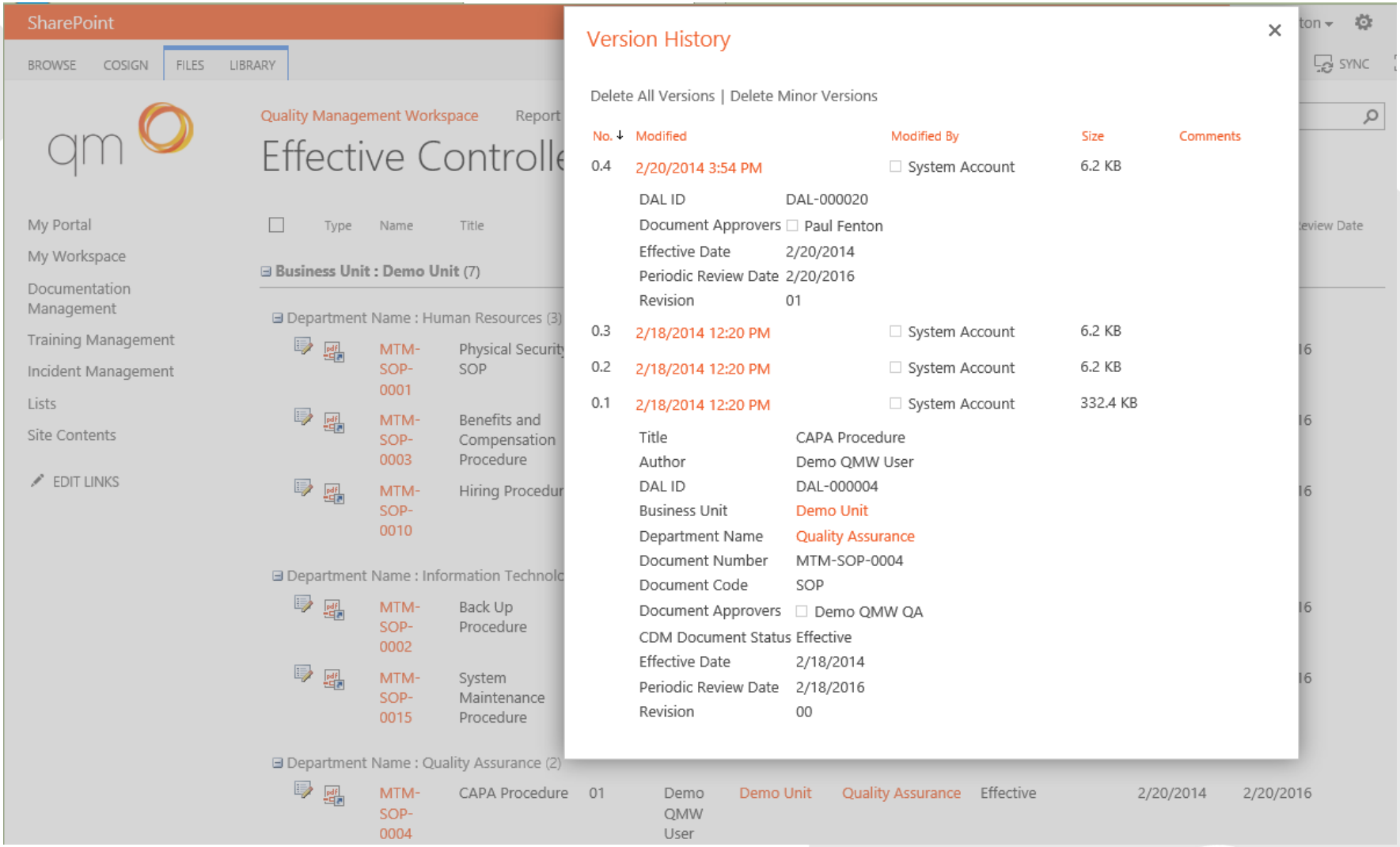
montrium
where people + processes + technology connect

Regulatory Requirements – 21 CFR Part 11

- **Requirement: 11.10(e)**: Record changes should not obscure previous entries

- **Control:** Version history of content or metadata is maintained

Version History



Regulatory Requirements – 21 CFR Part 11

- **Requirement: 11.10(f):** Use of operational steps to enforce permitted sequencing of steps and events
- **Control:** Would be managed in specific applications deployed to SharePoint

- **Requirement: 11.10(g):**Use of authority checks to ensure that only authorized individuals can use the system….
- **Control:** Managed through a combination of Active Directory and SharePoint security for authentication and user rights management

- **Requirement: 11.10(h):** Use of device checks
- **Control:** Would be managed by specific applications deployed to SharePoint

Regulatory Requirements – 21 CFR Part 11

- **Requirement:** **11.30**: Persons who use open systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt.
- **Control:**
  - Use of VPN, SSL or other encryption techniques to protect data as it transits over public networks
  - Use of authentication controls as in 11.10(d)

Qualification of SharePoint

- Focus on qualifying the **baseline features** of SharePoint which allow you to meet 21 CFR Part 11 requirements
- Complete a **regulatory assessment matrix** which defines the different technical and procedural controls
- Produce a **specification document** which details how each technical control must be configured
- Execute an **Installation Qualification** (IQ) which documents that all installation steps were completed correctly

Qualification of SharePoint

- Document all **configuration parameters** in the IQ or configuration specification
- Perform **operational qualification tests** to ensure that the configuration has been properly implemented
- Summarize the qualification in a **summary report**
- Ensure SharePoint falls under **change control** and **configuration control**
- Implement a **governance plan** and relevant **SOPs**

Corporate SharePoint Standards

- Clear and formal corporate **taxonomies** aligned with **industry standards** (TMF Ref Model, eCTD etc)
- Document **classification** and records management / retention standards and policies
- Uniform **Site structures**, site templates, **content types** and **metadata** standards across all departmental sites and libraries (should be aligned with Taxonomy)
- Security matrix and standards
- Numbering and **Nomenclature** standards

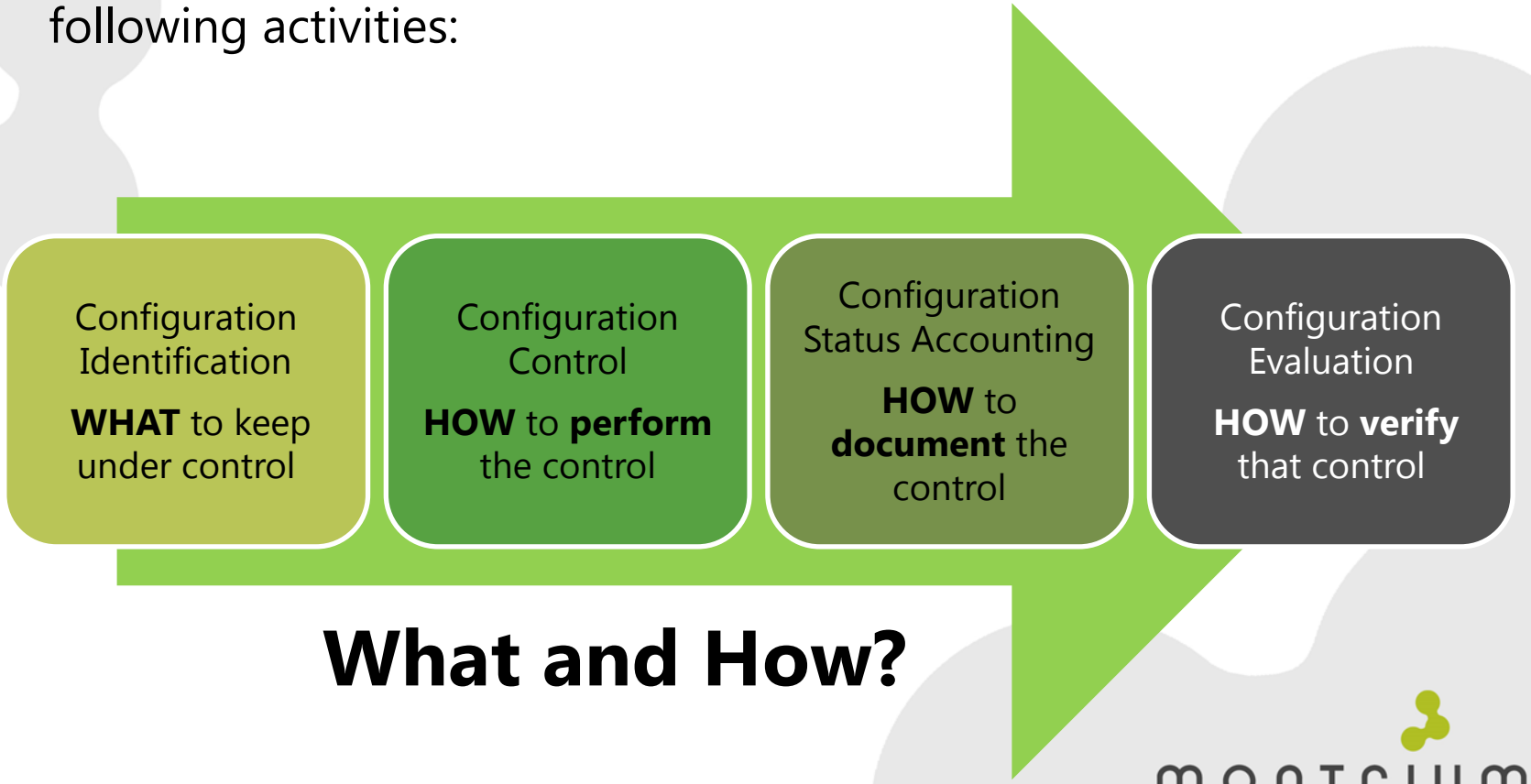
Poll

- Do you have formal standards, structures, and rules for regulated content?

montrium
where people + processes + technology connect

What is Configuration Management?

- According to GAMP 5, configuration management consists of the following activities:

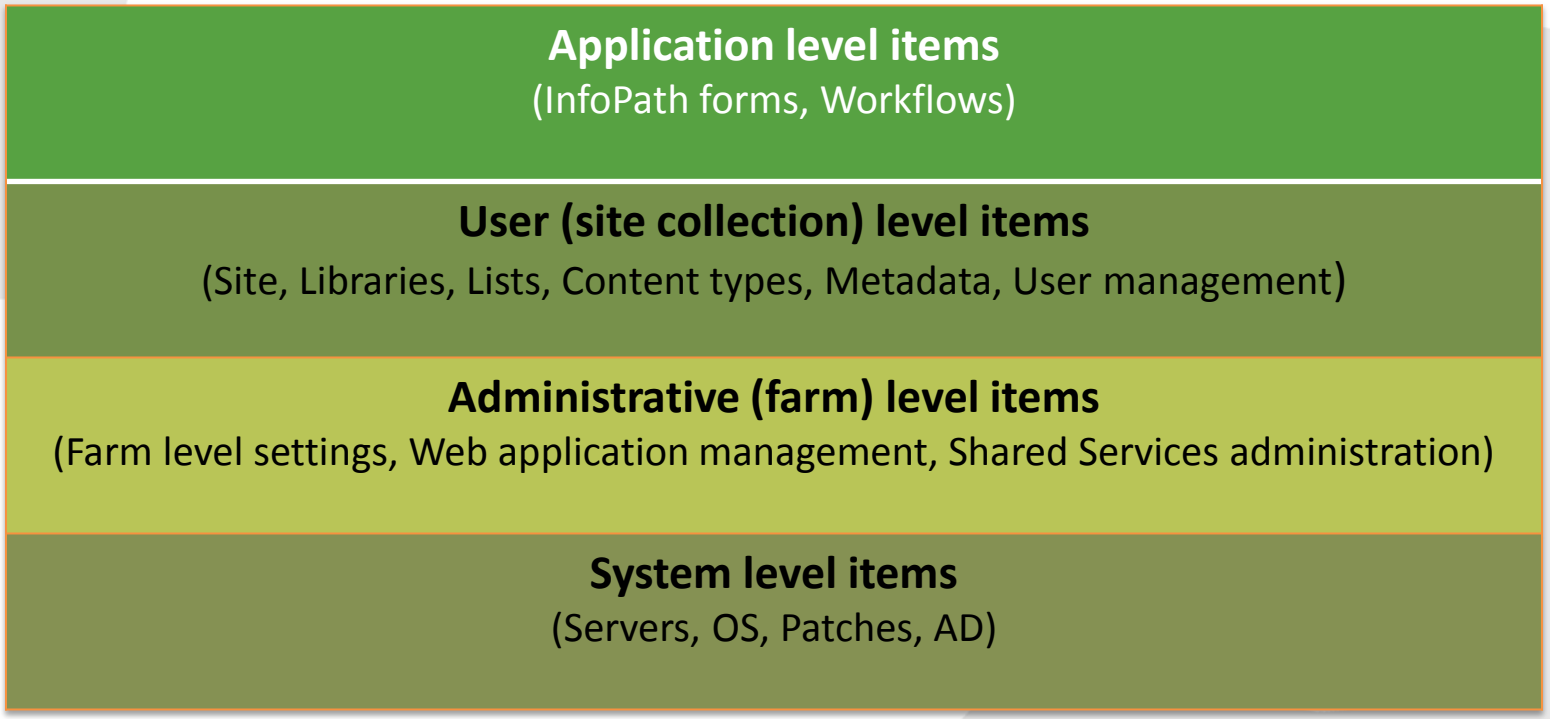


What and How?

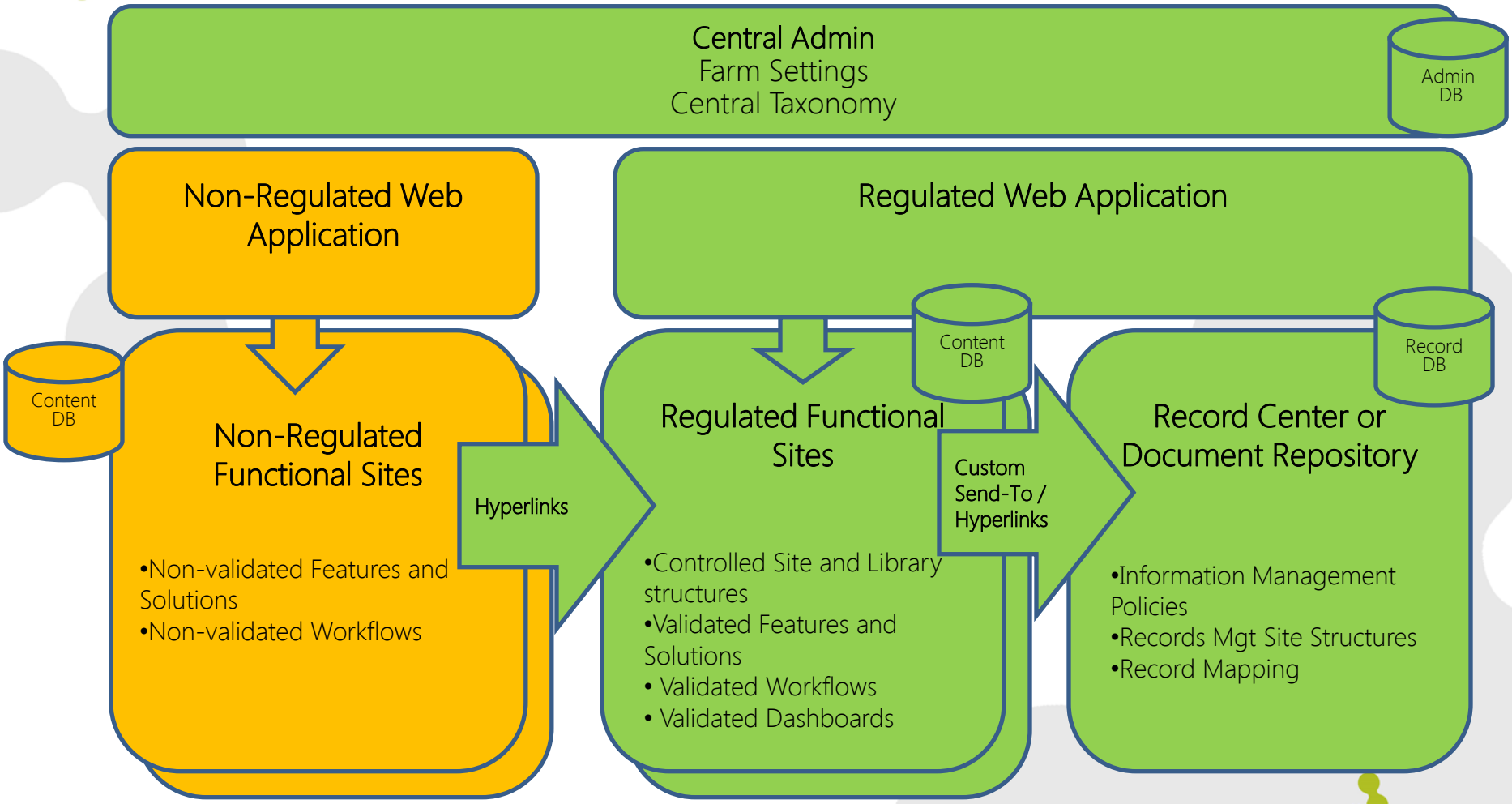
montrium
where people + processes + technology connect

Configuration Identification

The configuration items for SharePoint can be divided into 4 levels:



Regulated vs. Non-Regulated



montrium
where people + processes + technology connect

SharePoint Formal Procedures

- In order to use SharePoint for **regulated activities**, a clear process for deploying and controlling the environment is required
- This process should **aim to document** the design, configuration, QC and maintenance of **controlled** SharePoint workspaces including **3rd party applications**
- **Required** SOPs:
  - SharePoint Admin/Configuration SOP
  - Configuration Management SOP
  - Change Control SOP
  - Other IT SOPs such as Disaster Recovery, Backup, Security, Non-Conformance Management

Importance of governance

To ensure that:

- SharePoint **content organization** is standardized across the enterprise
- SharePoint is properly **structured** to allow flexibility while maintaining control
- Clear **roles and responsibilities** for the management of the platform are established
- There is proper integration with the **change control** and **configuration control** processes
- That SharePoint remains **manageable** and in a **validated controlled state**

Governance Plan - TOC

Table of Contents

1.0 Introduction / Purpose 5
2.0 Scope 5
3.0 Definitions 5
4.0 Roles and Responsibilities 7
4.1 Enterprise Level 7
4.1.1 Executive Sponsor 7
4.1.2 IT Steering Committee 7
4.1.3 SharePoint Governance Board 7
4.1.4 Regulated Content Governance Board 7
4.1.5 SharePoint Business Owner 7
4.1.6 SharePoint Administrator 7
4.1.7 Technology Backend Support 8
4.1.8 Technical Content Support (Software Development Department) 8
4.2 Site or Site Collection Level 8
4.2.1 SharePoint Site Sponsor (Business Owner/SMEs) 8
4.2.2 SharePoint Site Administrator (Super User) 8
4.2.3 SharePoint Content Reviewer 8
4.2.4 Users 8
5.0 IT Governance 9
5.1 Procedures and Policies 9
5.1.1 Computer Systems Validation 9
5.1.2 Physical Security 9
5.1.3 Logical Security 9
5.1.4 Records Retention and Archiving 10
5.1.5 System Administration and Maintenance 10
5.1.6 User Access Management 14
5.1.7 Backup and Restoration 15
5.1.8 Training Management 15
5.1.9 Documentation Management 16
5.1.10 Incident and Problem Management (Helpdesk) 16
5.1.11 Change / Configuration Management 17
5.1.12 Communication Plan 19

montrium	GOVERNANCE PLAN	Reference N°: [Document Number] Revision: 00
	TITLE SharePoint Governance Plan	

5.2 Asset Classification 19
5.3 Service Level Agreements 19
6.0 Information Management 20
6.1 Information Architecture 20
6.2 Site Lifecycle Management 20
6.2.1 Non-Controlled Site Templates 21
6.2.2 Controlled Site Templates 21
6.3 Central Taxonomy (Content Types, Site Columns, Central Lists) 21
6.4 Content Policies and Standards 21
6.4.1 Regulated Content 21
6.4.2 Non - Regulated Content 21
6.5 Information Access (User Access) Management 22
6.5.1 Security Matrix 22
7.0 Application Management 22
7.1 Customization Policy 22
7.2 3rd Party Integration, Web Parts / 3rd Party SharePoint based Solutions and Add-ons 22
7.3 Sandboxed Solutions 23
7.4 Branding 23
8.0 References 24
9.0 Appendices 25
A.0 Information Architecture 25
B.0 Security Matrix Template 25
C.0 Configure diagnostic logging (SharePoint Server 2010) 26
C.1 Best practices 26
C.1.1 Event log levels 27
C.1.2 Trace log levels 27
C.2 Configure diagnostic logging by using Central Administration 27
C.2.1 To configure diagnostic logging by using Central Administration 28
C.3 Configure diagnostic logging by using Windows PowerShell 28
D.0 Configure SharePoint Health Analyzer timer jobs (SharePoint Server 2010) 30
D.1 Use Central Administration to configure health data collection timer jobs 30

Deployment Options – To cloud or not to cloud?

- SharePoint can be deployed on **cloud based** environment
- **Windows Azure** supports cloud based SharePoint deployments
- **Office 365** also has an enterprise version of SharePoint Online which can be qualified
- Ensure the **same** adequate procedural and technical **controls** are in place
- Perform proper **due diligence** – you are still **responsible**
- You **still** need to **qualify** the Cloud and SharePoint environments unless it is fully managed by the vendor

Advantages of SharePoint for Regulated Content Management

- **Versatile** and **flexible** system which can be used across the enterprise for regulated and non-regulated content
- Can significantly improve **collaboration** and **traceability**
- Can be **easily qualified** to meet the requirements of **21 CFR Part 11**
- Can **replace** many of the **ad-hoc tools** used within GxP environments
- Can significantly improve **information** and **knowledge** management
- Can **reduce** total **cost** of ownership of regulated systems

SharePoint Validation and Governance Packs

SharePoint Validation Pack (2010, 2013)

- Built to be adapted to any organization
- Allows you to properly install and clearly document your SharePoint farm to meet part 11 requirements
- Based on GAMP 5

Governance Plan Template Pack

- Provides a governance plan template
- Uses industry best practices on governance of SharePoint
- Templates of necessary IT SOPs to meet part 11 requirements

montrium
where people + processes + technology connect

Montrium Connect Platform

SharePoint

montrium connect

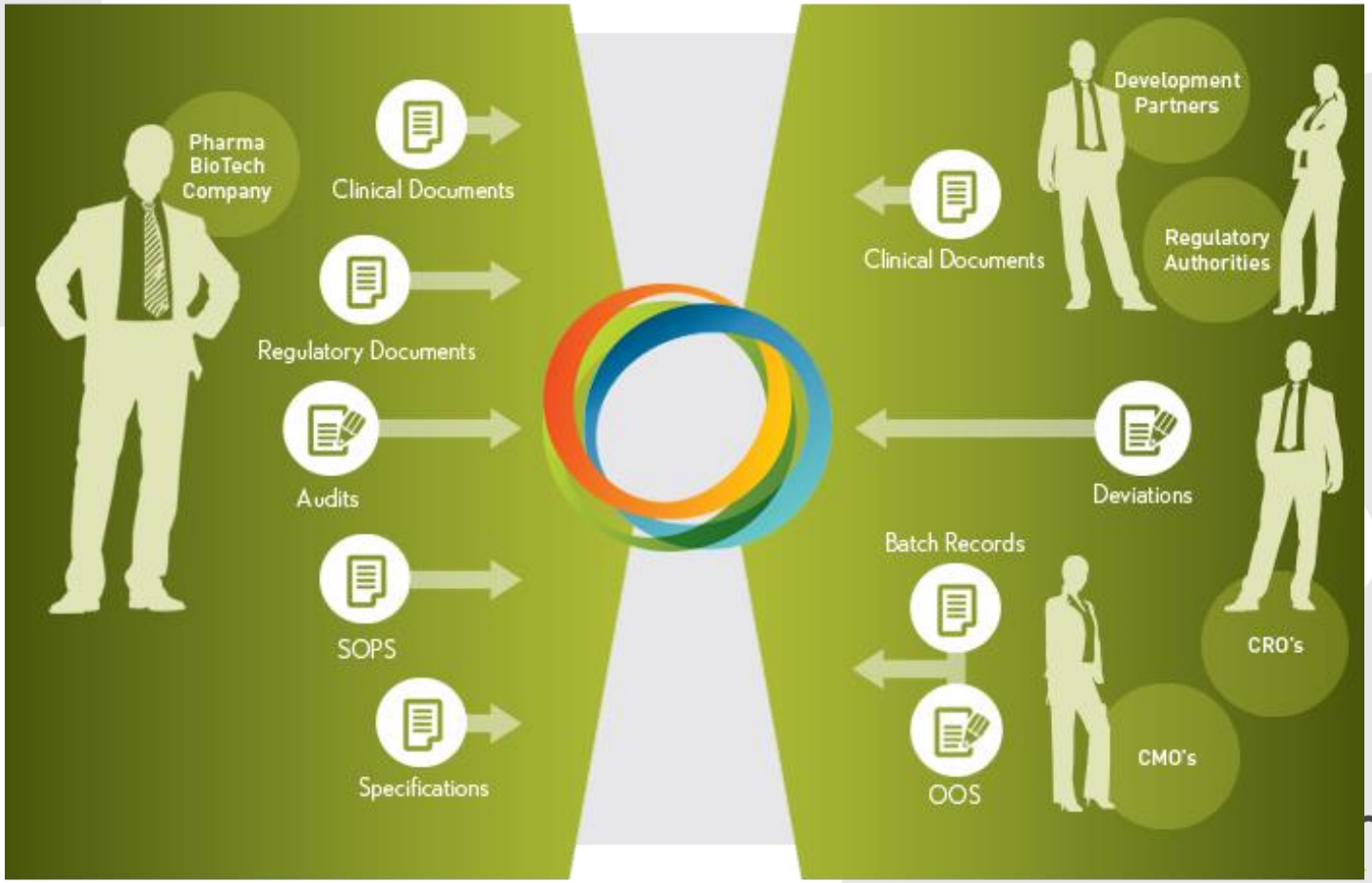
Windows Azure

montrium

where people + processes + technology connect

Centralized Collaboration

montrium connect



technology connect

Final Recommendations

- Clearly **identify** which regulated **content** could be managed within SharePoint
- Establish an **enterprise architecture** of your SharePoint environment
- Ensure that **SharePoint** is properly **qualified**
- Implement a strong **governance plan** and SOPs
- Leverage SharePoint as an **enterprise platform** to **consolidate** your existing regulated content sources
- Build out in a **step by step** manner

Poll

Based on the content provided in this webinar…Would you now consider using SharePoint for managing regulated content?

montrium
where people + processes + technology connect

Q&A

- Feel free to type questions in the question window of the webinar
- We will aim to answer them for you

montrium
where people + processes + technology connect

Contact Details

Montrium Inc.
507 Place d'Armes, Suite 1050
Montreal (QC) H2Y 2W8
Canada
+1.514-223-9153

Montrium S.A.
9, Avenue des Hauts-Fourneaux,
L-4362 Esch sur Alzette
Luxembourg
+352.20.88.01.30

pfenton@montrium.com

www.montrium.com

montrium
where people + processes + technology connect