



SharePoint Validation Pack

Are you looking to use SharePoint for regulated applications?

If so, you need to know how to best structure your validation approach to meet the requirements of 21 CFR Part 11 electronic records, while also minimizing the scope of the validation process.

To help you meet this challenge, Montrium has created a **validation pack** comprised of a series of **proven documents** and test scripts that allow you to **quickly and cost effectively qualify the baseline SharePoint* environment in weeks rather than months.**

Developing these validation documents on your own could take as long as five months. Implementing the SharePoint Validation Pack at a cost of only \$4,500 USD saves time and money by allowing you to allocate your limited resources toward other mission critical activities.

The documents have been developed to enable you to adopt and execute them on your own, however if you don't have the internal resources, Montrium's team of validation experts can help.

ACHIEVE REGULATORY COMPLIANCE

- Validate standard SharePoint functionality
- Allow use of SharePoint for regulated applications
- Step-by-step instructions for configuring a compliant Record Center

ENSURE TRACEABILITY AND CONTROL

- Link regulatory requirements with SharePoint functional specifications
- Configuration checklists help document system parameters
- All documents based on the GAMP5 industry standard

SAVE TIME & MONEY

- Proven documents minimize costly deviations
- Risk based approach focused on validating system functionality
- Easy to adapt to your existing validation procedures and IT environment



WHERE PEOPLE + PROCESSES + TECHNOLOGY CONNECT



SharePoint Validation Pack

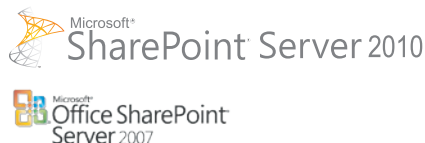
DOCUMENT	PURPOSE
User Requirement Specification	Identifies the requirements pertaining to electronic records management in SharePoint.
Validation Assessment	Assesses the regulatory impact of using the SharePoint application to generate and/or manage electronic records.
Functional Specification	Identifies functionality contained within the SharePoint application which can be used to meet the requirements pertaining to electronic records management.
Validation Plan	Describes the approach that will be taken to ensure that the SharePoint application is fully validated in accordance with applicable regulations.
Installation Qualification Protocol & Test Scripts	Defines the test strategy, procedures, documentation, and acceptance criteria that will be used in the verification of the proper installation of SharePoint and all its related components (hardware and software). Provides detailed SharePoint installation and Record Center configuration instructions.
Operation Qualification Protocol & Test Scripts	Defines the test strategy, procedures, documentation, and acceptance criteria to verify that the SharePoint application is properly configured and that it functions according to 21 CFR Part 11 regulations for electronic records management. Provides detailed step-by-step instructions for the tester to follow during test execution.
Validation Summary Report	Summarizes the entire validation effort as well as its outcome. Authorizes the release of the system for production use.

VALIDATION AND IMPLEMENTATION SERVICES

Montrium provides a full suite of services to help adapt the validation pack to your environment, execute validation and configure your 21 CFR Part 11 compliant SharePoint environments. Our team has significant expertise in both the deployment of validated SharePoint environments, as well as in the implementation of third party tools and the integration of SharePoint with other regulated systems.

21 CFR PART 11 COMPLIANT DIGITAL SIGNATURES

SharePoint does not have out-of-the-box 21 CFR Part 11 electronic signature capabilities. To offer you a fully electronic solution, Montrium has partnered with Arx, the industry's leading digital signature provider, to provide an integrated 21 CFR Part 11 compliant CoSign digital signature solution. Montrium has developed a full set of validation documents which can be used to document the installation and qualification of this solution. When used with our SharePoint validation pack these documents ensure compliance with all electronic records and electronic signature requirements.



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