

Validation of Adobe Sign Services

21 CFR Part 11 Compliant eSignatures

More and more, life science organizations are looking to leverage cloud-based e-signature solutions in order to remove their dependence on traditional paper-and-ink signatures. As a leading application that facilitates a GxP regulated process, Adobe Sign helps teams deliver verified and trusted electronic and certificate-based digital signatures anywhere, on any device. Most importantly, Adobe Sign has been built with the necessary technical features and the procedural controls to allow life science organizations to comply with the FDA's 21 CFR Part 11.

As 21 CFR Part 11 requires the validation of systems used for electronic records and signatures, those who wish to leverage Adobe Sign must establish that the system's functions and identity authentication settings have been configured to meet the FDA's requirements. To address this need, Montrium's Professional Services paired with the Adobe Sign Validation Template Pack demonstrate how the features and functions of Adobe Sign adhere to our customer's business needs and 21 CFR Part 11 regulations.



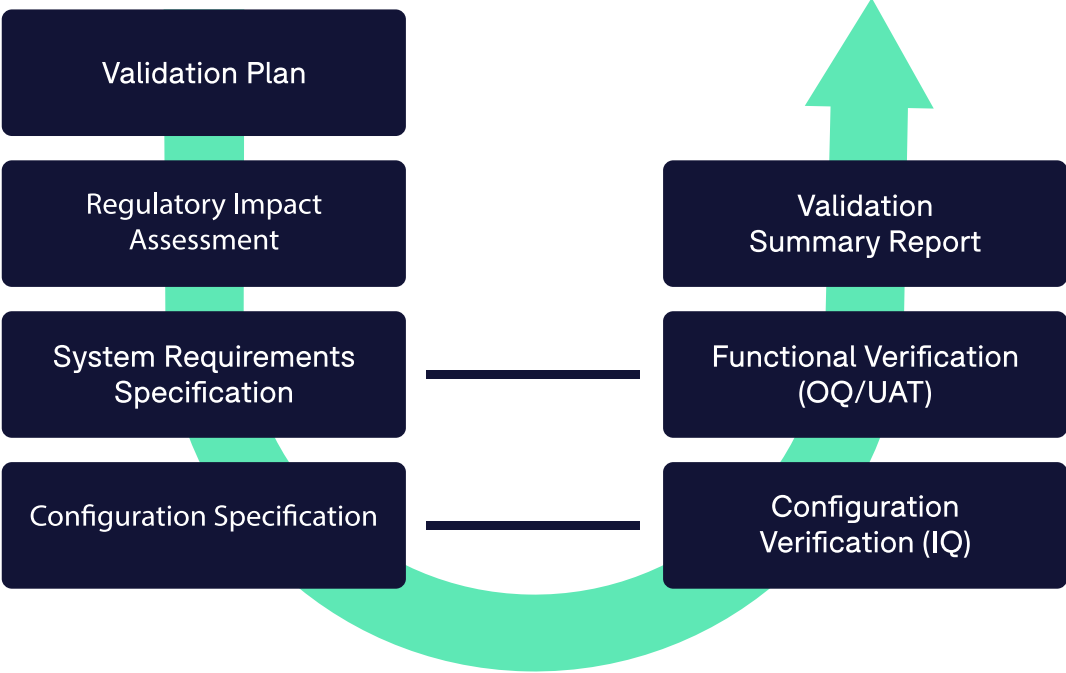
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An Experienced In-House Validation Team

Montrium's Professional Services division provides expert consulting services related to cloud compliance and computer system validation. We have assisted numerous life science organizations by developing and executing a comprehensive validation strategy of several GxP cloud-based platforms and applications including Adobe Sign. Together with internal process owners and system managers, our validation experts work to ensure Adobe Sign is properly configured and maintained in a controlled state by executing the Validation Template Pack.

Efficiency without compromise on Compliance

Montrium has produced a series of Validation Document Templates for Adobe to accelerate the validation of Adobe Sign and establish compliance with 21 CFR Part 11. Our services make it possible to adapt each template to your organization's unique requirements (e.g. Standard Operating Procedures, protocols) and prepare validation deliverables as part of a built-in framework for producing GxP signatures and records with Adobe Sign.



Our Process

Building the Foundation for GxP e-Signatures

Within the scope of Montrium's Adobe Sign Validation Services, we adapt the Validation Template Pack to your specific business requirements and facilitate the completion of the following validation deliverables:

Phase I. Business Analysis

- **Validation Planning** - In accordance with ISPE's GAMP®5 risk-based framework, we begin by producing a plan to define the validation approach, activities, responsibilities, and deliverables for the validation of Adobe Sign.
- **Regulatory Impact Assessment** - We assess the regulatory impact of using Adobe Sign for electronic and certificate-based digital signatures in the context of GxP regulated activities. The technical features and procedural controls required for the system to comply with 21 CFR Part 11 are also identified.
- **System Requirements** - Within the context of your business processes, we make sure that requirements for electronic signatures management are defined and risk mitigation activities are accounted for. We couple this with a description of the built-in Adobe Sign functionality that satisfies the requirements.

Phase II. Configuration

- **Configuration of Controls & Settings** - The organization's Adobe Sign Account is configured so that the system can be used in a way that complies with 21 CFR Part 11 requirements. Montrium and Adobe experts closely collaborate to onboard customer specialists and technical SMEs, providing the quickest time to value with Adobe Sign meanwhile ensuring compliance.

Phase III. Validation Execution and Reporting

- **System Setup Verification** - We define the test strategy, procedures, documentation, and acceptance criteria that will be used in the verification of Adobe Sign. The executed test scripts provide documented evidence that Adobe Sign is configured correctly and operates as intended.
- **Establish Traceability** - We demonstrate the relationship between the requirements and any relevant controls that have been implemented by the customer and Adobe (e.g. qualification testing, procedural controls, audits/assessments, and contractual agreements).
- **Validation Summary Report** - This report summarizes the entire validation exercise for Adobe Sign, including the outcome of validation activities and a statement of fitness for intended use.