USDM Life Sciences | DocuSign

DocuSign and USDM Life Sciences

DATASHEET

Achieving 21 CFR Part 11 Compliance with 100% Digital Processes

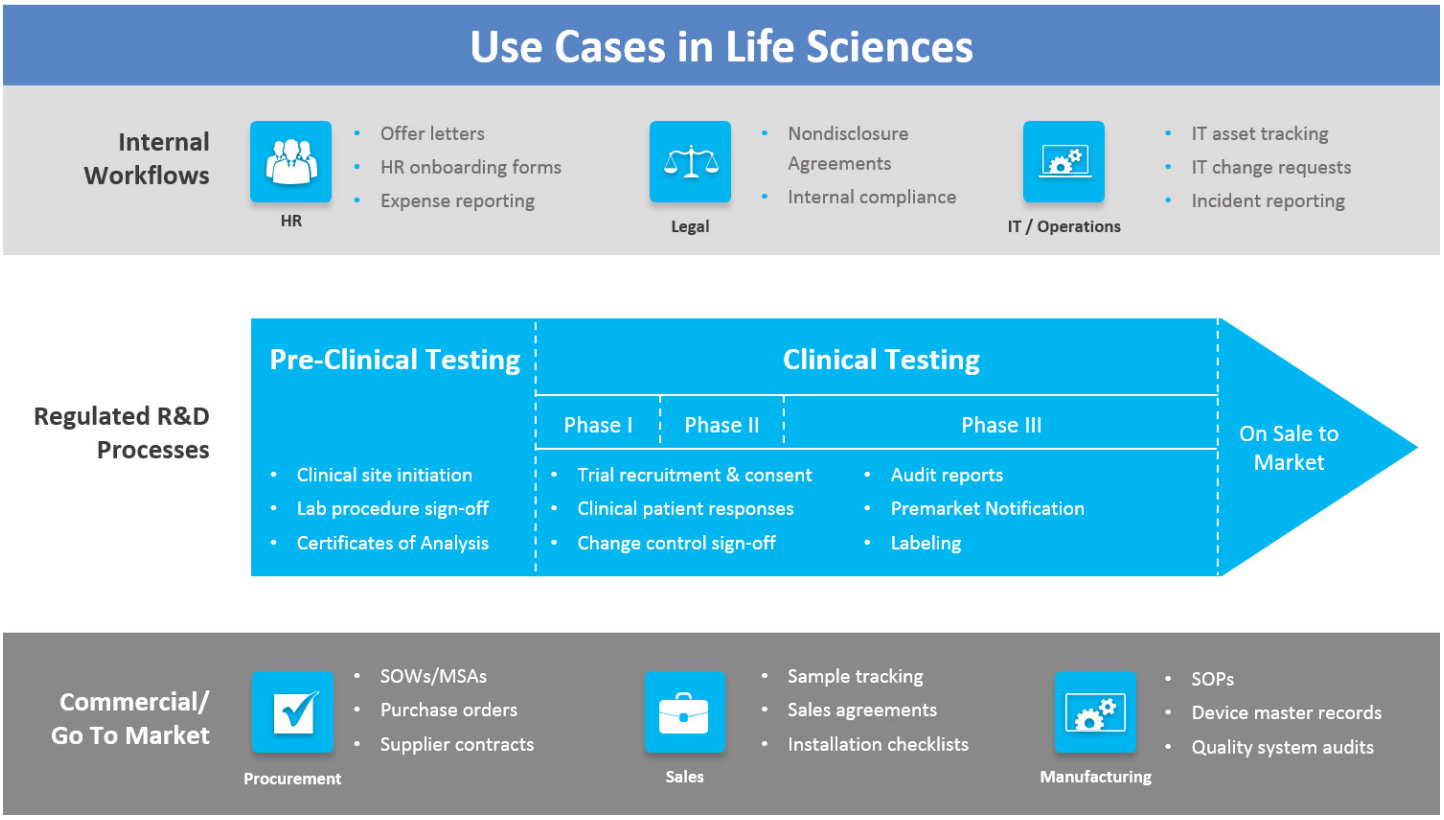
DocuSign and USDM Life Sciences have partnered to help life sciences organizations reduce drug and device development cycle time, bringing critical research and treatments to market sooner and improving compliance along the way.

Simplify GxP Regulated Processes

With USDM Cloud Assurance for DocuSign, life science customers can now use DocuSign to manage all aspects of GxP regulated business processes to:

- Eliminate paper, decrease approval times and reduce errors
- Enable an end-to-end digital solution throughout the GxP spectrum
- Reduce costs
- Improve collaboration

DocuSign's end-to-end digital solution facilitates compliance for a wide range of regulated use cases and can also be used for internal processes like HR forms and legal documents.

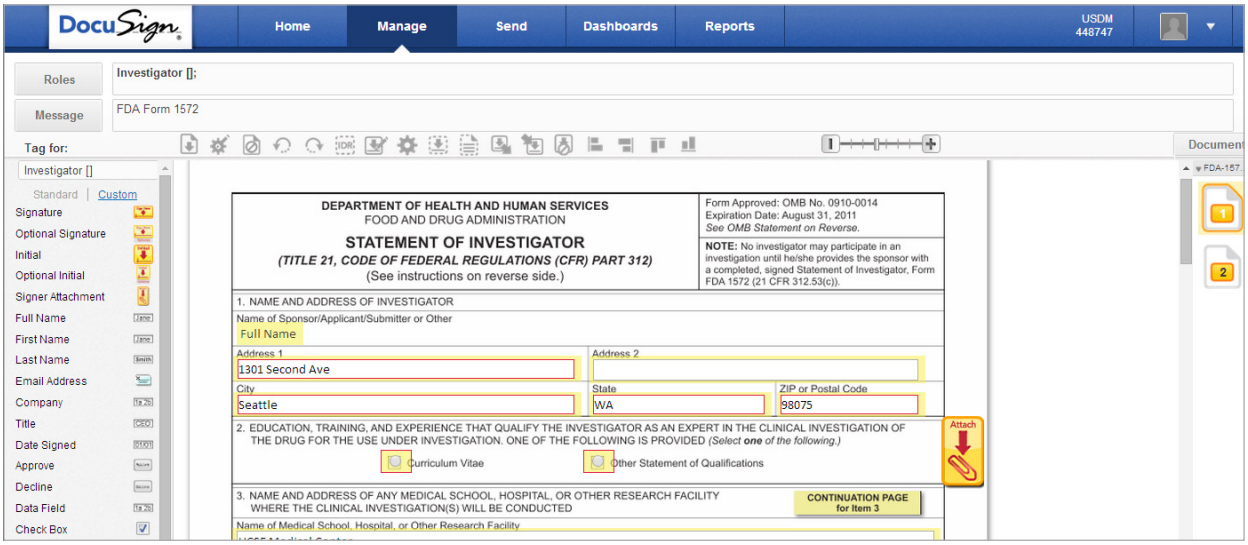


Facilitate 21 CFR Part 11 Compliance

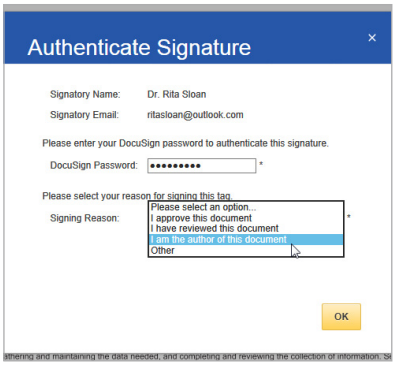
Together, DocuSign and USDM are helping life sciences organizations maintain compliance in the cloud.

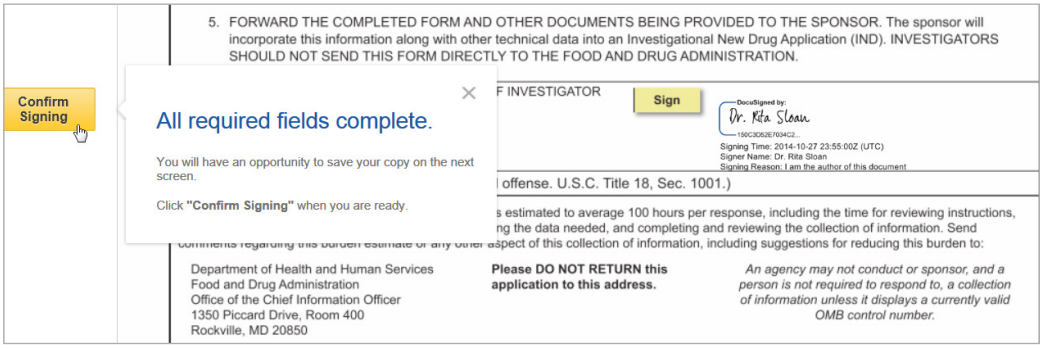
DocuSign is configured to facilitate compliance with 21 CFR Part 11, with digital workflows, signer and sender authentication, industry-leading eSignature technology and a fully traceable audit trail.

Prepare Document for Completion and Signature



Authenticate and Sign





USDM Life Sciences allows DocuSign customers to easily implement and validate the compliance of this fully digital solution, with the USDM Cloud Assurance Program, including a Validation Accelerator Pack (VAP) and compliance offering for DocuSign. USDM's Cloud Assurance offering for DocuSign is based on over 10 years of VAP development and created by leaders in the life sciences cloud.

The USDM Cloud Assurance offering for DocuSign includes:

- Validation Accelerator Pack (VAP)/Qualification Package
- Vendor Audit (updated annually)
- Validation Maintenance Package (updated as changes are made with new releases)
- Test automation options
- Subscription-based services that provide the ability to maintain compliance

The DocuSign VAP contains:

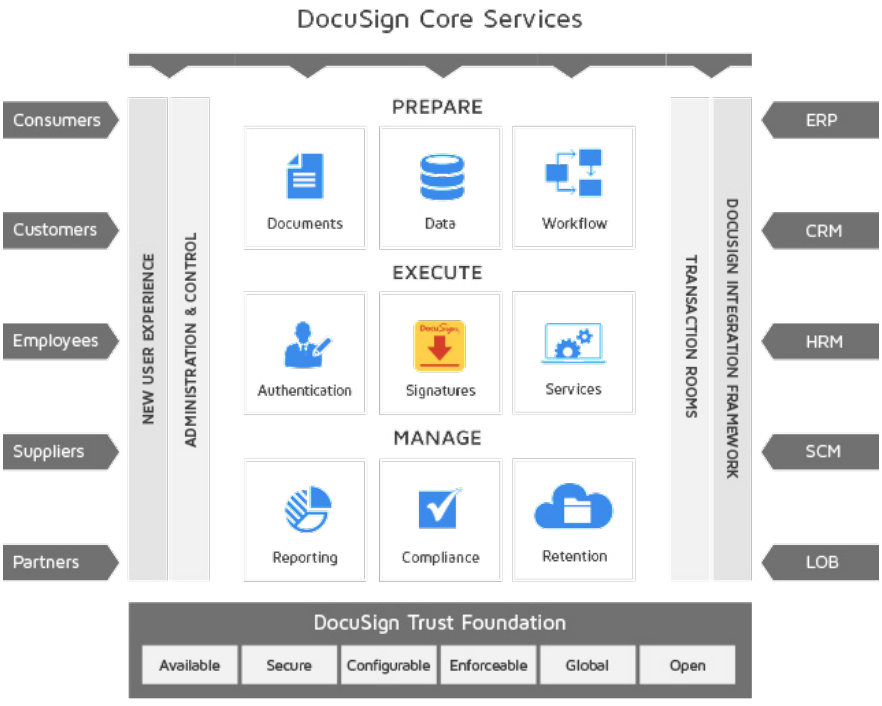
- Validation plans
- System requirements
- IQ/OQ/PQ test scripts
- A traceability matrix
- A vendor audit report

USDM Cloud Assurance

The Cloud Assurance offering provides updates to this VAP content with each DocuSign release and can be executed by USDM to save time and testing costs.

DocuSign Digital Transaction Management

DocuSign provides a 21 CFR Part 11 compliant Digital Transaction Management (DTM) platform that automates manual, paper-based processes and allows customers to Keep Business Digital™ with industry-leading identity management, authentication, eSignature, forms/data collection, collaboration, workflow automation, payment collection, and cloud storage. The DTM platform supports legally compliant electronic and digital signature processes tailored to meet requirements globally with localization in 43 languages.



USDM Life Sciences

USDM Life Sciences is a leading global regulatory consulting firm providing compliance, business intelligence, validation, qualification, quality auditing and IT services via project teams and staff augmentation to our clients in the Medical Device, Biotechnology, Biologics, Diagnostics and Pharmaceutical industries. USDM has more than 14 years of experience supplying our clients in the life science industry with compliance services during each phase of their drug and product development cycle while partnering with best of breed organizations to help companies simplify, unify and optimize their business and compliance objectives.

Get Started

For more information:

- Contact DocuSign sales at +1 877-720-2040, or email LifeSciences@DocuSign.com
- Contact USDM Life Sciences at +1 888-231-0816 ext. 161 or email usdm@usdm.com

The Global Standard for Digital Transaction Management™

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About DocuSign

DocuSign® is the Global Standard for Digital Transaction Management™. DocuSign accelerates transactions to increase speed to results, reduce costs, and delight customers with the easiest, fastest, most secure global network for sending, signing, tracking, and storing documents in the cloud.

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