

## 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.

## Use Cases in Life Sciences

### Internal Workflows



HR

- Offer letters
- HR onboarding forms
- Expense reporting



Legal

- Nondisclosure Agreements
- Internal compliance



IT / Operations

- IT asset tracking
- IT change requests
- Incident reporting

### Regulated R&D Processes

#### Pre-Clinical Testing

- Clinical site initiation
- Lab procedure sign-off
- Certificates of Analysis

#### Clinical Testing

##### Phase I

##### Phase II

##### Phase III

- Trial recruitment & consent
- Clinical patient responses
- Change control sign-off
- Audit reports
- Premarket Notification
- Labeling

On Sale to Market

### Commercial/Go To Market



Procurement

- SOWs/MSAs
- Purchase orders
- Supplier contracts



Sales

- Sample tracking
- Sales agreements
- Installation checklists



Manufacturing

- SOPs
- Device master records
- Quality system audits



## 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

The screenshot displays the DocuSign interface for editing a document titled 'STATEMENT OF INVESTIGATOR'. The document is identified as 'FDA Form 1572'. The interface includes a top navigation bar with 'Home', 'Manage', 'Send', 'Dashboards', and 'Reports'. A left sidebar lists document fields such as 'Signature', 'Optional Signature', 'Initial', 'Optional Initial', 'Signer Attachment', 'Full Name', 'First Name', 'Last Name', 'Email Address', 'Company', 'Title', 'Date Signed', 'Approve', 'Decline', 'Data Field', and 'Check Box'. The main document area shows the 'DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION STATEMENT OF INVESTIGATOR (TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)'. It contains several sections: 1. NAME AND ADDRESS OF INVESTIGATOR (with fields for Full Name, Address 1, Address 2, City, State, and ZIP or Postal Code); 2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION; and 3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY. A right sidebar shows document thumbnails labeled '1' and '2'. An 'Attach' button is visible on the right side of the form.

### Authenticate and Sign

The screenshot illustrates the authentication and signing process. On the left, an 'Authenticate Signature' dialog box is open, showing the signatory's name 'Dr. Rita Sloan' and email 'ritasloan@outlook.com'. It prompts the user to enter their DocuSign password and select a reason for signing (e.g., 'I approve this document', 'I have reviewed this document', 'I am the author of this document', or 'Other'). An 'OK' button is at the bottom. In the center, a 'Confirm Signing' button is highlighted. On the right, the document area shows a 'Sign' button and a signature block for 'Dr. Rita Sloan' with a digital signature and timestamp. Below the signature, there is a 'Please DO NOT RETURN this application to this address.' warning and contact information for the Department of Health and Human Services, Food and Drug Administration, Office of the Chief Information Officer, 1350 Piccard Drive, Room 400, Rockville, MD 20850.

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:

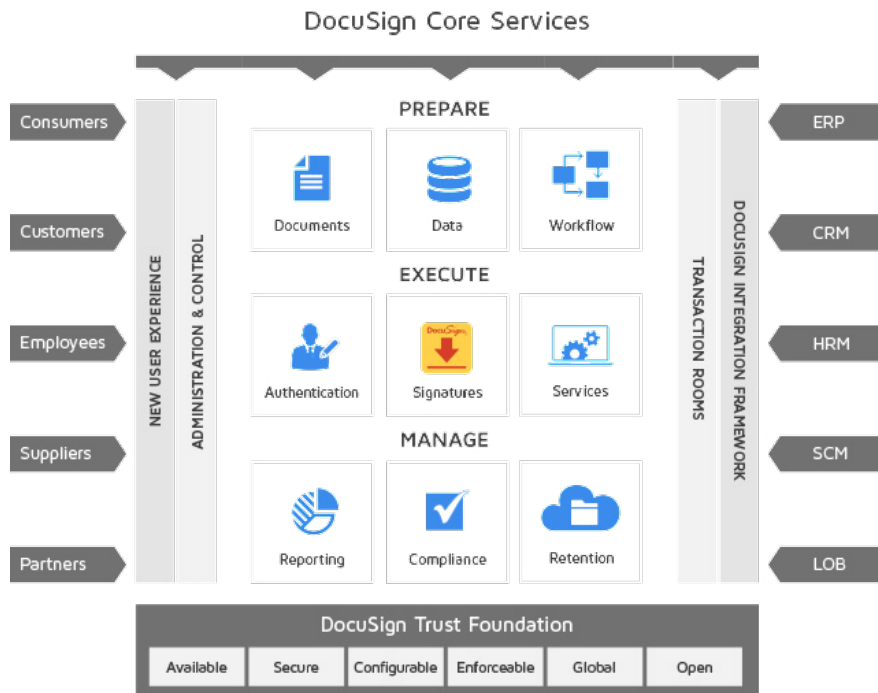
- Validation plans
- System requirements
- IQ/OQ/PQ test scripts
- A traceability matrix
- A vendor audit report



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](mailto:LifeSciences@DocuSign.com)
- Contact USDM Life Sciences at +1 888-231-0816 ext. 161 or email [usdm@usdm.com](mailto: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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