Increase Efficiency and Simplify Compliance with the Docusign Life Sciences Module

To keep up with the speed and complexity of the modern agreement landscape, pharmaceutical, medical technology, biotechnology and other life sciences professionals need to make a digital transformation. Docusign wants to help. That's why we built a product specifically for the industry: the Life Sciences Module.
This offering is the next chapter in Docusign history of building technology to accelerate innovation in the life sciences industry. More than 20 years ago, our groundbreaking eSignature technology allowed teams to collaborate with better reach and efficiency. In 2015, Docusign offered the first e-signature application that enables 21 CFR Part 11 compliance, introduced as part of our dedicated Life Sciences package. Today, the Life Sciences Module will help teams expand their digital agreement workflows without introducing new compliance risk.

The Docusign Life Sciences Module has three components:

- An eSignature solution that enables compliance with the FDA's 21 CFR Part 11 and Annex 11 regulation
- A validation solution that streamlines ongoing validation requirements to adhere to GxP
- Ability to authenticate signer identity via SMS text message in addition to email-based verification

Comply with the FDA's 21 CFR Part 11 requirements and GxP standards

The Life Sciences Module provides availability, security and customizability to enable compliance with life sciences regulations domestically and globally. The eSignature functionality offers prepackaged account configuration for regulatory requirements without manual setup, which reduces the risk of noncompliance. It's a critical component for any life sciences organization that utilizes electronic records and signatures.

Docusign offers world-class security and protection, with customization options to meet the needs of any team's signature process and accommodate the necessary parties. Life sciences organizations can use Docusign to build an integrated agreement process with centralized administrative control. It offers internal and external signers a seamless signing experience while maximizing administrative visibility, transparency and auditability.

"Docusign quickly became our most trusted technology platform that is now used in over 80 countries in just two years. Docusign continues to be a solution to meet our ambitious goals so that we can focus on achieving what matters to us most—improving the lives of our patients."

Boehringer Ingelheim
Associate Director
Global eSignature Solution

Docusign customer results

DKMS reduced the time it takes to move from donor clearance to physician acceptance by

97%

Thermo Fisher can complete

75%

of envelopes in **less than one week**

Improve the signer experience

Signer authentication is necessary to enable 21 CFR Part 11 compliance, but the process can be a hurdle or even a dealbreaker for some signers. Traditional methods to authenticate a recipient's identity are through email or SSO. In addition to these methods, the Life Sciences Module now incorporates recipient authentication via SMS text messaging in compliance with 21 CFR Part 11 requirements. Our mobile-friendly experience validates a signer's identity with a simple two-factor authentication process that sends a one-time code via SMS.

Life sciences organizations can choose to authenticate after each signature tag or while accessing and finishing a session. Signers aren't required to create an account to authenticate, so the entire process can be completed with a few clicks. SMS authentication is a critical tool for teams that want to expand clinical trials beyond traditional environments to include more diverse remote participants.

Streamline validation testing and documentation

The Life Sciences Module includes functionality that performs quality assurance (QA) tests on a sample CFR Part 11 Docusign account aligned to our release schedule to test against production and demo environments. Our Life Sciences Module produces monthly automated downloadable reports to provide evidence of successful completion of these QA tests. Those reports are sent to your team, including screenshots of each test and details of the specific provisions tested so you have all the necessary validation documentation.

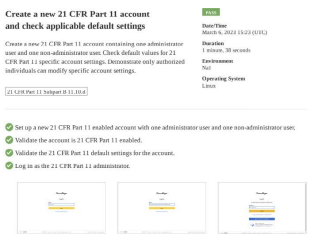
Below are examples of what a summary report and a specific test will look like. If you want to receive a sample report, contact your account executive.


Validator for Life Sciences Report

The DocuSign Validator for Life Sciences simplifies compliance and validation documentation by providing results for selected aspects of DocuSign's rigorous internal testing to ensure CFR Part11 functionality works. The information below shows details of QAtests conducted on the DocuSign production environment for Release 23.1.0.20803 to ensure any code changes made by DocuSign do not reduce the usability of CFR Part 11 module of DocuSign.

Results

- Create a new 21 CFR Part 11 account and check applicable default settings
- Require sender to log in to create and send envelopes
- Require recipient to have an account and log in to access envelope
- Honor recipient signing order
- Require recipient to authenticate and provide a signing reason in order to sign envelope
- Require recipient to input last 4 digits of phone number & code received via SMS, if sender chose "SMS for access & signatures"
- Download audit trail and all enclosed documents for envelope
- Allow account administrators to specify password criteria
- Lock out user after several invalid login attempts


Create a new 21 CFR Part 11 account and check applicable default settings

Create a new 21 CFR Part 11 account containing one administrator user and one non-administrator user. Check default values for 21 CFR Part 11 specific account settings. Demonstrate only authorized individuals can modify specific account settings.

21 CFR Part 11 Subpart B 11.10.d

PASS

Date/Time
March 6, 2023 15:23 (UTC)

Duration
1 minute, 38 seconds

Environment
Nax

Operating System
Linux

- Set up a new 21 CFR Part 11 enabled account with one administrator user and one non-administrator user.
- Validate the account is 21 CFR Part 11 enabled.
- Validate the 21 CFR Part 11 default settings for the account.
- Log in as the 21 CFR Part 11 administrator.

Get more information about the Life Sciences Module or talk to one of our experts to learn about how Docusign can help your team.

Customers use Docusign to complete a range of life sciences agreements

Discovery
Sponsored research
Investigator-initiated research
Laboratory results

Drug Development
Preclinical development
Clinical trials
Patient consent and enrollment
Site initiation
Regulatory submissions

Manufacturing
Batch records
SOPs
Quality agreements
Safety inspections
Recall notifications

Distribution
Partnership and distribution programs
Vendor/supplier contracts
Agency approvals

Sales and Marketing
HCP speaker agreements
HCP sponsor agreements
Order processing
Sample tracking
Sales agreements

About Docusign

Docusign brings agreements to life. Over 1.5 million customers and more than a billion people in over 180 countries use Docusign solutions to accelerate the process of doing business and simplify people's lives. With intelligent agreement management, Docusign unleashes business-critical data that is trapped inside of documents. Until now, these were disconnected from business systems of record, costing businesses time, money, and opportunity. Using Docusign IAM, companies can create, commit, and manage agreements with solutions created by the #1 company in e-signature and contract lifecycle management (CLM).

Docusign, Inc.
221 Main Street, Suite 1550
San Francisco, CA 94105
docusign.com

For more information
sales@docusign.com
+1-877-720-2040