## **DocuSign**<sup>®</sup>

# Increase Efficiency and Simplify Compliance with DocuSign's 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's history of building technology to accelerate innovation in the life sciences industry. More than 20 years ago, our groundbreaking <a href="estimate">eSignature</a> technology allowed teams to collaborate with better reach and efficiency. In 2015, DocuSign offered the first e-signature application that enables <a href="estimate">21 CFR Part 11</a> 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.

DocuSign's 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 <u>Life Sciences Module</u> 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

<u>DKMS</u> 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.

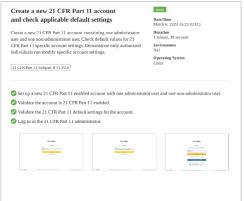
Life sciences organizations can choose to authenticate after each signature tag or while accessing and finishing a session. Signers aren't required to create an account to authenticate, so the entire process can be completed with a few clicks. SMS authentication is a critical tool for teams that want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





#### 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

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



DocuSign helps organizations connect and automate how they navigate their systems of agreement. As part of its industry-leading product lineup, DocuSign offers eSignature, the world's #1 way to sign electronically on practically any device, from almost anywhere, at any time. Today, over a million customers and more than a billion users in over 180 countries use the DocuSign platform to accelerate the process of doing business and simplify people's lives.

221 Main Street, Suite 1550 San Francisco, CA 94105

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