DocuSign®

Top 7 Reasons Customers Choose DocuSign 21 CFR Part 11 Life Sciences Modules

1/ Healthcare and life sciences industry leader

DocuSign is the leader in agreement technology. We pioneered electronic signatures starting in 2003. DocuSign created a special eSignature module to address the unique regulatory requirements in the healthcare and life sciences industry.

DocuSign Life Sciences Modules for 21 CFR Part 11 makes it possible to integrate electronic signatures in accordance with Part 11 requirements and GxP standards for electronic signatures and records. Customers use DocuSign for clinical research studies, other drug and medical device research and development activities both with internal and external recipients.

– DocuSign is the market share leader for electronic signatures for regulated and non-regulated use cases.

– DocuSign electronic signatures have been used by over a million customers and more than one billion users across over 180 countries.

– Open APIs and 400+ pre-built integrations with partner applications, such as those from Salesforce, Microsoft, SAP, Oracle and Workday.

2/ World-class data security and protection

– Meets ISO 27001, PCI Data Security and SOC1/ SOC2 Standards.

– DocuSign is certified as a Qualified Trust Services Provider on the EU Trust List, enabling DocuSign to issue eIDAS-ready advanced and qualified signatures for use across the 27 member states.

– Broad network of TSPs that enable local regulatory compliance across 180 countries.

– AES 256-bit, or equivalent, encryption key.

– Regular reviews by independent law firms and audits performed by our partner USDM to monitor DocuSign's eSignature Part 11 compliance.

– Stringent DocuSign document control:

　· Maintains a Policy Bank that contains established policies and procedures to enable repeatable and predictable results.

　· Secure replication of customer data to a geo-dispersed data centers in the US, Canada, Europe and Australia.

　· Deliver Part 11 role-based training to DocuSign employees through a learning management system ("LMS").

　· Additional security features available at the Trust Center.

14/15
top healthcare and life science companies

Boehringer Ingelheim Results

3 days
Turnaround time versus 13 days on average before DocuSign

88% reduction
in error rate

6x
ROI

3/ Centralized administrative control, visibility, transparency and auditability

– Pre-packaged account configuration for 21 CFR 11; no manual setup. Limited control to account admins only, which ensures users cannot adjust Part 11 specific settings that could put companies at risk of non compliance.

– Seamlessly switch between regulated and non-regulated signatures on a single DocuSign account without having to reconfigure settings each time.

– Visual markers across the product to differentiate a regulated workflow.

– Robust controls over DocuSign deployment, sending and signing workflows.

– Centralized management across all departments & organizations including Single Sign On, admin audit logs, envelope transfers, account comparisons and account setting export.

– Option to include sophisticated two-factor authentication (passcode, SSO etc.) for accessing and signing an envelope, with additional authentication and identification options available through our identity platform.

– Admins can easily identify patterns and find bottlenecks in signing behavior that spans beyond out of the box and basic reports to optimize the system.

– DocuSign Monitor includes real-time alerts with account activities from web, mobile and API to detect potential security threats and suspicious activities.

4/ An integrated compliance solution

– Printed name, date/time and signing reason in the signature manifestation, with two manifestation views—horizontal and vertical.

– Certificate of Completion includes secure and detailed transaction history and detailed audit trail that includes a date/time stamp for all transactions in perpetuity.

– Ability to archive records into an external system via web applications or APIs as a PDF. DocuSign uses X.509 certificates to digitally sign documents downloaded from the eSignature services to create a tamper-evident seal.

– DocuSign eSignature offers multiple options for verifying a signer's identity, uses AES 256-bit encryption and data protection policies that support customers' HIPAA compliance efforts. Read more about using electronic signatures to help manage HIPAA forms.

– Additional Security and Trust Assurance packet and traceability matrix provided regarding alignment to 21 CFR Part 11 and GxP standards.

Boston Scientific Results

Before DocuSign	After DocuSign
48% rate of not in good order on key regulatory form	**0** GDP errors
36 manual stages to complete active release form	**6** automates stages to complete active release form

ROI: $4.4M in savings

$2.1M
saved in distribution and product controls

$1.8M
saved in clinical trial administration

$500K
saved in regulatory administration

"When we talk about workflow, DocuSign is the epitome of how to streamline and gain efficiencies."

Kevin Clark
Manager
Global Clinical Operations PMO

5/ Trusted quality assurance

Even though DocuSign is not regulated by a government agency, the guidance below outlines how DocuSign can fit into validation procedures.

OQ (Operational Qualification)

– DocuSign follows a robust software development lifecycle process, software quality assurance process, and release management process based on Software-as-a-Service industry-standards.

– Automated testing to ensure new features, bug fixes and configuration settings meet the business requirements and to verify overall system health.

– The DocuSign Validator for Life Sciences helps with providing the quality assurance test results for DocuSign's Life Science Module, which are equivalent to the Operational Qualification scripts for DocuSign's internal validation of its products. The validation plan consists of activities including:

  · Testing performance of DocuSign eSignature features.

  · Checking system configuration.

  · Demonstrating DocuSign eSignature operates according to the defined specifications.

– IQ (Installation Qualification) and PQ (Performance Qualification).

  · As a cloud-based software, no "installation" is required. Our robust documentation and certifications outlined in the DocuSign Security, Trust, and Assurance packet showcase how we comply with regulations and meet performance standards.

6/ Seamless signing experience for internal and external recipients

– Automatic account creation for both external and internal recipients. One single seamless signing workflow that does not force signers to leave the session to create an account. Instead DocuSign automatically prompts the signer to create a username and password prior to accessing the document.

– Flexibility to choose between two Part 11 signing experiences based on whether the signer authenticates at every signature tag (Original Part 11 Signing) or while accessing & finishing the signing session (Rapid Part 11 Signing).

– Mobile-friendly responsive signing to allow patients and HCPs to have an easy experience. Documents automatically converted to HTML, improving the display of your documents based on the signer's device.

– Email, text message and online capabilities available to sign agreements in 43 different languages and to send them in 13.

– Automated complex workflows using conditional logic. Ability to configure routing, sequence, scheduled sending and allow multiple signers per routing step when simultaneous routing is desired. Automated post-signature tasks when an envelope is completed without requiring additional software.

7/ Commitment to Customer Success

– Our customer success team has over 700 experts across 12 global locations, the largest in the industry. Over 40 accredited system integrator partners.

– Flexible implementation services, DocuSign University live, and 24/7 support make it easy to get started.

DocuSign Agreement Cloud