DocuSign

Automate 21 CFR Part 11 compliance validation so you can focus on getting products to market faster.

Let us test, so you can do the rest.

The reality of meticulous testing to comply with regulatory requirements. Despite increasing pressures to improve the efficiency of R&D, manufacturing, and distribution, one thing that hasn't changed for life science organizations is the need to comply with stringent FDA and global regulatory standards. From initial onboarding to ongoing product releases, the number of rigorous tests and audits on regulated processes to comply with regulations like 21 CFR Part 11 is daunting and time-consuming. Not to mention resource intensive—manufacturing companies have been cited to spend upwards of $2.2* million a year on compliance efforts, with employee costs being the largest share of the spend.

Streamline processes while reducing regulatory risk with our Part 11 Module.

DocuSign's Part 11 Module for life sciences is designed to help organizations adopt fully digital approvals, agreements and processes for Part 11 regulated use cases. With DocuSign's digital audit trail, we make transactions traceable. We have invested in regulated life science capabilities to help you adhere to the global regulatory standards for digital transactions set forth by agencies like the FDA and EMA. Our customers range from small biotechs to large multinationals – we've helped them adhere to compliance standards like SOX, 21 CFR Part 11, Annex 11, Safe Harbor, and HIPAA.

Our open, standards-based approach makes it easier to integrate electronic signatures into existing processes and systems in accordance with Part 11 requirements. We help you fully automate your regulated processes, getting the most of your current investments and gain efficiencies. For the full details, check out our Part 11 Module white paper.

Automate testing and documentation of Part 11 capabilities and keep your company moving forward.

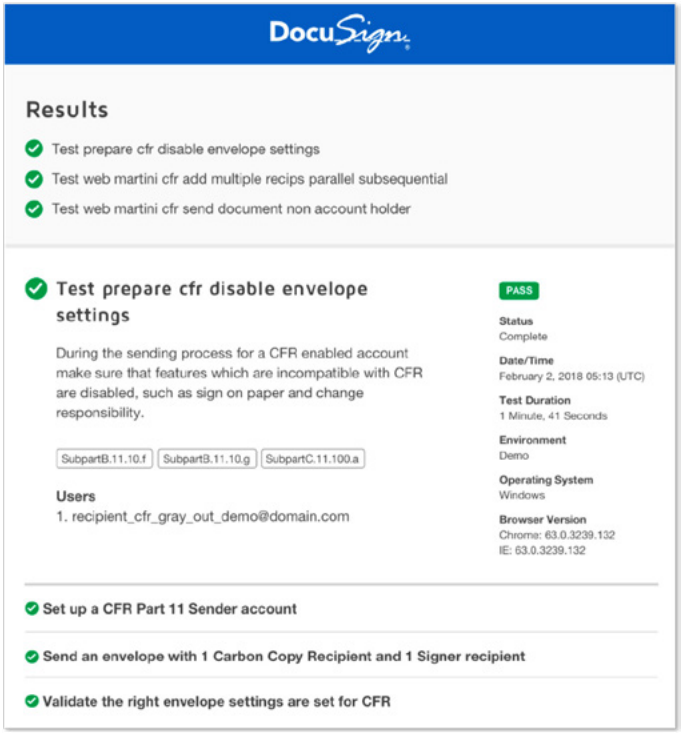
Accompanying our Part 11 Module, the DocuSign Validator for Life Sciences helps significantly simplify aspects of your compliance validation. We support careful testing of electronic signature system processes and provide corresponding documentation to demonstrate that our solution performs the necessary tasks to adhere to Part 11 regulations.

As part of our software development lifecycle process, we perform rigorous testing of our functionality prior to releases. For regulated use cases, we test the Part 11 enabled features to support compliance. We provide reports to your team that include screenshots of each test, details of the specific provisions tested, and the final test results.

[1] PhRMA Industry Profile
[2] Digital Signatures and Electronic Submissions: How SAFE Can Increase Information Liquidity

Here is an example validation report summary. Reports are delivered via a DocuSign envelope to your team.

For more consultation services and custom compliance validation, we partner with USDM Life Sciences to ensure you can deploy DocuSign to manage all aspects of GxP regulated processes. Learn more about the USDM Cloud Assurance offering for Docusign **here**.



Two reasons to partner with DocuSign on compliance validation

Simplify the rigorous and manual compliance testing so you can focus on getting drugs and devices to market faster.

Win back the time and resources to re-focus adding value to patients.

Whether you're just getting started with compliance validation or you've built a testing team out, DocuSign Validator for Life Sciences can simplify testing and documentation via automation. This means less time spent manually setting up and running tests, and more time focusing on reaching your company's goals.

Turnkey setup so you can automate testing now, not later.

We make access quick and painless – the testing and reports can be available by simply enabling it on your account. No additional effort is needed for your team to setup this testing. Gain peace of mind knowing all necessary documentation is automatically being collected for each test.

LifeSciences@docusign.com

About DocuSign

DocuSign helps organizations connect and automate how they prepare, sign, act-on, and manage agreements. As part of the DocuSign Agreement Cloud, DocuSign offers eSignature—the world's #1 way to sign electronically on practically any device, from almost anywhere, at any time. Today, more than 475,000 customers and hundreds of millions of users in over 180 countries use DocuSign to agree better.

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

For more information
Call +1-877-720-2040