

DocuSign and USDM Life Sciences Partnership Overview

Enabling Compliance for Regulated Operations

The average cost to develop a new drug - \$2.6 Bn - has doubled over the past decade¹. As pricing pressures and patent expiries compromise top line revenues, how will your organization sustain clinical operations? The answer is right under your nose: automating paper-based processes.

Industry experts estimate that 40% of life science R&D costs are linked to paper-based processes². And while the FDA sets standards for results and protocols along the way, you hold the keys to reducing time and cost throughout the process.

¹ PhRMA Industry Profile

² Digital Signatures and Electronic Submissions: How SAFE Can Increase Information Liquidity

Accelerate product development without compromising quality

Your patients, investigators, and employees are global – and the processes between them should allow them to complete agreements quickly, easily and securely while adhering to regulatory standards. DocuSign enables fully digital workflows and processes with a modern, purpose-built System of Agreement platform.

Prepare: Start by importing documents and data from key systems. DocuSign has pre-built integrations with platforms like Salesforce, Box GxP, and SharePoint, and our robust REST and SOAP APIs enable you to embed our regulated capabilities in other systems and custom apps.

Sign: Use DocuSign's legally binding and secure eSignature technology to authenticate patients, investigators, and employees around the world. DocuSign integrates with digital credentials compliant with eIDAS in Europe, and regulated Part 11 capabilities enable two-factor authentication and an enhanced signature manifestation with printed date, time and unique signer ID.

Act: After an agreement is signed, avoid rekeying data by automatically updating systems and triggering processes. For instance, you could prompt an update in your Clinical Trial Management System when a patient completes a clinical trial enrollment and notify investigators on the study.



Manage: Access and store agreements in the system of your choice – DocuSign can route completed documents to systems that reside behind your firewall. You set your own retention policies and we help you adhere to them.

Whether your agreement is a patient consent, a 1572 form, or a quality inspection, similar steps are involved to complete it. Digitizing a single agreement can shave days or weeks off your time to market – so imagine the impact when applied to the entirety of your global operations.

Implement and validate with trust and confidence

Global regulatory authorities hold you to a higher bar – and we hold ourselves to it too. Working together, DocuSign and USDM Life Sciences help you reinvent your business processes while providing implementation and validation services that allow you to deploy with ease and expertise. Consider us an extension of your team.

Working with you every step of the way

A key engagement is grounded in transparency, connectivity, and partnership. Here is what you can expect with us along the journey.

1. Consult with DocuSign and USDM Life Sciences.

Our teams help you assess the scope and expected ROI from investing in digital regulated processes. Under NDA, DocuSign will provide customers with a copy of our Software Development Lifecycle (SDLC) process, certifications, and internal policies that enable our product to adhere to global regulatory standards.

2. Implement digital, regulated processes.

Whether you're a growing biotech or a Fortune 50 medical device company, USDM Life Sciences has a track record of engagements with companies like yours. Working as an extension of your team, USDM will modernize your legacy System of Agreement and ensure your investment delivers the greatest ROI. This may include integrating DocuSign with other core systems like your CTMS, CRM, content management repository, or custom apps.

3. Subscribe to monthly testing reports.

The DocuSign Validator for Life Sciences simplifies compliance documentation by providing reports that contain results representing selected aspects of DocuSign's rigorous internal testing of our regulated functionality, delivered directly to your team. Reports include screenshots, details of specific provisions tested, and the final test results.

4. Perform ongoing validation.

Customized to your unique needs and systems, USDM Life Sciences offers a Validation Accelerator Pack that includes a validation plan, annual DocuSign audit report, and automated testing tools and templates to make your internal validation simple and turnkey. USDM Life Sciences also offers Cloud Assurance, a subscription service for ongoing support of new DocuSign releases, including updated scripts and ongoing regression testing.

Deliver results that matter

DocuSign and USDM Life Sciences have an established partnership and draw on expertise from deployments at top 20 global biopharma and medical device companies as well as high growth life science organizations.

Let's get started

Schedule a consultation with our team today.

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Contact USDM Life Sciences at +1 888-231-0816
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About DocuSign

DocuSign helps organizations connect and automate how they prepare, sign, act on, and manage agreements. As part of its cloud-based System of Agreement Platform, DocuSign offers eSignature—the world's #1 way to sign electronically on practically any device, from almost anywhere, at any time—and SpringCM, a scalable, secure contract and document management solution. Today, almost 430,000 customers and hundreds of millions of people in more than 180 countries use DocuSign to accelerate the process of doing business and simplify their lives.

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