DOCUSIGN + BOX INTEGRATION FOR LIFE SCIENCES

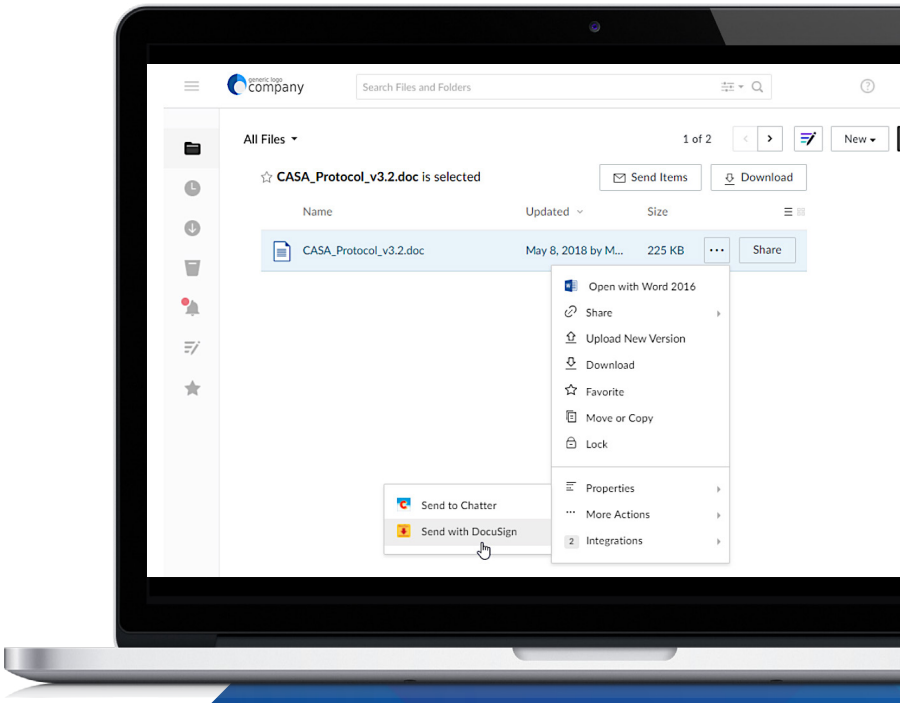
Accelerate regulated processes without compromising quality

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. Executives acknowledge the need to invest in cloud technologies to accelerate time to market — in fact, 74%* of life science executives believe their organizations are entering entirely new digital industries — but navigating this evolving digital landscape poses a fresh set of challenges. Keeping up with the pace of change while exceeding quality standards requires new partnerships and solutions designed for both efficiency and compliance.

Leverage digital solutions to streamline processes while reducing regulatory risk

Integrated solutions designed for GxP regulated processes allow life science organizations to work smarter and faster while optimizing for security and trust. Together, DocuSign and Box do just that, with a holistic solution that enables customers to prepare, sign, enact, and manage agreements and approvals while adhering to FDA and global standards.

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. Our open, standards-based approach makes it easy to integrate electronic signatures into existing processes and systems like Box, in accordance with Part 11 requirements.



*Stat source: Accenture Life Sciences Technology Vision 2017

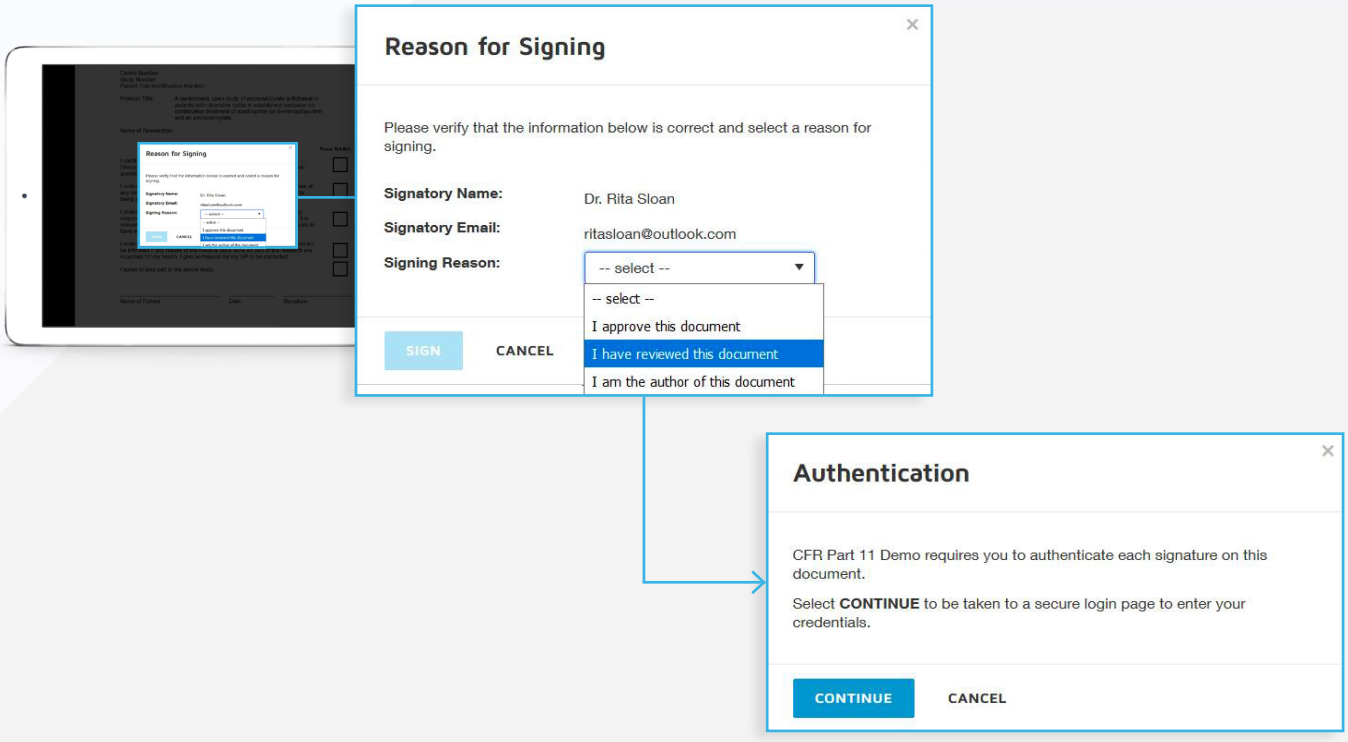
Box GxP Validation allows life science companies to access, share and manage information securely and in compliance with FDA regulations. All content can be standardized on a single content management platform, eliminating silos between multiple repositories and creating confidence that all content is in one compliant and secure system.

The DocuSign and Box integration automates and accelerates regulated processes ranging from patient consents to quality inspections, enabling Part 11 compliance across electronic records and signatures with a fully digital workflow.

Improve collaboration and security while providing end-to-end document visibility

Send regulated documents for signature directly from the Box console. A copy of the completed document is saved to the same Box folder it was sent from.

Approve documents using Part 11 e-signature capabilities including: signature-level credentialing, meaning (signing reason), and manifestation (printed name, date/time, and signing reason). DocuSign's Part 11 Module includes additional security and controls, resulting in a unique and customizable signing experience for regulated use cases.



Upon completion, the DocuSign system applies a digital signature to documents, which provides an open standards method for verifying document integrity outside of the DocuSign system. Any documents that originate in Box will automatically return to Box as a PDF.

Learn more about DocuSign and Box in our partnership overview.

Drive efficiency by accelerating core life science processes

Agreements are prevalent across the global life sciences value chain — here are a few areas where organizations can reap the benefits of DocuSign and Box across regulated and non-regulated processes.

Regulated Use Case Examples		
Research & Development	**Pre-Clinical Testing**	**Clinical Testing**
• Patient Consent • Investigator Onboarding • Site Initiation & SOP's • Contracting	• Clinical Site Initiation • Lab Procedure Sign Off • Certificates of Analysis	• Clinical Trial SOP Sign Off • Trial Recruitment & Consent • Change Control Sign Off • Audit Reports • Premarket Notification • Labeling
Non-Regulated Use Case Examples		
Manufacturing	**Commercialization**	**Provider & Patient Engagement**
• Procurement • Batch Records • Audit, QA and Compliance	• Sampling • Sales and Service Agreements • Patient Financing and Reimbursement	• HCP & Patient Portals • Patient Assistance & REMS Programs • Prescription Management

Remove friction from 21 CFR Part 11 compliance

Simplify contracts, approvals, and agreements to reduce regulatory risk and win back time, keeping your organization ahead of the ever-changing compliance landscape. With DocuSign and Box, regulated processes are fully traceable with a digital audit trail — helping life sciences organizations adhere to global regulatory standards for digital transactions.

For additional information on how DocuSign facilitates compliance with 21 CFR Part 11 controls, read DocuSign's Part 11 white paper.

Connect with us today: Email LifeSciences@docusign.com or call +1 877-720-2040

Follow Us:

About DocuSign

DocuSign is changing how business gets done by empowering anyone to transact anytime, anywhere, on any device with trust and confidence. DocuSign keeps life moving forward.