Pharma IT DocuSign

DocuSign™ Implementation Accelerator

Streamlining Part 11 Compliance

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Pharma IT and DocuSign are uniquely situated to provide your firm with a cost-effective solution to streamline Part 11 compliance.

"Our experienced consultants can get you started with DocuSign quickly, saving you time and resources. Plus, our innovative cloud solutions can ensure that your firm's use of DocuSign is completely validated and remains Part 11 compliant in the long-term."

Jakob Juul Rasmussen
Partner and Managing Director

PharmaIT's DocuSign™ Implementation Accelerator solution ensures Part 11 compliance

The number of tests and audits on regulated processes that are required to comply with regulations like 21 CFR Part 11 is a daunting and time-consuming task for many firms.

Our DocuSign Implementation Accelerator solution ensures that your use of DocuSign is completely validated and Part 11 compliant from both a technological and an internal procedural standpoint.

Our experienced consultants can help you streamline the process of meeting these rigorous regulatory demands

We offer completely GxP-validated documentation as a packaged solution, that includes templates, predefined documents and processes customized to your firm's needs.

Harness the Pharma IT Cloud to ensure long-term compliance

The Pharma IT Cloud comes fully GxP-validated, is easy to use, scalable, and tailored specifically to the demands of the pharma, biotech, and medical device industries.

Key benefits

Simplified Part 11 Compliance
Our solution ensures that your use of DocuSign is completely validated and remains Part 11 compliant.

Streamlined and Accelerated Implementation
Get started right away with a customized DocuSign package, saving you time and money.

The Pharma IT Cloud
Utilize our innovative and accessible cloud solution to minimize implementation costs and ensure long-term compliance.

Ongoing Support and Maintenance

Do you want to get in touch? Contact **Jakob Juul Rasmussen** at **jajr@pharmait.dk** or **+45 24 34 26 55**

Who are Pharma IT and DocuSign?

Pharma IT

Pharma IT is a one-stop consultancy shop for the pharma, biotech, and medical device industries

Pharma IT provides full domain coverage including IT, drug/device development, and management consulting. By remaining lean and client-focused, we provide maximum value and raise the standards of Pharma consulting.

Our solutions are developed by consultants with extensive knowledge of the pharma, biotech, and medical device industries – and a firm grasp of quality and compliance requirements.

To this end, our team of industry veterans and young talent remains up-to-date on the latest regulatory developments and trends through certification and continuing education.

DocuSign

DocuSign™ is the industry leader in electronic signature services.

DocuSign accelerates processes by allowing you to electronically send and sign documents securely, and is trusted by hundreds of millions of users every year.

DocuSign Part 11 module

The FDA's 21 CFR Part 11 regulation (Part 11) covers document signing and record retention for processes and documents.

DocuSign's Part 11 module is specifically designed to with the life sciences industry in mind, and provides a solid foundation for pursuing Part 11 compliance.

How our DocuSign™ Implementation Accelerator streamlines Part 11 compliance

DocuSign, on its own, is not enough to ensure full Part 11 compliance

DocuSign is an excellent cost-effective tool to provide functionality related to electronic signatures. However, its use must be implemented according to ISPE GAMP5 guidelines when used for GxP documents, and clients may find that its use as a long-term document archive is limited.

Pharma IT can help you harness the Cloud to ensure long-term compliance

Our innovative and accessible cloud solutions come fully GxP-validated, and minimize software purchasing and implementation costs for small/medium sized enterprises. Plus, they include fully compliant archiving features for long-term storage.

Our DocuSign package spans all core validation documentation needs

We can provide template and fixed price implementation of all GAMP5-required deliverables to support accelerated implementation of DocuSign's part 11 module, including all of the deliverables listed below.

1. Vendor Assessment
2. GxP Assessment
3. Risk Assessment
4. Validation Plan
5. User Required Specification
6. Configuration Specification
7. Performance Qualification & Traceability
8. Validation Report
9. System Administrator Manual
10. System User SOP
11. Support and Maintenance

.... and more! All customized to your needs and fully GxP-validated.

Meet our Customers

Pharma IT has more than 30 customers consisting of both small and large Biotech and Pharmaceutical companies. We value all types of assignments - from small projects to large enterprise solutions. Here is an excerpt of our customers:

Do you want to get in touch?

Call Jakob Juul Rasmussen at **+45 24 34 26 55**

Or write an email to **jajr@pharmait.dk**

We look forward to hearing from you!

Pharma IT

Improving the standards of Pharma Consulting