

Compliance Processes for Pharmaceutical Companies



USE CASE PROFILE: Pharmaceutical Companies

Challenge: Efficient Regulatory Compliance

Compliance teams at today's pharmaceutical companies face a world of drug regulations that are both costly and complex to manage. 21 CFR Part 11 requires pharmaceutical companies to implement controls including audits, system validations, audit trails, and documentation for software and systems involved in processing electronic data. Corporate Integrity Agreements negotiated with HHS mandate specific internal processes, reviews, and disclosure requirements. Maintaining compliance requires managing a myriad of signatures from the beginning of processes until the end, and often includes individuals, documents and workflows outside the corporate network. Doing so with paper is a burden, and adds cost and risk.

The DocuSign Solution

Switching from manual to electronic signatures can alleviate the burden of compliance tremendously, and allow pharmaceutical companies to easily work with physicians, key opinion leaders, and consultants outside the organization. Individuals simply sign online, any time, from any device. Automated reminders help ensure 100% compliance. Online dashboards and reports let you track exactly who has—and has not yet—signed each form, inside and outside the company. DocuSign's highly customizable workflows give you complete control over who has to sign and in what order. And DocuSign provides complete document retention capabilities.

DocuSign Key Benefits

Using DocuSign, eSignatures increases the reliability, integrity, availability, and authenticity of records and signatures, as required by the FDA. DocuSign's solution is fully compliant with ESIGN, UETA, ETSI, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and 21CFR Part 11. So when you implement electronic signatures from DocuSign, you will know that your signature processes are in compliance.

Switching from manual to electronic processes saves staff time and cost. Our forms library ensures your staff can easily access and send out the correct, current version of required forms. And as a cloud-based solution you can get up and running immediately, realizing faster time to benefit.

Customer Example

Streamlining Compliance

A Fortune 500 pharmaceutical company has been using DocuSign since July 2012 to streamline compliance in its HR functions, especially for contract processing and enforcement of contract regulations specified by the Affordable Care Act. The company reduced cycle time for physicians who provide services for consulting and clinical trials from three weeks to three days, and this project was so successful that the company is now re-examining all physical signatures.

About DocuSign

DocuSign® is the global standard for electronic signature®. DocuSign accelerates transactions to increase speed to results, reduce costs, and delight customers with the easiest, fastest, most secure global network for sending, signing, tracking, and storing documents in the cloud.



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