Compliance for Medical Device Manufacturers

DocuSign®
The Global Standard for eSignature

USE CASE PROFILE: Medical Device Manufacturers

Challenge: Efficient Regulatory Compliance

Compliance teams at medical device manufacturers face a world of regulations that are both costly and complex to manage. 21 CRF Part 11 requires implementation of controls including audits, system validations, audit trails, and documentation for software and systems involved in processing electronic data. Maintaining compliance requires managing a myriad of signatures from the beginning of processes until the end. Doing so with paper-based processes is a burden, and adds cost and risk.

The DocuSign Solution

Switching from manual to electronic signatures can greatly ease the compliance burden. Employees access and sign compliance documents online, any time, from any device. Automated reminders help ensure 100% compliance. Online dashboards and on-demand reports let you track exactly who has—and has not yet—signed required forms. And DocuSign's powerful, highly customizable workflows give you complete control over who has to sign and in what order. Plus, DocuSign provides complete document retention capabilities.

DocuSign Key Benefits

Using DocuSign for eSignatures increases the reliability, integrity, availability, and authenticity of records and signatures, as required by the FDA. DocuSign electronic signatures comply with both the General Signature Requirements and Electronic Signature Requirements as defined in FDA §11.50, §11.70, §11.100, §11.200(a), and §11.300 of Part 11 regulation. So when you implement electronic signatures from DocuSign, you will know that your signature processes are in compliance.

Switching from manual to secure 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.

DocuSign Means Compliance

DocuSign makes it easier for health plans and other healthcare providers to comply with requirements as specified by HIPAA, the Sunshine Act, FDA 21 CFR Part 11, ACA, PMDA, and Corporate Identity Agreements. It dramatically reduces the cost and burden of signing off on and sharing compliance documentation, forms, and agreements with all relevant parties. And forms are retained electronically for the required period and can be easily accessed for audits.

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.

DocuSign®
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