

FDA 21 CFR Compliance

Manufacturers of medical devices are required to meet the stringent standards set forth by the FDA, particularly Title 21 of the Code of Federal Regulations (21 CFR). Meeting these regulations can determine the success or failure of a medical device company. With the pressures of meeting the FDA regulations growing, many medical device manufacturers are turning to software solutions like Omnify Software to help develop products that adhere to the FDA guidelines and ensure the proper product development processes are in place.

21 CFR Part 11 - Electronic Records; Electronic Signatures

Medical manufacturers who track their documentation electronically and must maintain records or submit information to the FDA are subject to the 21 CFR Part 11 regulation. To be compliant, medical manufacturers must meet the electronic records and electronic signature guidelines set forth by the FDA.

Omnify Software is helping medical device companies manage product development for these FDA regulations by providing features such as:

- Password-protected signoffs
- Authorized electronic signatures
- History tracking for electronic audit trails

21 CFR Part 820 - Quality System Regulation (QS)/current Good Manufacturing Practices (cGMP)

Manufacturers of medical devices intended for commercial distribution in the United States may be required to adhere to 21 CFR Part 820. This regulation requires device manufacturers to have a quality system for the design, manufacture, packaging, labeling, storage, installation, and servicing of finished medical devices.

Omnify Software is helping medical device companies manage product development for these FDA regulations by providing features such as:

- Closed-loop Corrective and Preventive Action (CAPA) system
- Training records management
- Reporting and analysis (custom reports, DMR/DHR/DHF reports, customizable dashboards)
- Defined user roles to control accessibility

Key Benefits:

- Single, controlled location to store and manage all product, project, quality, and training records
- Easily generate compliance reports and perform analysis
- Eliminate disconnect between engineering and other groups in an organization
- Ensure enterprise-wide compliant product development processes
- Adhere to FDA guidelines while eliminating costly redesign and shortening development cycles



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