Medical Compliance

Design Safe, Effective and Compliant Products

Omnify Software is helping medical device customers design safe, effective and compliant products by providing the tools to properly manage product development processes for regulatory compliance and simplify the audit process. The Omnify Empower system offers a single location to manage all product data (BOMs, documents, engineering changes), quality/CAPA processes, and training records along with the necessary reporting capabilities. Omnify Empower eliminates the need to purchase multiple siloed solutions to address compliance requirements and ensures compliant product development processes across the entire organization.

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.

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. Omnify Software is helping medical device companies meet the Part 11 electronic records and electronic signature guidelines by providing features such as:

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

Quality System Compliance

21 CFR Part 820 - Quality System Regulation (QS)/ISO 13485/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. ISO 13485 applies to international quality system standards.

Omnify Software is helping medical device companies manage product development for Quality System 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 eliminates the need to purchase separate systems
- Easily generate compliance reports and perform analysis
- Eliminate disconnect between engineering and other groups in an organization
- Ensure enterprise-wide compliant product development processes
- Simplify the audit process with easy access to information
- Adhere to FDA and ISO guidelines while eliminating costly redesigns and shortening development cycles

"We selected Omnify Empower because we found that there are very few cloud/hosted PLM systems out there that are cost-effective while ensuring that there are no compromises on features and controls required for meeting regulatory requirements."

-Program Director, Agisyl, LoneStar Heart, Inc.

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