

Identify, Resolve and Analyze Quality Issues

Omnify Software provides a single, secure location to manage the complete product record including: product data, bill of materials, engineering changes, product documentation, project, quality/CAPA, and training records information. The system enhances visibility into the entire product development process by capturing design, manufacturing, quality, service, and customer information and associating it to the product record.

The Omnify Empower PLM system offers a Quality Management module to provide a unified location to manage all product *and* quality data. The Quality Management module is directly integrated with all product data stored in Omnify, improving the awareness of quality issues across all product development teams. The Quality Management module offers a mechanism to classify quality issues, automate steps to closure and easily analyze data to avoid future problems.

Closed-Loop Corrective and Preventive Action (CAPA) System

The Quality Management module automates capturing and routing of data related to product issues and defects in a closed-loop Corrective and Preventive Action (CAPA) system. Manufacturers can easily define the resources, timeframes and actions required for closure on issues with Resolution Tasks.

The system can be customized to manage any type of product quality information such as:

- Corrective Action (CAR)
- Preventive Action (PAR)
- Supplier Corrective Action (SCAR)
- Non-Conforming Material Report (NCMR)
- Customer Complaints

FDA Compliance

Many companies in the Life Science/Medical Device markets are required to have structured quality systems in place for FDA approval. The FDA 21 CFR Part 820 Quality System Regulation (QSR) requires device manufacturers to have a current Good Manufacturing Practice (cGMP) compliant quality system for the design, manufacture, packaging, labeling, storage, installation, and servicing of finished medical devices intended for commercial distribution in the United States. The Quality Management module supports these requirements and helps manufacturers meet compliance.

Key Benefits:

- Unified location to manage all product and quality data
- Enhance visibility of quality issues across all teams
- Assure Good Manufacturing Practice (GMP/cGMP)
- Easy analysis to eliminate recurring product issues
- Meet regulatory compliance requirements (FDA/ISO)
- Shorten produce development cycles
- Achieve better design practices
- Improve product quality



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