

Omnify Empower Mitigates CAPA Woes

Omnify Software

Omnify's robust software suite aligns PLM with quality measures to achieve FDA compliance.

[Omnify Software](#) [1], a leading provider of product lifecycle management software for medical device and other manufacturers, has launched Omnify Empower, its next generation PLM solution, based on the Microsoft .NET Framework. New functionality such as Project Management, Quality Management, and Training Monitor, improves visibility to all aspects of product development, and mitigates problems with managing training and quality programs that impact FDA compliance.

Empower functionality fills in gaps, including a closed-loop corrective action capability that automates data capture and routing related to product issues and defects. It simplifies the capture and routing process as well as provides much needed documentation for FDA-required audit trails.

Empower's project-management capabilities are also beneficial to manufacturers. Capturing all product and program data in Empower creates executive views, which are used to more easily recognize common problems. Ultimately, this leads to better resource allocation, and streamlined processes that impact deadline-sensitive development activities. Managers can look at a dashboard that displays project-management metrics such as status, percentage complete, and completed milestones to determine project status at a glance.

"We have incorporated more than 200 enhancements and new function requests into Empower, which is a direct result of our continued focus on providing our customers with what they say they need to be competitive," said Chuck Cimalore, Chief Technology Officer for Omnify Software. "Extending the capability of the system to capture manufacturing, quality, and customer information and tie it back to the product record, improves visibility to all aspects of product data to help drive better design and streamline product development even further," added Cimalore.

Omnify Empower leverages Web Services to deliver the next level of open

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architecture for easier data sharing and customization. Web Services enhances Omnify Software's existing open platform for 3rd party integrations and enables easy customization of user interfaces and reports. The ability to tailor user interfaces creates a familiar environment for users, assuring a simple transition from legacy practices. Custom reporting offers high-level views of key development data to identify trends and issues early in the development cycle.

Key New Modules and Enhancements

The Quality Management Module automates capturing and routing of data related to product issues and defects (CAR, NCMR, SCAR, field complaints) in a Closed-loop Corrective and Preventive Action (CAPA) system. This provides a mechanism to identify, classify and resolve quality issues. The system's Resolution Tasks help manufacturers identify the resources and actions required for closure on issues.

The new Training Monitor tracks and documents all internal and external training. This provides a facility to associate required training and/or testing, directly with events such as new product launches, implementation of product changes, and internal process changes. The Training Monitor assures Regulatory Compliance for manufacturers and, combined with Quality Management, fulfills the specific needs of medical manufacturers required to meet the FDA 21 CFR Part 820 Quality System Regulation.

The Project Management Module automates the management of tasks and project schedules for a more accurate view of project progress and completion. Project Management also offers Automated Tasks that allow external and system actions to automatically update project progress. Capturing all product and program data in Empower offers executive views for accurate prediction of deliverables, and analysis features facilitate recognition of common problems that impact deadline-sensitive development activities.

Additional enhancements include increased system performance, improved reporting, and extended vendor data and service objects management. A new Help Desk feature supports multiple formats including video, html, PDF, among others, and allows users to incorporate their own help and guidance to ensure adherence to corporate guidelines.

"The added functionality delivered in Omnify Empower is the next step towards tighter integration between people, materials and processes," stated Barry Mendell,

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Engineering Services Manager for Still River Systems. “The decision to build Omnify Empower on the .Net platform will enable managers and users to create views of data and provide daily metrics and reporting specific to their needs. Both comments are testimony to the fact that Omnify continues to listen closely to their customers’ needs and delivers the goods,” continued Mendell.

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Links:

[1] <http://www.omnifysoft.com>