PLC Medical Systems Implements Omnify Software as Core of Quality Management System

PLC Medical Systems

Challenge: Homegrown Access database to manage product data

PLC Medical Systems Inc. a medical technology company specializing in innovative technologies for the cardiac and vascular markets, was managing product data with a homegrown Access database system. Requiring a great deal of manual intervention and paper processes, something as small as a change in a Quality document required the document to be printed out, old documents pulled from a folder and put in the new version, and then brought from person to person (engineering, quality control, operations) for sign-off. This setup did not have the proper tracking for who was actually trained on a certain procedure, or who signed off on an Engineering Change Order (ECO) and when. In addition, it did not allow PLC to capture employee product knowledge should someone leave.

Documentation control at PLC Medical Systems [1] has always been highly rated and cited by auditors as being complete and thorough. The homegrown system, while cumbersome and labor-intensive, was compliant with Food and Drug Administration (FDA) and International Standards Organization (ISO) regulations. Over the years, however, as the database grew, maintenance of the system became too tedious.

Goals: Automated system vs. 'walking system'

PLC wanted to replace the homegrown database/manual system with a solution that would allow Documentation Control to keep ECOs moving through an automated system. In addition, being in a highly regulated industry required PLC to set up more formal, automated processes. "Auditors prefer to see commercial software in place for managing data and controlling processes," stated Mr. Jeff Steward, Director of IT for PLC Medical Systems.

Presenting a business case to invest in PLM

Before setting out to find a solution, IT and Document Control needed to justify to management the investment in a product lifecycle management (PLM) system. The PLM selection team showed the CEO and CFO how involved and resource-intensive the ECO process was, the potential labor savings, the efficiencies gained due to centralizing information and the improved support for FDA and ISO compliance

through automated processes that could be realized with a PLM system. A Risk Analysis of the loss of tribal knowledge when an employee left the company was also presented and became a key factor in convincing management to invest in a PLM system.

Solution

“We began a search on ECO management systems and came across Omnify Software [2],” said Mr. Steward. “We found that Omnify also had solutions for the full product data management spectrum that we were looking to solve plus had many customers with whom we were familiar.”

The PLM selection team knew of the high costs commonly associated with PLM software systems, so finding an affordable Product Lifecycle Management solution was a key priority. “Omnify’s affordable price and flexible purchase options made it even easier for us to invest in a PLM solution,” stated Steward. “The openness of the technology to integrate with any system so that we were not locked into any one CAD or ERP system was also significant as we were considering new tools.”

Several departments are benefiting from Omnify at PLC - including Product Development, IT, Document Control, Quality, Purchasing and Manufacturing - encouraging expanded collaboration. Omnify Empower enables PLC’s external partners, both local and offshore, to have secure access to the database. This ensures that their partners have access to the most current product data and are working off of the latest design, eliminating discrepancies due to lost emails or old data.

Automated Training Management

A significant benefit for PLC as a medical device manufacturer is Omnify’s Training Management functionality, replacing PLC’s manual training process that required Document Control to walk around the building to update the book.

Providing Training Management within the Omnify system not only eliminates the need for PLC to purchase and manage a separate training solution, but also associates training events with all product and project data stored in the Omnify database. Now PLC can have training as part of the change process to easily track product and procedure revisions. PLC can also automatically configure new training requirements and generate new training alerts for affected personnel.

“The Omnify PLM system lets us know who was notified, when and on what,” added Mr. Steward. “This is very important for us or anyone looking to be FDA or ISO compliant.”

Through this system engineers have instant access to product data such as specifications, engineering parameters and product documentation, as well as a simplified process for sharing data with external partners, suppliers, and auditors. The more efficient processes allow the company to remain focused on delivering high quality, innovative cardiac and vascular medical device-based technologies.

Time and cost savings

By automating their ECO process, the time from the engineering change approval to production has been cut significantly. With all of their product documentation in electronic format PLC no longer needs to store information in file cabinets, has eliminated the need to use a copy machine to print out documents, and time is not wasted by engineering and document control walking around to find and update data. The 'green' benefits are significant in reducing paper, toner and in-house storage expenses on a daily basis, as well as curtailing offsite storage expenses. Their established IT backup and recovery process ensures that we have redundancy and disaster recovery capability without housing any paper records.

ISO Auditor gives praise to PLC for automated system

In addition to providing a controlled environment to manage all of PLC's product data and design processes, the system provided complete history tracking on all changes for compliance with electronic audit trails, and security features to guarantee valid electronic signatures.

According to Mr. Steward, the quality, purchasing and manufacturing departments have easily adopted the FDA 21 CFR Part 11 compliant electronic signature process and are capitalizing on both the workflow-driven change process and the speedy distribution of approved changes. Steward also commented that their development team is taking great advantage of the online Device Master Records and searchable Design History Files. In their most recent ISO compliance audit, the PLM system was noted as a significant enhancement and a demonstration of PLC's commitment to continuous improvement, with glowing remarks from the auditors.

"PLC Medical's Quality Management System continues to perform well and has shown improvement over the last audit in regards to implementation of the Omnify electronic database for documentation control," commented one auditor. "The company complies with the requirements of EN ISO 13485:2003, MDD 93/42/EEC and has incorporated the requirements of the MDD into the Quality Management System. The objectives of the audit have been fulfilled and the auditors recommend recertification to DIN EN ISO 13485:2007 and MDD Annex II."

Links:
[1] http://www.plcmed.com
[2] http://www.omnifysoft.com