CUSTOMER SUCCESS

Leader in Innovative Technologies for the Cardiac and Vascular Markets Automates Engineering Change and Training Processes for Continuous Improvement and FDA/ISO Compliance

Customer

PLC Medical Systems Inc. is a medical technology company specializing in innovative technologies for the cardiac and vascular markets. PLC pioneered the CO_2 Heart Laser System, which cardiac surgeons use to perform CO_2 transmyocardial revascularization (TMR) to alleviate symptoms of severe angina. PLC's newest product, RenalGuard, is approved for sale in the EU as a general fluid balancing device.

Challenge/Situation

Homegrown Access database to manage product data

The company was managing product data with a homegrown system developed in an Access database that required a great deal of manual intervention and paper processes. If someone changed a Quality document they would have to print it out, pull out the old document from a folder, put in the new version and then walk around from person to person for sign-off. This setup did not have the necessary tracking for who was actually trained on a certain procedure, who signed off on an Engineering Change Order (ECO), or when items were signed-off. In addition, it did not allow PLC to capture employee product knowledge so if anyone left the company they took that knowledge with them.

Documentation Control at PLC Medical Systems 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, as the database grew, maintenance of the system became too tedious. "The search for an appropriate replacement was initiated by IT and Documentation Control to gain efficiencies and to retire archaic practices and hand-routed manual documents," stated Ern Damon, Document Control Manager for PLC Medical Systems.

For More Information:
t: 978-988-3800
e: info@omnifysoft.com
w: http://www.omnifysoft.com

Key Benefits

- Automate manual, paper-based processes
  - Improve ECO and Training process efficiencies
  - Eliminate questions of who, when, and what
  - Secure environment to manage product data
  - Eliminate wasted time with a 'walking system'
  - Eliminate tribal knowledge
- Time and cost savings
  - Substantial labor savings
  - Significant cut in change approval to production time
  - Reduce in-house and offsite (paper) storage expenses
- Meet FDA and ISO compliance requirements
  - Automate Training Management/associate with product and project information
  - Continuous improvement system- electronic audit trails/ complete history tracking
  - FDA 21 CFR Part 11 compliant electronic signature process
  - Online Device Master Records and Design History Files
  - EN ISO 13485:2003 and MDD 93/42/EEC quality management system compliance
- Affordable
  - Flexible purchase options (term or perpetual)
  - Lower price point compared to competitive products
  - Floating license model
- Business-ready solution
  - Easy to use/intuitive interface
  - Minimal IT maintenance
  - Open technology platform for integration with any CAD or ERP systems
  - Secure remote access for external users
- Customer-focused
  - Professional support staff
  - Listen and respond to customer feedback
  - Ensure successful implementation
  - Reliable external resource

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Customer Goals

Automated system vs. 'walking system'

PLC was looking to replace the homegrown database with a solution that would allow Documentation Control to keep ECOs moving through an automated system rather than a 'walking system' where they had to physically walk from person to person for sign-off. 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 Jeff Steward, IT Director for PLC Medical Systems. Due to the past experience of the IT and Documentation Control staff, they decided that a Product Lifecycle Management (PLM) system would meet their requirements for automated processes, capturing data and supporting compliance.

Presenting a business case to invest in PLM

Before setting out to find a solution, IT and Documentation Control needed to justify the investment in a PLM system to management. The PLM selection team presented their case to the CEO and CFO by showing them how involved and resource-intensive the ECO process really was with the manual setup. "Sharing knowledge of this process and showing the inefficiencies was very helpful," commented Mr. Steward. They also showed the labor savings, the efficiencies gained due to centralizing information and automating processes, and the improved support for FDA and ISO compliance 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 was a key factor in convincing management to invest in a PLM system.

> *"PLC's validation of Omnify Empower confirmed that we chose wisely in selecting a PLM product. Quality, Purchasing and Manufacturing 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. Our development team is taking great advantage of the online Device Master Records and searchable Design History Files."*
>
> **-Ern Damon, Document Control Manager, PLC Medical Systems, Inc**

Omnify Solution

Flexible purchase options and flexible system

"We began a search on ECO management systems and came across Omnify Software," said Jeff. "We found that Omnify also had solutions for the full product data management spectrum that we were looking to solve and had many customers we were familiar with."

Finding an affordable PLM solution was a key priority. The PLM selection team knew of the high costs commonly associated with PLM software systems. "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."

Several departments are benefiting from Omnify at PLC including; IT, Documentation Control, Product Development, Quality, Purchasing and Manufacturing - encouraging expanded collaboration. PLC has enabled Omnify to be used via a Remote Desktop/Terminal Server so that external users, both local and offshore, are able to securely and easily access the Omnify database.

Automated Training Management

A huge benefit for PLC as a medical device manufacturer is Omnify's Training Management functionality. This has eliminated PLC's manual training process. "Prior to Omnify, we had a red book of procedures and Document Control had to physically walk around the building to update the book and leave an ECO for people to sign," noted Steward. "There was no confirmation that someone had actually been trained on the new procedure."

Providing Training Management within the Omnify system not only eliminates the need for PLC to purchase and manage a separate training solution, it associates training events with all product and project data stored in the Omnify database. With Omnify, PLC has a training database that allows them to have training as part of the change process to easily track product and procedure revisions, automatically configure new training requirements and generate new training alerts for affected personnel. “The Training Management module provides improved communication and record keeping features at a significant labor saving over the paper process it replaced,” stated Mr. Damon.”

“Having our Training process managed in Omnify helps to determine if people were actually trained and 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.”

Customer Success

Omnify Empower PLM has created a climate for PLC to improve innovation by making it easy to share information with Engineering, Suppliers and Auditors. Through more efficient processes, the company is able to remain focused on delivering high quality, innovative cardiac and vascular medical device-based technologies to U.S. and international markets.

Time and cost savings

By automating their ECO process, the time from the change approval to production has been cut significantly. PLC has also realized substantial labor savings due to the efficiencies gained through Omnify.

With all of their documentation in electronic format PLC no longer needs to store information in file cabinets, they have eliminated the need to use a copy machine to print out documents, and time is not wasted walking around to find and update data. “By using Omnify Empower, all Quality Management System and product documents, document change history as well as distribution and training records are electronic,” said Mr. Damon. “The ‘green’ benefits of the Omnify system are significant in reducing paper, toner and in-house storage expenses on a daily basis, as well as curtailing offsite storage expenses.” Jeff also added that, “our 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

“Omnify is the core of our Quality Management System,” said Mr. Steward. “In our most recent ISO compliance audit, Omnify Empower was noted as a significant enhancement and a demonstration of our commitment to continuous improvement.”

“PLC’s validation of Omnify Empower confirmed that we chose wisely in selecting a PLM product,” stated Mr. Damon. “Quality, Purchasing and Manufacturing 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.” Damon also commented that, “our development team is taking great advantage of the online Device Master Records and searchable Design History Files.”

Omnify offers the ability for PLC to increase visibility into their compliance information. All of the information is tracked and managed in one central location and is readily available. The recent completion of their ISO audit resulted in 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,” continued the auditor. “The objectives of the audit have been fulfilled and the auditors recommend recertification to DIN EN ISO 13485:2007 and MDD Annex II.”

“The entire team at Omnify made sure the product was a success at PLC and our interactions with them have always been pleasant, professional and productive,” concluded Mr. Steward.