

Case Study of Corporate Account

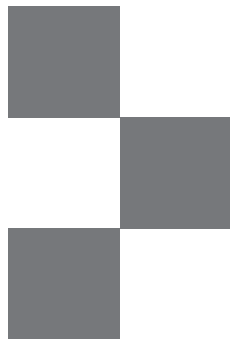
The Heart of SynCardia: Electronic Document Management Solution Implemented in Record Time to Improve Efficiency and Comply with 21 CFR Parts 11, 820, and ISO 13485

SynCardia Systems Inc., based in Tucson, Ariz., manufactures the CardioWest™ temporary Total Artificial Heart (TAH-t), the world's first and only temporary Total Artificial Heart approved by the Food and Drug Administration (FDA) and the European Commission (CE). The CardioWest TAH-t is used as a bridge to cardiac transplantation in transplant-eligible patients at imminent risk of dying from non-reversible biventricular failure.

In the pivotal clinical study of the TAH-t, according to a New England Journal of Medicine paper published on August 26, 2004 (NEJM 2004; 351: 859-867), the one-year survival rate for patients receiving the device was 70 percent, compared to just 31 percent for control patients who did not receive it. One-year and five-year survival rates after transplantation among patients who had received the TAH-t as a bridge to human heart transplant were 86 and 64 percent, respectively.

Over 700 patients throughout the world have benefited from the company's pneumatically driven bi-ventricular device, which is implanted into the chest to replace the bottom half of the patient's heart. The device completely replaces the patient's native ventricles, leading to normalized blood pressure and restoration of the kidney and liver functions. The TAH-t was developed based on the technology and design of the Jarvik-7 total artificial heart, which made history in 1982 as the first artificial heart to be implanted. On July 14, 2006 SynCardia received the CE mark for the TAH-t portable driver in Europe, allowing patients to be discharged from the hospital and await their heart transplants at home.

In 2006, TAH-t certified implant centers increased from nine to 20 centers worldwide. The projected number of certified implant centers is expected to expand to 34 in 2007 and 72 in 2008. SynCardia's goal is to serve the majority of 200 such medical facilities worldwide. Some of the world's finest cardiac hospitals and surgical teams have become TAH-t certified centers, several of which were included on the U.S. News and World Report "2006 Best Heart Hospitals," including: Cleveland Clinic (ranked #1), Barnes-Jewish Hospital (#10), Hospital of the University of Pennsylvania (#13), University of Michigan Health System (#23) and Ohio State University Medical Center (#39). In Europe, certified centers include the Heart and Diabetes Center NRW at Bad Oeynhausen, University of Muenster, University of Cologne, University of Munich, La Pitie in Paris, and the German Heart Institute in Berlin.



Challenges

As is the case with many small medical device manufacturers, SynCardia Systems, Inc. initially utilized a hybrid (electronic / paper-based) document change control system. “Because SynCardia has been around a long time, we had a lot of documents in a lot of different formats,” said Ann Clock, SynCardia’s System Administrator. “Policies and procedures had to be created.” Document Change Orders were generated and logged electronically; however, each page contained in the approval packet was required to be hand-stamped and numbered. These packets were then hand-delivered to each approver. In the event that an approver was unavailable, the process would be delayed until all the appropriate signatures were obtained. Additionally, as in any manual approval routing system, SynCardia also ran the risk that these document packages could be misplaced. The completed documentation was stored in hard copy form, dispersed among several file cabinets. Network folders stored 1,200 files, accessible only to SynCardia Quality Technicians. Some legacy drawing files were inaccessible because the file extensions were associated with antiquated software.



As SynCardia’s business grew, it quickly became apparent that it would be necessary to implement a more robust electronic system. “There is too much going on in the medical device field to not have all our ducks in a row,” said Clock. “When you have a lot of activity, you couldn’t manage it with a paper system. It’s just not possible to avoid errors that cost the company a great deal of money without an electronic system.” The major culture change in business systems shifting from hard copy documentation to an electronic process was only one of the obstacles SynCardia faced—the company not only had to make the transition quickly, but had to simultaneously implement an Enterprise Resource Planning (ERP) system.

Solutions

SynCardia’s search for a document control and forms management solution was instigated by an FDA audit in June of 2005. The inspector’s suggestions for improvement seemed best implemented and managed by a yet-to-be-discovered modern solution. After exhaustive research, SynCardia CEO Rodger G. Ford said, “the cream constantly rose to the top.” From one reference source to another the name MasterControl, Inc. repeatedly appeared. SynCardia selected a fully integrated MasterControl™ suite consisting of MasterControl Documents™, MasterControl Forms™, and MasterControl Training™ to insure compliance, validation and document control.

Implementation

The MasterControl GxP process management and advanced document management system was initially installed in July of 2005 and matured throughout 2006. In just three months, SynCardia’s Validation Team—aided by MasterControl Professional Services—completed the installation and validation of the system, set up the database, and loaded all the

current documentation. SynCardia's implementation broke the validation completion record of all previous start ups. The MasterControl system, according to Clock, "provides enormous leverage of human capital." Customer Experience Reports and Corrective and Preventive Actions (CAPA) are entered and followed with precision and the document change process has been immensely simplified.

"As we put documents into the system, we improve our processes and clean up documents that need it," Clock said. "Employees have become much more knowledgeable about the bigger picture here at SynCardia. An electronic document system forces you to be accountable and responsible for your work."

Compliance: Audit Ready at All Times

Routine internal audits are performed at SynCardia's request by independent consultants to review the effectiveness of the quality and business systems and to ensure compliance with SynCardia's established policies and procedures. SynCardia strives to be audit ready at all times, actively embracing a spirit of continuous improvement—a goal made possible by MasterControl solutions.

"Forms, training and document systems are here to stay and we are moving at light speed to meet FDA audit requirements," said Clock. "There's no way we could have gotten this far without MasterControl. This is the third company I've been with that had MasterControl and I understand the value of the system and how remarkable it is."

Within the past year, SynCardia has successfully undergone several external Quality Systems Audits. The British Standards Institute, the notified body for SynCardia in Europe, concluded that SynCardia is in compliance with ISO 13485-2003 (the Medical Devices-Quality Management Systems Standard). SynCardia also complies with the Active Implantable Devices Directive (AIMDD) and the Canadian Medical Devices Conformity Assessment System (CMDCAS).

MasterControl enables consistent compliance with 21 CFR Part 11, which impacts any FDA regulated manufacturer utilizing technology to create, modify, maintain, archive, retrieve, or transmit regulatory documents. MasterControl automatically requests and stores a user's justification for every modification to a document. This makes it possible for FDA inspectors to easily review the history of any document.

Additional features of the MasterControl solution that address 21 CFR Part 11 include the following:

- Dual passwords that require two distinct identification components for document approval.
- Password encryption and password expiration.
- Account and intruder lock-out capabilities that secure regulatory documentation.



- Specific security measures such as change control and audit trails.

Adding Value and Efficiency

Since implementing MasterControl's fully automated, Web-based system, SynCardia employees have noted dramatic improvements and benefits, primarily:

- Global accessibility
- Ease of use
- 21 CFR Part 11 compliance
- Electronic CAPA, NCR, MRB and Customer Experience forms provide timely reporting, tracking, trending and resolution
- Efficient route approvals and step modification allows entry and exit of users during the routing process
- Multiple viewers for one document simultaneously
- Accelerated revision cycle
- Security of documents and user access
- Training component easy to set up, access, implement, track, and complete
- "Out of Office" feature provides backup when a particular user is not available
- Publishing made more efficient since viewable files can be created from legacy drawings
- Collaboration process increases accountability and insures rapid task accomplishment
- Audit trails simplify review process
- By saving time, the system saves SynCardia money

MasterControl Continues to Provide Service

SynCardia employees know that they can depend on MasterControl for continuous technical support as they learn to utilize the comprehensive change management and document control capabilities of the software. The continual training of new and advanced users supports the growth of the system. Clinical training document revision made possible by the MasterControl solution now insures that the external training of SynCardia-approved medical centers remains current.

"We now use MasterControl to the max," Clock said. "MasterControl keeps us compliant. You can't be effective in your work if your doors are locked because of non-compliance. Because everyone can look at documents at the same time, an electronic system is a huge timesaver. We have an average of 2,600 interactions by 30 users every month—can you imagine handling that with a paper system?"

About MasterControl

MasterControl produces software solutions that enable regulated companies to get their products to market faster, while reducing overall costs and increasing internal efficiency. MasterControl securely manages a company's critical information throughout the entire product lifecycle. Our software is known for being easy to implement, easy to validate and easy to use. MasterControl QMS and QEM solutions include quality management, document management/document control, product lifecycle management, audit management, training management, bill of materials, supplier management, submissions management, and more. Supported by a comprehensive array of services based on industry best practices, MasterControl provides our customers with a complete information management solution across the entire enterprise. For more information about MasterControl, visit www.mastercontrol.com, or call: 1.800.825.9117 (U.S.); +44 (0) 1256 325 949 (Europe); or +81 (03) 6801 6147 (Japan).