



SOLTA MEDICAL

Manufacturer of Aesthetic Applications Completes Software Validation and Meets FDA 21 CFR Part 11 Requirements with Omnify Software

Customer

Solta Medical, Inc. (Nasdaq: SLTM) is a global leader in the medical aesthetics market providing innovative, safe, and effective anti-aging solutions for patients that enhance and expand the practice of medical aesthetics for physicians. Solta Medical is a recent collaboration of the industry's two leading brands: Thermage®, the pioneer in non-invasive skin tightening and contouring, and Fraxel®, the premier solution for skin resurfacing.

The Thermage product line is the gold standard for skin tightening and contouring. The technology has 33 patents issued in the United States, and the system is in more than 2,300 medical practices in 80 countries. More than 500,000 Thermage treatments have been performed worldwide.

Challenge/Situation

Manual Product Development Processes

The Thermage solution is a Class II medical device and therefore is required to meet stringent Food and Drug Administration (FDA) compliance requirements. Solta Medical must have a proper document structure in place to show the history of how a product was built, with signed and dated documents. "We were managing product data with paper processes that provided little security and made searching for product information challenging," stated Andy Kuver, Sr. Document Control Specialist for Solta Medical. "An FDA audit can happen at any time. With the manual setup, our files were decentralized. Documents and files need to be stored in one central location for easy access in the event of an audit."

A manual engineering change process consisted of a paper Engineering Change Order (ECO) being passed around from person to person for changes and signoff, and then returned to the originator. Generating about 100 ECOs per quarter in this manner was a burden for the Thermage product development team. "We could spend days walking around to complete an ECO," said Mr. Kuver. "Our ECO cycles were too long - about 2-3 weeks - and we did not have a clear picture of where the products were at- the status, the BOM, etc."

Key Benefits

- Centralized Product Data
 - Streamline communication
 - One version of the truth for all data
 - Easy access to information for better design decisions/cost savings
 - Ensure accuracy of information across internal and external teams
- Automate manual, paper-based processes
 - Efficient design processes
 - Eliminate manual entry of data/errors
 - Secure environment to manage product data
 - Eliminate waste in manually searching for product information
- Meet FDA Compliance Requirements (**21 CFR Part 11**)
 - Robust security features
 - Electronic audit trails/complete history tracking
 - Able to complete Software Validation in short timeframe
- Business-ready solution
 - Easy to use/intuitive interface
 - Fast user adoption for existing and new staff
 - Open technology platform for integration with existing ERP system, **Expandable ERP**
 - Cost-effective

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The company also needed a better way to manage Bill of Materials (BOMs) and BOM structure and have the ability to share this information with their ERP environment, Expandable to eliminate manual BOM entry and get clear history tracking on all changes. “We ultimately needed a better way to manage information because it was becoming too cumbersome,” added Andy.

“We decided on Omnify Empower mainly because it met all of our requirements for what we wanted to do now as well as what we wanted the system to do in the future. In addition to the minimal cost and delivering superior customer support, we determined that Omnify would better support our requirements over the long term.”

-Andy Kuver, Sr. Document Control Specialist, Solta Medical

Customer Goals

Central Location to Manage Product Data

Solta Medical wanted a central and secure location for all Thermage product data to be vaulted so that they could easily track, manage and find information. They also wanted to implement a system that would support better compliance and manufacturing processes. Knowing that Product Lifecycle Management (PLM) was exactly what the doctor ordered, Mr. Kuver was persistent in his pursuit to implement a solution at Solta Medical.

Mr. Kuver, along with a software selection team comprised of representatives from Engineering, Quality, Clinical, Operations, IT and executive sponsors, set out to find a PLM solution to help automate their Thermage product development processes. After looking at their manual practices and defining what they wanted to transition to the PLM system, the team established a set of software requirements defining exactly what they wanted the system to do and what they were looking for from a vendor. Some preferred criteria included:

- Easy to use for existing staff and new hires
- Complete Bill of Material (BOM) management
- Straightforward searching to find information (status, version, etc....)
- Ability to integrate with existing ERP system, Expandable
- Meets FDA 21 CFR Part 11 electronic documentation guidelines
- Training records management capabilities
- Security (access control)
- Strong support services
- Cost-effective

Solta Medical also limited their search to include only on-premise solutions. A hosted model would not support their requirements for a high level of security, integration and configuration. The continuous product updates of a hosted solution would also make Software Validation difficult.

The selection came down to Omnify Empower PLM and another leading PLM vendor. “We decided on Omnify Empower mainly because it met all of our requirements for what we wanted to do now as well as what we wanted the system to do in the future,” said Mr. Kuver. Solta Medical wanted a PLM solution that could scale as they added various manufacturing sites, allowed vendors to access the system, and implemented other ERP/MRP systems. “In addition to the minimal cost and delivering superior customer support, we determined that Omnify would better support our requirements over the long term.”

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Omnify Solution

The selection team was able to get the Omnify Empower PLM system implemented, tested and validated fairly quickly. “We performed a risk assessment of the program and how it might affect our current, hardcopy system so that we would be prepared for any potential surprises that would be challenging as we moved forward,” said Mark Blakely, Sr. Software Quality Assurance Engineer for Solta Medical. “We evaluated what could go wrong with a PLM system, not specific to Omnify, just in general.”

Solta Medical was able to convert all of their paper processes into electronic format without any issues. All Thermage ECOs and part numbers are now exclusively created and managed in Omnify Empower. “Keeping all product documentation in Omnify electronically makes information available at our fingertips rather than searching for previous revisions of documents that are in file folders or in offsite storage,” commented Mr. Kuver. “Users are able to just type in a keyword to find what they need instead of spending valuable time searching through files.”

Transitioning to Electronic Processes - 21 CFR Part 11 Compliance

Implementing Omnify Empower PLM and transitioning to electronic processes meant Solta had to comply with the FDA’s Part 11 of Title 21 of the Code of Federal Regulations (21 CFR Part 11) requirements for electronic product data management. These regulations require medical manufacturers who manage their information electronically to meet certain electronic records and electronic signature guidelines, such as authentic/password-protected electronic signatures, electronic audit trails, and controlled design processes.

In addition to providing a controlled environment to manage all of their product data and design processes, Omnify Empower PLM provides complete history tracking on all changes for compliance with electronic audit trails, and security features to guarantee valid electronic signatures.

“Robust security features and limiting access to information to assure only appropriate employees are accessing, changing and approving documentation are very important FDA requirements,” said Ven Saldajeno, Design Control Specialist for Solta Medical. “Electronic signatures are legally binding and we need to make sure everyone understands this and is in compliance. We were able to establish two different passwords for logging into the Omnify system and then for signing off on documents, as well as set up alerts requiring passwords to be changed on a regular basis.”

With the formation of Solta Medical, Thermage has to consider limiting access to product information before they merge with the other company. The Business Units feature in Omnify has helped Solta Medical limit access to information for different product lines based on roles and permissions. “I have set up Business Units and different vaults that contain various roles for different departments such as Engineering, Quality Assurance, and Design Control,” said Mr. Kuver. “The system is robust enough to securely integrate the other company as we merge.”

Software Validation

The last step in shifting to an automated system for FDA compliance is Software Validation. “Validation requires us to test the functionality of the Omnify PLM system to prove it does what it is intended to do,” stated Mr. Saldajeno. “Process Qualification requires us to show how we use the system to perform functions such as creating a BOM, creating an ECO, attaching affected items, tracking document revisions, processing secure signoffs, and how it talks to Expandable ERP.”

“Our Validation documentation highlights the FDA requirements and shows how we are compliant in order to make sure we have evidence of what we did,” added Mark Blakely. “Not only do we have to show how we use the system, we have to prove that it does what it is supposed to do, such as notify the appropriate people on an ECO.”

“Solta Medical does not take shortcuts so we were very diligent with our validation,” commented Mr. Blakely. “We brought in a consultant and it took us about six weeks to complete. This was fairly quick compared to other validations I have done.”

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“Omnify is a highly configurable system which allows companies like Solta Medical to fit the system to meet their exact needs,” stated Penny Goss, Compliance Consultant. “Because I validate multiple PLM, ERP and Quality Systems each year, I am able to efficiently aid my clients in getting their systems validated and into production. It was a pleasure working with the excellent team at Solta Medical and with the Omnify system.”

Implementing the Omnify solution has positioned Solta Medical to maintain their competitive position in the market as the leader in aesthetic products by helping the company to improve product development efficiencies and continue to create innovative products while meeting the stringent requirements set for by the FDA.

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