Axonics

Establishing Design Controls with Omnify Empower Helps Axonics Receive CE Mark for Sacral Neuromodulation

Customer

Axonics ModulationTechnologies, inc. is a privately-held medical device company developing an innovative neuromodulation platform based on miniaturized rechargeable technology. The Axonics Sacral Neuromodulation System™ (Axonics r-SNM System™) is the first CE-marked rechargeable SNM system designed to improve the experience of both clinicians and patients suffering from Urinary and Fecal dysfunction.

Challenge

Paper-based Product Development Processes

The team at Axonics had previous experience with Product Lifecycle Management (PLM) at another medical device start-up. They knew the benefits that an electronic, online PLM solution could provide a small to medium-sized medical device company.

One particular area where Axonics saw the greatest benefit of a PLM solution was with electronic sign-offs. With paper-based processes and insufficient signatories, approvals are serial in nature and the absence of a key approver can translate into a major delay. Axonics wanted to prevent this issue with an automated system that offered the ability for Axonics staff to continue the approval process for documents/drawings/training/etc., on or off-site, via remote logins and allow for the assignment of signatories.

Goal

Product Development Compliant to ISO 13485 and the FDA CFR

Axonics wanted a software solution that would facilitate Active Implantable Medical Device (AIMD) product development under a Quality System compliant to ISO 13485 and the FDA CFR (Code of Federal Regulations), as well as other regulatory frameworks.

Customer Success

Proper Design Controls to Meet Ambitious Timelines

Omnify Empower PLM was selected based on past successes, ability to meet Axonic's requirements as a new medical device company, and also because a large portion of the team was familiar with it. Implementation of Omnify Empower took only a few weeks and an ISO 13485-compliant Quality System was established within five months of the first DCO (Document Change Order) release.

Omnify offers a flexible and configurable system for medical device companies. Axonics currently utilizes the Document Control, Supplier Management, Training Management, Equipment Management, and Bill of Material (BOM) management modules. The company has also configured Omnify Empower to address areas such as: material citations (used to accelerate biocompatibility risk analysis and answer other regulatory queries), calibration and preventive maintenance, component characteristics such as electrical part footprints, supplier part number decoders, and Design History File (DHF) auto-generation.

"DHF index compilation in particular is a manual and time-consuming process for many medical device companies with moderate to complex product designs," stated Joseluis Espinosa, Director, Quality Engineering for Axonics Modulation Technologies.

Quick Facts:

Company: Axonics Modulation Technologies

Industry: Medical Device

Key Benefits:

-Flexible and configurable system for growing medical device company

-Fully implemented in only a few weeks

-Able to receive CE marking in just two years compared to industry average of five years

-Met goal of having an automated system for electronic sign-off with signatories

-ISO 13485 and FDA CFR-compliant Quality System

-Established Design Controls

Axonics Sacral Neuromodulation System. First CE-marked rechargeable SNM System

Omnify Software

Axonics Modulation Technologies

Customer Success

"To address this, we've added custom DHF attributes to define Active Project Phase, Design Control Category, and Deliverable Owner which are added or checked routinely during every DCO." Axonics then performs an Omnify Database Search to auto-generate a DHF by adding the custom attributes, in combination with other pertinent fields such as Document Number, Description, Revision, and Date Released. Device Master Records (DMRs) are also created in a similar but simplified manner as Omnify BOMs, dramatically saving time and effort. Axonics uses the Document Packager to download an entire zipped DHF or DMR for training, auditing, regulatory review, and other purposes.

"Because we are a new company we do not have data to compare our previous processes to our current processes with Omnify Empower," said Mr. Espinosa. "However, we were told by industry experts that a new Sacral Neuromodulation product would take five years to receive CE marking, but we accomplished that milestone in just two years after initiating design controls with Omnify Empower." Mr. Espinosa added that, "Omnify facilitates rapid design, document, and BOM controls in tandem with supplier approvals and vendor item linkages. All these aspects and more allow us to achieve our ambitious timelines."

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-Joseluis Espinosa, Director, Quality Engineering , Axonics Modulation Technologies

About Omnify Empower

Omnify Software provides a single, secure location to manage the complete product record including: product data, bill of materials, engineering changes, product documentation, project, quality/CAPA, and training records information. The Omnify Empower system enhances visibility into the entire product development process by capturing design, manufacturing, quality, service, and customer information and associating it to the product record. Omnify Empower is a business-ready solution that is easy to use, quick to implement and can be deployed on-premises or in the cloud.

Omnify Software