# BionX

## Meets Time-to-market, Compliance and Efficiency Goals to Produce World's Only Active Prosthetic Foot

### Customer

**BionX Medical Technologies, Inc., now Ottobock,** produces the world's only active prosthetic foot and ankle solution available in the market – the emPOWER Ankle. It replaces the function of the muscles and tendons with an actively driven ankle joint, and supports the user by supplying additional energy while walking.

### Challenge

*Paper-based Document and Change Control System*

As a small developer and manufacturer of a complex robotic prosthetic device, maintaining a paper-based document control and change control system was becoming unmanageable. The complexity of the device meant that even a small change to the product or documentation resulted in a large paper documentation package which had to be manually compiled and routed for review and approval.

With a major re-design project on the immediate horizon, it was essential to identify and implement a more efficient document control solution ahead of the large volume of new product design documentation that was expected.

### Goal

*Transition to an Electronic System Suitable for Medical Devices Regulated by the FDA*

BionX wanted to transition from their paper processes to an electronic system that would be able to efficiently manage a multi-level product structure/Bill of Material (BOM) and engineering change orders with the ability to expand into other electronic records management such as Training Records, CAPA/Quality issues and supplier management. A key requirement was that the system met the FDA 21 CFR Part 11 compliance requirements for electronic records and electronic signatures.

"We went through a discovery process over the course of several months, evaluating about five different solutions," stated Rick Smith, Sr. Director, Quality & Regulatory for BionX Medical Technologies. "The system needed to be flexible, without being overly complex, with a fairly intuitive administrative interface. Pricing and ongoing licensing costs were also a factor, given our small size and limited resources." Mr. Smith added that, "a matrix of requirements was created and the different solutions were ranked as to how well they solved our particular needs and Omnify Empower PLM was our top choice."

### Customer Success

*Time-to-market, Compliance and Efficiency*

Adoption of Omnify Empower PLM was very well received at BionX Medical Technologies. The R&D group is very satisfied with the ability to work solely with electronic documentation rather than maintain paper records, and management has been pleased with the ability to approve changes electronically and remotely, along with the increased overall visibility into product design and development activities within the business.

The company chose to implement Empower in stages based on business needs, starting with document control, change control and validation of 21 CFR Part 11 compliance. Shortly after, they executed Training Management which enables employees to record training procedures and easily see tasks assigned to them.

### Quick Facts:

**Company:** BionX Medical Technologies, now Ottobock

**Industry:** Prosthetic Devices

**Key Benefits:**

**-Time to market:** A fast-paced development effort, which launched a completely overhauled product iteration from concept to sales in 15 months, on schedule, would never have been possible in an old paper system.

**-Compliance:** Electronic signatures and workflows with mandatory data requirements have improved documentation compliance. Also, the ability to efficiently pull up procedure, records and approval history has been a great benefit in external compliance audits, such as a recent ISO 13485 re-certification resulting in no non-conformances.

**-Efficiency:** ECO cycle time reduced to less than five calendar days (not previously measured, but was much longer).

**emPOWER Ankle**
World's only active prosthetic foot and ankle solution.

# BionX Medical Technologies

## Customer Success

The next stage was Supplier Management in order to manage Supplier Qualification documentation and link qualified suppliers to specific parts. Currently, the company is working on implementing Service Objects for maintaining Device History Records (DHRs) and Service Records, and Quality/CAPA (Corrective and Preventive Action) for non-conforming material.

"The Omnify Empower implementation has been extremely useful during business reviews with external parties in that information regarding testing, design, suppliers, marketing material, and training can be accessed in real-time in a clear and presentable manner," stated Mr. Smith. "Several external reviewers have commented on how useful that has been and was particularly helpful with our recent ISO 13485 re-certification."

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> **-Rick Smith, Sr. Director, Quality & Regulatory for BionX Medical 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