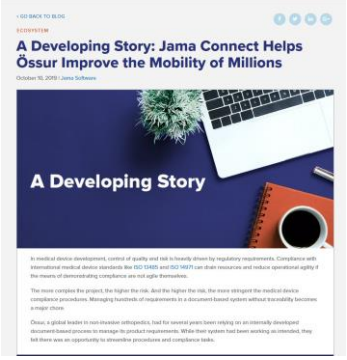
CLIENT Jama Software

PROJECT Blog post: Össur Case Study

OBJECTIVE Call attention to how the client's requirements management platform can help companies in the medical device sector

COPY EXCERPT

Jama Connect Helps Össur Improve the Mobility of Millions



Call or write CopyEngineer to receive a PDF of the complete case study.

Or view/download it online at: www.jamasoftware.com/blog/jama-connect-helps-ossur-improve-the-mobility-of-millions/

In medical device development, control of quality and risk is heavily driven by regulatory requirements. Compliance with international medical device standards like ISO 13485 and ISO 14971 can drain resources and reduce operational agility if the means of demonstrating compliance are not agile themselves.

The more complex the project, the higher the risk. And the higher the risk, the more stringent the medical device compliance procedures. Managing hundreds of requirements in a document-based system without traceability becomes a major chore.

Össur, a global leader in non-invasive orthopedics, had for several years been relying on an internally developed document-based process to manage its product requirements. While their system had been working as intended, they felt there was an opportunity to streamline procedures and compliance tasks.

The Costs of a Rigid Requirements System in Medical Device Development

Continually evolving its processes has always been a key to success for Össur, whose cutting-edge prosthetics technologies have been showcased in publications like Popular Science and have been worn in competition in the Olympic Games. They examined their development cycle for inefficiencies and noted their requirements process unfolded in a sequential manner that was costing them an enormous amount of time and effort.

In specifying a highly complex Össur medical device, several engineers would collaborate on drafting requirements and compiling the requirements document. The document would then be circulated for review. Once approved, the requirements would be verified. If any requirement needed to be added or changed, however, the entire review and approval cycle had to be repeated.

"Our old system was very rigid," said David Langlois, Director of R&D for Bionic Solutions at Össur. "The minimum effort was always quite high, which means the overhead was also high."

Össur knew it was time for a change. They wanted something that was as close to a turn-key solution as possible — one that would provide traceability and dynamic content management, and would be scalable across their organization. Plus, it needed to be capable of handling the complete development chain — from requirements through verification and validation, along with easing the path to compliance to ISO standards like ISO 13485 and ISO 14971 — for a diverse product line.

After evaluating several alternatives, including some designed specifically for medical device development, Össur chose Jama Connect™.