CUSTOMER STORY

Microsurgical Robot Developer, Microsure, Leverages Jama Connect® to Ease the Path to Compliance and Speed Time to Market

After being slowed down by their previous Word and Excel solution for requirements management, Microsure can now involve all team members in development, efficiently manage change, and quickly provide necessary regulatory documentation.

ABOUT microsure robot assisted microsurgery

- Developer of the MUSA, the world's first clinically available CE-certified surgical robot for microsurgery
- Headquartered in Eindhoven, Netherlands
- Founded by Eindhoven University of Technology and Maastricht University Medical Center in 2016
- Recent recipient of the European Innovation Council (EIC) Accelerator grant for Dutch startups developing top-class innovations

Founded in 2016 by Eindhoven University of Technology and Maastricht University Medical Center, Microsure is the developer of the first clinically available CE-certified surgical robot for microsurgery. They are among seven other companies in the Netherlands to receive the European Innovation Council (EIC) Accelerator grant.

Microsure is headquartered in Eindhoven, a Dutch town that is famous for being a technology and design hub.

CUSTOMER STORY OVERVIEW

Microsure's mission is clear – and ambitious. To maximize microsurgical performance by offering superhuman precision through robotic assistance, enabling the development of new surgical treatments and improving the outcome of existing procedures, reducing healthcare costs and improving patients' lives.

With so much at stake when it comes to quality management and regulatory compliance, they knew they needed a requirements management tool that could help them get there.

CHALLENGES

- Implementing design changes was cumbersome and time-consuming
- Documentation for regulatory compliance was scattered and difficult to produce
- The quality system was complex, and few understood it

SELECTION

- The platform was easy-to-use with a quick learning curve
- It was highly suggested from the medical device community
- Team members had previous positive experience with the platform
- It increased their confidence in regulatory compliance
- Jama Software® stood out as a true business partner

OUTCOME

- The ability to involve all team members in the development process, even non-technical stakeholders
- Realizing an easier path to regulatory compliance thanks to increased professionalism with regulators, efficient change management, and automatic regulatory documentation generation
- Decreased time to market

OBJECTIVES

From the start of the company in 2016, the Microsure team had been using Word and Excel to manage their requirements. MUSA-2, the first product developed by the Microsure team, is a clinically available CE-certified surgical robot for microsurgery. The team has developed the MUSA-2 to obtain additional clinical data to support a MUSA-3 development.

As the team began research and development activities for the MUSA-3, they knew they wanted to do things differently.

Although they were able to successfully release the MUSA-2, the following were issues the Microsure team experiences with using Word and Excel for requirements management:

- Implementing design changes was cumbersome and time-consuming
- Documentation for regulatory compliance was scattered and difficult to produce
- The quality system was complex, and few understood it

"With Word and Excel, if something is changed and a link is broken, the document is gone and it's literally floating around somewhere in the cloud without linkage to anything. This makes it very scary, especially from a quality or regulatory perspective," said Rene Wenmekers, Director of Quality and Regulatory at Microsure.

"Our Word and Excel process evolved with the organization and therefore it was put together layer by layer, making it really hard to have the full depth of knowledge about how the quality system works," said Wenmekers.

"We work in a highly regulated environment, and Microsure's product has hundreds of requirements on system, subsystem unit, and component levels. And from a regulatory documentation standpoint, information is scattered," said Robin Brouns, Software Team Lead.

"When we make changes in medical device development, they need to be reported to the notified body. And when that change hits the level of 'significant change,' the whole documentation set needs to be provided to the notified body to be reassessed on safety and efficacy. Every time a requirement changed, it needed to be updated across the whole documentation path. This was not sustainable using Word and Excel, and it was risky," said Wenmekers.

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> **Robin Brouns**
> Software Team Lead
> Microsure

SELECTION

The selection process was straightforward for the Microsure team. Because the team is in Eindhoven, famous for being a technology and design hub, Microsure had access to a strong network of medical device manufacturers who were willing to share their experience with requirements management solutions.

The community overwhelmingly recommended Jama Connect.

In the evaluation process, Jama Connect won out over other solutions because:

- The platform was easy-to-use with a quick learning curve
- It was highly suggested from the medical device community
- Team members had previous positive experience with the platform
- It increased their confidence in regulatory compliance
- Jama Software stood out as a true business partner

"Our selection process was very straightforward. We needed a system that would support us, not a system that we needed to support. That's why we chose Jama Connect," said Wenmekers.

While the team initially evaluated Intland codebeamer, it was quickly ruled out.

"The partnership was a valuable aspect of the decision-making process, and it seemed like codebeamer was trying to fit us into their narrative, rather than showing us how we could work together. It created some resistance," said Wenmekers. "On the other hand, Jama Software listened to us and demonstrated that they would be a true business partner. This gave us so much more confidence moving forward with them."

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>
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"As a startup, speed to market is crucial. We are solely dedicated to getting our flagship product out into the market. We knew we had to get this right on the first shot, and that's why we chose Jama Connect," said Wenmekers.

OUTCOME

Even though the Microsure team hasn't been using Jama Connect for long, the benefits are already being felt across the organization.

Microsure has already benefited from these quick wins:

- The ability to involve all team members in the development process, even non-technical stakeholders
- Realizing an easier path to regulatory compliance thanks to increased professionalism with regulators, efficient change management, and automatic regulatory documentation generation
- Decreased time to market

"The most striking change that I have seen is that finally our clinical team has access and visibility into technical requirements. They can now understand how everything is linked. This is a huge advantage because we can involve non-technical departments in the requirements discussion. It's clear how a technical requirement finally evolves in clinical validation and where it comes from. The involvement of the bigger group in the organization is incredible," said Wenmekers.

"In our previous, paper-based system, as you add requirements the complexity increases, and the difficulty increases exponentially. The pile of documents grows and the links between those documents grow, and at a certain point you just lose track. Jama Connect makes that simple and reduces the complexity and work significantly. Jama Connect handles the complexity and maintains the upstream and downstream traceability for each requirement, making the number of requirements no longer an issue," said Andre Kleibeuker, Senior System Architect.

Wenmekers continued, "Now that we've gotten rid of our documents-based system and moved to Jama Connect, we finally have a clear change management driver. This is going to increase our time to market immensely."

"Jama Connect has helped us to have a higher level of professionalism with regulators because it's a trusted tool for developing medical devices. We knew that in the audit process regulating bodies would recognize the level of detail and clarity

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Senior System Architect
Microsure

that the tool gives us. If we were to use a tool that they've never heard of, say an open-source tool, that would raise red flags – they would likely need to look much deeper into our development activities," said Wenmekers.

"With Jama Connect, we have the confidence that we can easily show regulators the linkages between each individual item, with full traceability from top to bottom. I can easily click through the whole storyline of how requirements fit into the V-model and what actions we took."

When asked if he had any advice for other medical device companies in the early stages of development, Wenmekers said "Do some benchmarking on your current processes. Identify the issues that you are trying to solve. Evaluate what's on the market for requirements management, and once you've done that, it'll be clear which solution is right." And for them, it was an obvious choice, Jama Connect.

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Rene Wenmekers
Director of Quality and Regulatory
Microsure

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ABOUT JAMA SOFTWARE

Jama Software® is focused on maximizing innovation success in multidisciplinary engineering organizations. Numerous firsts for humanity in fields such as fuel cells, electrification, space, software-defined vehicles, surgical robotics, and more all rely on Jama Connect® requirements management software to minimize the risk of defects, rework, cost overruns, and recalls. Using Jama Connect, engineering organizations can now intelligently manage the development process by leveraging Live Traceability™ across best-of-breed tools to measurably improve outcomes. Our rapidly growing customer base spans the automotive, medical device, life sciences, semiconductor, aerospace & defense, industrial manufacturing, consumer electronics, financial services, and insurance industries. To learn more, please visit us at jamasoftware.com.