CUSTOMER STORY

Medical Device Startup, Proprio, Chooses Jama Connect® to Drive Innovation

A study on the value of a requirements-driven product development process and the limitations of the typical Quality Management System (QMS).

ABOUT | Proprio

- Founded in 2016
- Series A funded – June 2020
- Headquartered in Seattle, WA
- Product Focus: Real-time immersive video and mediated reality interaction for surgical assistance

  End Markets: USA (FDA)
  Device Classification: Probable Class II device
  Standards Met: 21 CFR 820.30, ISO 13485, and ISO 14971

Proprio is on a mission to improve the way surgeons work with the help of advanced and innovative technologies. Their technology will allow surgeons around the world to improve the precision and efficiency of surgery with the development of computer vision, machine learning, robotics, artificial intelligence, augmented and virtual reality, and medical imaging.

Like many innovative medical device startups, Proprio's staff is composed of talented people with different backgrounds – some of whom were not familiar with the specific practices required in developing a complex medical device.

When Rama Pailoor joined as the VP of Software Engineering, he knew it was imperative to establish a requirements-driven development process from the very beginning. Pailoor recognized that their existing approach of using only a Quality Management System (QMS) was not capable of supporting the level of complexity needed to develop their product.

> *Establishing a requirements-driven development process helps to formalize the user needs, getting all the stakeholders to come to a common forum, to express the requirements from their perspective, and avoid confusion. The right requirements management solution can facilitate all of that.*

Rama Pailoor
Vice President of Software Engineering, Proprio

CHALLENGES

Given the level of complexity and regulatory scrutiny of medical device products, using a Quality Management System alone to manage medical device design controls was not sufficient.

Like many document and spreadsheet-based processes, the Quality Management System (QMS) Proprio had in place technically supported requirements management at face value, but when it came to complex engineering efforts, the system came up short.

Experiencing the Limitations of a QMS

As the team completed the initial conceptual phase of development and moved into the more technical phases, it became abundantly clear that they needed a requirements management tool that could handle complex product development.

"All-in-one" QMS solutions on the market were simply not suited for the complexity of what Proprio was setting out to build. Pailoor quickly recognized the opportunity to transition to Jama Connect and highlighted, "This QMS was sold to my team as the 'Swiss Army Knife' for product development. It sounded too good not to consider."

Many Quality Management Systems tout an 'all-in-one' solution, but rarely are they equipped to manage design controls for complex medical device product development and are often relegated to an electronic file cabinet for audit purposes. In turn, this leaves product development teams managing requirements, risks, tests, and traceability in documents and spreadsheets until final Part 11 signoff. "It was going to be a huge hurdle for us to manage requirements, to conduct reviews, to establish traceability and so forth prior to using Jama Connect," Pailoor added.

> *Clearly, if it's a very simple product, it might address your needs. But for the kind of products we are developing here at Proprio, these 'all-in-one' QMS solutions just don't cut it."*

Rama Pailoor
Vice President of Software Engineering
Proprio

THE SOLUTION

The Clear Requirements Management Tool for Medical Device Innovators:

Proprio turns away from a limited QMS and selects Jama Connect for the complete functionality needed to address complex medical device product development.

Proprio selected Jama Connect for Medical Device Development and now reports that it is helping the team make an impact in these significant areas:

1. Streamlining implementation of Medical Device Design Controls based on 21 CFR 820.30, ISO 13485, and ISO 14971
2. Proactively managing complex traceability to accelerate product development and regulatory approval
3. Accelerating innovation made possible with requirements-driven development

Streamlining Implementation of Medical Device Design Controls

The selection process was short and simple. As a veteran of medical device development and a seasoned engineer, Pailoor knew there was only one solution that would fit his team's needs. He also understood that more functionality in a requirements management platform often comes with more confusion, training, and the need for an in-house expert. With a recognition that the team needed a mature approach to requirements management and design controls, Pailoor turned to a trusted partner to find the right balance.

"Tools that try to be an all-in-one requirement and QMS system don't have the functionality needed to address complex product development. I knew it was a great opportunity for me to push to implement Jama Connect, especially because there are templates already set up to address the needs of medical device companies," said Pailoor.

As a medical device startup, the company needs to comply with a long list of IEC, FDA, ISO, and cybersecurity standards as they head towards FDA submission, and the team at Proprio knew that quickly establishing a design control process was critical.

> *Right from the get-go, we could just use the existing template and adapt it as we needed. This flexibility is really important for us and saved us weeks or months that we would have spent establishing a schema.*
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> **Rama Pailoor**
> Vice President of Software Engineering, Proprio

With the Jama Connect for Medical Device Solution that comes pre-configured like 21 CFR 820.30, ISO 13485, and ISO 14971; Proprio was able to save potentially months in the process of establishing proper medical device design controls.

> *I told the team it was a very easy-to-use solution. But people were shocked at how fast it came together. Within hours, we were going and setting up the structure for our requirements. There were many other people in the company who had used Jama Connect before and supported our selection. It was a clear choice for medical device innovators like us.*
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> **Rama Pailoor**
> Vice President of Software Engineering, Proprio

Proactively Managing Complex Traceability to Accelerate Product Development and Regulatory Approval

With a formal system now in place for requirements-driven development with Jama Connect, Proprio can take a very proactive approach to requirements traceability.

For teams that put off this process, traceability is often not maintained in real-time, and documentation is held off until the end, where it leads to hectic fire drills and costly delays and gaps that are identified late in development. But with Jama Connect, traceability is automatically captured during the development process, and alleviates the need to create traceability retroactively.

Now, the team is positioned to quickly generate the needed Design History File (DHF) and Risk Management documentation as a byproduct of the engineering work performed in Jama Connect.

> *Jama Connect establishes traceability proactively from user needs, risk controls, all the way through verification."*
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> **Rama Pailoor**
> Vice President of Software Engineering
> Proprio

Accelerating Innovation Made Possible with Requirements-driven Development

In the short time Proprio has been using Jama Connect, the feedback has been immediately positive, and the effect can be felt organization wide.

"Now that we have Jama Connect, I'm seeing the entire team coming together, and evaluating the established requirements in a way that is very open and transparent," said Pailoor. "And then that allows you to iterate on that, refine the requirement. And then take timely actions to address the changes that come about as a result."

The team is seeing a major reduction in meeting time as the Jama Connect platform enables remote collaboration and communication. The team's review cycles have also shortened, thanks to Jama Software's unique licensing model that allows for an unlimited number of people to participate in reviews.

"Not having to worry about having licenses for all team members and stakeholders gives the team greater visibility and allows us to have a more thorough review process. This is a big plus when compared to most solutions, where you need a license to even review requirements," said Pailoor.

With the implementation of Jama Connect, the team has now established a requirements- and test-driven development process – which has a significant impact on innovation.

LOOKING FORWARD

While the Proprio team hasn't yet completed an entire development cycle with Jama Connect, they already know that the first order of business for additional products will be establishing Jama Connect as the single source of truth for requirements related work from the very beginning.

"As we expand our product line and plan for future releases, we'll be engaging Jama Connect in a more upfront way than before. It will be great to see engineers and non-engineers get into actively communicating their expectations in a formal way using Jama Connect," said Pailoor.

Further entrenching Jama Connect into their larger ecosystem of tools is also a next step for Proprio. Pailoor says Jama Connect's ability to integrate with other applications and work in conjunction with other systems like their QMS will play a big role in future product development – it's one of the reasons he believes that Jama Connect is the right choice for innovators.

"We're looking forward to connecting Jama Connect to some of our other tools and frameworks. And to make our development process truly requirements-driven, we need to establish that connection," said Pailoor. "It's easy to do with Jama Connect. That's one of the reasons why I advocate for Jama."

> *As we expand our product line and plan for future releases, we'll be engaging Jama Connect in a more upfront way than before. It will be great to see engineers and non-engineers get into actively communicating their expectations in a formal way using Jama Connect.*

Rama Pailoor
Vice President of Software Engineering
Proprio

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