jama software®

LEX Diagnostics

LEX Diagnostics Boosts Efficiency by Modernizing its Requirements Tool with Jama Connect®

ABOUT LEX DIAGNOSTICS

LEX Diagnostics is redefining point-of-care diagnostics with its ultra-fast PCR system. Their launch product, the VELO system, delivers positive results for Flu A, Flu B, and COVID-19 in as little as six minutes, enabling cost-effective decisions during a single appointment.

CUSTOMER STORY OVERVIEW

After inheriting an existing requirements management tool, LEX Diagnostics sought to modernize their approach. Switching to Jama Connect® provided a user-friendly platform with direct product support and flexible licensing that aligned with their agile goals.

CHALLENGES

LEX Diagnostics encountered hurdles in integrating their existing tool with their agile, startup environment. The team identified several areas where an improved solution could better support their workflows and rapid development pace.

- **Need for Responsive Support** Jama Software's flexible support model was a key advantage at important points in LEX's development journey allowing the company to avoid manual workarounds which had historically been necessary and highlighting the importance of a partner that provides direct and timely product support.

- **Complexity Impacting Usability** The LEX team found the Jama Connect interface easy and intuitive to navigate, which encouraged adoption by users who weren't full time administrators resulting in the tool being more widely used across the organization. Jama Connect reduces the steps required to execute routine tasks, saving LEX significant time and money.

- **Need for Scalable Licensing** Startups like LEX thrive on agility and collaboration, requiring tools that adapt to their dynamic workflows. Thanks to a flexible licensing model, Jama Connect allowed the entire team to participate directly in the development process, ensuring that critical reviews and updates happened within the platform itself. The software removed barriers to access and kept everyone aligned with a single source of truth.

WITH JAMA CONNECT, USERS EXPERIENCE:

- **A Modern, Intuitive Interface** that empowers users to manage requirements, create documents, and enhance collaboration without a steep learning curve.

- **Flexible Licensing and Widespread Adoption** that allows the entire team to contribute to projects, creating a single source of truth and improving internal knowledge sharing.

- **Responsive, Expert Support** that provides clear answers and reliable timelines, saving weeks of project time and eliminating administrative delays.

"It's very compatible with the sort of startup model where everybody will be doing a little bit of everything. The person with the best skill set is the one who solves a particular problem."

Tim Schuller, VP of Engineering, LEX Diagnostics

"Our head of software...just figured Jama Connect out himself in about 15 minutes. It's just night and day with simplicity."

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"It's a useful confidence boost to see that the workflows we've built in Jama Connect closely align with standard medical device and regulatory workflows, reinforcing trust in our approach."

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SOLUTION

LEX Diagnostics decided it was time to update its requirements management tools and chose Jama Connect, supported by internal champions with positive prior experiences with the platform.

- **Seamless Onboarding and Hands-On Support:** Following a trial where the team could test the platform's full capabilities, Jama Connect's tailored onboarding and hands-on support ensured a smooth transition.

- **An Intuitive, User-Friendly Platform:** The simplicity of Jama Connect offered immediate value to the engineering team, allowing them to focus on innovation rather than tool management.
  "Our head of software...just figured it out himself in about 15 minutes," Tim Schuller, VP of Engineering noted. "It's just night and day with simplicity."

- **A Flexible Licensing Model:** Jama Connect's flexible licensing model, including unlimited reviewer seats, suited LEX Diagnostics' startup environment, fostering collaboration across departments.

OUTCOMES

Since adopting Jama Connect, LEX Diagnostics has seen significant improvements in its processes, team morale, and confidence in meeting regulatory requirements.

- **Improved Adoption and Internal Knowledge:** Flexible licensing has driven widespread adoption. Teams now use Jama Connect for internal software and hardware development — projects they previously managed in disparate documents.
  "It's very compatible with the sort of startup model where everybody will be doing a little bit of everything," Schuller explained. "The person with the best skill set is the one who solves a particular problem."

- **Increased Efficiency and Reduced Timelines:** The direct support and user-friendly interface have streamlined administrative tasks. Schuller estimates the responsive support from Jama Connect saved **four to five weeks of potential delays**. When the FDA requested further details during review of their 510(k) submission, generating documents from Jama Connect was faster and easier.

- **Enhanced Regulatory Confidence:** With built-in templates aligned with standards like ISO 14971, Jama Connect gives the team a validated framework for their workflows that has provided a "useful confidence boost." The ability to easily version changes within the platform has also freed them from manual paperwork tracking and potential audit complexities.