




CUSTOMER STORY

Streamlining Workflow and Strengthening Collaboration When Developing Medical Devices

Jama Software Helps RBC Medical Innovations Unify Processes and Enhance Traceability



Getting to market quickly requires a medical device contract development and manufacturing company to have exceptional team collaboration and outstanding workflow efficiencies.

When it was time to upgrade from semi-manual processes to a completely integrated and streamlined solution, RBC Medical Innovations turned to Jama Software.

With Jama Connect™, RBC saw opportunities for greater efficiencies, stronger requirements management, and a better way to stay on top of quality and regulatory compliance issues.

Earning Recognition in a Competitive Market

Based in the Kansas City area, RBC designs and manufactures a wide range of diagnostic and therapeutic medical devices for industry clients that supply hospitals and healthcare facilities. In business since 1994, RBC prides itself on its diverse product experience, skilled cross-functional development teams, and deep expertise satisfying regulatory requirements.

RBC COMPANY SUMMARY:

- Founded in 1994
- Client partners include a variety of startups and industry leaders
- Provides medical device manufacturing, development, and design



CHALLENGES

- Semi-manual processes that required significant labor and increased the chances of errors
- Lack of a central development process dashboard
- Traceability to ensure that essential requirements were linked to the necessary test coverage

SOLUTIONS

- Unify its development environment
- Gain better visibility into tasks, tests, and costs
- Keep team members informed on each aspect of a project

RESULTS

- Number of team-member days saved on a state-of-the-art capital equipment development project: 123
- Approximate cost savings per project: \$150,000

CHALLENGE

Improving Efficiency While Meeting Regulatory Requirements

The challenges of building medical devices that perform vital diagnostic functions and patient treatments go beyond the product design itself. The labyrinth of rules and regulations that impact the release of a medical device requires dedicated resources from the earliest stages of product development.

RBC was looking to upgrade its development to improve upon:

- Semi-manual processes that required significant labor and increased the chances of errors
- Lack of a central development process dashboard
- Traceability to ensure that essential requirements were linked to the necessary test coverage

RBC faced another ongoing challenge: maintaining its identity as an industry-leading product design and manufacturing firm using a development methodology that could outperform both internal research as well as external development and design organizations bringing medical devices to market.

Faster Time to Market With Less Risk

Workflow efficiencies are vital to RBC's product development methodology. The company must be able to ensure that it meets customer and regulatory requirements in order to maintain its ISO 13485 and ISO 9001 certification, and FDA registration as a contract manufacturing facility.



As we onboard team members to Jama Connect, there's an immediate excitement as people start using it. It's great to have them come in and say, 'Wow, this is awesome.'

Scott Britt, Systems Engineering Manager,
RBC Medical Innovations

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Previously, there was no easy way to know details concerning what progress had been made. It was challenging to know whether we were on track to meet the cost and schedule targets for the project.”

Scott Britt, Systems Engineering Manager, RBC Medical Innovations

Previously, RBC often built its own internal development tools to solve design challenges and meet specialized requirements.

While this strategy was successful for several years, as both products and the surrounding regulatory environment grew in complexity, RBC realized it had outgrown its internal tools.

“Over a period of years, we’ve been increasingly aware that we needed to improve our development workflow,” Britt says. “It wasn’t optimal and team members knew it could be improved.”

“A big symptom of the problem was noticeable when we would ask about our progress on verification,” Britt continues.

RBC chose Jama Connect to:

- Unify its development environment
- Gain better visibility into tasks, tests, and costs
- Keep team members informed on each aspect of a project

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These are very conservative numbers just for one project, and that alone pays for Jama.”

Scott Britt, Systems Engineering Manager,
RBC Medical Innovations

SOLUTION

A Cost-Effective Way to Simplify Workflow, Collaboration, and Compliance

RBC's nimble approach to design and development means it is perpetually seeking solutions and technologies that enhance its efforts. Selecting Jama Connect™ to augment its development environment produced notable benefits almost immediately.

As a versatile solution that integrates collaborative efforts and streamlines workflow from design through product release, Jama

Connect meets many of RBC's primary development challenges. A key Jama Connect capability — flexible integration with many of the tools commonly found in development environments — meshed well with RBC's design agility and desire to work with whatever tools prove most effective for the task at hand.

Jama Connect Capabilities for Medical Device Product Development

RBC is continuing to discover Jama Connect's capabilities to improve medical device development. Through requirements management, workflow automation, and collaboration tools, teams gain extended visibility into processes across the entire product lifecycle. The tracking and reporting functions also help meet regulatory compliance goals and drive quality assurance. Among the capabilities RBC finds particularly useful for developing medical devices:

- **Reviews and approvals:** To maintain the chain of approval and increase stakeholder participation, Jama Connect's Review Center streamlines and expedites the review process and has the ability to tie electronic signatures to specific reviews or baselines in compliance with regulations.
- **Design verification and validation:** Jama Connect manages V-model traceability, including test cases used for verification and validation. It also helps when providing objective evidence of compliance with government regulations and standards.
- **Audit trails with reports:** Real-time reporting and baselining tracks all changes to information within the system.

Jama Connect Excels at Meeting Additional Challenges

Since its deployment, the engineering team at RBC increasingly trusts Jama Connect to speed development, using it for a wider range of tasks — such as test management and defect tracking synced through an integration with Microsoft Team Foundation Server.

“After we understood our requirements, test case, and defect management,” Britt says, “we tested some Jama Connect reviews and it became obvious how efficient it was. Then we began building other deliverables in Jama Connect, not just requirements documents. For instance, now we’re creating planning materials in Jama Connect as well.”

As numerous companies have discovered over time, and RBC confirmed in its project work, Jama Connect unifies a complex development environment and gives teams the ability to track progress, optimize quality, and audit results — all of which are critical factors in the development of successful medical devices.

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Jama Connect frees us up to focus on the design of the product, not the logistics of the work that needs to be done. We are able to spend our time more effectively — helping our customers.”

Scott Britt, Systems Engineering Manager,
RBC Medical Innovations

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.