

CUSTOMER STORY

MilliporeSigma Streamlines Complex Device Development and Enhances Requirement Quality with Jama Connect®

ABOUT MILLIPORESIGMA

MilliporeSigma, the U.S. and Canada Life Science business of Merck KGaA, Darmstadt, Germany, a leading science and technology company, is focusing on providing innovative solutions and products supporting, among others, the following activities: Research and Development, Biopharmaceutical production, and a wide range of Laboratories. The company's BioMonitoring business unit develops solutions for Pharmaceutical and Food&Bev microbiology Quality Control laboratories

CUSTOMER STORY OVERVIEW

For years, the company has leveraged Jama Connect to navigate the complexities of regulated product development. As their projects and teams evolved, they faced a persistent challenge: maintaining requirement quality and consistency across a large, multi-team organization. As requirements grew more complex, the team identified opportunities to improve clarity and consistency to reduce rework and streamline reviews.

The company set out to strengthen requirement quality at the source. By becoming an early adopter of Jama Connect Advisor™, they integrated intelligent authoring guidance directly into their development workflow. This powerful combination allows the company to standardize its requirements process, improve collaboration, accelerate testing, and ensure compliance, reinforcing its position as an innovator in the life science space.

WITH JAMA CONNECT, USERS EXPERIENCE:

- Enhanced requirement quality and consistency across teams with intelligent authoring guidance.
- Reduced rework and project delays by improving clarity at the source.
- Accelerated testing and validation cycles with clear, verifiable requirements.
- Streamlined audit readiness with robust traceability and simplified exports to a QMS.

“As review cycles became less burdensome and more focused, collaboration across teams has noticeably improved. Jama Connect Advisor helps us reduce ambiguity right from the start, so everyone understands exactly what’s required.”

Fabrice Comini, System Design Expert, MilliporeSigma,
the U.S. and Canada Life Science Business of Merck KGaA, Darmstadt, Germany

CHALLENGES

In the highly regulated world of pharmaceutical development, requirement clarity is essential. With different teams authoring requirements in varied ways, the MilliporeSigma team began to ask the fundamental question of "what is a good requirement?".

This simple question surfaced opportunities to strengthen cross-functional alignment:

- **Improved Alignment and Reduced Rework:** Aligning on clearer requirements would help marketing, development, and testing teams stay in sync to reduce the need for later revisions.
- **More Predictable Delivery Timelines:** More consistent specifications would support smoother execution and more predictable project timelines.
- **Stronger Foundations for Testing:** Establishing well-defined requirements earlier would enable the testing team to develop effective validation protocols without interruption.

"The idea of having Jama Connect Advisor was to answer a simple question: is the requirement, as I wrote it, clear enough for all participants? We understood that if we want a product to be well-developed and well-tested, we have to be clear on what we want as a product through all its requirements."

Fabrice Comini, System Design Expert, MilliporeSigma, the U.S. and Canada
Life Science Business of Merck KGaA, Darmstadt, Germany

SOLUTION

To meet their goals, MilliporeSigma adopted a proactive approach, using the combined power of Jama Connect and Jama Connect Advisor to build a standardized, intelligent, and collaborative development process.

- **Centralized Collaboration and Single Source of Truth:** Jama Connect serves as the unified workspace for all stakeholders, including external partners, eliminating silos and ensuring everyone accesses the most current information throughout the product lifecycle.
- **Intelligent Requirements with Jama Connect Advisor:** As an early adopter of Jama Connect Advisor, the company now empowers engineers with real-time guidance and analysis, enabling clear, complete, and testable requirements from the start.
- **Review and Export for Quality Systems:** Collaborative review features streamline asynchronous feedback, making reviews more efficient and less cumbersome. Teams can also easily export audit-ready documentation for the formal Quality Management System (QMS), supporting regulatory needs without creating extra process overhead.

OUTCOMES

By improving requirement quality at the point of creation, the company has achieved significant benefits downstream. Development cycles are more efficient, and teams have greater confidence in meeting project timelines.

The clear, verifiable requirements created with support from Jama Connect Advisor have streamlined the entire process, from authoring to validation.

Looking ahead, the company plans to expand its use of the platform for tracking project management KPIs and is exploring advanced features like batch analysis and the upcoming automated test case generation to drive even greater efficiency.

“On some projects, we have already seen real benefits and improvements in the quality of the requirements, which make the test case writing much easier.”

**Muller, Manager of Validation, MilliporeSigma, the U.S. and Canada
Life Science Business of Merck KGaA, Darmstadt, Germany**

Learn how **Jama Connect** helps life science companies reduce rework and streamline audit readiness.

ABOUT JAMA SOFTWARE

Jama Software is focused on accelerating product velocity with AI-driven development across multidisciplinary engineering organizations. Using Jama Connect, engineering organizations can now adopt AI-driven development while intelligently managing the complexity and compliance of parallel development, automated pipelines, and industry standards. Our rapidly growing customer base spans aerospace & defense, automotive, medtech & life sciences, semiconductor, industrial manufacturing, consumer electronics, infrastructure, robotics, and energy. For more information about Jama Connect services, please visit <https://www.jamasoftware.com>.