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DATASHEET

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Managing RUO and LDT Product Requirements with Jama Connect for Medical Devices

Research Use Only (RUO) products are non-invasive and non-diagnostic which only require “For Research Only” labeling under FDA guidelines. The FDA defines Laboratory Developed Tests (LDTs) as in-vitro diagnostic products (IVDs) that are intended for clinical use and are designed, manufactured, and used within a single laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high complexity testing.

RUO and LDT development teams often use Word and Excel documents to keep track of product requirements. The challenge with this approach lies in the manual updating and sharing of disconnected documents, which becomes unreliable and inefficient when managing numerous changes and review cycles across multiple individuals or teams.

Companies developing RUO or LDT products often have plans to add features or expand indications resulting in medical devices that must be compliant to regulations. Properly managing requirements from the start will help create a much smoother transition if compliance is eventually required.

Realize Faster, More Compliant Product Development with Jama Connect

Jama Connect for Medical Devices provides a flexible, efficient, easy-to-use framework that enables development teams to manage RUO and LDT requirements, with the flexibility to comply with FDA regulations if they expand indications to be classified as a medical device. Top global medical device & life sciences companies choose Jama Connect to efficiently manage product requirements, tests, risk analysis, and design controls to accelerate time to market, reduce risk and rework, and simplify audit preparations and regulatory submissions.

KEY BENEFITS:

Define RUO requirements as good business practice

Ensure that RUO products will be delivered on time and perform as expected by implementing an easy-to-use and administer solution for managing your requirements.

Prepare for future iterations

Although RUO and LDT products are not subject to FDA regulations, businesses can use the technology as a springboard to developing devices with expanded indications. The best companies start early with robust product development practices to allow for an efficient transition to a medical device if necessary.

Reduce wasted time and risk with automated tracking and collaboration

Replace manual documents-based tracking of requirements and tests with an efficient item-based requirements management solution featuring automated workflows for collaboration and reviews, real-time tracking of new and changed requirements, and identification of issues for earlier resolution.

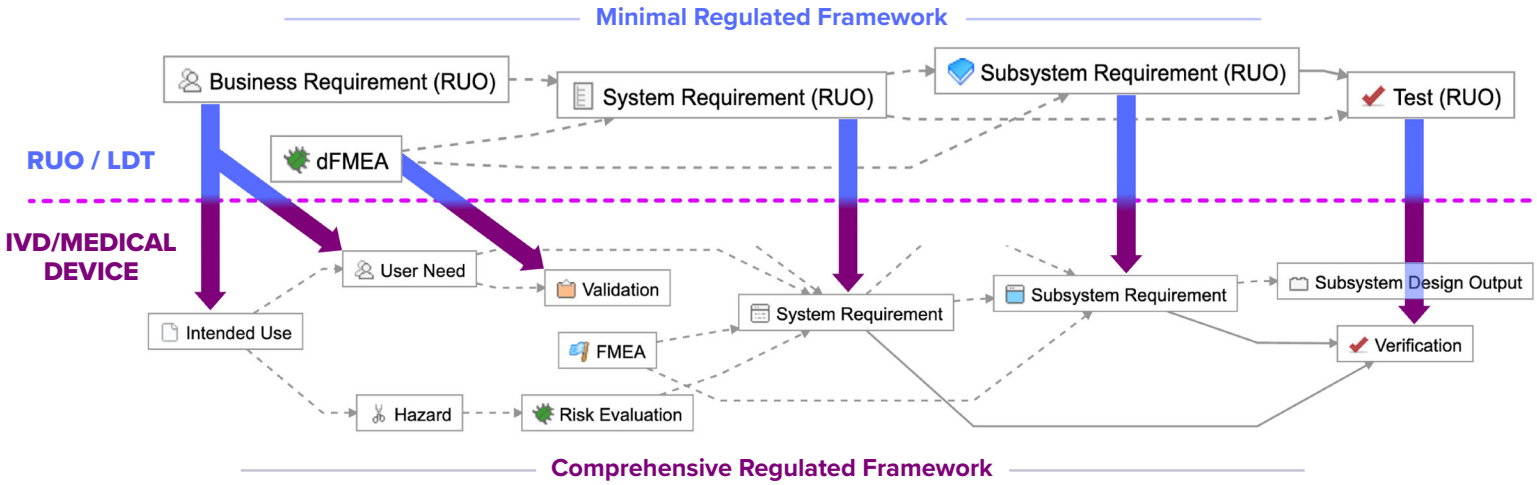
Jama Connect Delivers Live Traceability™ Across Your Development Tool Chain

Development teams use a variety of software tools for design, simulation, modeling, and testing. Jama Connect delivers Live Traceability across best-of-breed tools throughout the end-to-end product development lifecycle — ensuring that everyone is always working from the most up-to-date version of your requirements, tests, and traceability.

Jama Connect for Medical Devices offers RUO/LDT product development teams an out-of-the-box, flexible framework including a Traceability Information Model for RUO products that can be configured to suit specific business requirements. Developers can begin with this framework and seamlessly transition to the regulatory compliant medical device framework when ready. This approach accelerates development by leveraging existing information, so teams have an existing foundation to build upon.

See the diagram below that presents two regulatory compliance scenarios. The top half represents the ability to continue developing in an RUO/LDT minimal regulated framework while the bottom half represents the ability if necessary to transition to a comprehensive regulated framework.

Managing RUO and LDT Product Requirements in Jama Connect for Medical Devices



Jama Connect is the only multi-tenant requirements management software platform that offers a secure cloud solution designed for Medical Device & Life Science customers that need to validate their intended use of the system.

- Suitably validated by TÜV SÜD for safety-related development per IEC 62304
- Compliant with all EU Privacy Shield Framework program requirements
- Jama Connect is SOC2 Type 2 certified in both the server and application
- Ensures strong privacy management practices
- Data transferred is secured and encrypted

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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, visit us at: jamasoftware.com.