



EBOOK

Risk Management for Class II & III Medical Device Companies

Overcoming the Challenges of Connectivity,
Competition & Compliance

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INTRODUCTION

Medical device companies are facing a volatile new reality

The market for medical devices continues to boom as innovative connected technologies become more integrated into inpatient, outpatient, and home care. And there are no signs of a slowdown, as KPMG estimates that global annual sales of medical devices will rise by over 5 percent a year to reach nearly \$800 billion by 2030.¹

The growing success of this market yields several byproducts, including increased public awareness and media scrutiny. From investigative reports to social media campaigns, medical device companies are now squarely in the public eye and have little margin for error.

That notion isn't lost on teams developing medical devices, who are already under immense pressure to innovate on short timelines and tighter budgets while still complying with strict safety regulations.

With the stakes so high, medical device development teams must now walk a path rich with opportunity but rife with catastrophic risk.

¹KPMG, "Medical devices 2030," 2018



From our perspective, medical device companies that want to succeed in the future must evaluate how their development process stands up to three main challenges:



The Rise of Connected, Software-Driven Medical Devices

The increased use of software and connectivity in devices dramatically complicates the development process and introduces new risks.



Increasingly Strict Medical Device Regulation

Compliance with government and industry regulations remains a heavy burden, especially as regulatory bodies struggle to keep pace with the fast-paced market and updated standards that broaden inclusions to keep consumers safe.



Sophisticated Market Entrants Increasing the Pace of Competition

New competitors — especially those outside the traditional medical device space, with abundant resources but little to no background in FDA compliance — are disrupting the market, instantly capitalizing on expansive brand recognition and expertise in developing both innovative and complex systems.

This paper examines these three hurdles and how companies can adjust their processes to overcome them.

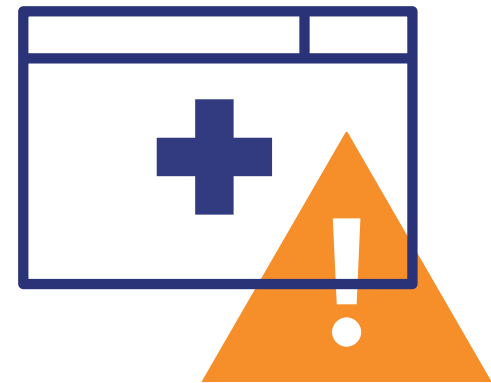
CHALLENGE ONE

The Rise of Connected, Software-Driven Medical Devices

In the past, medical device software was generally used to control programs to simply switch the equipment on and off and display readings. Today, software and its functions dominate much of the features, making devices far more integrated, complex, and connected-and growing more so every year.

A survey released in October 2018 of 148 healthcare IT and security executives, conducted by Klas Research and the College of Healthcare Information Management Executives (CHIME), showed that an astonishing 18 percent of provider organizations had medical devices impacted by malware or ransomware in the last 18 months.ⁱⁱ

The reliance on devices being connected isn't going to ebb, and the increased complexity will only make the management and reporting of interconnected information across product definition and verification more difficult and inefficient. This inefficiency is only exacerbated by the use of document-based requirements management, which introduces more risk into the process.



ⁱⁱ [Healthcare IT News, "Malware hits medical devices at 18 percent of healthcare orgs in last year," 2018](#)

CHALLENGE ONE **The Rise of Connected, Software-Driven Medical Devices**

To achieve better results with projects of mounting complexity, teams must get a stronger handle on their process and avoid gaps in development. A better solution for traceability can do just that. Traceability, normally a sub-discipline of requirements management, ensures that engineering design aligns with the identified needs of users and patients; manages scope by ensuring alignment between engineering work and actual user needs; confirms that device needs are addressed at all levels through gap analysis; and connects the design of the device directly to the verification.

Small teams building simple products may be able to get by initially with spreadsheets, documents, and emails, but with the rise of software-driven, connected medical devices and increasing system complexity, traceability quickly becomes too convoluted to be handled manually.

And the evidence is crystal clear. According to Stericycle's Recall Index,ⁱⁱⁱ software issues were consistently one of the top causes of medical device recalls through 2017 and 2018.

Medical device development contains too many scope changes, remote team members and reviewers, and requirements to be easily managed in documents and emails. Using Excel or an internally developed requirements management solution or system diverts scarce resources and availability away from the important tasks of product development. Instead, team members have to focus on attempting to assemble and maintain traceability, usually resulting in the trace being hastily thrown together in the end for the design history file (DHF).

Why You Shouldn't Be Developing Medical Devices Without Traceability

Traceability ensures a collaborative and unified timeline from conception to market, meticulously documenting everything in between.

[Read more on our blog](#)



ⁱⁱⁱ Stericycle Expert Solutions, "Q1 2019 Recall Index"

Streamline Your Development Process with Jama Connect

Jama Connect™ allows you to organize your design controls process so teams can spend more time on innovation and less time on paperwork. In Jama Connect – which has an IEC 62304 certification for medical device software from regulatory experts TÜV SÜD – you can create relationships to connect risks to requirements and map out the interdependencies among different items and the people involved in the decisions.

By capturing and managing requirements, verifications, and risk analysis in a single platform, traceability (i.e., the trace matrix) becomes a byproduct of various disciplines and teams working in Jama Connect. For example, system engineers are responding to and tracing

design inputs to user needs in the same Jama Connect workspace as engineers defining sub-system requirements to fulfill system needs. Verification teams capture and trace requirements, resulting in a V-model captured and traced in a single system.

TRACEABILITY

Traceability also increases efficiency, drives alignment, and mitigates organizational risk. With Jama Connect, teams can link and decompose high-level requirements to more detailed system and sub-system requirements, including associated risks and hazards, to ensure proper verification and validation before release.

CHALLENGE ONE SOLUTION Streamline Your Development Process with Jama Connect

Fine-grained impact analysis also provides insights to drive informed decision-making as requirements evolve throughout the full development cycle.

Once requirements have been created, Jama Connect's Review Center also makes collaboration more efficient by allowing teams to conduct live reviews. Review Center enables you to invite and assign key stakeholders, add comments and action items that need to be addressed, and formally approve requirements so that you can move on to the next phase of development with confidence.

By bringing the latest comments and revisions into Jama Connect, you eliminate the need to pass documents back and forth. Streamlining your development process and relying on traceability ultimately boosts productivity, saving you time and effort in the short run and money in the long run.

**Jama Software Helps
RBC Medical Innovations
Save \$150K per Project**

Learn how one of Jama's medical device customers, RBC Medical Innovations, uses our platform to unify processes and enhance traceability.

[Download the customer story](#)



CHALLENGE TWO

Increasingly Strict Medical Device Regulation

For all the ways medical device technology is improving and saving lives, it's still struggling with major quality issues.

In 2018, medical device recalls skyrocketed to their highest point since 2005, according to Stericycle Expert Solutions, with the leading cause being software problems followed by mislabeling and quality issues.

The impact of a recall can be catastrophic for medical device companies. McKinsey has estimated that the cost of a major recall can be as high as \$600 million,^{iv} which can include everything from lost market share to lawsuits, public relations nightmares, and decline in industry position.

Then there's the human toll. For the most part, a medical device will usually be stocked and used to treat patients before a safety concern is even discovered, according to the *Journal of Health & Life Sciences Law*.^v Given that fact, medical device companies have every reason to make compliance and risk mitigation major foci in their development before release.

Preventing Medical Device Recalls More Critical Than Previously Thought

Professors from Harvard, Indiana, and Georgetown universities analyzed over a decade of US Food and Drug Administration data to learn the real impact of medical device recalls.

[Read the story on our blog](#)

^{iv} McKinsey & Company, "The Business Case for Medical Device Quality", 2013

^v AHLA, *Journal of Health & Life Sciences Law*, 2018

CHALLENGE TWO **Increasingly Strict Medical Device Regulation**

For many medical device companies, meeting regulations can be a cumbersome process. Proving compliance, with its many documentation requirements, can hamper innovation instead of fostering it.

And compliance is increasingly costly because of changes in the market — such as the prevalence of software-driven devices and patients taking devices home from the hospital — making regulatory standards harder to interpret. It doesn't have to be that way.

While processes should not be implemented for the sake of regulations alone, when done correctly, they can actually drive the development of innovative, quality products and reduce rework and recalls.

Regulations and standards point device companies in the same direction: toward a holistic approach that ensures medical device design and development quality, and one that includes managing supply chain risk.

The actual business problem many companies face is getting and staying aligned. From the first stages of design to the point of customer use, you need software to support design and safety integrity.

One of the most difficult and time-consuming aspects of proving compliance is sorting through the documentation produced by the design and development teams,

including outputs from multiple software tools. Even in a best-case documentation scenario, determining the right documentation to show FDA compliance and systematic management of risks is tricky.

As medical devices increasingly rely on software and connectivity, and as the market itself moves out of the hospital and into patients' homes, compliance becomes even more critical.



The Jama Connect Risk Management Center

Medical device companies need a better way to mitigate risk, guide compliance, and make the requirements process easier and less prone to error.

The [Jama Connect Risk Management Center](#) enables medical device developers to identify risk directly within the platform, in accordance with ISO 14971. Development teams can participate in risk assessment and risk mitigation, utilize risk plan templates, connect verifications back to requirements, and export analyses for sign-off. By working with live data, teams ensure they are viewing and properly mitigating risks with confidence, so they can quickly move to the next phase of development.

The Jama Connect Risk Management Center ([watch a demo](#)) was developed from best practices working with companies that deliver products in safety-critical industries. Development teams can participate in risk management techniques including Preliminary Hazard Analysis (PHA) and FMEA in accordance with ISO 14971 and IEC 60812. By working with live data, teams can efficiently identify and mitigate risks early in the development process, ensuring quality and safety in complex product development.

Application of Risk Analysis Techniques in Jama Connect to Satisfy ISO 14971

The FDA requires risk assessment as part of design validation and prescribes ISO 14971 as the mandatory standard.

[Learn how Jama can help you better manage risk with ISO 14971 by downloading our white paper](#)



CHALLENGE TWO SOLUTION **The Jama Connect Risk Management Center**

Without risk analysis integrated into Jama Connect, your requirements and tests lack context from information contained in risk and hazard analysis. By storing everything within Jama Connect, the probability of error decreases, along with the amount of time and frustration spent comparing requirements with spreadsheets.

When you do update risks in Jama Connect, you always know you're working from the latest version, because the data is updating as needed instead of getting lost in static, emailed documents or scattered spreadsheets.

And since risk analysis is a never-ending endeavor, it should be an ongoing part of your development lifecycle. By making risk analysis accessible, easy to use, and part of a standardized process, teams and stakeholders are more likely to perform frequent analysis. That should allow for more risks being identified earlier in the process, thereby increasing confidence in the safety of the product.

You also can't account for risks you don't know about. By including risk and hazard analysis in Jama Connect, you're able to easily track open risks and mitigations. This allows you to ensure that all existing risks are covered with the proper mitigations, so you can move on to your next development phase.

With the combination of Risk Management Center and Jama Connect, as well as our [Medical Device Services](#), customers can better manage design inputs, risks, and verification in one powerful platform, making regulatory submissions and audit preparations a straightforward process while adhering to FDA and ISO regulations.



CHALLENGE THREE

Sophisticated Market Entrants Increasing the Pace of Competition

It's really an industry-agnostic problem, but when some of the world's biggest tech companies decide to start competing with you – as has been the case in healthcare – everything intensifies.

Big tech healthcare is a rapidly growing segment. In fact, major tech companies participated in 27 rounds of healthcare financing within the first eight months of 2018, equal to the total amount of rounds in 2014 alone, according to a CB Insights research brief.^{iv}

Major players such as Google, Amazon, Alibaba, and Apple continue to either contemplate entering or directly enter the medical device market across the world. These sorts of household names benefit from instant brand recognition, quick distribution, and seemingly

unlimited resources.

For an example, look no further than Apple's Watch Series 4, which received a Class II de novo clearance from the FDA for both its electrocardiogram (EKG) and notification of irregular heart rhythm clearances. While it was clearly stated the watches were "not intended to replace traditional methods of diagnosis or treatment," solutions like these are changing the way consumer electronics companies like Apple think about and develop products.

Accelerate Medical Device Development While Reducing Risk

With a majority of FDA recalls attributed to human factors or use error, managing risk through traceability is vital to the success of medical device development. Mitigating design-related problems that contribute to unsafe or ineffective use is critical to overall risk management and speed to market.

[Watch our webinar to learn more](#)

^{iv} CB Insights, "Where Big Tech Is Placing Bets in Healthcare," 2018

CHALLENGE THREE **Sophisticated Market Entrants Increasing the Pace of Competition**

As most traditional medical device companies know by now, compliance requires a deep level of organization, document and information management, and detailed communications previously unseen in most tech industries. This introduces new risks for tech companies with nontraditional FDA-regulation backgrounds and creates fresh challenges for the FDA's evaluation of each software solution, which has prompted an overhaul of that system.

For medical device companies, this situation sharpens the focus on an ongoing business problem: You have to evaluate how your processes are being executed and make sure you're getting your product right the first time. True, you must work quickly, but with escalating competition, you need confidence that you're building the right product now.

The problem is that traditional development processes don't include key stakeholders early enough. You need

immediate and ongoing collaboration among the diverse teams that come together to build the product, even if everyone is in different geographic locations.

Too often, though, traditional processes enable team silos and fail to facilitate the cross-functional communication required to get the job done. An important part of modern medical device development is ensuring that the requirements management software you employ helps you conquer the challenges of poor collaboration. And that's something Jama Connect does extremely well.

The good news is that being a new entrant into the medical device market doesn't automatically put you at a disadvantage. And you shouldn't have to start from scratch when trying to create a process that satisfies FDA auditors.

Make Your Regulatory Strategy a Competitive Advantage

Jama Software helps you get up and running quickly with the power of Jama Connect and our Medical Device Services – which are based on a process tightly aligned to governing regulations ISO#13485:2016 and 21 CFR 820.30.

Medical Device Services are designed to accelerate time to value from Jama Connect and give teams confidence that their design control processes and outputs adhere to FDA and ISO regulations.

Medical Device Services offerings include:

- Process documentation detailing how Jama Connect is best used to adhere to relevant parts of governing regulations ISO 13485:2016 and 21 CFR 820.30
- Out-of-the-box configuration supporting medical device design control and verification activities in Jama Connect
- Relevant templates to produce required documentation for your design history file, including design inputs, design control plan, and traceability documents
- User training tailored to your process to get your team up and running
- Additional consulting to tailor Jama's approach to your unique needs and support your teams as they begin working in Jama Connect
- Medical Device Services is simply the fastest and most effective way to start developing the right medical devices, right now, with Jama Connect

CHALLENGE THREE SOLUTION **Make Your Regulatory Strategy a Competitive Advantage**

From Chaos Comes Clarity

The array of changes impacting the medical device industry ups the ante considerably, but you can reclaim control.

With the right software, support, process, and team, you can still be extremely successful. You can enhance the traceability that must underpin your efforts and ensure that quality and innovation drive your design and development. With Jama Connect, every element of your design control and risk management process collaborates effectively and efficiently.

Jama Connect helps your teams meet milestones and expectations. It also makes your design control and risk management processes more efficient, fully auditable, and visible to all stakeholders — and it accomplishes that by helping every team in every department communicate with one another in real time.

Traceable communication. Documented decisions and actions. Mitigated risk. All product and systems information organized and contextualized from concept to launch in one easy-to-access place.



With Jama Connect,
Risk Management Center, and
Medical Device Services, your future
in medical development is bright.

A woman with curly hair, wearing blue scrubs, is looking intently at a large screen displaying several medical MRI scans. The screen shows various cross-sections of a human head and brain, with some areas highlighted in red. The woman's hand is visible, pointing at one of the scans on the screen. The overall scene is dimly lit, with the primary light source being the screen itself, creating a professional and focused atmosphere.

ABOUT JAMA SOFTWARE

Jama Software provides the leading platform for requirements, risk and test management. With Jama Connect and industry-focused services, teams building complex products, systems and software improve cycle times, increase quality, reduce rework and minimize effort proving compliance. Representing the forefront of modern development, Jama's growing customer base of more than 600 organizations includes Boston Scientific, Johnson & Johnson, Cochlear and Merck.

Visit jamasoftware.com to learn more about Jama Software for Medical Device Development or start a [free trial of Jama Connect](#) now.