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WHITE PAPER

# Risk Management for Modern Medical Device Makers

## Resolving the Challenges of Connectivity, Competition & Compliance

**F**or medical device manufacturers, new realities present favorable circumstances and worrisome challenges. For example, medical devices are now more integrated into inpatient, outpatient and home care. And technological advances continue to evolve medical device design and manufacturing. But as modern health reform increases patient connectivity, it also increases media scrutiny, leaving manufacturers with precious little margin for error.

Medical device manufacturers face numerous challenges, and each presents its own business problems. Three challenges rise to the top:

**1. The increased use of software and connectivity in devices complicates the development**

**process and introduces new risks at almost all stages of design and manufacturing.**

**2. New competitors—especially atypical competitors from outside the traditional medical device space—disrupt the market, with customer name recognition and expertise in developing both innovative and complex systems.**

**3. Compliance with government and industry regulations remains a challenge, especially as regulatory bodies update standards that broaden inclusions to keep consumers safe.**

This paper examines these three challenges and how companies can change their processes to meet them.

## Challenge One:

### The Rise of Software-driven Medical Devices

In the past, medical device software was generally used to control programs to switch the equipment on and off and to display readings. Today, though, software and its functions are far more complex.

The Rhythmia Mapping System, owned by Boston Scientific, is a software-driven device. It combines a multi-electrode catheter with three-dimensional mapping software to track the heart's shape and signals. Before Rhythmia, surgeons relied on electrodes to listen to the heart's activity and find heartbeat abnormalities.



The Rhythmia Mapping System from Boston Scientific combines a multi-electric catheter with 3D mapping software.

With this mapping system, surgeons build a 3D map to visualize the heart's shape and electrical signals and spot irregularities with more precision in less time. It's a remarkable advance in treatment for arrhythmias, but it brings new frustrations for development. The Rhythmia Mapping System requires both hardware and software teams, which introduces additional risk, due to the software's complexity.

Software in medical devices also helps the devices communicate with other instruments, monitors and documentation systems—the Internet of Things (IoT) for healthcare. Manufacturers focus on new ways to aggregate data across instruments to enhance a provider's view of a patient. To get there, communications protocols must be synched, and technical details for connecting medical devices to home networks and public WiFi and cellular signals become critical issues. A recent report from the security firm TrapX noted that hackers exploited IoT weaknesses to use medical devices, including x-ray scanners, to penetrate other parts of a hospital's information technology infrastructure.

The rise of digital health isn't going to ebb. Accenture predicts that Food and Drug Administration approvals of digital health solutions will triple by the end of 2018, to 100, from 33 in 2014. That rise creates a new business problem for medical device manufacturers: Manual traceability is unreliable, and it introduces risk.

Traceability, normally a sub-discipline of requirements management, contributes to the development of quality products by documenting the life of a requirement, tracking every change and linking it to other items within a project. Small teams building simple products can get by with spreadsheets, documents and emails to track traceability. But with the rise of software-driven medical devices and increasing system complexity, traceability quickly becomes too convoluted to be handled manually. There are too many scope changes, too many remote team members and reviewers and too many requirements. And humans are prone to error too, which introduces risk.

## The Solution:

### Automate Traceability

You need traceability that establishes consistent, accurate links between each step of the work. With structured templates and a modern requirements management tool, much of the traceability process can be automated and streamlined. In Jama, you can create relationships to connect everything and map out the interdependencies among different items and the people involved in the decisions. If you need to make a change, automated traceability will help you assess the impact of the change before it occurs. Once the change is made, Jama flags related information to highlight the downstream effects of changes upstream.

## Accenture predicts that Food and Drug Administration approvals of digital health solutions will triple by the end of 2018

Automated traceability also provides a huge productivity boost that saves you time and effort in the short run, and money in the long run. Upstream market requirements, product requirements, test cases and defect tracking are all clearer and better connected, giving your teams the confidence, through verification and validation, that all potential harms have been accounted for and mitigated.



## Challenge Two:

### Sophisticated Market Entrants Increase the Pace of Competition

The number of pre-market approvals by the FDA jumped by more than 40% from 2013 to 2014. This is a result of factors such as demand, innovation, startups and technology advancements. In particular, software-driven medical devices bring atypical players like Google, Apple and Amazon into the marketplace. Their experience developing for complex environments gives them an edge in a growing and demanding consumer-focused marketplace.

For example, Google's research arm, Google X, is developing an accurate tracking band for medical use in clinical trials. It's also working on a smart contact lens for diabetics—it reads glucose levels in tears—and has acquired a company that makes spoons designed for patients who suffer from tremors. Google has also held meetings with FDA officials about additional device options.

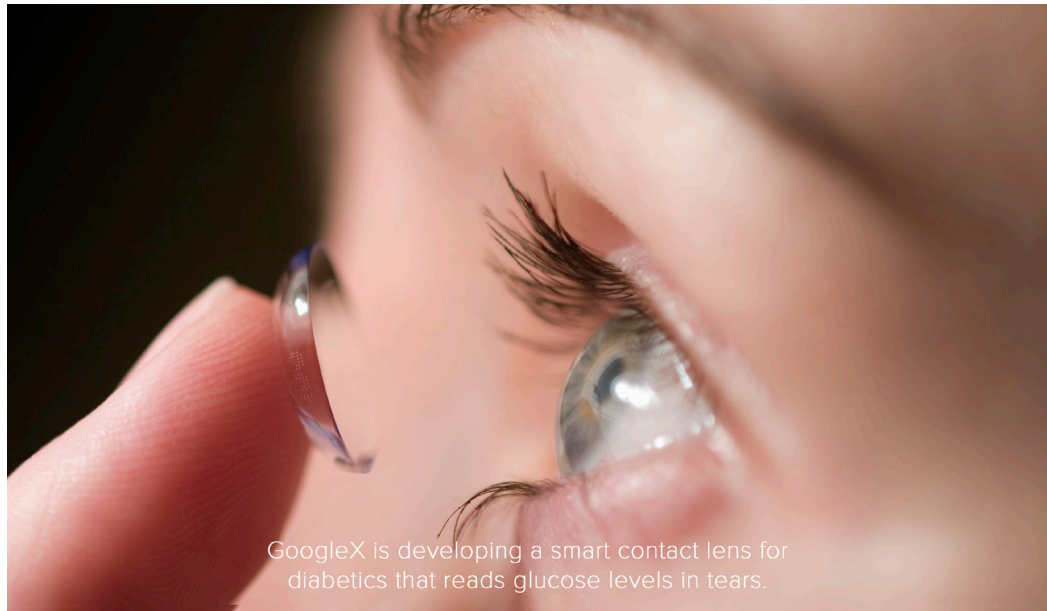
When Apple met with the FDA in 2013, it was a harbinger of its move into medical devices. Apple Watch isn't one, CEO Tim Cook says, because the gauntlet of FDA approvals would keep it off the market too long. But the company may release a regulated medical device soon, the executive has said. And now Amazon has aligned with Royal Philips for a variety of digital device endeavors. The resources Google, Apple and Amazon have, combined with their knowledge of complex systems development, give them an opportunity to disrupt the medical device market.

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For medical device manufacturers, this situation sharpens the focus on an ongoing business problem: You have to get your product right the first time. You have to work quickly, but with new competition, you need confidence that you're building the right product. The problem is

that traditional processes don't bring in key stakeholders until it's too late for them to affect meaningful change—and that puts your device development at risk. You need immediate and ongoing collaboration among the diverse teams that come together to build the product, even if those teams are in different geographic locations.

Too often, though, traditional processes work in silos, and they fail to facilitate the communication required to get the job done. So an important part of modern medical device manufacturing is ensuring that the requirements management software you employ eliminates the harmful effect of those silos.



GoogleX is developing a smart contact lens for diabetics that reads glucose levels in tears.

## The Solution:

### Establish Purposeful Communication

Purposeful communication must be a priority, so that the goal of building the right product—delivered with high quality to resonate with the desired market—can be reached as efficiently and rapidly as possible. And the conversations with development teams, stakeholders and customers need to be captured in a system of record.

Jama brings in your clinical experts and design and development teams to define, validate and verify requirements and ensure that risks are accounted for and mitigated early, at every stage in development. By using Jama as your system of record, your teams capture all product development-related communications—including reviews and approvals, conversations and decisions—in one place. You can shorten milestone phases, improve efficiency and identify risk earlier in the development process. That translates into products that come to market faster without compromising quality.



## Challenge Three: Proving Compliance


For many medical device manufacturers, compliance can be a burden. Proving compliance, with its many documentation requirements, can hamper innovation instead of fostering it. And compliance is increasingly costly because changes in the market—such as software-driven devices and patients taking devices home from the hospital—make compliance standards harder to interpret. It doesn't have to be that way. While processes should not be implemented for the sake of compliance alone, compliance done right can actually engender the development of innovative, quality products.

That's not to say that compliance can ever be easy.

- **The International Organization for Standardization will release an updated ISO13485 this year to beef up standards for software embedded in medical devices. It's also expected to apply more broadly to the entire supply chain, including companies that offer components and services. Ultimately, ISO13485 will increase the attention paid to risk management of the system from beginning to end.**
- **"Current good manufacturing practices" for medical devices, as detailed by the FDA in 21CFR 820, are still in place, and may be interpreted differently by the FDA to account for the increasing variations devices are being applied. The Quality System Regulation dictates that manufacturers use good judgment during system development and establish requirements for each type of device, to maximize safety.**
- **New regulations are published every day. In January 2016, the FDA issued draft guidance on ways medical device manufacturers should address cybersecurity risks. It details recommendations for monitoring, identifying and addressing vulnerabilities in medical devices before they have entered the market, and afterward.**

Regulations and standards point device manufacturers in the same direction: toward a holistic approach that ensures medical device design and manufacture quality, and includes managing supply chain risk. The business problem many 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



Within one year of working with Jama, a major medical manufacturer for home care provides enough evidence to get their products rights reinstated.

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, more complex and more costly.

## Solution:

### Reduce the Cost of Compliance

Compliance today requires a level of organization, document and information management, and detailed communications previously unseen in the medical device industry. As an example, a medical manufacturer for home products approached Jama after a FDA audit suspended their production rights. The FDA required the company to document their requirements management process, complete traceability and meet standards including ISO 14971, ISO 13485 and 21 CFR Part 11. They partnered with Jama to redesign their process and configure the solution to support it. Within one year, they reduced their risk and produced the necessary evidence to give the FDA confidence that their product was safe for consumers.

Your software must be designed to focus on not only the technical aspects of medical device development—the engineering specs, the regulatory mandates, etc.—but also on the collaboration of those technical aspects as well. You can use Jama's Review Center for both risk and design controls reviews to invite feedback from subject matter experts and stakeholders. With Jama configured to your workflows and best practices, teams spend more time on product development, and less time managing compliance processes and documentation.



And when you have questions about why a risk was estimated in a certain way, Review Center serves as the source of truth. Using Review Center and documenting the information in the project space allows teams to collaborate on risk definitions and add more as they arise, discuss mitigation plans and verification test results, collaborate on solutions, and finalize and document decisions.

Jama also allows you to track risks as individual items:

- **Complete a preliminary estimation of the risk by defining the probability of occurrence of the harm and the severity of that harm.**
- **Use the calculated risk priority number to assess whether the risk is acceptable.**
- **As you define mitigations, use relationships to illustrate them in Jama, and then update the risk priority number post-mitigation.**

When telling the story of your medical device's development lifecycle to the FDA, it can be a struggle to

organize the information in a cohesive manner. And if documentation is missing or decisions and action items aren't recorded, the gaps could result in a product failing to reach the market—or being pulled from shelves.

## From Chaos Comes Opportunity

The changes roiling the medical device manufacturing space up the ante considerably, but you can reclaim control. With the right software, you can enhance the traceability that must underpin your efforts. You can ensure that quality and innovation drive your design and manufacturing. With Jama, you can ensure that every element of your design and manufacturing processes collaborates effectively and efficiently.

Whether you're complying with regulations or developing hardware, software, systems processes or any requirements/scoping effort, Jama can help your teams meet milestones and expectations. Jama helps make your product development processes more efficient, fully auditable and visible to all stakeholders—and it accomplishes that by helping every team and each department communicate with each other in real time.

**Picture this:** Traceable communication. Documented decisions and actions. All product and systems info organized and contextualized from concept to launch. With Jama, it's your reality. [Try Jama](#) and see how we can help you solve your team's systems engineering challenges.

## About Jama Software

Jama Software is the definitive system of record and action for product development. The company's modern requirements and test management solution helps enterprises accelerate development time, mitigate risk, slash complexity and verify regulatory compliance. More than 650 product-centric organizations, including NASA, Boeing and Caterpillar use Jama to modernize their process for bringing complex products to market. The company is headquartered in Portland, Oregon. For more information, visit [www.jamasoftware.com](http://www.jamasoftware.com).

