Jama software® + VELENTIUM

WHITE PAPER

How to Execute a Successful Design Review When Building Medical Devices

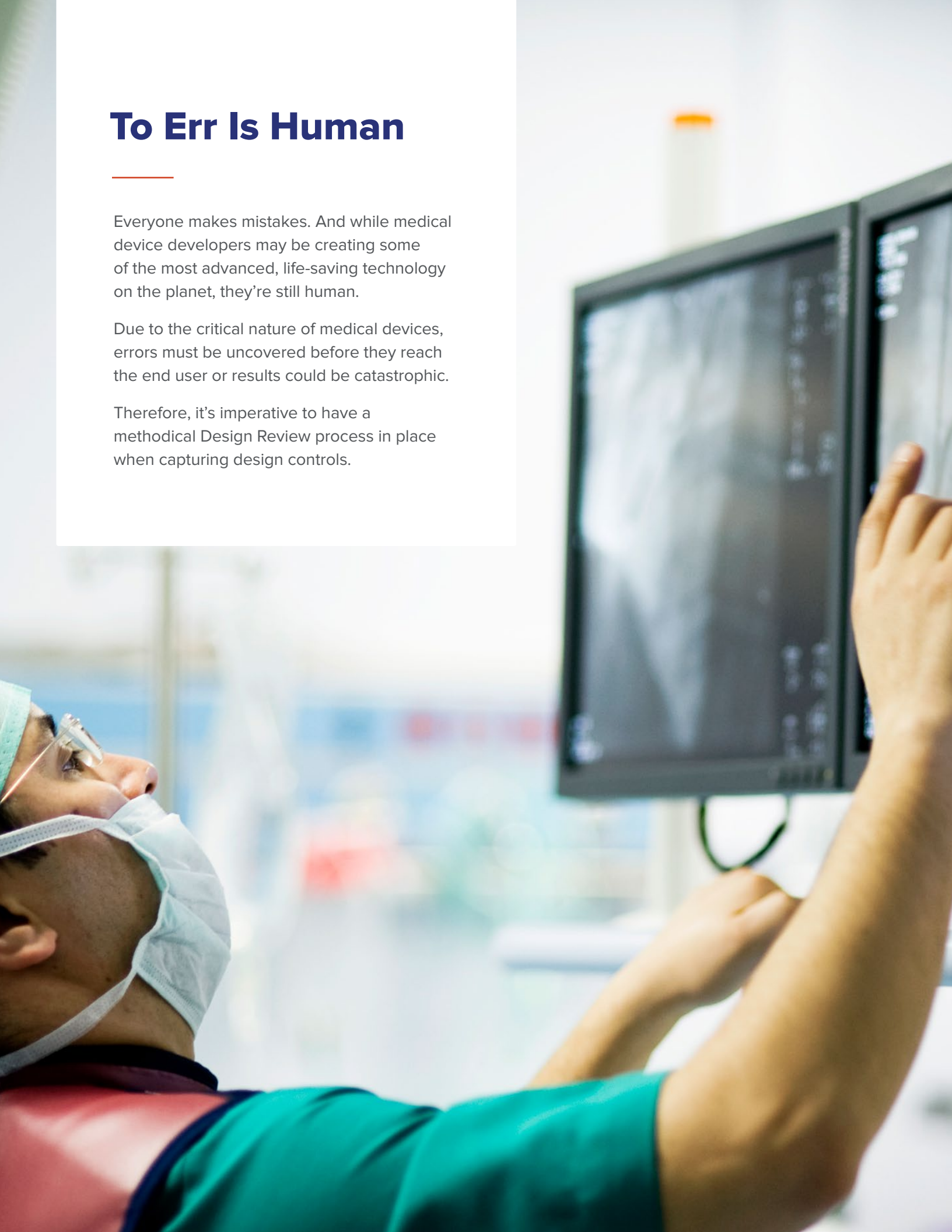
Shifting the mindset to a review-focused organization

To Err Is Human

Everyone makes mistakes. And while medical device developers may be creating some of the most advanced, life-saving technology on the planet, they're still human.

Due to the critical nature of medical devices, errors must be uncovered before they reach the end user or results could be catastrophic.

Therefore, it's imperative to have a methodical Design Review process in place when capturing design controls.



Shifting the Mindset

The key to implementing a successful Design Review process during medical device development is creating a culture in which there is no fear of repercussions when defects are uncovered.

An anxiety-free environment makes room for presenters and reviewers to create a positive process to shake out potentially tragic errors.

That's why it's important to challenge the belief that mistakes shouldn't happen and embrace a new perspective. Think: *Everyone needs reviews. There are always defects*. And understand that the defects are the enemy – not the people doing the work.

Yes, it may be frustrating to have outsiders dissect hours of hard work and find flaws. However, the alternative is far more alarming.

> "A defect-free review should not be cause for celebration, but a red flag that something was missed."
>
> **Randy Armstrong**, Chief Technology Officer, Velentium

Risk Management and Compliance

Reviews are conducted to find blind spots in design and to identify defects. They are meant to mitigate risks to both the end user and the company itself.

Companies also perform reviews to be compliant with regulations and standards so, when ready, the devices can successfully go to market.

> "While often presented as two different things, and most companies think of them as such, risk management and compliance are actually one and the same."
>
> **Randy Armstrong**, Chief Technology Officer, Velentium

This, too, may require an organization-wide mindset shift. Remember that regulations and standards were created as a part of the risk management process to ensure proper developmental practices are followed that protect users. They are clinically validated solutions that save time, work, and extra documentation.

The Burden of Reviews

Changing the culture of the review process at any company will not happen overnight. If the tools or processes are cumbersome or overly bureaucratic, even review enthusiasts can become disillusioned.

There are many aspects of the review process that could be affecting attitudes and hindering a complete mindset shift, from inaccurate traceability to insufficient tools.

How defects are identified and then tracked for improvement can be especially tedious. For instance, a review might uncover ten defects, all of which then need to be updated. The related documents need to be changed and reviewed again. This can be a vicious cycle if the process contains a lot of paperwork and requires participants to navigate many different systems or tools.

Using rudimentary documents poses issues at many points of the review process. One such problem is that developers often find themselves spending more time creating and formatting a document than working on the information it is meant to record.

Also, sending documents via email requires a lot of mind-numbing administrative work such as ensuring everyone is reviewing the same, correct version and confirming feedback is tracked from all parties.

FIND OUT HOW RBC MEDICAL INNOVATIONS UNIFY PROCESSES AND ENHANCE TRACEABILITY

Read: Streamlining Workflow and Strengthening Collaboration When Developing Medical Devices

Legacy systems also present many challenges. For example, the context is not always as complete as it is in current technology, which facilitates easy access to information and collaboration. In those cases, a person needs to communicate context to the team. This often requires an extra meeting, scheduling that person's time — if they are still at the company — and adding more hours to the process overall.

Any of these shortcomings in a review process can add unnecessary stress to an organization. When this occurs, it can be hard for teams to stay motivated about reviews. The result: reviewers go through the Design Review process on autopilot and important defects fall through the cracks.

Conducting Successful Reviews

Yes, a cultural shift to an eagerness for reviews is imperative to success. But even if everyone is on board, a methodical approach is needed to execute the process.

Use the following six “right” attributes as a framework for planning and implementing a successful Design Review process.

1. The Right Time

The purpose of the review process is, as mentioned, to identify defects. And it’s important to find the right time in the development process to conduct the reviews.

Review too early and it’s wasting time because there are too many missing elements that will still have to be reviewed later.

Review too late and it’s likely things will be missed or teams will end up reworking defects that should have been caught sooner.

2. The Right Scope

If too many things are being reviewed at once, it’s possible that the reviewer won’t be able to give attention to each item at the right level of detail. If the items are low risk, this might be sufficient. However, high-risk deliverables require undivided attention to find a blind spot.

The project manager or systems engineer should distinguish low- and high-risk items prior to reviews, and plan resources accordingly.

3. The Right Participants

One of the biggest challenges of reviews is getting the right reviewer for the job. A reviewer must be independent of the project, yet qualified for the materials they are reviewing.

By being an outside observer, they are not simply motivated to “rubber stamp” the material just to keep things moving. Likewise, an unqualified person would not know enough about the material to read between the lines and uncover blind spots.

It’s also important to remember that both sides of the equation benefit from the review process. Presenters get their material reviewed, which is of course their goal. But the process is also valuable for the reviewer. It’s an opportunity for cross-pollination of knowledge and experience. The teams can mentor one another and have the favor returned in future projects. And, if nothing else, it’s a free lunch.

4. The Right Criteria

A review is not the time for opinions. They are not conducted according to whether the reviewer likes or dislikes the style of a product or its development. Specific criteria must be laid out so the review is conducted based on the objectives of the material.

It's the job of the systems engineer or product manager to call out in the project plan any specific criteria that must be met for that set of deliverables. And it's important not to go overboard – the criteria should be the minimum set of things the reviewer needs to look for.

If there are no specific criteria outlined, a generic list of acceptance criteria should be followed:

- Is it complete?
- Is it necessary?
- Is it feasible?
- Is it consistent?
- Is it detailed?
- Is it verifiable?
- Is it traceable?

5. The Right Records

Missing review documentation could have serious ramifications. If a lawsuit is brought up against the company, there is no proof to dispute claims.

Furthermore, it can be damaging from a compliance perspective. A Federal Drug Administration (FDA) audit could result in a warning letter stating that design controls aren't being followed. This can shut an operation down, delaying approval, shipping, or selling of a device.

Documentation not only proves a review took place, it's an efficient way to have the list of what was found and corrected. This provides a great deal of understanding about how designs evolved.

Reviews can also be the genesis of future product enhancements. An idea may come up that isn't right for the current generation but can be logged in a recommended improvements database.

> "If a review is not recorded, it may as well never have happened."
>
> **Randy Armstrong**, Chief Technology Officer, Velentium

6. The Right Collaborative Infrastructure

Developing medical devices requires open lines of communication. Having the right development technology in place allows teams to make sure the right participants are included at the right time, and that they have the right level of information, thus reducing the number of late-stage changes and delays.

Having built-in traceability within a development solution also gives a clear view of where the review deliverables fit into the overall project. This shows what materials are high-risk versus low-risk so the scope can be adjusted accordingly.

When specific acceptance criteria can be noted in the system along with the materials, the reviewer understands exactly what to review against. And no documents means no version control issues.

Additionally, when all reviews are recorded within a centralized system and you have the ability to easily export as needed, fewer questions arise when it comes time for audits and regulatory approvals. The right collaborative technology eliminates many burdens of the review process and instills a positive culture of reviews.

LEARN HOW MEDICAL TECHNOLOGY COMPANIES USE JAMA CONNECT™ TO BETTER MANAGE RISK AND SPEED TIME TO MARKET

Read: Application of Risk Analysis Techniques in Jama to Satisfy ISO 14971

Telling Legendary Stories

The big ones make news headlines: "*Company A's defective medical device doesn't perform as it should.*" The story tells what went wrong and how it could have been prevented. The company scrambles through press conferences, people lose their jobs, and the company may even go out of business.

On some scale, every organization has stories about "the one that got away."

Fortunately, every company also has tales of "the big catch" — the heroic detective work that stopped a major defect from going into production. The found error that kept the company out of the media's crosshairs.

Telling these legendary stories within a development organization can help build a culture of quality reviews. It can encourage contributors who are eager to ensure their work is reviewed and corrected, and thus secured against potential pitfalls. It can also foster individuals excited to be the curious sleuth.

These stories remind people that "to err is human," and it's everyone's job to find mistakes.

Jama Connect Review Center

Jama Connect™ Review Center acts as a central hub designed to simplify the review process for all parties involved. Within Review Center, teams are better equipped to collaborate in real time and stay aligned throughout the review process. The result is quicker response times, faster review cycles, and fewer questions during audits or regulatory approvals.

With Review Center, teams can quickly and easily solicit and gather input from a diverse range of stakeholders, which enables holistic thinking about customer needs. This safeguards against blind spots further on in development, thus reducing late-stage changes and delays.

Stakeholders can also easily provide feedback where required so they are not mired down in a litany of materials they are not meant to cover. This helps lessen the likelihood of "review fatigue" and makes stakeholders more likely to spot defects. And for those overseeing the review process, Review Center shares information related to which stakeholders have made progress in their reviews and how much work still needs to be done.

Furthermore, good collaboration — facilitated by Jama Connect Review Center — improves risk management and compliance. Since reviews and approvals are all tracked as proof that the right participants reviewed the required materials, risks are mitigated in compliance.

Read our brief to learn more: Jama Software for Medical Device Development

Review Center can also be used as a tool to achieve compliance objectives like FDA 21 CFR Part 11 with workflows designed to meet requirements for electronic signatures and records.

Going one step further than most platforms, Review Center also allows organizations to maintain reviews as electronic records. In terms of the storage, security, and maintenance of electronic records, Review Center provides organizations with the ability to:

- Add specific electronic signature roles
- Prevent reviews that have captured electronic signatures from being deleted
- Review activities that may modify electronic records for audits
- Export reviews in a readable format to a formal system of record such as a quality management system (QMS)

Designed with both compliance and user-friendliness in mind, Review Center makes it easier to prepare for audits and gain regulatory approvals.

Industry-leading medical device development customers praise Review Center for its ease of use and its impact on the process overall: shorter and fewer meetings and increased confidence in what they are building. To visualize the savings Review Center produces for Jama Connect customers, check out our infographic.

The information in this white paper is jointly based on the expertise of Randy Armstrong, Chief Technology Officer at Velentium, and Jama Software's experience working with developers of Class II and III medical devices.

ABOUT RANDY ARMSTRONG

Randy Armstrong is the Chief Technology Officer at Velentium. In 30 years of designing medical devices – specializing in active implantables – Armstrong has more than 25 commercially available product designs and 54 U.S. patents. He is also a U.S. delegate to ISO for the development of medical device standards.

ABOUT VELENTIUM

Velentium is a professional engineering firm, specializing in the design and manufacturing of therapeutic and diagnostic active medical devices. We have experience working with all sizes of clients, ranging from startups seeking seed funding to established Fortune 500 companies. We exist to transform your IP into a safe and secure product that will change lives for a better world.

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.