Tech-Clarity

Medical Devices Manufacturers Software Selection Guide

Selecting the Right Software for a Competitive Advantage

Tech-Clarity

Table of Contents

***This summary is an abbreviated version of the report and does not contain the full content. A link to download the full report is available on the Tech-Clarity website, http://www.tech-clarity.com.**

If you have difficulty obtaining a copy of the report, please email the author at michelle.boucher@tech-clarity.com.

Executive Overview

Medical device companies are in the business of making people's lives better. As Joel Hembrock, Senior Designer and CAD Administrator at Medtronic says, "*Our patients are the people who benefit from our products. Restoring life is our main focus. [We want] to be giving people their lives back, restoring their health, allowing them to actually live again and not have their disease or any other ailment keep them from being able to live*."

With lives at stake, patient safety is of the upmost importance. As such, the industry faces heavy regulations. Compliance is so critical that if medical device companies do not adhere to FDA, EU and other worldwide standards and regulations, they will not be profitable. However, so much time, effort, and cost goes into compliance documentation, it takes efforts away from innovating and ensuring high quality products. Consequently, it is harder to take advantage of opportunities that will boost profitability.

So much time, effort, and cost goes into regulatory compliance documentation, it takes efforts away from innovating and ensuring high quality products, reducing opportunities to boost profitability.

On the other hand, medical device companies who adopt practices focused on high quality devices can expect greater patient satisfaction, improved competitiveness, and higher profits. In fact, McKinsey estimates that companies who adopt quality focused best practices can increase profits by 3% to 4% of revenues. They estimate the revenue increase alone could be a $3.5 billion opportunity for the industry[1] and this doesn't even factor in profitability improvements by avoiding costly quality issues.

McKinsey estimates that companies who adopt quality focused best practices can increase profits by 3% to 4% of revenues.

To achieve this, companies need to be empowered to shift from a document centric process to one that focuses on high quality, innovative products that meet patient needs. The good news is that with investments in the right technology, this is possible. Technology can reduce manual, time intensive reporting processes to a push of a button. Rather than structuring processes around documentation, technology can allow you to focus on developing the right products and services that will meet patient needs.

For these reasons, some medical device manufacturers are integrating quality processes into core product lifecycle management activities. By integrating quality processes

[1] Ted Fuhr, Katy George, Janice Pai, "The Business Case for Medical Device Quality," *McKinsey Center for Government, McKinsey & Company,* October 2013

throughout the product design and delivery lifecycle, companies can improve efficiency. With this approach, time spent searching for compliance supporting documentation and reporting, can instead be invested in quality and innovation. The result will be greater profitability.

Other changes in the medical device industry are coming from recent trends such as the transition to outcome-based healthcare in the US. In some cases, to be compensated, medical professionals must show positive patient outcomes. One way to accomplish this is to take advantage of innovation enabled by the Internet of Things (IoT). This along with requirements for Unique Device Identifiers (UDI's) can provide new levels of traceability and communication that can demonstrate device effectiveness. However, to take advantage of this and manage it, the right technology must be in place.

While many of these issues may require new investments in technology, existing systems that are working well, should be leveraged. Working solutions such as Manufacturing Execution Systems (MES), Enterprise Resource Planning (ERP) and Product Lifecycle Management (PLM) should be considered when selecting a complete solution to manage medical devices. The new solution should use a platform that will leverage and extend the investments made in existing solutions.

While many of these issues may require new investments in technology, existing systems that are working well, should be leveraged.

With so much to consider, how do you know what will be the right technology? This buyer's guide will serve as guidance to help you select what is right for your company.

This guide consists of four major sections covering software tool functionality required for medical device companies, implementation requirements, vendor attributes, and special company considerations (Figure 1). Each section includes a checklist with key requirements to investigate when selecting software tools. This guide is not an all encompassing requirements list. It provides a high level overview.

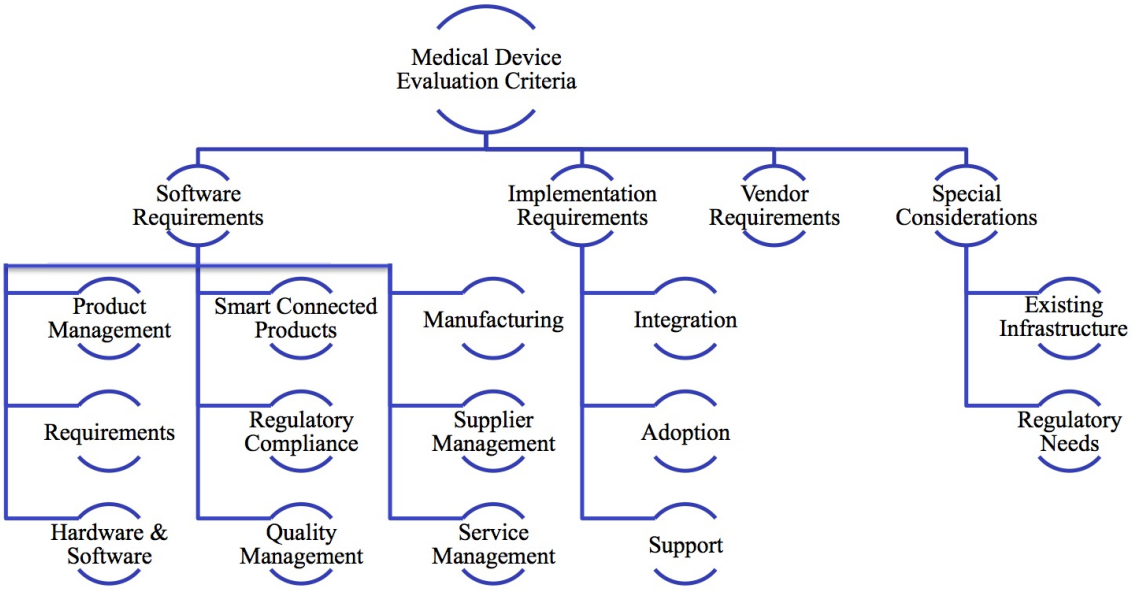

Figure 1: Medical Device Evaluation Framework

Conclusion

Medical device companies looking to improve profitability should shift their focus from a document centric process to a product centric process that will enable them to concentrate on quality. The cost of poor quality can be significant. In fact, McKinsey estimates that non-routine quality events cost the industry up to $5 billion. On the other hand, companies that focus on high quality enjoy a significant advantage with a potential increase in profits of 3% to 4% of revenues, according to McKinsey. The FDA has also concluded that a greater focus on quality is required. Unfortunately, making this shift, while still meeting regulatory requirements is hard. However, with the right technology, companies can make it much easier.

The right solution should consider all aspects of the product lifecycle from requirements, through design, testing, manufacturing and service. It should streamline the regulatory process and automate as much as possible. With traceability across the lifecycle and all deliverables, it will be much easier to provide regulatory compliance documentation. That traceability should also extend to suppliers. The right software solution can make it much easier to bring the right, high quality medical device to market, providing a competitive advantage.

Recommendations

Based on industry experience and research for this report, Tech-Clarity offers the following recommendations:

- Identify the top challenges you company needs to solve with bringing medical devices to market.
- Consider a solution that can support the entire lifecycle of your product, from patient needs and requirements to, design, test, manufacturing and service.
- Use a vendor who is familiar with medical device regulatory requirements and has the technology to reduce the manual effort required to be in compliance.
- Ensure you have the ability to manage the device and all associated document, design details, and changes, while having traceability across everything.
- Support requirements with a solution that will work across all disciplines and has traceability across all stages and deliverables to support changes and compliance.
- Empower each team member including design, quality, procurement, manufacturing, and service with tools that work for them, while still ensuring a single source of truth for product information.
- Support quality management with traceability from requirements to test and reporting tools to ensure monitoring of trends that impact quality.
- Ensure tight controls on suppliers so as not to put compliance at risk.
- Select a solution that will support manufacturing so that devices are produced as design and regulatory requirements are met.
- Think about medical device service requirements and use a solution that will support current and future service models.
- Select a vendor who can integrate with your existing solutions while implementing new solutions where needed.
- Consider future needs for potential revenue streams and future needs for technologies such as IoT, 3D printing, and Augmented Reality.

About the Author

Michelle Boucher is the Vice President of Research for Engineering Software for research firm Tech-Clarity. Michelle has spent over 20 years in various roles in engineering, marketing, management, and as an analyst. She has broad experience with topics such as product design, simulation, systems engineering, mechatronics, embedded systems, PCB design, improving product performance, process improvement, and mass customization. She graduated magna cum laude with an MBA from Babson College and earned a BS in Mechanical Engineering, with distinction, from Worcester Polytechnic Institute.

Michelle began her career holding various roles as a mechanical engineer at Pratt & Whitney and KONA (now Synventive Molding Solutions). She then spent over 10 years at PTC, a leading MCAD and PLM solution provider. While at PTC, she developed a deep understanding of end user needs through roles in technical support, management,

and product marketing. She worked in technical marketing at Moldflow Corporation (acquired by Autodesk), the market leader in injection molding simulation. Here she was instrumental in developing product positioning and go-to-market messages. Michelle then joined Aberdeen Group and covered product innovation, product development, and engineering processes, eventually running the Product Innovation and Engineering practice.

Michelle is an experienced researcher and author. She has benchmarked over 7000 product development professionals and published over 90 reports on product development best practices. She focuses on helping companies manage the complexity of today's products, markets, design environments, and value chains to achieve higher profitability.