Tech-Clarity

Medical Device Manufacturers' Software Selection Guide for 2018

Selecting the Right Software for Competitive Advantage

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*** 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 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*." It is an exciting time for the industry as technology advancements have opened up new and exciting opportunities that have the potential to further this mission. On top of this, an aging Baby Boomer population will create additional demand for medical devices. Consequently, the industry should see significant growth. In fact, the *Evaluate MedTech World Preview 2017, Outlook to 2022* report forecasts a 5.1% growth rate every year for the next five years.

However, it will be the companies who can overcome the unique challenges in the industry who will be best positioned to take advantage of this growth. With lives at stake, patient safety is of the utmost 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 go into compliance documentation; it takes resources away from innovating and ensuring high quality products. As a result, it is harder to take advantage of opportunities that will boost profitability.

So much time, effort, and cost go into regulatory compliance documentation, it takes resources 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 firms who embrace quality focused best practices can increase profits by 3% to 4% of revenues. They predict the revenue increase alone could be a $3.5 billion opportunity for the industry[1] and this doesn't even factor in the profitability improvements of avoiding costly quality issues.

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

Unfortunately, for the industry, quality has been getting worse, not better. The FDA's *Medical Device Recall Report FY 2003 to FY 2012* shows that there has been a striking 97% increase in the number of recalls. To reverse this trend, medical device companies should adopt new approaches that enable a greater focus on quality.

One way to achieve this by shifting from a document centric process to one that is product centric. This shift enables more focus on high quality, innovative products that meet patient needs. The good news is that with investments in the right software solutions, this is possible. Software solutions can reduce manual, time intensive reporting processes to a push of a button. Rather than structuring processes around documentation, software solutions can allow you to focus on developing the right products and services that will meet patient needs.

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For these reasons, some medical device manufacturers integrate quality processes into their core product lifecycle management activities. By incorporating quality processes throughout the product design and delivery lifecycle, companies can improve efficiency. With this approach, instead of wasting efforts searching for compliance supporting documentation and reporting, companies can use that valuable time for can quality and innovation. The result will be higher profitability.

Other changes in the medical device industry 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. A way to accomplish this is to take advantage of innovation enabled by the Internet of Things (IoT). For example, IoT combined with software capabilities can be used to meet requirements for Unique Device Identifiers (UDIs) that will provide new levels of traceability and communication to demonstrate device effectiveness. the right software solution must be in place to effectively manage it.

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While UDIs present one possible use case for IoT, the potential opportunities for IoT go even further. IoT and other technological advancements such as augmented reality (AR) and 3D printing, create new opportunities for profitable new business models by enabling services that align with customer and patient needs. However, companies stuck following traditional document centric workflows may struggle to find the bandwidth to innovate with these new technologies. Meanwhile, competitors who can devote the resources to

innovation will be well positioned to capture a leading market position. This situation makes it an ideal time to invest in a software platform that enables a product centric approach for the entire lifecycle of your device.

As you evaluate your current needs, think through how your business needs may evolve due to the impact of technological advances in medical devices. For example, designing for connectivity may require new approaches to design. You will now need to consider things like sensors, ecosystems, and new IT development roles that will play a critical part of product development. Ensure your software platform will be able to meet both current and future needs as your product portfolio evolves.

While you consider investments in software solutions, leverage existing systems that are working well. The new solution should use a platform that will leverage and extend the investments made in existing solutions, such as Manufacturing Execution Systems (MES), Enterprise Resource Planning (ERP) and Product Lifecycle Management (PLM) if you are happy with them.

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

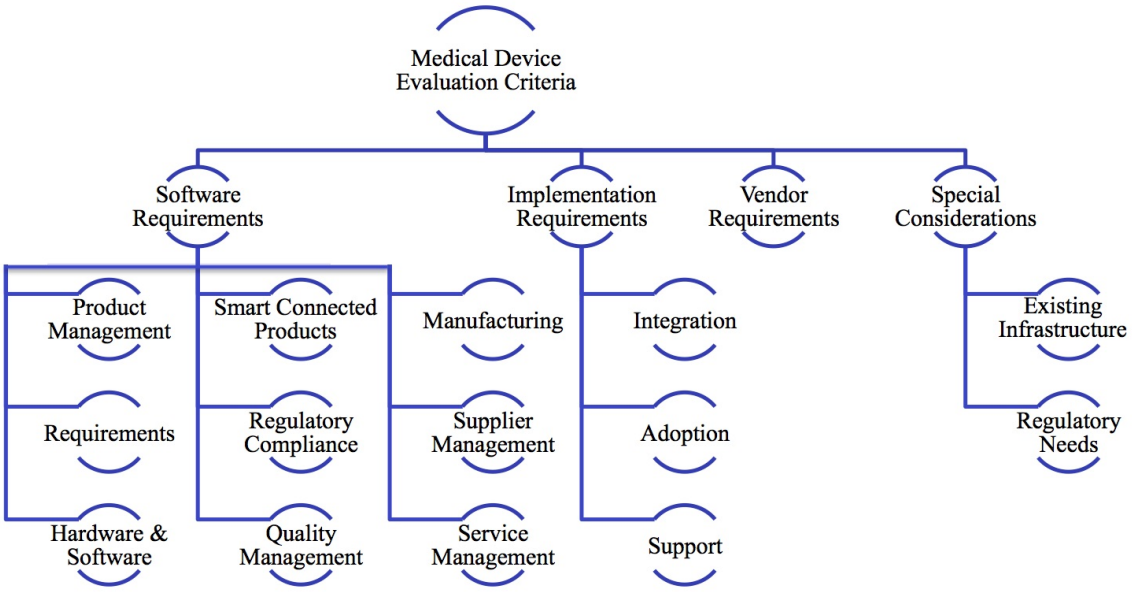

Figure 1: Medical Device Evaluation Framework

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

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. For example, they have found recalls have increased by 97%, with design errors being the leading cause. With the Case for Quality initiative, quality should be come an area of heightened focus, which a product centric approach supports. 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.

When making such a significant investment, you should also anticipate how your requirements will evolve to remain competitive in the future. Technological advancements such as IoT, AR, and 3D printing create opportunities for very profitable new business models that can increase the quality of patient care considerably. Features such as predictive and remote service offer flexibility around downtime to minimize the impact on patient health. These technologies can help medical device companies advance their mission of making people's lives better.

Recommendations

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

- Identify the top challenges your company needs to solve when 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.
- Look at solutions that will support the Case for Quality. A product centric approach and in integrated PLM and Quality Management System can help keep the focus on quality throughout the entire lifecycle.
- Use a vendor who is familiar with medical device regulatory requirements and has the technology to reduce the manual effort required to comply with regulations.
- Ensure you can 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 you produce devices as designed and meet regulatory requirements.
- Think about medical device service requirements and use a solution that will support current and future service models such as predictive and remote service.
- 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 ten 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.

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