



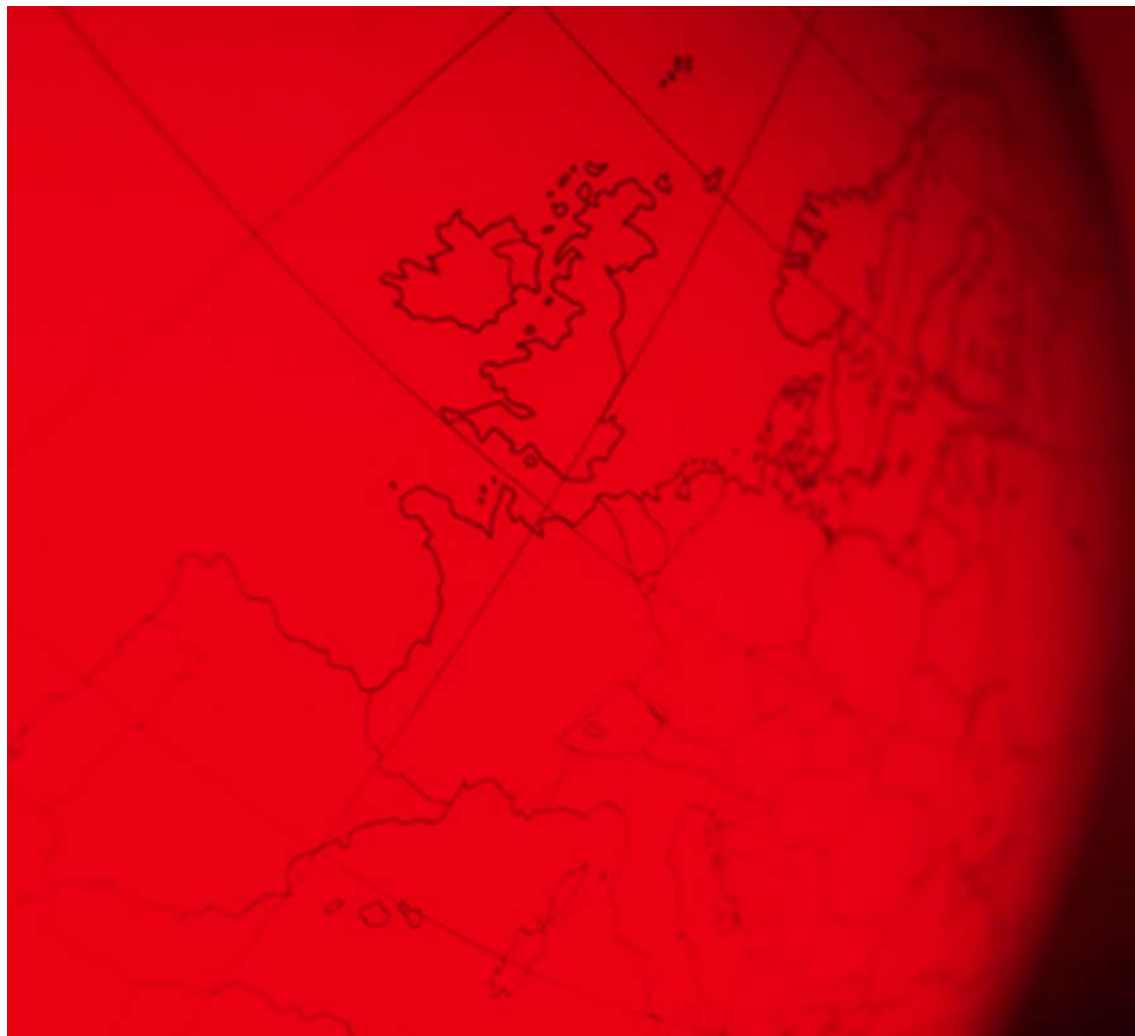
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GUIDEBOOK

SIEMENS PLM FOR LIFE SCIENCES



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TOPICS

Enterprise Applications

THE BOTTOM LINE

Siemens product lifecycle management (PLM) Software for life sciences can help medical device manufacturers manage compliance requirements while supporting greater collaboration, ultimately reducing costs while improving patient outcomes. Deployed properly, Siemens PLM Software can deliver payback in less than a year.

Siemens PLM Software for life sciences provides support for end-to-end product lifecycle management and collaboration on a common platform. Key capabilities that support medical devices manufacturers include:

- Teamcenter is a single source of product and process data that supports automatic device master record (DMR) creation, linking, maintenance, and validation against Federal Drug Administration (FDA) guidelines; device history record (DHR) creation, validation, and revision; and support for integrated corrective and preventive action (CAPA) complaint tracking, related workflows, and reporting.
- NX supports design and styling requirements, visualization, real-time and photorealistic rendering, and digital simulation.
- Tecnomatix supports manufacturing planning and simulation so that factors that affect cost, quality and productivity can be evaluated virtually so changes to product and production designs can be made early in the process.

Siemens PLM Software enables manufacturers to systematically manage regulatory compliance with end-to-end traceability and reporting while providing authorized outside parties with the ability to access and provide input.

THE SITUATION

Medical device manufacturers face strict regulatory requirements but are also pressured to constantly innovate and improve their product to impact patient outcomes. Like many other manufacturers, those in the medical device industry are challenged to:

- Do more with less. To remain competitive, they must submit more designs for regulatory approval in less time and reduce process costs while proving their processes have consistent and repeatable performance.
- Reduce time to market. To win in the market, they must be first to deliver on new patentable devices or innovations, so manufacturing, engineering, quality control, compliance management, and marketing must all work in concert.
- Ensure compliance. Medical device manufacturers must leverage a global supply chain while ensuring that it meets local regulatory requirements in the markets where its products will be used.

The most effective way to meet these challenges is to support one version of the product data from research and development to design to manufacture to marketing to maintenance, yet few medical device manufacturers today have end-to-end product lifecycle management systems in place. In fact, most rely more on disparate silos of information, limited collaboration between teams, and document or process focused systems.

Siemens PLM software enables medical device manufacturers to meet regulatory requirements, address increasing competition and time-to-market pressures, and drive innovation. Key benefits manufacturers achieve from implementing such a system include:

- Reduced costs
- Increased productivity
- Reduced design errors
- Reduced time to market
- Greater predictability
- Improved patient outcomes

This Guidebook explores the best practices, fine-tuning tips, and missteps to avoid for medical device manufacturers to maximize returns from their investment in Siemens PLM software.

BEST PRACTICES

Companies deploying Siemens PLM software achieve more rapid time to value by leveraging the solution's ability to support end-to-end management of the medical device industry product lifecycle. Key best practices include configuring interfaces for user needs, taking a pilot approach to deployment, training users based on their roles and profiles, leveraging their vendor's industry expertise, and developing a deployment plan that balances security with openness.

Configure interfaces based on your users

Physicians are not traditional users of PLM software; however, physicians will increasingly need to interact with such systems, especially if they desire to connect more closely with device and equipment manufacturers in order to better meet individual patient needs. Although engineers and product developers may require numerous detailed drawings, views, and specifications documents, physicians accessing or entering patient-specific medical product information are unlikely to drill down through a file tree to find what they need. Providing a flexible interface that can be configured for various types of users will increase adoption and reduce training time and cost. Additionally, when the standard interface can be a standard Web browser, training barriers to adoption can be reduced further.

For example, one manufacturer of orthopedic implants needed a virtual process for customizing surgical plans to suit individual patients. Siemens configured its Web interface to support a role-based view of the surgical planning process. Surgeons accessing the application are not exposed to the typical granularity and richness of a PLM application; they only view the forms and data that they need to provide input into the implant customization process.

Take a pilot approach to deployment

Most PLM deployments find greater success with a pilot approach; this is particularly important in the medical devices field. A pilot approach can reduce the complexity of the first initiative, gain feedback from pilot users to improve the experience of future adopters, and enable manufacturers to focus on one area that can deliver rapid benefits — ultimately driving a self-funding rolling deployment

approach. Taking a “learn as you go” approach through a pilot can help adjust small mistakes before they become adoption barriers and provide a controlled limited environment where the PLM team can validate or adjust their initial assumptions about how the application can best support PLM efforts.

Starting, for example, with a small group of physicians and engineers with a similar focus, such as knee replacements, can ensure training and interface requirements changes are met at a small scale before a broader buildout to a broader user base and a broader product and therapy portfolio.

Leverage vendor’s industry expertise

Rather than trying to recreate the wheel, manufacturers can accelerate deployment and adoption cycles and drive faster time to value by taking advantage of industry best practices and solutions that have both broad PLM and collaboration capabilities and pre-built support for the specific needs of their industry. Teamcenter’s integrated support for DMR creation, viewing, validation, revision, and retrieval; in-process DHF management; CAPA management functionality; and monitoring dashboards are a few examples of areas where manufacturers can take advantage of Siemens’s investment and experience in the medical field.

Balance security with openness

Persistent traceability is a requirement for regulatory compliance in the medical device industry. However, manufacturers must ensure compliance while still supporting easy collaboration across internal and external parties in the supply chain to drive innovation. Siemens PLM solutions help manufacturers to balance the need for security and compliance while supporting appropriate information access and exchange.

Title 21 CFR Part 11 of the Code of Federal Regulations defines the rules under which electronic records and signatures are considered as reliable as paper records. This is important to medical manufacturers because it requires them to institutionalize audits, system validations, and documentation of validation processes for software and systems that will process electronic data that are required to be maintained or used to demonstrate FDA compliance. It also applies to FDA submissions made in electronic format.

Siemens PLM provides compliance management, traceability, and reporting capabilities, as well as the ability to integrate compliance information into standard business processes. Responsibility tracking and dynamic digital signature and watermark generation capabilities further support compliance, while the Teamcenter platform supports ease of access and collaboration.

FINE TUNING TIPS

Beyond initial deployment, manufacturers will find they can achieve additional incremental ROI by adopting some common strategies. Some companies find that they are more comfortable with taking a pilot approach to PLM and then expanding. In the case of medical devices, this may mean selecting a single therapy area or device application, working through the initial model with a small group of interested physicians, and then expanding vertically (for example, within the same

therapy but to more physicians) or horizontally (such as to similar related therapeutic areas).

Identify additional integration opportunities

The holy grail of patient-specific orthopedics is in integrating across the entire product lifecycle, from initial patient diagnosis through computer-aided design (CAD) and computer-aided manufacturing (CAM) applications to manufacturing and delivery to the operating room.

Device manufacturers taking the first steps today should be thinking about future integration goals and ensure their initial efforts can be extended in the future. Those who have automated some portion of the lifecycle today can identify additional integration opportunities to reduce costs and streamline business processes. Teamcenter's support for many different CAD authoring tools via its embedded visualization capacity, JT, can make integrating other teams and processes possible without expensive and time-consuming retraining.

Balance tactical advancements with strategic goals

There are many tactical requirements that device manufacturers must meet on an ongoing basis to ensure both regulatory compliance and innovation. The benefit of standardizing on an integrated PLM environment is the ability to automate many of those tasks so research and development, design, marketing, and medical experts can focus on innovation and improving patient outcomes instead of design rework, corrections, and paperwork. Beyond the initial PLM initiative, looking at what other processes can be automated or streamlined can further free users to innovate.

Expand your physician footprint

Breadth (how many people access an application) and repeatability (how frequently people access it) are at the core of maximizing ROI from any technology deployment, so it naturally makes sense that putting medical devices in the repertoire of more medical experts would drive both greater breadth and repeatability and, thus, greater ROI. Manufacturers deploying Siemens have found the relative ease of use of Teamcenter and the ability to provide physicians with role-based views that limit adoption barriers are the most effective ways to expand their footprint; ensuring distributors and marketers are also in the PLM collaboration loop can help drive a broader, more educated sales network.

MISSTEPS TO AVOID

Manufacturers that watch out for common missteps to avoid can keep their PLM initiatives on the right course, and ultimately maximize their return on investment from PLM and innovation efforts.

Don't assume that you can build it from scratch

Many medical device firms have looked to point-to-point integration, extension of document and content management systems, or custom-built applications to support the specific needs of their industry, and found that the initial and ongoing cost and lack of flexibility can far outweigh any short-term benefit. Similarly, manufacturers should look before they leap into any extensive changes to an existing PLM solution. Companies that do their homework in adopting PLM take some time to understand fully the capabilities of the solution, and usually spend

less time and money on customization and have fewer maintenance and support needs on an ongoing basis.

Don't assume if you build it they will come

Adoption challenges are part of the PLM story in most industries, as any significant PLM initiative will by definition require business process changes. Engaging different groups of users early in the development process, focusing on usability as much as functional detail, and (particularly in the case of medical professionals) flattening the learning curve as much as possible will help ensure your PLM will be broadly adopted. Taking advantage of Teamcenter's integration with Microsoft Office applications can also help ease adoption: Microsoft Office is embedded in Teamcenter and Teamcenter places its own ribbon bar in the Microsoft Office suite.

Don't assume you're finished: the addressable product lifecycle is expanding

Continuous innovation is key to remaining competitive in the medical device industry. To be most successful, manufacturers should use the knowledge gained from initial PLM efforts to drive ongoing process improvements and greater collaboration. Siemens's SOA and Web services offer many opportunities to integrate and extend the platform to other components and applications in the medical device field, and in some cases, even as far as the medical devices themselves. The winners in medical device innovation will be those who continue to innovate not just in research and development and product design, but also in automating the integration of real patient data and outcomes on an ongoing basis.

CONCLUSION

Increasingly, medical device manufacturers seek to have a unified view of their entire product development lifecycle with the ability to drill down and trace every product detail. They also drive innovation and research and development efforts with a strategic focus on improved patient outcomes.

An integrated PLM environment can support the complex needs of medical device manufacturers while improving cross-team collaboration. Deployed properly, Siemens PLM Software solutions in the medical device industry can deliver rapid time to value and enable manufacturers to reduce costs, increase productivity, and accelerate time to market.