Medical equipment development solutions

Enabling predictable program schedules and cost with competitive capability and performance
Stay in control

Control is crucial for medical device companies. Competition, regulations, costs and organizational complexity increase your risks and require you to be prepared for a wide range of complications. Despite these complications, you not only have to build the right product, you must also build the product right. The best way to get there is to make better, more informed decisions, based on:

• Integrating all cross domain knowledge together in a single, logical location accessible by individuals – no matter where they are in the world or in the organization – so that knowledge is available to every person making a decision anywhere in the process, in the context of their decision
• Giving decision makers the ability to make more collaborative decisions in concert with others, while knowing how the decisions they are making impact others throughout the organization, whether it is mechanical design impacting electronics; electronics design impacting software; or the ripple effect of a change throughout the entire system
• Enabling cross-functional knowledge sharing, and giving individuals what they need to make the right decision as quickly as possible

The best way to stay in control and make better decisions for your development, manufacturing and quality process is a strong PLM solution. Learn why the world’s best medical instrument and equipment companies rely on Siemens PLM Software solutions to achieve balanced control.
Meeting medical equipment industry challenges

Medical instrument and equipment companies must manage increasingly complex product development processes.

Developing a medical device has always been a complex process, or rather a network of complex and inter-related processes. Today’s medical instrument and equipment companies must manage increasingly complex product development processes with the highest efficiency. Meanwhile, the pressure mounts to meet such challenges as:

Regulatory requirements, including traceability, quality standards and materials compliance require companies to stay in complete control of their product development and all documents created in R&D, manufacturing and the supply chain.

Systems engineering and risk management requires companies to manage the risks of many different processes simultaneously as products become a more complex array of functions, including software, electronic and mechanical. Other challenges include globalization and meeting the needs of consumers from emerging markets for different feature sets and price points, even as new competitors enter the market. To stay competitive, you must leverage development and manufacturing resources and synchronize them around the world.
Competition is everywhere. New products are introduced every day and growing your market share is difficult. You must be sure to use your resources efficiently, including powerful design and data management tools to increase productivity and introduce best-in-class products to market.

Increasing costs of doing business in this industry are affecting all medical device manufacturers. New taxes, scarce resources and rising cost of healthcare require you to take steps to be profitable. An organization that has a clear picture of its projects and processes is able to stay nimble and ahead of rising costs.

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Smarter decisions, better medical devices through high-definition PLM

Just as HD-TV delivers a much higher definition viewing experience, Siemens’ collaborative decision support platform, HD-PLM, brings high definition to the product development experience because it is built on an architecture that continuously adapts and grows.

HD-PLM is comprised of three core concepts:
1. Intelligently integrated information
2. Future-proof architecture
3. High-definition user experience

To create an intelligently-integrated information environment, PLM must provide a consistent process framework across all domains. By intelligently organizing and integrating systems engineering, providing an integrated definition of the product and closing the loop between product and production, HD-PLM drives a real step change in medical instrument and equipment development and production, improving productivity, time-to-market and first-time quality – helping you build the right product and build it the right way.
To effectively support decision-making, the Siemens PLM Software HD-PLM architecture will never become obsolete. It will remain upgradeable and expandable to permit the introduction of new technologies and innovations, to easily integrate with other business systems and adapt to changes in your business. This environment provides a future-proof architecture to ensure your IT investment will continue to evolve in concert with ours.

Siemens PLM Software is “open for business,” which means we subscribe to open standards, and provide a set of application programming interfaces (APIs) that allow others to integrate with our solutions. Our solutions are scalable to serve the needs of users in any company, from a single-person business to multi-thousand person enterprises. You’ll have the flexibility to configure the solutions to your business needs without building customized in-house solutions.

The HD user experience is all about personalizing the interface to your role and task at hand – clarifying rich product information so you can understand the data more easily and make smarter decisions.
Medical instrument and equipment companies need a product development process that fosters innovation, quality and productivity. At the same time, they need to reduce risk and stay in control of complex requirements.

Siemens PLM Software’s solutions for medical instruments and equipment enable you to achieve balanced control, leading to improved visibility to assess and manage risk, reduced time and cost for regulatory submissions and faster ramp up to target production volumes. Additionally, our end-to-end PLM solutions enable you to be sure your product features are aligned with your end customers’ needs, as well as marketing and sales expectations.

The Siemens PLM Software solution is built on open standards to allow for integration between our applications as well as with legacy data systems and other third-party applications. This gives you the flexibility to implement the business process you require, even as you take advantage of best-of-breed applications, and aggregate work from diverse authoring environments and authors. Throughout the entire process, everyone will be working with a single source of the truth.
Siemens PLM Software’s full set of product lifecycle management solutions enables medical instrument and equipment companies to achieve balanced control, predictable program schedules and costs with competitive capability and performance by taking advantage of:

- Integrated engineering applications with world-class features and functions to enable efficient product and process development, even in a multi-CAD environment
- Document controls and lifecycle traceability, connecting workflows and deliverables from R&D, manufacturing, quality, services and regulatory; reducing risk and enabling re-use for future products
- Predictable design control, connecting schedules and deliverables with actual workflow execution and confirmation of outputs through verification and validation
- Purchasing controls to leverage your supply chain and facilitate secure and easy collaboration anywhere on the globe
- Production and process controls with manufacturing, engineering and quality management applications integrated with existing systems to ensure efficiency and quality in development and production

End-to-end medical device product lifecycle management
Siemens PLM Software solutions enable medical companies to improve innovation, productivity, and flexibility with greater control of their product development process.

Here is just a sampling of the successes that our customers experience:

• Enable efficient product and process development – reduced new product introduction (NPI) from 18 to 3 months, engineering change orders (ECOs) ready in minutes rather than hours, and one physical prototype instead of two or three

• Control document and design knowledge – 80 percent information re-use, secure design history files (DHF) visible to teams that need it, regulatory data generation in minutes rather than months, lower compliance submission fees, smaller design/regulatory staff needed

• Facilitate collaboration – single source of truth for all global groups, open file format for easy transfer of multi-CAD data from suppliers saving time and resources

• Optimize production and service – reduced manual plant design, decisions based on analysis rather than gut-feel, spare parts catalog created with bill of materials (BOM) for easier serviceability
Why do so many medical equipment companies use Siemens PLM Software?

Undergraduate biomedical engineers at the Rose-Hulman Institute of Technology designed this prosthesis with Siemens PLM software.

**Customer loyalty** – Top 100 medical device customers have chosen Siemens PLM Software solutions for more than 13 years

**Industry coverage** – 29 of the top 30 medical device companies use PLM solutions from Siemens

**End-to-end PLM supplier** – Only PLM provider with full set of solutions – digital product development (DPD), digital lifecycle management (DLM), digital manufacturing (DM), and manufacturing execution systems (MES).

**Open, flexible, stable** – Solutions built on an open platform with interoperability with existing products and other platforms. Strength in multi-CAD management and authoring. Backed by industry conglomerate Siemens AG
About Siemens PLM Software
Siemens PLM Software, a business unit of the Siemens Industry Automation Division, is a world-leading provider of product lifecycle management (PLM) software, systems and services with nine million licensed seats and 77,000 customers worldwide. Headquartered in Plano, Texas, Siemens PLM Software helps thousands of companies make great products by optimizing their lifecycle processes, from planning and development through manufacturing and support. Our HD-PLM vision is to give everyone involved in making a product the information they need, when they need it, to make the smartest decision. For more information on Siemens PLM Software products and services, visit www.siemens.com/plm.

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