Digital Industries Software

Improving medical device product development

Adopting new design and manufacturing methodologies to enhance performance while reducing costs

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Medical device providers need to bring new designs to market faster while controlling both product development and final product costs. At the same time, medical devices must provide best-in-class performance, pleasing aesthetics and injury-preventing ergonomics. Improving product development performance will enable medical device manufacturers to better respond to changing market demands.

Medical device manufacturers need to accelerate the development of innovative, high-quality products that are easy for both medical professionals and patients to use safely, and that fully comply with all relevant government relations. Regulatory pressures and the need to meet specific customer requirements are having a big impact on medical device design and manufacturing.

Regulatory requirements are evolving and can vary from country to country. This is driving increased complexity in many aspects of medical device development. Manufacturers must prove regulatory compliance, which

Major trends that are impacting medical device manufacturers include:

• Regulatory pressures are driving many aspects of device design
• Increasing global competition results in pressure to bring new designs to market faster and at lower cost
• The need to adopt new design and manufacturing technologies to improve product performance while reducing costs
impacts how design and manufacturing processes are managed and documented. The complexity of providing supporting documentation and traceability is continually increasing and regulation changes seem almost commonplace, yet the cost of noncompliance can be high.

Another trend in this industry is growing global competition. In an increasingly global manufacturing environment, competitive pressures from across the world are a reality. Competition is resulting in pressure to bring new designs to market faster, while ensuring these designs have excellent appeal and performance for the end user.

Additionally, medical device manufacturers need to be aware of the opportunities presented by new design and manufacturing technologies. For example, additive manufacturing (AM) has the potential to improve product development flexibility while reducing product and manufacturing costs. New technologies, including reverse engineering, generative design and additive manufacturing, enabled by new convergent modeling techniques and integrated into 3D CAD software, increase the ability to integrate medical devices with individual customers’ organic shapes.

Solid Edge® software, which is part of the Xcelerator portfolio, the comprehensive and integrated portfolio of software and services from Siemens Digital Industries Software, enables manufacturers to respond to major trends that are impacting the medical device industry.
To respond to these trends and succeed in competitive global markets, manufacturers will benefit from improving performance in key process areas.

**Design mechanical components:**
- Designers and engineers are under pressure to produce complex component designs quickly and accurately
- The 3D computer-aided design (CAD) models are often supplied in third-party CAD formats
- With its unique synchronous technology, Solid Edge is a comprehensive, proven 3D CAD software that enables fast and efficient design. It works easily with data supplied in third-party CAD formats by directly opening in these 3D models

**Develop sheet metal enclosures:**
- Medical equipment, including electrical components, needs to be securely and attractively housed for reliability, safety and hygiene
- Streamlining sheet metal design and manufacturing speeds design and reduces scrap and rework
- Solid Edge includes capabilities that enable rapid design of these components and the creation of accurate flat patterns that simplify and speed manufacturing

**Model organic shapes:**
- Medical devices often involve the creation of complex shapes that must be modeled quickly and accurately
- Solid Edge integrates facet-based models with b-rep models using convergent modeling to model complex, attractive looking surfaces and solids
- Solid Edge includes subdivision modeling techniques to quickly create aesthetic, smooth forms

**Construct large assemblies quickly and accurately:**
- Designing components in the context of an assembly to ensure fit and function can speed the product development process and reduce costs
- Using Solid Edge streamlines and simplifies the process of finding 3D models of off-the-shelf catalog components using integrated, cloud-based catalogs
- The software helps you quickly and easily create and manage even the largest assemblies without lags or crashes

**Design wiring schematics and wire harnesses:**
- Creating 2D wiring schematics for electrical circuits and wire harnesses can be a challenge for manufacturers of products that include electrical components
- A seamless co-design mechanical CAD/electrical CAD (MCAD/ECAD) environment such as Solid Edge can be used to avoid late-stage design changes
- Solid Edge Wiring and Harness Design software enables the rapid creation of data-driven wiring schematics and wire harness designs and includes validation of electrical circuits with simulation and design-rule checking

**Leveraging software to support innovation**
Route electrical wiring in 3D:
• Electrical wiring in complex designs must meet compliance specifications as well as system performance within mechanical constraints
• Using Solid Edge Electrical Routing enables you to automatically route wiring in complex assemblies, while synchronizing wiring schematic and wire harness design intent using a unique connected mode between MCAD/ECAD environments
• Wire routings can be optimized, correct wire lengths calculated and accurate bill-of-materials (BOMs) created for electrical components

Integrate printed circuit boards (PCBs) into electromechanical products:
• Using 3D CAD models of PCBs during the design process can ensure they are housed accurately and safely in electromechanical assemblies
• Solid Edge PCB Collaboration enables users to send design aspects between electrical and mechanical disciplines so changes can be accepted or rejected
• Solid Edge PCB Collaboration supports the mapping of 3D models to Siemens’ PADS™ Professional software and Xpedition™ software products and integrates with third-party solutions using the IDX format

Validate for safety and quality:
• Identifying and resolving design challenges prior to manufacture provides a significant drop in cost and time-to-delivery
• Solid Edge Simulation may be used to analyze static loads, buckling, heat transfer and vibration
• Integrated computational fluid dynamics (CFD) solutions like Simcenter™ FLOEFD™ for Solid Edge software can be used to optimize products before manufacturing using integrated analysis of fluid flow performance

Optimize design for human factors:
• Medical devices must be operated correctly by both medical professionals and patients so ease-of-use and reliability are paramount
• By creating 3D parts and assembly models, human factors can be taken into consideration as an integral part of the design process
• Using Solid Edge enables the user to rapidly create virtual prototypes for testing and evaluation and creates clear technical documentation to support installation, use and maintenance
 Manufacture accurately and efficiently:
- Choosing the best manufacturing process to create toolpaths that are efficient and produce high-quality parts can reduce errors and rework in manufacturing.
- Using additive manufacturing techniques can minimize the need to stockpile spare parts. Manufacturing small volume parts efficiently can significantly reduce tooling costs.
- Solid Edge CAM Pro enables you to create accurate and efficient 2.5-, 3- and 5-axis milling and turning processes. It works with data supplied in different CAD formats while creating associative toolpaths.

Create clear technical documentation:
- Medical devices should be manufactured, installed, used and maintained correctly to ensure performance and reliability.
- Dynamic technical publications can clearly communicate step-by-step procedures for correct operation of complex devices.
- Solid Edge Technical Publications can be used to create documentation that includes 3D graphics to effectively communicate installation, operation and maintenance procedures.

Visualize new products:
- Improve communication of designs to highlight the unique value of innovative solutions using photorealistic imagery and animations made from 3D models.
- Design visualization techniques, such as augmented reality (AR), bring ideas to life.
- KeyShot capabilities launched directly from Solid Edge can help you create high-quality renderings, animations and interactive visuals. Solid Edge also provides AR capabilities.

Collaborate with customers and suppliers:
- Manufacturers need to share design data in a controlled way while protecting intellectual property (IP).
- Faster and controlled communication of design intent with suppliers and customers reduces errors and speeds product development.
- Xcelerator Share supports collaboration around design data in multiple formats. This cloud-based collaboration solution closely integrates with Solid Edge.

Manage projects and engineering changes:
- Data management capabilities built into CAD allow project development teams to access and track project management and engineering change information, speeding new product development.
- Solid Edge built-in data management capabilities can be leveraged to help manage engineering changes efficiently and safeguard data integrity using revision and release management features.
- Solid Edge provides a growth path to Teamcenter® software when you need more comprehensive product lifecycle management (PLM) capabilities.

Manage customer requirements:
- Early definition of device configurations can capture a customer’s needs in a systematic way, providing an accurate assessment of costs and lead time.
- Proposing practical solutions that are predictable and competitive can reduce business risk.
- Solid Edge Requirements Management software captures and tracks customer requirements and relevant industry standards.
Benefits of using Solid Edge

Solid Edge provides an on-ramp to digital transformation, enabling manufacturers to create a comprehensive digital twin of their products and includes solutions for mechanical design, electrical design, simulation, manufacturing and technical publications. It also includes solutions for data management for all the technical data that is created and consumed when supporting the comprehensive digital twin. It facilitates collaboration both within manufacturing companies and with external resources including suppliers and customers.

The cornerstone of the Solid Edge portfolio is its market-leading CAD application. Developed from the ground up to be an open and extensible tool, Solid Edge with synchronous technology provides the freedom to easily design naturally and iteratively, whether you are working on a new design or editing existing parts, assemblies or products. That’s because synchronous technology contains built-in intelligence that interprets design intent regardless of where the design originated.

**Benefits achieved by medical device manufacturers using Solid Edge:**
- New project development time reduced from 12 months to five months
- Design and prototype development time reduced by 50 percent
- Productivity increased by 50 percent
- Reduced need for physical prototype builds
- Shorter learning curve for new engineers
- Improved efficiency for design changes
- Increased use of standard parts
- Fewer errors with automatic interference checking
- Higher numerical control (NC) machining precision
- Significantly shorter lead times for custom designs

To learn more about how Solid Edge enables medical device manufacturers to be successful, please visit solidedge.siemens.com/en/industries/medical-devices.

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About Siemens Digital Industries Software
Siemens Digital Industries Software is driving transformation to enable a digital enterprise where engineering, manufacturing and electronics design meet tomorrow. Xcelerator, the comprehensive and integrated portfolio of software and services from Siemens Digital Industries Software, helps companies of all sizes create and leverage a comprehensive digital twin that provides organizations with new insights, opportunities and levels of automation to drive innovation. For more information on Siemens Digital Industries Software products and services, visit siemens.com/software or follow us on LinkedIn, Twitter, Facebook and Instagram. Siemens Digital Industries Software – Where today meets tomorrow.

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