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Fast-track innovation and speed to market with powerful collaboration tools

Taking your product to market quickly amid the pressures of increased medical device complexity and regulatory expectations requires that product design and development stay flexible. Meanwhile, consumer demands both at the patient and provider levels require increased product capabilities and intelligence to deliver better safety and efficacy. Digital processes and systems can help automate processes, but are valuable only if they can offer complete traceability, transparency and accessibility. Collaboration across manufacturing domains is a key factor to introduce a successful device that can compete in today's marketplace.

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An integrated approach to quality-by-design

As medical devices become smarter and more connected, manufacturers have been tasked with mastering the associated complexity. Market pressures urge fast-tracking products into the marketplace, but regulatory demands can stymie progress. Developing markets and aging populations are helping to increase globalization, which puts a strain on R&D, manufacturing and supply chains.

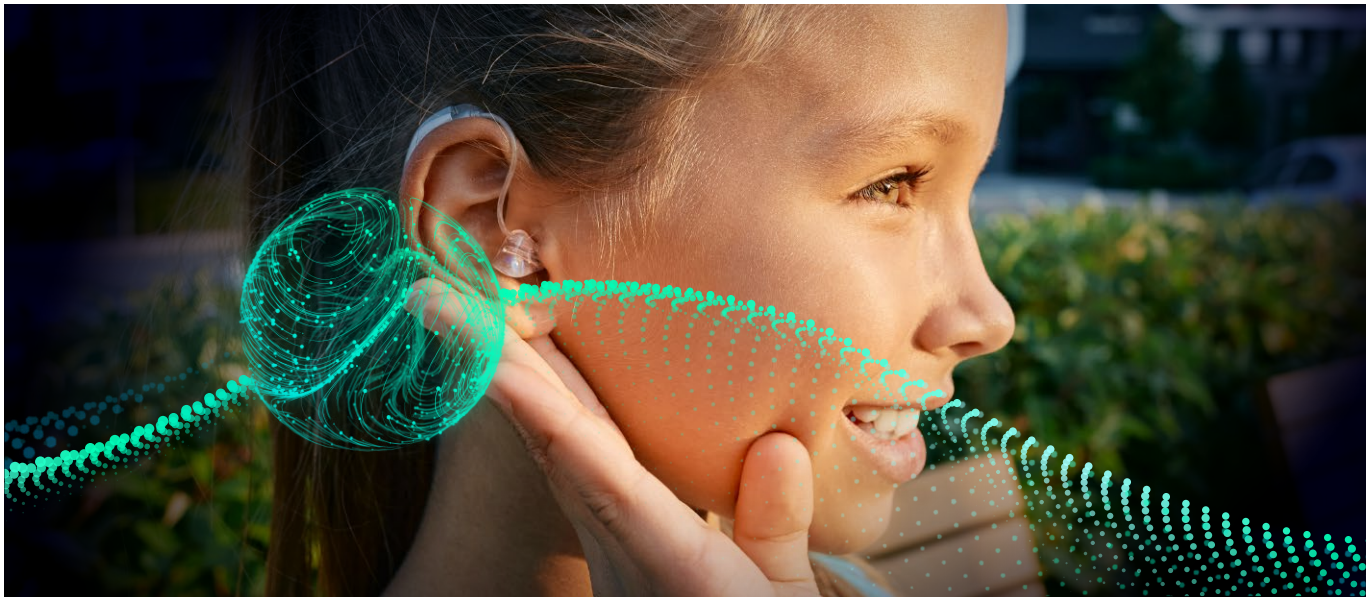
Manufacturers are also expected to show more of their design process and deliverables with ever-greater transparency. Failure to comply can result in delays, lost revenue and legal issues. To add to the complexity, product recalls are on the rise. Analysis shows a 119% increase in the annual number of medical device recall events for a 10-year period, increasing from 540 in FY2007 to 1,183 recalls in FY 2016.

Product complexity can be managed through re-use, context capture and collaboration, which can help identify issues earlier and result in faster time to market and significantly reduced quality risks. These improvements can be achieved if mechanical, electronic and software engineers work together; however, many existing systems make it difficult for them to find the right information quickly, keep global design data synchronized and share the design information with manufacturing.

One impediment to a smooth transition to manufacturing starts with the Bill-of-Materials (BOM). Issues include parts errors, invalid supplier data, missing information and obsolete parts.

There are four common root causes to these issues:

1. **A multidomain design process that's generating an incomplete BOM**
2. **A lack of shared understanding of the product configuration and all its variants**
3. **Differing global design and manufacturing processes that can't access and analyze information early to prepare and optimize procedures**
4. **Product quality issues that drive up warranty costs**



Challenges in managing the product lifecycle

If a company's product lifecycle is supported by fragmented IT systems or manual work that obstructs progress, complexity can increase and quality suffers. It can lead to innovation being stifled by non-value added work and engineering teams devising workarounds that bypass intended processes. This disconnect can result in data incompatibilities, late discovery of problems, and regulatory compliance violations.

In addition, businesses that do not effectively use digitalization and an integrated end-to-end product development solution can hurt their competitive advantage. For example, after launching a successful product, a manufacturer may want to create additional product versions, improvements, or leverage the data and analysis created during the initial development.

Unless the design and associated data was developed with this flexibility in mind, they won't have the capability for re-use, which increases development costs and chips away at their chance to stand out in the industry.

A limited engineering IT strategy can limit a company's ability to innovate and develop new devices. Manufacturers that settle for CAD and PDM systems might improve engineering productivity, but a product lifecycle management (PLM) strategy can drive overall business performance. PLM can accelerate innovation and top-line revenue to help a company grow. And with the availability of cloud-based platforms, PLM systems can cost less to implement than expected.

How PLM for Medical Devices can help fuel collaboration and efficiency

Manufacturers can overcome stifled innovation and siloed processes through the digital transformation of product development. Working concurrently across domains is crucial for teams to function collaboratively, control costs and manage timelines.

PLM systems enable re-use of development data and evidence to facilitate control of complexity and maintain integrity. PLM systems for medical device manufacturers automate compliance, submissions and reporting. Cross-discipline design teams gain the ability to share work in progress (WIP) to refine the development process. Teams can also utilize integrated product planning and multi-CAD data management that's connected to quality processes such as engineering and manufacturing BOM management, design history file (DHF) and device master record (DMR) deliverable management, corrective and preventative actions (CAPA), and change management. Rich connection to downstream enterprise resource planning (ERP) and manufacturing systems helps users comply with region-specific submission processes imposed by various regulatory agencies.

There's also ongoing value for product development via connection to the cloud. Manufacturers of all sizes can scale product development, risk management, traceability to design controls, verification and validation (V&V) capabilities to match product and compliance requirements. New technologies can be utilized quickly and cost-effectively. And ecosystems can be leveraged as a network of innovation partners through browser-based, anytime access from any device.

Challenges in managing the product lifecycle

A cloud-based PLM system helps manufacturers by streamlining design data management, product line management and quality process management activities so that they can deliver high-quality, compliant medical devices faster. Automating, standardizing and optimizing processes leads directly to cost savings and speedier development. Here's how:

• Design data management

Processes are digitalized to enable data to define, measure, analyze, improve and control bringing a product to market. Design activities become parallel across domains —systems, mechanical, electrical and software — so that all team members can easily share WIP and quickly find the right design and regulatory information.

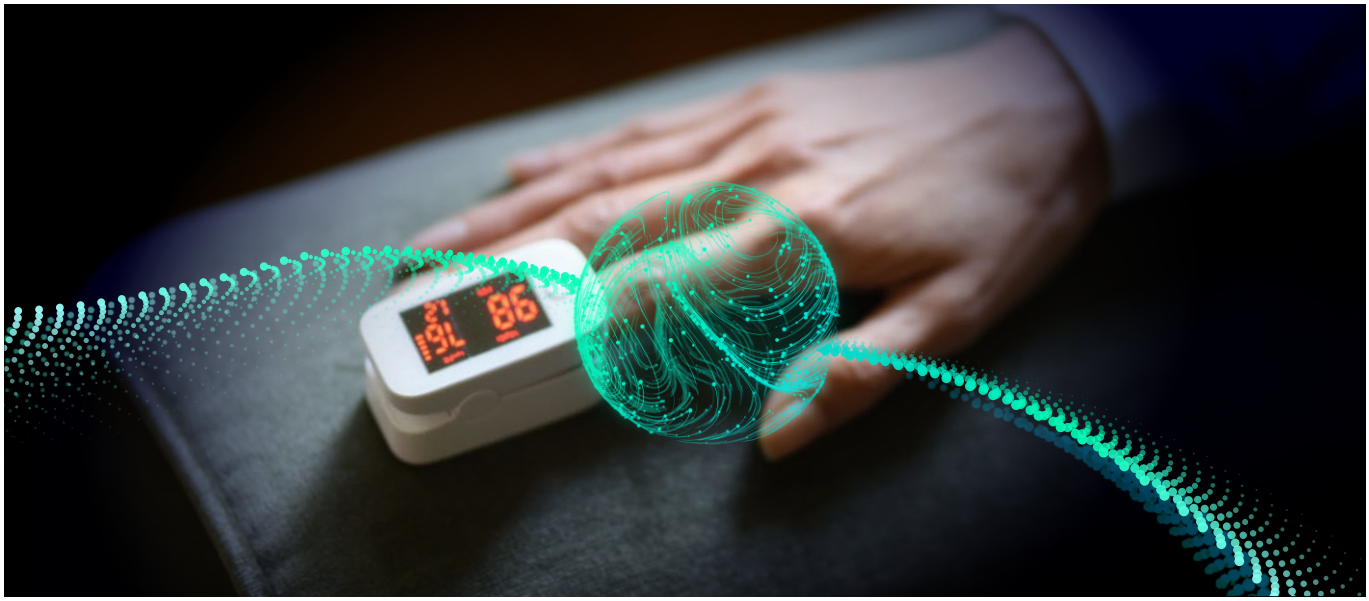
• Product line management

Processes can more accurately identify, create and synchronize structured definition of product and manufacturing specifications. It's easier to manage, change and manufacture product variations according to regional needs through visibility and integration across the value chain. Multi-BOM management ensures integrity of interactions with suppliers and production.

• Quality process management

Processes are improved through a master system of record with compatibility to all discipline workflows and data trace, history and change control. PLM enables modular and discrete re-use of requirements, risk analysis and testing objects from similar designs. Users gain the ability to map requirements to V&V activities, including BOMs.

PLM systems created specifically for medical device manufacturers can not only manage the complexity of cross-domain interactions but can also help maintain data integrity and provide the infrastructure to ensure compliance. Cloud accessibility and AI-supported usability create a flexible environment that changes as a company's needs change. That helps companies speed their devices to market safely and maintain competitive advantage.



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Americas: 1 800 498 5351

EMEA: 00 800 70002222

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