What is PLM Accel and how can it help your medical device company innovate more while easily managing requirements and product quality? Here’s the what, why, and how of this leading pre-configured solution.

**Q - What are some of the key challenges that the medical device industry currently faces?**

**A -** Today, medical device companies face growing demands for innovation, intense competition, and constantly evolving environmental and regulatory requirements, including the FDA’s rule for Unique Device Identification (UDI). Combined with the ongoing need to better manage product quality across corporate functions, these pressures complicate their ability to design and deliver winning products to market.

**Q - What is PLM Accel for Medical Device?**

**A -** PLM Accel for Medical Device™ is a pre-configured model based on leading practices in innovation and product development, built on PTC’s Windchill® application. It is designed to help medical device companies minimize configuration needs, accelerate implementation, facilitate user adoption and maximize the ultimate value of PLM.

PLM Accel is pre-configured for document (record) management and a closed-loop change management process to provide a fully FDA compliant record management system. It includes system validation templates and protocols that provide up to 75% of documentation requirements.

For smaller companies in a highly regulated industry, PLM Accel provides a turnkey solution to help them manage product and quality information in a validated system. For larger companies with an existing system validation process, PLM Accel provides a faster implementation and time to value.

**Q - Why did Kalypso develop this solution offering?**

**A -** Through our medical device client work, we identified a need for system validation tools that are easy to implement. We found clients looking to modernize their paper-based, antiquated document and record management processes with a modern, web-based solution offering workflow automation and the ability to streamline processes and remain compliant.

We see many medical device companies looking to gain the benefits from traceability and linkage of their design and product development activities with their document and quality systems, and Windchill offers companies exactly that opportunity with the Windchill 10 solutions. We also see many companies under pressure to jumpstart their implementations with document and change management for quality and medical records.

We think this offering will help medical device companies looking for out-of-the-box implementation and quick time to value. PLM Accel takes advantage of all the power and capabilities of Windchill as a document and record management solution.

**Q - Are there other similar solutions in the market? How is Kalypso’s offering different?**

**A -** Kalypso is the only PTC Service Advantage Partner that offers a pre-configured solution for document and records management for medical device industry. We have taken the initiative to apply our years of industry experience and PTC Windchill solution expertise to offer clients a pre-configured Windchill 10 system, including document types, workflows and reporting, where we are completely leveraging out-of-the-box capabilities to make rapid, best practice implementations a reality.

Kalypso believes that Windchill is a uniquely flexible and capable platform that allows companies to adapt the technology to meet industry and company requirements without customizing the solution. We chose to develop PLM Accel for Medical Device on Windchill 10 for this reason.

**Q - What size organizations are best suited for PLM Accel for Medical Device?**

**A -** Organizations of any size could benefit from implementing PLM Accel for Medical Device. Many companies use Windchill to manage global design processes and CAD data, so PLM Accel is a great opportunity to take advantage of Windchill capabilities, expand their usage model and get more benefit from their Windchill investment.
Smaller organizations looking to implement a document management solution and eventually expand into full PLM solution can benefit greatly from a quick win, and lower cost, lower risk initial investment and expand their usage later.

Q - What are the key benefits that organizations can expect if they use PLM Accel?

A - PLM Accel accelerates the adoption of PLM by pre-populating PTC’s Windchill solution, reducing the complexity, time and effort and getting to value faster. The reduced demands on time and resources enable medical device companies to gain PLM benefits faster than ever before.

Q - Are there plans to further advance this solution in the future? What other capabilities can users expect?

A - Yes, we plan to expand the pre-configured solution to include CAD data and part management including the validation scripts to support the increased functionality.

We will look at expanding our industry templates into other adjacent PTC products like Integrity for requirements management, Windchill Quality Solutions, and Windchill Product Analytics as PTC continues to invest heavily in its products and provide new functionality for the medical device industry.

About the Author

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