Medical device companies today face growing demands for innovation, intense competition and unprecedented pricing pressures. They also face strict yet evolving environmental and regulatory requirements, including the FDA’s rule for Unique Device Identification (UDI), and the ongoing need to better manage product quality across corporate functions.

The world’s most respected medical device manufacturers are turning to product lifecycle management (PLM) solutions like PTC Windchill® to help manage product quality early and across the entire product lifecycle, resulting in reduced risk, streamlined compliance and accelerated innovation.

Kalypso provides medical device companies with a cost-effective accelerator for traditional PLM implementations with PLM Accel™ for Medical Device.

What is PLM Accel?

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 uses leading practices to help medical device companies minimize configuration needs, accelerate PLM implementation, facilitate user adoption and maximize the ultimate value.

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 enables companies to get up and running with Windchill in as little as 16 weeks, managing product information, processes and decisions throughout the lifecycle. With PLM Accel, companies demonstrate value quickly and can build incrementally on success.

For medical device companies, PLM Accel borrows from Kalypso’s deep industry experience to quickly apply proven processes and technology that solve specific industry needs and drivers, removing uncertainly from the solution design process, building confidence and shortening the time to implement a compliant solution.

PLM Accel Implementation Methodology

When combined with Kalypso’s comprehensive focus on strategy, technology, people and process, PLM Accel builds strong stakeholder alignment and faster benefits realization. To ensure a successful implementation, the Kalypso team guides your key people, processes and changes throughout the process.
PLM Accel for Medical Device includes:

- **Pre-defined security model**
  Add/assign pre-defined organizations, roles and privileges for users

- **Pre-defined workflows**
  Pre-defined workflows represent leading design control practices

- **Pre-configured DHF/DMR report**
  Represent common documents like DHF and DMR for audits and regulatory requirements

- **Validation templates**
  Pre-configures, validation-ready regulatory templates

PLM Accel provides a low-risk option for medical device companies to jumpstart their PLM journey. The reduced demands on time and resources enables medical device companies to gain PLM benefits faster than ever before.

When Combined with Windchill, PLM Accel Offers:

- Reduced setup time
- “Production ready” validated software system
- Leading industry practices specifically for medical device
- Swift user adoption by leveraging out-of-the-box features
- Structured design control process
- Leading engineering design workflow practices to better manage and control approval process
- Electronic signature and security controls
- Effective change control practices

Accelerate Your PLM Journey

With PLM Accel, medical device companies can achieve the full benefits of PLM, including a single version of truth for all product data, a lower cost of validation and regulatory compliance, and improved product quality.

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.

For more information about rolling out PLM Accel to your company, contact Van Gresham at van.gresham@kalypso.com.

About Kalypso

Kalypso is the world’s premier innovation consulting firm, helping clients improve performance, drive profitability and create sustainable results by delivering on the promise of innovation. The people of Kalypso are leading business professionals who combine unparalleled expertise in innovation, product development, and product lifecycle management (PLM) with a depth of experience in the consumer goods, high technology, manufacturing, life sciences and retail industries. For more information, visit kalypso.com. Follow @KalypsoLP on Twitter and at facebook.com/KalypsoLP.