Product Lifecycle Management for Medical Device Manufacturers

By Cathi Crist and Noel Sobelman

Innovation has been a hallmark of the medical device industry for years. But with mounting economic and regulatory pressures, evolving business models, growing complexity, and shrinking new product pipelines, the ability for an organization to drive and manage innovation that is both profitable and sustainable is more important than ever.

For medical device manufacturers delivering on the promise of innovation in today’s competitive environment means achieving faster time to market, lowering costs and increasing profitability - all while ensuring regulatory compliance. Leading companies are turning to product lifecycle management (PLM) processes and software to help address these challenges, and are realizing the benefits.

By implementing a PLM platform at the core of their product development activities, medical device manufacturers have not only been able to achieve significant productivity and effectiveness results, but have also reaped the benefits of replacing manual processes, siloed applications and legacy document management systems with one single system.

One Single Source of Truth

The first step in implementing a PLM system is defining the product data record. The product data record is a logical data model that defines all data elements and documents necessary to fully describe a device, its accessories and its packaging, from development through launch, globalization and end of life. With PLM software, these product attributes, associated documents and requirements are always linked to product and process development, qualification and ramp-up activities. Additionally, PLM systems have the ability to manage the complex interrelationships between these important data components, while also providing strong program management capabilities and support for regulatory registration and quality system compliance (i.e. design control, validations, etc.).

Because the product data record provides traceability back and forward from any lifecycle state of a product, process or idea in its development cycle from concept to manufactured product, the product data record becomes the blueprint to guide a company’s PLM initiatives.

This platform for master data management is critical to medical device manufacturers not only to ensure compliance but also to facilitate design reuse across highly collaborative networks (i.e. global design centers, suppliers, etc.)

Key Initiatives for PLM

PLM is a compelling tool to support the uniqueness of the medical device industry and to address its many business challenges.

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Key initiatives for PLM adoption include:

**Innovation and product line strategy** – The right approaches to identify opportunities to bring products with both clinical and economic value to market.
- Translating voice of customer into product requirements
- Facilitating collaborative innovation both internal and external to core teams

**Market Planning** – The right products for the right opportunities in the right segments at the right time
- Understanding the marketplace and defining the target segments
- Defining market launch strategies that optimize market and share growth

**Portfolio Management** – The right investment in development across brands, product platforms and products tied to ROI, strategic direction, reimbursement and risk
- Conducting analysis and dynamically balancing the portfolio
- Critically assessing the product opportunity proposal
- Establishing a consistent launch cadence

**Product Development** – Effective processes that facilitate reuse from concept through verification and validation activities
- Executing product development across a well-defined stage gate
- Creating and maintaining Electronic Design History Files (eDHF)
- Using Model-Based Engineering (MBE) principles, practices and collaboration

**Launch and Globalization** – Efficiency in the commercialization in initial launch market and expansion into global markets including people, process and technology
- Managing product transfer and scale-up aligned to targeted margins
- Throttling inventory buildup with capacity and demand
- Filing international registration and offering
- Managing country-specific configurations

**Quality System Management** – Visibility to and action based on in-process and in-market process and product data and performance
- Managing complaints and providing closed loop feedback to development
- Implementing timely Corrective and Preventative Actions (CAPA)
- Reducing incidents of Non-Conforming Materials (NCM)
- Conducting and closing out internal and external audits according to pre-established schedules

**Core Business Objectives for PLM**

By deploying PLM software, medical device manufacturers can achieve real benefit:
- Develop cost-effective robust products with highly capable manufacturing processes
- Achieve development stage gate outcomes and design control deliverables within new products project timelines (i.e. improve time to market)
- Improve links between research and development, clinical research, field education, and post-market surveillance data for developing marketing requirements
- Enable capacity planning and collaboration between the development, clinical and operations organizations
- Deliver robust DHFs and technical dossiers that achieve regulatory clearance and approvals without added delays
- Successfully scale-up and transfer process/technology to operations and external manufacturing partners
- Integrate internal and external systems to eliminate errors, improve operational agility and ensure compliance

In order to achieve lasting business results and accelerate time to value, organizations must clearly define their PLM vision and IT platform.

Kalypso is here to help. Our PLM team has developed practical tools to help medical device manufacturers build a PLM platform and identify major business improvement opportunities, improve data integrity, and increased knowledge sharing and collaboration.

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