

Utilizing ERP and PLM Technologies

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Medical Device Manufacturers' business needs have changed significantly over the past several years, evolving the roles that technology plays within their manufacturing process. Two key technologies, Enterprise Resource Planning (ERP) and Product Lifecycle Management (PLM), have developed into critical success factors for these manufacturers. Each technology brings unique value to the enterprise, and when combined, ERP and PLM provide a wholly collaborative environment that has a major impact on successful product development performance and the ability to maintain a competitive advantage.

ERP and PLM address different business needs for manufacturers. There is some confusion in the industry as to what role each system plays in a company's business process. Clarification of the key features of ERP and PLM, where they fit in the product development and manufacturing process, and how integrating these environments can deliver positive results is important for medical manufacturers to truly understand why each is so critical to their success. In addition, having this clarification will help medical manufacturers maximize the functionality of each system and gain the most from their investment.

Synchronization of Information

It is the integration between ERP and PLM systems that allows direct sharing of engineering and manufacturing data through an automated process. It eliminates the tedious and error-prone task of hand-entering information, resulting in improved data integrity across the organization. An integrated environment decreases redundant efforts and guarantees that all departments involved in the product development and manufacturing cycle have access to current and accurate product data. By synchronizing these two systems and validating the processes, engineering teams are able to access business-level data from the ERP system to support better design processes and manufacturing is ensured receipt of the most current design information for more efficient production processes.

ERP, integrated with PLM, reduces data duplication, speeds product development cycles, improves new product turnaround time, and supplies one version of the truth (Device Master Record) for easier FDA (Food and Drug Administration) and ISO (International Organization for Standardization) compliance initiatives. An integrated environment enhances the overall process in getting medical device products to market and ultimately sustains a company's competitive position.

Case in Point

Understanding the importance of creating a cohesive environment between ERP and PLM was quite clear for a leading developer of medical aesthetic applications.

The company was running into data inaccuracies due to manual processes and disparate product information. Engineering, operations, document and quality control team members were each tracking their design and operations data manually and in separate databases. Synchronization of these databases was a time-consuming task and proved to be a considerable strain on resources. The manufacturer had an ERP system in place to manage all of the operations-centric business activities such as financials, purchasing, planning, and work orders, but the ERP system did not address their engineering design requirements and the need to have clear history tracking of engineering changes. The manufacturer lacked a system that understood revision control and engineering change processes. In order to gain control of their product design, eliminate disparate product information, and support better compliance and manufacturing processes, the manufacturer purchased a PLM system.

A PLM system is designed to manage the full gamut of engineering information in a single location through the many stages of a design. The medical aesthetics manufacturer used the PLM system to manage the lifecycle and all revisions of their Bill of Materials (a listing of components used in a product), provide revision control of engineering documents (such as assembly drawings, schematics, and datasheets), electronically route approvals for New Part Requests (NPRs), manage and automate their Engineering Change Orders (ECOs), and control Approved Manufacturer's List (AML) changes. The PLM system also supported their requirements for meeting the FDA's Part 11 of Title 21 of the Code of Federal Regulations (21 CFR Part 11) for electronic data management with complete history tracking on all changes for compliance with electronic audit trails, and security features to guarantee valid electronic signatures. More importantly, the PLM system helped bridge the gap between engineering and manufacturing. By providing direct data sharing with the ERP system, any changes made in the PLM system were automatically uploaded to ERP so that engineering and manufacturing were always in synch.

Creating a collaborative product development ecosystem by integrating their ERP and PLM environments helped the Class II device manufacturer to completely eliminate manual synching of engineering and operations information, greatly improving data integrity and easily meet compliance requirements. Previously, resources were spent manually entering Bill of Material (BOM) information into the ERP system without a guarantee that the information was accurate. With direct data sharing between their ERP and PLM environments, the need to perform such maintenance in both systems no longer exists.

The ability to directly share data between the two environments and pull information from ERP into the PLM database gave engineers visibility into extended information including cost, inventory, vendor status and lead times. Access to this type of information allowed engineering to perform analysis on cost, product availability, and compliance early in their design/development cycle, helping make better design decisions and eliminate costly late-stage re-design.

Understanding the function of each technology (ERP and PLM) and the value each

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added, positioned the manufacturer to focus on their core competencies, cut new product introduction time in half and beat their competitors to market.

ERP-Managing the Business Data

An ERP system is a business management tool used to fulfill the needs of many facets of a company including; finance and accounting, distribution, human resources, customer service and manufacturing. ERP supports these various departments by delivering improved processes such as an automated method for order fulfillment, providing a single location for tracking cost information to ensure consistency, and helping human resources to standardize their information.

ERP is used to manage the logistics of getting a product to market once a design is released (from engineering). It is geared toward capturing information at the manufacturing stages of a product; prototypes, production runs, redesigns, etc. This information typically consists of a Bill of Material (BOM), manufacturing and test procedures, schedules/timelines, and logistics which is then used to execute the entire manufacturing process.

Due to the inherent purpose of an ERP system, many are not designed to manage the amount and type of information required for engineering. Most of systems do not contain the detailed information that engineers need to drive design including part specifications, design and test notes, and vendor supplied documentation. In addition, ERP systems typically do not provide the security or capability to enable external manufacturing partners to directly access product data and participate in development processes.

As mentioned above, the medical aesthetics manufacturer leveraged their ERP system to manage all of their business-centric information such as inventory management and purchasing processes. When they wanted to achieve control over all of the design and development information, the manufacturer turned to PLM technology.

PLM-Managing the Product Data

PLM was designed to manage product data throughout the product life cycle. A PLM system is crucial during the design phase, where engineers need instant access to product data including specifications, engineering parameters and documentation. PLM centralizes all of this information for easy access by all team members. PLM tracks and manages component data, BOMs, product documentation, engineering changes and revisions, as well as compliance data. PLM systems also offer the flexibility to support the many iterations of a design before it reaches the prototype and manufacturing phases.

A key component of a PLM system is that it provides an automated Change Management facility that allows users to electronically propose product changes (redlines) to BOMs, documents, and vendor/supplier information. Leveraging a workflow engine, these changes are then automatically routed to the appropriate resources for electronic signatures. Once all constituents have approved the

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change, the PLM system automatically updates the affected products with the suggested changes, and then provides the updated information to the ERP system. An electronic change process eliminates manual data entry errors, streamlines routing, and allows all involved resources to view and sign changes simultaneously. All of these factors results in a significant reduction in the engineering change process.

Automating product design processes can enhance overall product development by shortening cycle times for engineering changes and new part requests, improving data integrity by eliminating the human error from hand-entering data and ensuring all product data is accurate by sharing information between engineering and manufacturing.

In Summary

It is important to understand the value that technology brings to each department and the enterprise as a whole. Enterprise applications that complement each other like PLM and ERP play a key role in supporting and improving product development and achieving bottom line operational benefits. Recognizing the distinctive features offered by ERP and PLM as well as the benefits of creating an integrated environment will help medical manufacturers maintain their competitive edge. Adoption of a PLM system to work in conjunction with ERP greatly enhances a manufacturer's product development performance. The result is the ability to deliver higher quality products in less time and maintain a competitive advantage in the marketplace.

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