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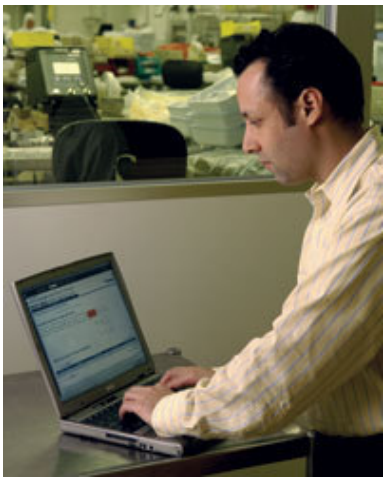
New Products

Supporting an Outsourcing Strategy With PLM

Medical device manufacturers are constantly looking for the competitive advantage that will enable them to exceed customers' requirements. Outsourcing is one such enabling factor. This exclusive report will focus on how companies can use software to aid in the oversight of internal procedures, as well as those of their outsourcing partners, throughout the design and manufacturing cycle.

By Bryan Stolle



On the cover: Dave Hart, project manager for Haemonetics Corp., monitors the product record, managed with Agile PLM. Haemonetics is a global company engaged in the design, manufacture, and worldwide marketing of automated blood processing systems.

At a Glance

- Reducing waste
- Increasing productivity
- Enhancing communication
- Improving bottom line

In the medical device industry, simply designing a better product is not enough to guarantee success. Because of the profitability challenges imposed by strict government regulation and highly competitive environments, companies must find ways to produce high quality medical products at a lower cost. Outsourcing is becoming a key strategy for medical device companies to lower operating expenses. Whether it is sending work to corporate facilities overseas or to domestic and international vendors, outsourcing can be very economical. In fact, outsourcing can be the extra advantage that enables smaller companies to compete in a global medical device market against world-class organizations.

The challenge to outsourcing the design or manufacture of medical devices, however, is communicating and sharing product data with stakeholders in other countries or other companies, and controlling business processes now that they are performed remotely. One solution to both of these challenges is to maintain an up-to-date and accurate product record.

The product record is an aggregation of a company's information assets—a comprehensive data store that defines the product throughout each stage in its lifecycle. Efficient management and effective use of the product record is critical for a medical device company to maximize product profitability. A PLM (product lifecycle management) solution that is developed specifically for the medical device industry is essential to managing and leveraging the product record to support outsourcing, strengthen product quality, reduce time to market, and lower costs.

Sharing Data Globally

Collaboration within a company's global community is critical to success in the medical device market. This means collaboration with alliance partners and vendors, as well as

between geographically dispersed teams. One key capability to support collaboration is providing timely access to product data to those who need it, no matter where they are located around the world. A PLM system provides this necessary visibility and access into the product record.

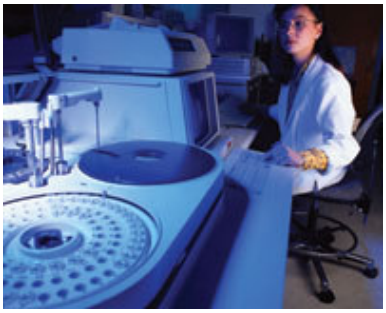
Haemonetics Corp., a global leader in blood processing technology, implemented PLM software to provide global access to the product record. Prior to implementation, the company's products—automation of patient blood salvage in cardiovascular and orthopedic surgeries and collection of plasma, platelets, and red cells for transfusion or further manufacture—were managed by manual paper-based processes and decentralized systems with a complicated path of traceability back to the product record.

Now Haemonetics uses the PLM solution to manage the product record throughout the product lifecycles, from research and development through regulatory approval, new product introduction, and end-of-life. Haemonetics' goal for the PLM implementation was to drive improved profitability, collaboration, and compliance at each stage of the product lifecycle.

Haemonetics markets products in over 50 countries around the world, and employs 1,500 people in 14 countries. This wide distribution of personnel presented a challenge in sharing product data. Because many of the employees were in different time zones, spoke different languages, and were not physically located in the mainstream of the company headquarters, they did not have the same level of visibility and collaborative input to product development activities prior to the software implementation. It became increasingly difficult to keep everyone so deeply involved in the process using paper-based manual processes. PLM helped to solve this problem, delivering real-time 24-hour data access to a single database of all product information for Haemonetics' teams worldwide.

Integrating employees and partners around the world more actively into the product development process supports the collaboration that results in higher quality designs. The fact that collaboration takes place earlier in the process also drives innovation and improves product quality. More stakeholders around the world have immediate access to product documentation and a business process that solicits their input.

Controlling Processes Externally



Chemist conducts product testing and tracks results to the product record, managed in Agile PLM.

Conversely, in addition to providing visibility into the product record, a company also needs visibility into the tasks the partners or offshore facilities are handling and a way to continue to manage these processes to ensure they are meeting the company's requirements and ultimately the customer's expectations. Losing control of the process due to outsourcing could result in reduced product quality and higher costs that impact profitability.

Maximizing profitability means managing a product across the lifecycle from concept, through development and clinical trials, to introduction, volume production, and phase-out. Problems must be corrected such as high material costs, lost productivity, late market introduction, slow ramp to volume, lost customer loyalty, and product quality issues. PLM provides the visibility needed to manage business and alliance partners or offshore facilities, bring them back into the company's business processes, and close the loop on the execution of changes and corrective actions.

Higher Productivity, Lower Costs

Haemonetics serves as an excellent example of the advantages a medical device company can derive from the implementation of a PLM system. By employing PLM to provide improved product data access and collaboration across the corporation (including offshore teams) and by gaining greater control over the business processes that drive product development and manufacturing, Haemonetics made dramatic gains in productivity for activities related to documentation and new product development. Productivity gains and documentation process cycle time reduction achieved impressive results, exceeding the original expectation of 25%. These numbers show that Haemonetics is not only improving the quality of products through early global collaboration but is also getting these improved

products to market faster. Achieving product launch deadlines is becoming more important than ever for medical device companies to stay competitive and PLM is a proven enabler.

In addition to these benefits, Haemonetics was also able to use PLM to standardize and streamline processes, improve productivity and resource efficiency, and aid in decision-making at all levels of the organization. For example, by preserving an up-to-date product record, a company can significantly reduce redundant tasks because the information they are looking for is right at their fingertips. Without PLM, a company may have to run the same tests over again because that is a faster alternative than rummaging through paper files trying to find the original data. PLM solves this problem by making all data easy to find.

Ensuring Compliance

In addition to facilitating outsourcing and all the resulting benefits, PLM is a vital tool in ensuring compliance. Medical device manufacturers face intense regulatory scrutiny from the FDA in the U.S. and numerous other local, regional, and international regulatory agencies. PLM software simplifies regulatory compliance for companies like Haemonetics by providing the infrastructure to meet the requirements outlined by the FDA's quality system regulations (Title 21 CFR Part 820).

Medical design engineer compares prosthetic femur developed with Agile PLM to x-ray and product design.

Medical device manufacturers operate under a multitude of procedures and protocols that control their operations. The software allows companies to catalog these procedures and policies so that they are readily available in an electronic repository for viewing or printing, consequently eliminating the need to store and manage paper copies of procedures.

The FDA requires companies to investigate and respond with an action plan within five to thirty days, depending on the device. PLM streamlines the process of collecting and distributing all supporting compliance documents for review and approval by the appropriate personnel. Electronic routing and approval provided by the software greatly expedites submittal to the FDA.

The FDA also requires validation for all software used as part of a company's quality system. Developing validation plans and protocols and then executing them can be time-consuming and expensive. It would be best for medical device manufacturers to find a PLM solution that offers a suite of protocols that medical device manufacturers can use in their validation efforts.

PLM helps companies like Haemonetics to meet the requirements of FDA Title 21 CFR Part 11, which prescribes the accepted use of electronic records and signatures. It captures all comments and approvals associated with every release revision within the product record. These records contain the electronic signatures, comments, and justification for the change, providing an audit trail that completely covers the Part 11 requirements.

Since the implementation of the PLM software, Haemonetics has received favorable feedback regarding their use of the system during audits from customers and regulatory organizations. In addition, the lower costs and resources required to comply with regulations, due to the streamlined compliance processes built into it, are all added to the company's bottom line.

Conclusion

Outsourcing is an excellent way for medical device companies to focus on their core talents, while tapping into the resources of other countries or other companies to reduce costs. Smart companies leverage PLM to take advantage of this opportunity, while streamlining their own internal processes such as product development and regulatory compliance.
PLM is an essential tool to help medical device manufacturers increase product profitability. A single product record, accessible in a PLM solution designed to meet the unique needs of medical device companies, enhances visibility and collaboration, improves product quality, enables rapid new product introductions, increases productivity, reduces expenses, and ensures regulatory compliance—ultimately contributing to bottom-line results.

Dave Hart, Project Manager for Haemonetics, reports, “PLM touches nearly all of the company’s key business processes enabling collaboration, improved efficiencies, and greater access to data for making important business decisions.”

ONLINE

For additional information on the technologies and products discussed in this article, see the following websites:

• www.haemonetics.com

• www.agile.com

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