



BUSINESS STRATEGY

Business Strategy: PLM for Life Science Manufacturers – Operational Excellence Through Product Life-Cycle Management

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THIS IDC BUSINESS STRATEGY EXCERPT FEATURES: ARENA SOLUTIONS PLM

IN THIS EXCERPT

The content for this excerpt was taken directly from Business Strategy: PLM for Life Science Manufacturers – Operational Excellence Through Product Life-Cycle Management (Doc # US40510416). All or parts of the following sections are included in this excerpt: IDC Health Insights Opinion, In This Study, Situation Overview, Case Study, Future Outlook, Essential Guidance, Appendix and Learn More.

IDC HEALTH INSIGHTS OPINION

This IDC Health Insights study explores the scenarios and solutions offered by product life-cycle management (PLM) software to life science companies. PLM has gained widespread acceptance in many industries, first as an innovation platform for organization of engineering and research tasks and documentation and then as an integral and crucial aspect of manufacturing and collaboration with suppliers, sales and service teams, customers, and other stakeholders. Further:

- While the life science industry as a whole may be playing catch-up to more traditional PLM users in industries such as consumer packaged goods (CPG), automotive, aerospace, and electronics, adoption within the medical device industry is widespread and has been prevalent for several years. The pharmaceutical and biotech industries, which in some respects resemble process industries such as chemical and energy more than discrete manufacturing, are looking closely at PLM and the opportunities it offers for improving efficiency, safety, and time to market for their own products. In addition, the unique and extensive regulatory environment of the life science industry is moving manufacturers to look at PLM as a method of automating regulatory filings and storage of critical product and design information as well as sharing and collaborating with supply chain partners including material and component suppliers, distributors, and contract manufacturing organizations (CMOs).
- Previously separate processes involving quality management, document management, inventory and warehouse processes, engineering change management, and others are being incorporated into a PLM framework, utilizing technologies such as cloud computing, IoT, big data and analytics, mobile devices, and even augmented reality.
- It is clear that PLM is offering life science companies a framework that can improve processes, quality, and ultimately patient safety in many ways, and that a wide variety of solutions and expertise are available to match available PLM software and technology to the many different needs of life science companies.

IN THIS STUDY

To help illustrate how life science companies are approaching comprehensive innovation and collaboration through the use of PLM software, IDC has compiled several case studies of implementations in the life science industry, including medical devices and diagnostic equipment, pharmaceutical manufacturing, and biotechnology production and R&D. PLM spans functions from discovery and research to distribution and after-sales support. Several vendors of PLM software were featured as well as consultants and service providers that have planned and implemented PLM for life science customers.

SITUATION OVERVIEW

Product life-cycle management software has been widely adopted in many industries including automotive, aerospace, electronics, and a wide range of industrial and consumer goods. Adoption has been slower in the life science industry, particularly in pharmaceutical and biotechnology, because of unique challenges in the development, testing, and regulatory environments. However, vendors of PLM software are working together with the life science industry and service providers to move the industry forward and realize the organizational, financial, and regulatory benefits of PLM adoption. In this study we interviewed users of a variety of PLM systems about their experiences with several leading vendors and service providers involved in PLM implementation.

The medical device industry, particularly in complex systems such as diagnostic imaging equipment, is very advanced in the use of PLM, including systems utilizing IoT devices within equipment at customer sites worldwide.

Life science customers are actively evaluating PLM systems and vendors for:

- Experience in PLM implementation
- Life science industry-specific products and expertise
- Ease of use
- Cost of ownership
- Communication and collaboration with other systems and stakeholders
- Automation of compliance reporting and record keeping

THE APPROACH

IDC Health Insights conducted in-depth interviews of users of a variety of PLM solutions within the life science industry in 2016. The following case study provides illustrative examples of how life science companies are using PLM technology to improve efficiency, collaboration, innovation, and quality throughout the industry.

Case Study: Arena Solutions PLM Automates FDA Submissions for Emerging Medical Device Developer

In late 2014, a Midwestern U.S. developer and maker of innovative medical devices faced a challenge that threatened the company's future. After a surprise audit of the company's quality systems, the ISO 13485 auditors found the paper-based quality system to be insufficient and gave the management team six months to correct all findings and conduct a return audit. The audit team found that the company was following documented processes but not closing out corrective actions and nonconforming material reports routinely. Final sign offs were frequently missing or incomplete, and there was no automated system in place to flag open cases.

The COO and founder of the medical device company decided to search for a solution that could be implemented in time for the return audit and within the company's budget. At the time, 12 different devices were under development at multiple sites, which indicated that a cloud-based solution would be ideal due to the multiple remote teams collaborating on development and quality reporting efforts. After evaluating several options, the company decided on a cloud-based Arena Solutions PLM solution, which promised to automate the filing of FDA submissions, corrective and preventive actions (CAPAs), and design history files (DHF's).

The medical device developer went live on the Arena PLM system only six weeks before the scheduled return audit. In those six weeks, bills of materials (BOMs), quality document templates, and DHFs (some containing up to 350 entries) were entered into the PLM system. When the ISO 13485 auditors returned, the team was able to conduct the audit completely within the Arena system "without ever leaving the room," according to the COO. In addition, the internal quality team of four quality engineers and an inspector plus a director of Quality was able to be redeployed, retaining only the director and the inspector.

Today, remote development teams are able to log onto the PLM system on the cloud. Researchers who prefer to record data in lab notebooks are able to scan their notebook entries directly in the device history record (DHR). The company also uses several overseas contract manufacturers for low-complexity, high-volume devices. The contract manufacturers "feed that data into the DHRs on the Arena system – we know every part, component, lot number, and serial number," said the COO.

"Instead of needing to customize our quality system for Arena, we were able to configure the Arena PLM system to match our internal processes," the COO said. He reported that for a small company like his, the Arena PLM system "cost less than 40% of the next least expensive option" when subscribing on a per-seat basis. Combined with the savings in automating and redeploying the quality group, the Arena PLM system has more than paid for itself.

FUTURE OUTLOOK

The adoption of product life-cycle management in the life sciences is increasing rapidly. Cloud computing, analytics, IoT, mobile devices, augmented reality, and other new technologies are facilitating automation and collaboration for product development and manufacturing in ways that were not possible even a few years ago.

Industry regulators including the FDA and EMA are appropriately demanding of manufacturers and developers of these products, which save millions of lives and improve the quality of life of millions of others every year. Solutions in response to industry regulations such as IDMP in Europe, serialization

and track and trace mandated by DQSA in the United States, and other national and regional mandates are being found in PLM implementations.

The medical device industry, particularly in complex systems such as diagnostic imaging equipment, is very advanced in the use of PLM, including systems utilizing IoT devices within equipment at customer sites worldwide.

In the coming years, we expect widespread adoption of PLM within life science companies, particularly in the process-oriented pharmaceutical and biotech industries.

ESSENTIAL GUIDANCE

Life science customers should evaluate PLM systems and vendors for:

- Experience with PLM implementation
- Life science industry expertise
- Ease of use
- Cost of ownership
- Communication with other systems
- Collaboration with partners
- Automation of compliance reporting and record keeping

Actions to Consider

- Map existing and desired processes first before searching for solutions.
- Consider using outside experts to assist in planning and implementation of PLM.
- Ask vendors and consulting teams for customer references in life science PLM.
- Consider the regulatory environment in countries where your products are designed, sold, and used.
- Evaluate PLM technology and use in other industries.

LEARN MORE

Related Research

- *IDC MarketScape: Worldwide Life Science Manufacturing and Supply Chain Digital Transformation 2016 Vendor Assessment* (IDC #US40510516, September 2016)
- *Market Analysis Perspective: Worldwide Product Life-Cycle Management Software, 2016* (IDC #US40541616, September 2016)
- *Pivot Table: Worldwide Product Life-Cycle Management IT Spending Guide, Version 1, 2016* (IDC Manufacturing Insights #US41763615, September 2016)
- *Business Strategy: Top Software Vendors in the Life Science Industry, 2015* (IDC Health Insights #US40503316, June 2016)

Synopsis

This IDC Health Insights report explores the scenarios and solutions offered by product life-cycle management (PLM) software to life science companies. PLM software has gained widespread acceptance in many industries, first as an innovation platform for organization of engineering and research tasks and documentation and then as an integral and crucial aspect of manufacturing and collaboration with suppliers, sales and service teams, customers, and other stakeholders. While the life science industry as a whole may be playing catch-up to more traditional PLM users in industries such as consumer packaged goods, automotive, aerospace, and electronics, adoption within the medical device industry is widespread and has been prevalent for several years. The pharmaceutical and biotech industries, which in some respects resemble process industries such as chemical and energy more than discrete manufacturing, are looking closely at PLM and the opportunities it offers for improving efficiency, safety, and time to market for their own products. In addition, the unique and extensive regulatory environment of the life science industry is moving manufacturers to look at PLM as a method of automating regulatory filings and storage of critical product and design information as well as sharing and collaborating with supply chain partners including material and component suppliers, distributors, and contract manufacturing organizations (CMOs).

Mike Townsend, research manager, Life Sciences Business Systems Strategies for IDC Health Insights says, "The adoption of product life-cycle management (PLM) in the life sciences is increasing rapidly. Cloud computing, analytics, IoT, mobile devices, augmented reality and other new technologies are facilitating automation and collaboration for product development and manufacturing in ways that were not possible even a few years ago. The use of PLM in the medical device industry is already widespread and growing. In the coming years, we expect greatly increased adoption of PLM within life science companies, particularly in the process-oriented pharmaceutical and biotech industries."

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