

DELIVERING INNOVATION AND QUALITY WITH COMMON PROCESSES:

A Medical Device Manufacturer's Case Study



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Executive Summary

An aging global population, technology wizardry, and societies with higher expectations than previous generations are all factors fueling a worldwide demand for sophisticated medical devices. As the demand for higher quality medical devices grows, government agencies are implementing more stringent compliance regulations aimed at protecting their citizens.

This whitepaper describes why a Fortune 100 medical device manufacturer chose a Product Lifecycle Management (PLM) strategy to bridge the gap between innovation and compliance. Working with an experienced strategic partner, Dassault Systèmes ENOVIA®, the medical device manufacturer wanted to:

- *Save time and money* by building regulatory compliance into the product design phase
- *Replace information silos* with global Web-based access to accurate and real-time data (a single version of the truth)
- *Enhance innovation* and ensure better compliance by centralizing product development and quality systems processes in a common environment
- *Improve product quality* by deploying automated processes across the supply chain
- *Deliver products to the market more quickly* for a lower total cost of ownership (TCO) and reduced IT maintenance
- *Improve decision-making* by using online global collaboration to harness the intellectual property (IP) located across multiple sites

Dassault Systèmes PLM solutions for life sciences are comprised of industry-ready applications, services, and methodologies that address the unique needs of medical device manufacturers, pharmaceutical and biotech, and patient care companies. Our solutions enable medical device manufacturers to improve compliance, focus on innovation, and reduce research and development (R&D) costs. Coupled with a strong, success driven, services organization and value oriented methodology, Dassault Systèmes brings a complete solution proven across a diversity of medical device companies and the PLM standard at 9 of the top 20 medical device manufacturers in the world.¹

Industry Overview

Medical device technological advances are akin to miracles. New materials and manufacturing processes are creating instruments and prosthetic appliances that improve patient care at a level unthinkable a generation ago.

Today's orthopedic devices enable more people to increase their range of motion and remain active in later years. Surgeons work with medical instruments small enough for minimally invasive procedures, reducing hospital stays and allowing patients to recover quicker.

These technology quantum leaps have raised consumer expectations for a higher level of continuous improvement—increasing competition for faster innovation and higher quality products that pass government scrutiny.

At the core of meeting consumer demands, passing government regulations, and making a profit, is the need for data integrity. Out-dated, redundant, and incomplete data sources are the main cause of product quality issues, missed revenue expectations, and time to market delays.

Many product development and regulatory compliance activities occur separately in organizational silos using niche solutions that fail to communicate adequately with each other. Multiple information systems, coupled with manual processes, create error-prone data. Manual business processes stymie the workflow as well-intended employees sift through paper and disconnected business systems, trying to find the latest and most accurate information.

Innovation becomes an afterthought because too much time is wasted trying to find the correct information. A frustrated workforce sees no end to their situation, exemplifying problematic business procedures that hinder growth and competitiveness.

The Challenge: A Medical Device Manufacturer's Case Study

When faced with internal and external business challenges, the medical device manufacturer profiled in this whitepaper chose to implement Dassault Systèmes' PLM solutions for life sciences.

Implementing common processes was important because this Fortune 100 company operates globally with thousands of employees and suppliers, delivering products to hospitals, physicians, diagnostic laboratories, and clinics. Historically, each division had operated independently.

Global market realities changed the company's operations strategy and it became necessary to optimize and enhance "speed to business value" from IT investments. The idea of sharing and leveraging processes and people took on a sharper focus. The push to deliver new and innovative products more quickly to the market required addressing 21st century business drivers such as:

- Achieving greater operational efficiency and control across multiple businesses located globally
- Enhancing growth and business agility by simplifying and standardizing IT solutions where possible
- Building regulatory compliance into the product design process earlier
- Reducing product costs by harmonizing global business processes and leveraging the benefits across all divisions
- Improving product quality and increasing the ratio of preventive-to-correct actions
- Eliminating islands of automation and establishing a single version of the truth

The Solution: Fusing Innovation and Compliance

The company learned that Dassault Systèmes PLM solutions for life sciences could reduce process complexity and save time, money, and resources by creating a common system.

Today global teams easily access relevant data and participate in automated business processes (workflows) over a unifying foundation (see Figure 1) built on a single, global platform. The PLM solutions eliminate communication bottlenecks by connecting reference documents and files for immediate visibility to all pertinent organizations.

The turnkey Dassault Systèmes PLM solutions for life sciences manage product disposition, including approval and verification, assignable cause analysis, and immediate corrections.

Quality is improving because the company can enforce the collection of all required information, assessments, and approvals while automating the approval process and providing status visibility.

As a result, the company can track, investigate, and dispose of field complaints, product inquires, and services requests. In the US facilities, Corrective and Preventive Action (CAPA) site leaders can determine a request's legitimacy and if any further action is necessary, problems can be escalated up, between categories, and tracked. When needed, information gathered through these activities can populate European Union, Canadian, and US regulatory forms.

The company was impressed further with the ability of the Dassault Systèmes solutions to integrate all PLM processes and other enterprise applications such as Enterprise Resource Planning (ERP). The engineering change order (ECO) process was enhanced by integrating engineering and quality concerns.

Auditing is easier because there is an automatic process for tracking auditors' requests and providing responses. The responses, such as a manufacturing procedure, are linked automatically to the relevant data in the PLM system. Users can develop an audit schedule now to track and plan internal, supplier, and external audits.

Stakeholders save time and money by identifying quality issues earlier in the product development process. Speed to market increases because, instead of conflicting with each other, compliance and innovation stakeholders contribute to each other's success.

Users now access a single system to drive product related business processes such as design control, manufacturing, and sourcing.

Innovation occurs more quickly because users can track market needs with physical designs and engineers can manage complex, multi-level product engineering bills of material (BOMs) and manufacturing BOM structures. Compliance risk and discrepancies are minimized because all elements of the Device Master Record (DMR) are managed from a single integrated data source.

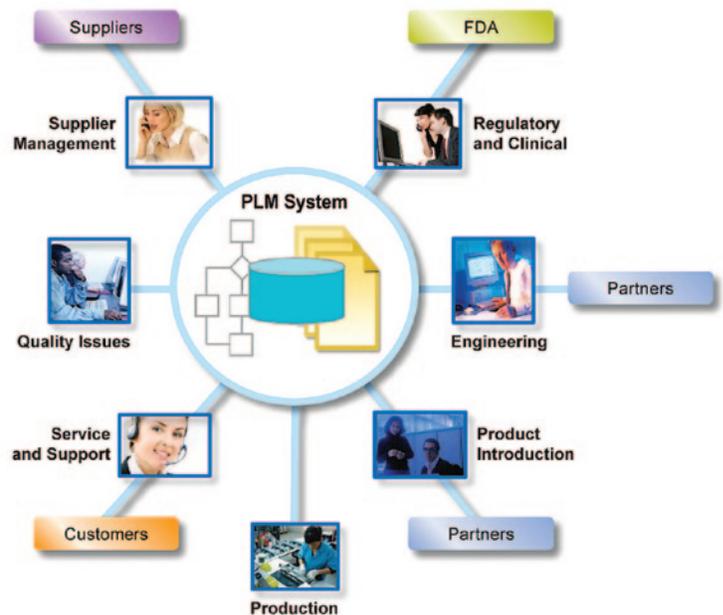


Figure 1: PLM System connects all departments, both inside and outside of the organization.

The Results: Faster, Smarter Innovation

Today, the company is bringing innovative products to market more quickly because accurate information is available throughout the development process. Workers no longer worry about audits because the Dassault Systèmes solutions offer traceability.

The Dassault Systèmes solutions are helping the company further comply with various global and US government mandates including the US Code of Federal Regulations (CFR) part 820, which covers the following:

- CAPAs
- Nonconforming Reporting (NCRs)
- Design History Files (DHF)
- Medical Device Reporting including Title 21 US (CFR) Part 11, which prescribes the accepted use of electronic records and signature
- Quality Systems Requirements

Innovation is flourishing because online global collaboration capabilities have harnessed the company's intellectual property (IP) across the entire supply chain.

Conclusion: The Power of Common Processes

About 35% of an enterprise's software maintenance budget is spent on maintaining the multitude of point-to-point application links already in place. Research shows that the use of a common information infrastructure can reduce the number of hours to build interfaces between applications by between 25 and 43 percent, depending on the complexity of the interface.²

By centralizing product development and quality systems processes in a common environment, this medical device manufacturer expects to improve innovation and regulatory compliance while reducing costs. A common process enables medical device manufacturers to:

- Save time and money through greater leverage of the infrastructure, processes, validation, and other key components
- Enhance decision-making through greater visibility of related process information
- Improve compliance through tighter enforcement
- More effective management review because of higher confidence in the quality of the information
- Stricter adherence to Quality initiatives such as Six Sigma because of stronger metrics reporting

Why Dassault Systèmes?

Dassault Systèmes (DS) delivers Life Sciences PLM solutions to life sciences organizations and their suppliers, accelerating innovative product development while streamlining quality assurance processes for regulatory compliance.

Internally within the organization and throughout the value-chain, DS is committed to helping our customers advance the pursuit of innovation by delivering solutions that integrate business environment with cutting-edge tools for design, engineering, and manufacturing planning.

Our solutions leverage the strengths of our brands — CATIA® for designing the virtual product, SolidWorks® for 3D mechanical design, DELMIA® for virtual production, SIMULIA® for virtual testing, ENOVIA® for global collaborative lifecycle management, and 3DVIA® for online 3D lifelike experiences.

Coupled with a strong, success driven, services organization and value oriented methodology, DS brings a complete solution proven across a diversity of medical device companies and is the PLM standard at 9 of the top 20 medical device manufacturers worldwide.

Dassault Systèmes and Integware Partnership

Dassault Systèmes and Integware have a unique partnership and are committed to serving the needs of the life sciences market. Integware provides life sciences industry-tailored software solutions based on deep experience working with leading-edge customers. Through a common vision and comprehensive strategic relationship, the two companies combine to provide visionary PLM product processes, business excellence, and software solutions that address the unique business needs of the life sciences industry.

The ENOVIA® Life Sciences Accelerators™ offer customers a flexible solution, integrating businesses processes for better managing core intellectual property. Based on the DS Version 6 (V6) PLM service-oriented architecture (SOA), the Life Sciences Accelerators facilitate seamless interaction between all ENOVIA PLM business processes as well as CAPA, Product Complaints, Change Control, and Product Development.

Endnotes:

1. *Medical Devices Industry Issues, Opportunities, and Challenges*, ARC Advisory Group, April 2008

2. <http://www.ameinfo/28506.html>



Delivering Best-in-Class Products



Virtual Product Design



Global Collaborative Lifecycle Management



3D for Professionals



Information Intelligence



Realistic Simulation



Social Innovation



Virtual Production



Online 3D Lifelike Experiences

Dassault Systèmes, the 3D Experience Company, provides business and people with virtual universes to imagine sustainable innovations. Its world-leading solutions transform the way products are designed, produced, and supported. Dassault Systèmes' collaborative solutions foster social innovation, expanding possibilities for the virtual world to improve the real world. The group brings value to over 150,000 customers of all sizes in all industries in more than 80 countries. For more information, visit www.3ds.com.

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