

From Innovation to Execution: How PLM Provides a Competitive Advantage for Life Sciences Companies

The life sciences industries are some of the fastest growing industries on the planet. Over the last 30 thirty years, the US population alone grew by over 36 percent, while the number of Americans over the age of 40 increased at twice that rate.¹ As the population of the US and the world ages, the business opportunities for life sciences companies will grow to match the larger markets, spawning medical discoveries for managing chronic health problems and eradicating diseases.

Every day life sciences companies face the realities and responsibilities associated with developing, producing, and distributing products that improve our quality of life. From pharmaceuticals that defeat disease to medical devices that restore wellbeing, a 'day in the life' of these companies means:

- Working within the constraints set by stringent regulatory pressures and compliance expectations
- Navigating elaborate business processes that require extensive collaboration between diverse experts, regions, and cultures
- Developing increasingly complex products that blend mechanical, electronic, software, chemical, and biological innovations
- Coordinating the activities of intricate development and manufacturing ecosystems that encompass global sites, suppliers, and markets

With these pressures bearing down, successful life sciences companies have realized that business excellence is the result of effectively managing the delicate relationship between rapid customer-focused innovation, operational efficiency, and regulatory compliance.

Product Lifecycle Management (PLM) solutions automate the key business processes involved in the product lifecycle. For life sciences, PLM works successfully in two distinct areas — Product Design Collaboration and Strategic Business Process Integration.

Product Design Collaboration involves bringing together the product managers, designers, and other stakeholders in the product development process to bring to market quickly innovative products that delight customers.

Strategic Business Process Integration provides the glue to integrate the product design process to all other strategic business processes. It manages documents, data, and business processes to increase a company's

A marked increase in the complexity of product portfolios at life sciences companies is driving the need for robust product lifecycle management (PLM) processes and technologies... But faced with mounting regulatory and financial pressures, the product portfolios of life sciences companies will continue to expand and diversify, becoming increasingly complex in the process.

Life sciences companies need processes and technologies that stitch together the "fuzzy front end" of new product discovery with product and process development, tech transfer, commercialization and lifecycle management.

**AMR Research Report
The Growing Need for PLM in Life Sciences
August 2008.**

agility and minimize risk. Users can collaborate globally, harnessing the collective intelligence of everyone with a vested interest – from developers to suppliers to consumers. The result is greater efficiency, faster product development, and improved quality.

The ENOVIA Solution

By combining years of life sciences industry experience with a best-in-class collaborative platform, Dassault Systèmes (DS) ENOVIA PLM solutions provide the tools that facilitate fast, successful product introductions based on US Federal Drug Administration (FDA) and International Organization for Standardization (ISO) regulations.

The ENOVIA solutions include a number of ready-to-use business processes, such as product development, change, validation, Corrective and Preventive Action (CAPA), supplier, and regulatory management, to name a few.

These ready-to-use business processes allow companies to improve time to market and lower costs by enforcing “best practices” throughout their business processes. A single platform facilitates the interconnection of data as well as the deep integration of strategic business processes, opening the door for users to drill down easily into related business processes, when necessary. Based on a Service-Oriented Architecture (SOA), ENOVIA solutions facilitate the seamless interaction between all life sciences business processes.

The Business Value of PLM in Life Sciences

• *Visibility, Control, Measurement*

Providing enterprises and executives with real-time insight and control into ongoing projects and product development initiatives resulting in better decision making and more efficient portfolio planning

• *Turning Market Requirements into Product Design*

Delivering winning products to market that meet customer needs requires marketing and product planning teams to collaborate actively with other functional groups, customers, and suppliers in order to thoroughly capture requirements and define new products, features and capabilities

• *Synchronized Design*

Allowing diverse design disciplines to synchronize around design activities and changes, significantly reducing the critical errors and cost associated with poor collaboration

• *Global Product Development*

Permitting a company’s globally dispersed product teams to collaborate on product development efforts effectively to continually drive out cost and delay from the new product introduction process

• *Supplier Collaboration*

Enabling companies to maximize productivity and innovation with design partners, sub-contract manufacturers and offshore resources to improve quality, reduce costs and speed time-to-market

• *Regulatory Compliance*

Providing companies in regulated industries with the systems necessary to ensure compliance with existing and future regulations around product development, manufacturing, and documentation

Overall, ENOVIA life sciences solutions:

- Achieve cost and time savings through efficient re-use of Intellectual Property (IP)
- Reduce overall engineering time through one cohesive solution that allows management and collaboration of design information and visibility into the complete product development process
- Improve global new product introduction processes to drive profitable growth through cycle time reduction and increased resource productivity
- Optimize supply base and develop strategic suppliers and partners
- Emphasize process definition and improve common enterprise processes, then track and measure those processes as a basis for improvement
- Help comply with Quality System Regulation (QSR) and ISO regulations
- Speed regulatory compliance including Title 21 Code of Federal Regulations (CFR) Part 11, which prescribes the accepted use of electronic records and signatures

The ENOVIA Life Sciences Accelerator™ Solutions

ENOVIA and Integware are committed jointly to serving the needs of the life sciences market and have a comprehensive strategic relationship that includes product development, support, sales, services, and marketing. Integware provides industry-tailored software solutions based on deep experience working with leading-edge life sciences customers. Together, 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.

ENOVIA provides a host of life sciences solutions aimed at specific business processes such as change control, quality, engineering design, and stage gate projects. The Life Sciences Accelerators are compatible with the DS V6 platform and offer customers a single, flexible solution, integrating business processes for better managing core intellectual property. Based on a service-oriented architecture (SOA), the Life Sciences Accelerators facilitate seamless interaction between all ENOVIA PLM business processes including Corrective and Preventive Actions (CAPA), Product Complaints, Change Control, Product Development and Supplier Control.

ENOVIA solutions for quality and change control lower regulatory risk while streamlining these processes. Other benefits include:

- Provides ready-to-use business processes for managing CAPA and complaints
- Interacts seamlessly between the CAPA process and other PLM business processes such as change control, product development, and supplier control
- Ensures greater regulatory compliance through the controlled execution of business processes enforcing critical requirements

Solutions for engineering design and stage gate enable lean product development by providing visual dashboards of the deliverables, stages, and functional swim lanes, and embedding best practices and Critical-To-Quality (CTQ) drivers into standard, repeatable project templates.

Additional benefits include:

- Bringing industry-leading products to market quicker and more reliably by focusing on the creative aspects of the design process rather than the administrative details of the Device Master Record (DMR)
- Responding more quickly to market opportunities through streamlined product designs, submissions, and product ramp-up activities
- Meeting time and budget criteria by automating DMR assembly and reusing existing information
- Improving quality and consistency of Design Control deliverables and dramatically reducing regulatory risk with real-time reports from a single system of record

PLM 2.0 brings life to knowledge

In 2008, Dassault Systems (DS) introduced PLM 2.0, PLM online for everyone, a 3D environment for experiencing a product virtually and harnessing all user interactions to generate and enrich intellectual property (IP). PLM 2.0 allows the product innovation process to start with online communities for consumer preferences and end with a virtual lifelike “test drive” of the product. PLM 2.0 is to PLM what Web 2.0 is to the Web.

Version 6 (V6) is the DS next generation platform for enabling PLM 2.0 and harnessing the collective intelligence among online communities. PLM 2.0 brings life to knowledge — from idea to product experience —merging the real and virtual in an immersive lifelike experience. V6 delivers the flexibility, open standards, scalability, and industry-specific functionality today’s life sciences companies need to tie together multi-discipline engineering groups and other key contributors successfully.

Life sciences companies can benefit from PLM 2.0 in such ways as:

- Improved time to market as virtual design validation and electronic submissions replace paper-based activities
- Reduced risk and increased accuracy because automated business processes are inherently compliant
- Better responsiveness with improved reuse of specific sections of lengthy documents as users move from unstructured text documents to structured “data enabled” XML documents

ENOVIA Life Sciences Customer Experience

ENOVIA provides PLM solutions to eight of the top 20 medical device manufacturers in the world and is the PLM standard at four of the top six. Below is a sampling of our customer base.

MEDRAD, an affiliate of Bayer AG

MEDRAD® MEDRAD products are sold to hospitals and medical imaging centers in over 85 countries.

James Rolfe, IT program manager, noted that: “...ENOVIA’s solutions enable us to bring products to market quickly and more reliably by allowing us to focus on the creative aspects of the design, rather than administrative details.”

Mölnlycke Health Care



The Mölnlycke Health Care headquarters is located in Gothenburg Sweden. MHC employs 5,500 people and has manufacturing facilities in Belgium, the Czech Republic, Finland, Malaysia, Thailand, and the UK.

*"...Today we have a PLM solution that enable us to handle all our R&D processes more effectively, ensuring better collaboration and a more accurate approach to compliance," says **Claes-Goran Andersson, PLM & Business Process Director, Mölnlycke Health Care.***

Conclusion

As technology plays a greater role in life sciences product development and distribution, the value of PLM grows as well. The future holds a multitude of business transformation opportunities that PLM will enable furthering improvements in managing data, documents, and processes.

By combining years of life sciences industry experience with best-in-class collaborative business processes, ENOVIA PLM solutions provide companies with the tools they need to ensure a successful, FDA and ISO compliant product rollout. Whether you are in the medical device, pharmaceutical, biotechnology, or other life sciences industry, ENOVIA can help you. Our solutions streamline business processes and reduce new product development time through one cohesive source of information. ENOVIA solutions allow management and collaboration of design information and visibility into every product development process.

¹ <http://www.census.gov/ipc/www/idb/pyramids.html>

About Dassault Systèmes

As world leader in 3D and Product Lifecycle Management (PLM) solutions, the Dassault Systèmes group brings value to more than 90,000 customers in 80 countries. A pioneer in the 3D software market since 1981, Dassault Systèmes develops and markets PLM application software and services that support industrial processes and provide a 3D vision of the entire life cycle of products from conception to maintenance. Our offering includes integrated PLM solutions for product development (CATIA®, DELMIA®, ENOVIA®, SMARTEAM®), mainstream product 3D design tools (SolidWorks®), 3D components (Spatial/ACIS®) and SIMULIA®, DS' open scientific platform for realistic simulation. Dassault Systèmes is listed on the Nasdaq (DASTY) and Euronext Paris (#13065, DSY.PA) stock exchanges. For more information, visit 3ds.com.

About ENOVIA

ENOVIA is the recognized leader in delivering collaborative PLM solutions. We enable companies from a broad range of industries to dramatically accelerate innovation, time-to-market and revenue generation by collaboratively developing, building and managing products. Our solutions facilitate the sharing of concepts, content and context across product lifecycles and throughout value chains of employees, customers, suppliers and partners.

ENOVIA collaborative PLM solutions help global enterprises bring together people, processes, content and systems to achieve a compelling competitive advantage. Our interoperable solutions unify and streamline processes across the product lifecycle, enabling companies to easily and cost-effectively work on projects within and outside of their enterprises. Our adaptable, scalable technology is built to accommodate the ever-changing marketplace.

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