



ENOVIA Life Sciences Accelerator for Engineering Design

Product Objective

Many leading medical device manufacturers are using product lifecycle management (PLM) solutions to manage product data and design specifications and increase collaboration and control in order to deliver more innovative products to market at a more rapid pace. The ENOVIA® Life Sciences Accelerator™ for Engineering Design gives these companies the ability they need to manage the vast array of product data centrally including bills-of-materials (BOMs), product specifications, and Device Master Records (DMRs).

Product Overview

The ENOVIA Life Sciences Accelerator for Engineering Design helps:

- Bring industry-leading products to market more quickly and reliably by focusing on the creative aspects of the design process instead of administrative details
- Respond rapidly to market opportunities by streamlining product development and change processes
- Complete projects on time and within budget by facilitating the creation and reuse of product data
- Improve quality and consistency of design control deliverables by dramatically reducing regulatory risk with a single system of record
- Satisfy QSR/ISO regulatory requirements for DMRs
- Satisfy Federal Drug Administration (FDA) Part 11 requirements with a full audit trail and signature authentication controls
- Jump-start validation with predefined scripts for quick implementation

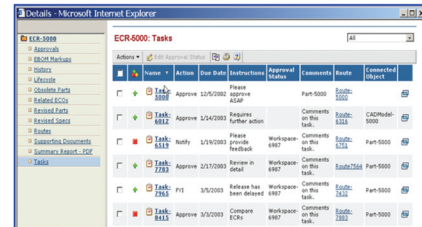
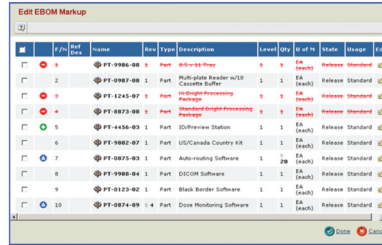
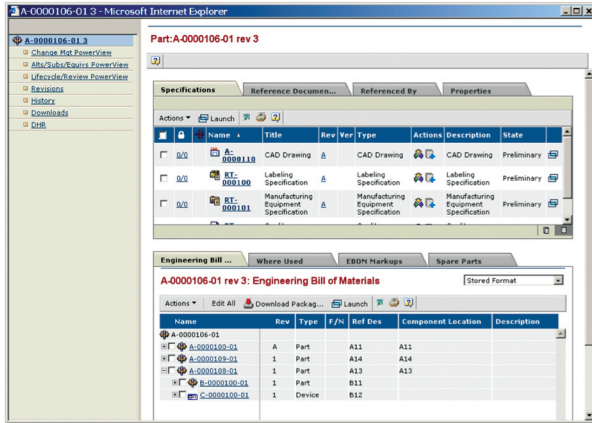
Product Highlights

- Single Source of the Truth - Establish a mechanism to capture and leverage all product information centrally including that generated by other Product Lifecycle Management (PLM) processes.
- Part Management - Product development and component engineering teams can manage parts on a global basis.
- CAD Data Management - Structured or unstructured Computer-Aided (CAD) data files can be developed and managed in parallel to part/BOM development, with links tying them together, providing improved product development communication, and throughput.
- Documents - Microsoft Office or other documents can be managed independently or associated to parts, improving communication and company knowledge capture.
- BOM Management - Global development teams have a single, persistent definition of new and existing product Engineering Bills of Material (EBOMs), which reduces errors due to time delays in communication and data.
- BOM Alternate and Substitute Parts - Reduce manufacturing downtime and quality issues by providing a list of engineering approved "alternate" or "substitute" parts that replaces the primary engineering part.
- BOM Markup and Compare - An intuitive BOM markup tool allows users to markup, approve, and apply BOM changes.
- Device Master Record - Manage all elements of the DMR from a single, integrated source.
- Engineering Change Management - Engineering Change Requests (ECRs) are used to qualify, analyze, review, and approve change requests for released parts, and technical documentation

Key Customer Benefits

- Deliver market-leading products by focusing on the creative aspects of the design process instead of administration details such as maintaining the Device Master Record (DMR) and responding rapidly to market opportunities
- Drive responsive execution by streamlining product designs, submissions and production ramp-up activities with real-time reporting capabilities and leveraging existing information
- Achieve Lean Quality and Compliance by maintaining a single system of record that integrates all aspects of the design process and satisfies 21 CFR Part 11 with full audit trail and signature authentication and Part 820 with complete verification and validation controls





The role of ENOVIA V6 and PLM 2.0

ENOVIA Life Sciences Accelerator for Engineering Design supports PLM 2.0, product lifecycle management online for everyone, and the ENOVIA V6 values: global collaboration innovation, single PLM platform for intellectual property (IP) management, online creation and collaboration, ready to use PLM business processes, and lower cost of ownership



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.

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 Euronext Paris (#13065, DSY.PA) stock exchange. For more information, visit 3ds.com.



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