

Medical Device Accelerator For Regulatory Compliance

Due to the complexities of medical devices today, design processes must support a global array of contributors and stakeholders. At the same time, FDA and international regulators increasingly expect companies to leverage vast amounts of data and documents to enhance control over these complex products and processes.

Most importantly, medical device companies must constantly produce new and innovative products faster than before while containing costs in an ever-shifting organizational landscape.

The Solution

The MatrixOne Medical Device Accelerator for Regulatory Compliance™ is a comprehensive PLM solution that manages your QSR and ISO-regulated design processes, projects, documents and data. Based on the MatrixOne PLM Platform, it provides the foundation for a flexible, enterprise-class PLM solution with system-wide facilities for administration, security, workflow and integrations. Base capabilities include full audit trails and powerful authentication controls, which make the Medical Device Accelerator FDA Part 11 compliant, meeting strict FDA standards.

The MatrixOne Medical Device Accelerator for Regulatory Compliance is composed of three key parts: Enterprise Design Control, Documentation and Change Control and Project and Program Control.

Enterprise Design Control

The Enterprise Design Control capabilities lie at the heart of the MatrixOne Medical Device Accelerator. These features enable:

- Leverage configurable projects, document and workflow templates to streamline design processes and deliverables
- Track and report customer requirements, project schedules, design specifications and risks from a central location to facilitate project management and design reviews
- Dynamically synchronize Design History Files with New Product Development project deliverables
- Manage all elements of the Device Master Record from a single, integrated source. This includes product data such as mechanical and electrical Bill-of-Materials (BOMs), CAD models, configurations and related documentation such as drawings, specifications, procedures and quality standards
- Manage Corrective and Preventive Action (CAPA) incidents from initiation through change control to closure while maintaining electronic linkages to the implicated products and documents

Documentation and Change Control

The Documentation and Change Control capabilities provide a central repository for all of your controlled documents and data. These features enable:

- Easy and secure access to all documentation from a users desktop to promote reuse of intellectual assets
- Change management of all documents, specifications, procedures and product configurations using a single, flexible, Part 11-compliant electronic Change Control process
- Control of product data such as Engineering BOMs, Manufacturing BOMs, alternate and spare parts, and part configurations in complete agreement with product documents
- Automation to enforce critical change control rules to minimize compliance risk

Project and Program Control

The Project and Program Control capabilities provide an enterprise collaborative environment to manage a wide array of projects and activities throughout new product development. These features enable:

- Embed best practices and Critical-To-Quality drivers into standard, repeatable project templates
- Administer and track projects by allowing team members to collaborate and manage design activities
- Real-time status of project tasks based on actual progress of document deliverables
- Easily create and navigate complex programs of interdependent projects to view dashboards and key metrics regarding design, quality and validation

Industry Accelerator



With the MatrixOne Medical Device Accelerator for Regulatory Compliance, your company can:

- Bring industry-leading products to market quicker and reliably by focusing on the creative aspects of design instead of administrative details
- Respond rapidly to market opportunities by streamlining product designs, submissions and production ramp-up activities
- Finish projects on time and within budget by automating project execution, reusing existing information and avoiding unnecessary setbacks
- Improve quality and consistency of document deliverables to dramatically reduce regulatory risk with real time reports
- Satisfy QSR/ISO regulatory requirements
- Achieve Six Sigma objectives through enhanced process control and metrics
- Satisfy FDA Part 11 requirements with a full audit trail with signature authentication controls
- Jump-start validation with predefined scripts for quick implementation
- Leverage out-of-the-box integrations to many popular enterprise and desktop applications
- Achieve maximum system availability, scalability and security from a centrally managed web based application

Benefits of the MatrixOne Medical Device Accelerator for Regulatory Compliance

Deliver Market-Leading Products

The MatrixOne Medical Device Accelerator for Regulatory Compliance enables organizations to bring industry-leading products to market more quickly and reliably by focusing on the creative aspects of design rather than the administrative details. Product teams can collaborate easily with various contributors and stakeholders to plan projects, develop designs, expedite documentation and release new products.

Drive Responsive Execution

The MatrixOne Medical Device Accelerator for Regulatory Compliance enables organizations to respond more quickly to market opportunities by streamlining product design, submissions and production ramp-up. Finish more projects on time and on budget by automating project execution, visibility to dependent projects, reusing available information and avoiding unnecessary setbacks.

Achieve Lean Quality and Compliance

The MatrixOne Medical Device Accelerator for Regulatory Compliance helps to improve quality and consistency of document deliverables in order to dramatically reduce regulatory risk and avoid audit findings. Organizations can satisfy QSR/ISO regulatory requirements as well as key business requirements. It can help organizations achieve Six Sigma objectives through enhanced process controls, metrics and real time reporting.

Proven Business Value

The MatrixOne Medical Device Accelerator for Regulatory Compliance delivers results across several business processes, functional areas and quality systems by improving quality, reducing errors and maximizing the timeliness of information used in critical business processes. With the MatrixOne Medical Device Accelerator for Regulatory Compliance, customers find that the time to execute a change is often reduced by 15-45%, on-time product launches improve by 15-40%, and lost sales due to launch delays drop by 15-30%. For more information on the business value achieved by medical device companies, refer to the ENOVIA MatrixOne Insight for Medical Device Companies, an analysis of business benefits using ENOVIA MatrixOne Industry Solutions.



Additional PLM Components

Several additional ENOVIA MatrixOne PLM components are available to enhance the capabilities of the MatrixOne Medical Device Accelerator for Regulatory Compliance.

- **MatrixOne Centrals** are the building-blocks for extending your PLM solution.
 - Business Metrics and Reporting – MatrixOne Business Metrics Module™ enables companies to track key performance indicators and drive continuous business improvements for improved efficiency and throughput.
 - Supplier Collaboration and Control – MatrixOne Supplier Central™ enables companies to give their global partners and suppliers real-time access to relevant product information including drawings, specifications and related documentation.
 - Packaging and Labeling – MatrixOne Specification Central™ enables companies to manage the development, review, approval and distribution of product specifications including those related to packaging, raw materials and formulas.
- **MatrixOne Integrations** are the keys to building integrations with popular enterprise and desktop applications.
 - Microsoft Office Integration – Utilize prior investments in MS Project software and training with this bidirectional integration. Manage document files easily with Window's drag-and-drop capabilities while allowing secure, enterprise-level collaboration.
 - Full Text Search Integration – Easily find relevant information by searching both metadata and document content within MatrixOne and other critical enterprise systems.
 - Graphics Viewer Integration – View and markup CAD drawings, image files and documents for wide availability and collaboration without the need for full-blown graphics applications.
 - CAD Integration – Automatically manage revisions/versions, dependencies and relationships to ensure a seamless link between the design community and the rest of the organization.

To learn more about how your company can benefit from ENOVIA MatrixOne PLM solutions, call us today at 978 589 4000, or visit MatrixOne.com

The ENOVIA MatrixOne PLM Environment

Being the industry's most robust and flexible PLM environment, ENOVIA MatrixOne provides organizations with a single, secure environment that eliminates the barriers caused by geographically dispersed organizations and value chains, multiple disparate systems and increasing security requirements.



About ENOVIA MatrixOne

MatrixOne, Inc. was acquired by Paris-based Dassault Systèmes in May, 2006 and today is part of its ENOVIA PLM Collaborative Environment family of solutions. The ENOVIA MatrixOne solutions enable companies to accelerate product innovation to achieve top line revenue growth and improve bottom line profitability. ENOVIA MatrixOne is focused on helping companies across the automotive, aerospace & defense, consumer, machinery, medical device, semiconductor and high-tech industries solve their most challenging new product development and introduction problems. More than 850 companies use ENOVIA MatrixOne solutions to drive business value and gain a competitive advantage, including industry leaders such as BAE Systems, Bosch, Comau, General Electric, Honda, Johnson Controls, Linde AG, NCR, New Balance, Nokia, Philips, Porsche, Procter & Gamble, REI, Sony Ericsson, STMicroelectronics and Toshiba. ENOVIA MatrixOne (www.MatrixOne.com) is headquartered in Westford, Massachusetts, with locations throughout North America, Europe and Asia-Pacific.

