

# INsights

## Medical Device

### Industry Drivers

Competition, Market forces, Regulatory Requirements, Growth goals...

- Increased global competition is renewing emphasis on product innovation and accelerating product time-to-market.
- Evolving and localized regulatory requirements are placing greater emphasis on managing quality certifications and compliance.
- Increased Design Reuse (IP) and Customer Quality/CAPA requirements are forcing better collaboration and management across the dispersed enterprise and supply-chain.
- Industry is actively pursuing acquisition, consolidation and alliances.
- Increasing product liability claims, failed regulatory compliance, mislabeled device/packaging and insurance costs are increasing margin volatility.
- Product longevity is lengthening the timeframe for tracking product management and product information requirements in support of product litigation.

### Corporate Strategies

Common strategies adopted in response to industry drivers

- Take cost out of processes across the organization via automation, streamlining and synchronized communication.
- Consolidate supply base and develop strategic suppliers and partners.
- Emphasize process definition – improve common enterprise processes, then track and measure those processes as a basis for improvement.
- Adopt quality and regulatory methodologies (Six-Sigma, ISO and FDA) and best-practices (CMII) for critical processes.
- Focus on improving the program/project estimates, throughput, striking under-performing projects earlier and maintaining time-to-market schedules in order to ensure the profitability of an opportunity.
- Securely leverage design-chain innovation to increase competitive position.
- Achieve cost and time savings through re-use of Intellectual Property (IP) via consolidated systems.
- Digitize GMP/Quality System Regulations and Validation with commercial-off-the-shelf products.
- Reduce product CAPA and Quarantine incidents through more complete product requirement and change accuracy.

### Business Value Assessment



ENOVIA MatrixOne, is a recognized leader in Product Lifecycle Management (PLM) for the Medical Device Industry. We understand the industry drivers and corporate strategies necessary to deliver innovative new products to the market, and the role that PLM can play in that success.

In this report you will find specific metrics that our customers are using to measure the success they have achieved in developing strategies and solutions for improved product development through PLM.

These results have come from the MatrixOne Business Value Assessment program.

### What is a BVA?

- The Business Value Assessment (BVA) is a methodology and analysis toolset provided by MatrixOne. It enables customers to evaluate and link software solution capabilities with benefit metrics and their associated improvement values.
- The BVA complements the technical capability evaluation of a software solution by answering the question: how and where will I realize the benefits of the solution?
- A BVA is often run in parallel to a formal technical evaluation process and maintains the objectivity of that process.
- The output of a BVA is a business and financial case for the MatrixOne software solution as well as a roadmap of metrics to be measured for value attainment.

## The Metrics

Metric improvements observed or projected

Time Metrics (Average Reduction %)		Operational Metrics (Average Improvement /Reduction %)	
Searching Data	20-60%	BOM Accuracy	35-80%*
Entering/Re-keying Data	10-85%	On Time Product Launch	15-40%*
Managing CAPAs	15-25%	Product Launch Costs	10-35%
Design Authoring/Management	5-30%	Cost of Poor Quality (Rework, Scrap, Obsolete, Excess)	15-40%
Change Initiation/Management	15-45%	Cost of FDA Product Cert's/Sub's	15-50%
Project/Program Management	35%	Cost of Audit/Avoidance	25-50%
Program Financial Analysis	20%	Cost of CAPA/Quarantine Avoidance	10-25%
Time Preparing Reports	20-50%	Shorter Mfg Line Turns Times	5-10%*
Personnel (Hiring Practices) Metrics (Average Reduction %)		IT Maintenance and Admin. Costs	15-35%
Staff Avoidance (Program, Procurement, IT)	2.5 - 15% FTE/Year	Revenue Metrics (Average Reduction /Improvement %)	
Cost of Staffing	20% 1 <sup>st</sup> Year FTE	Lost Sales/Margin Product Launch Delay	15-30%*
Cost of Goods Metrics (Average Reduction %)		Number of Product Launches	15-35%
Direct Components/Assemblies	3-15%	Lost Margin - Launch Velocity	5-15%*
Vendor Premium/Penalties	10-25%	Lost Margin	10%
Overtime	10%	<small>Results may vary. Information contained in this document is provided "AS IS" and is subject to change. MatrixOne does not make and disclaims any express or implied representations, warranties or guarantees, including any implied warranties of merchantability or fitness for a particular purpose, regarding metrics, results, benefits, savings, value or any other information contained in this document.</small>	
Direct Material Cost	0.5-5%		
Outsourcing Costs	10-25%		

## Enabling Solutions

Solution components driving metric improvements:

- Matrix PLM Platform™ provides global access to and automatic distribution of data. Additionally, provides dynamic modeling studio that keeps pace with business changes.
- MatrixOne Enterprise Integrations provide connectivity and the ability to exchange data with design tools (Mech CAD, Elec CAD, software CASE tools), business systems (ERP, MRP, Mfg Execution Systems), collaborative applications (visualization, redline/markup), and critical legacy systems (desktop suites, layout apps, etc.). Integrations provide for the seamless flow of data in processes spanning the entire product lifecycle.
- MatrixOne Medical Device Accelerator for Regulatory Compliance™ provides product regulatory compliance governing the design and manufacture of medical devices intended for human use. Includes OTS web-based solution, integrating compliance elements from FDA Title 21 CFR Part 11 for process histories and electronic signatures, CFR Part 820 for "Good Manufacturing Practice" (GMP). A robust and flexible collaborative documentation and project management environment that provides direct management of the Device Master Record (DMR) and Device History Record (DHR). Phase/Gate design control processes with templates and links to product deliverables that provides internal/external audit and validation deliverable tracking for Device History File (DHF) records. Includes Corrective Action/Preventative Action (CAPA) processes.
- MatrixOne Sourcing Central™ provides required functionality for internal and external quote development via eRFQ templates, workflow, and quote collaboration tools and analysis.
- MatrixOne Supplier Central™ provides capabilities that support quality methodologies for supplier development and measure quality performance including score-carding, supplier development plans, and part development plans.



210 Littleton Road, Westford, Massachusetts 01886 978 589 4000 MatrixOne.com 3DS.com

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