LIFE SCIENCES Transforming
# Medical Devices with Sustainable Innovation

DS DASSAULT SYSTEMES
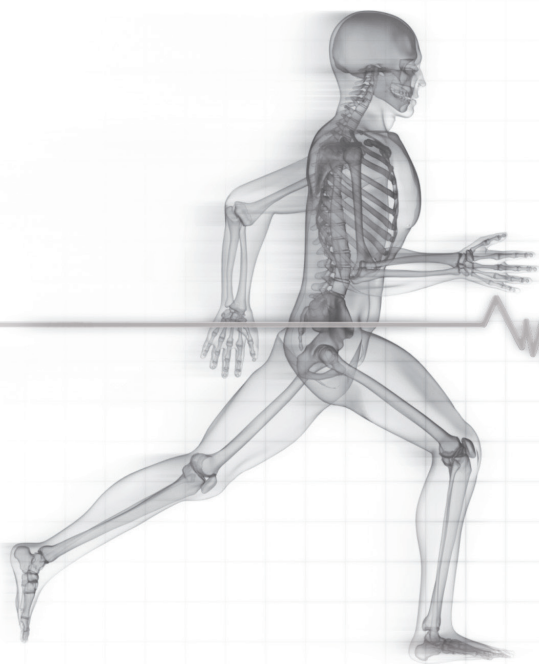
Increasing Innovation in Medical Devices

Every day, medical device companies face the realities and responsibilities associated with developing, producing and distributing products that improve quality of life. To be successful, they continually need to produce more innovative products while complying with extensive governmental regulations.

Product development and regulatory compliance functions are usually conducted in different organizations, however, and rely on multiple information systems and manual processes, resulting in difficulty obtaining information and much wasted time. Now Product Lifecycle Management (PLM) software applications provide a major leap forward with a single environment spanning the entire development and quality system processes. Instead of conflicting with each other, compliance and innovation become complimentary processes that contribute to each other's success.

FDA Global Traceability
Regulatory
Life Sciences
Complaints Quality
3D Simulation DHF
Product Development Medical Device
Supply Chain Productivity
Compliance DMR
Audit PLM
Risk Management Cycle
Speed to Market Time
Innovation NPI
Collaboration Post-market
CAPA/NCR
Optimization
Requirements

Experience it
Sell it
Make it
Manage it
Dream it
Test it
Design it
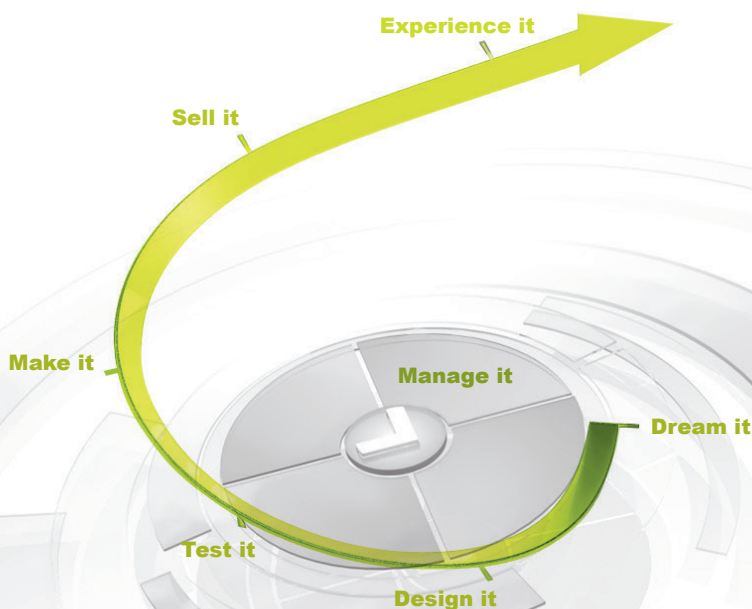
Dassault Systèmes' Solutions for the **Medical Device Industry**

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To maintain competitive advantage, Medical Device companies must deploy cross-functional business processes that span the lifecycle of the product.

Opportunity & Risk Analysis
Project Definition Acceptance
Concept & Feasibility
Initial Design Acceptance
Design & Development
Formal Design Acceptance
Product Launch Preparation
Product Launch
Post Market Surveillance
End Of Sales

Enterprise Governance Processes

Voice of the Customer

Portfolio Management

New Product Introduction

Quality Management

Risk Management

Cross functional BOM Management

Service & Support

Regulatory Affairs Processes

Regulatory Affairs

Systems Engineering Processes

Systems Engineering

Product Engineering Processes

Product Engineering

Scientific Processes

Voice of the Science

Clinical Trials

Supply Chain Management Processes

Supplier Relationship Management

Component Supplier Management

Manufacturing Processes

Manufacturing & Production Operations

Supply Chain Management
Handle the complexity of a globally dispersed ecosystem by maintaining a single, comprehensive product data master repository that is accessible securely to multiple functions within the ecosystem.

Realistic Simulation & Validation
Assess robustness and performance of product and package designs with digital prototypes.

Engineering
Streamline design collaboration and align the team with product goals and user requirements. Manage intellectual assets effectively across the supply chain.

Regulatory Compliance
Enforce regulatory compliance and industry best practices throughout the product lifecycle, reduce errors that pose regulatory risk and build quality into the design process early on.

Enterprise Program/Project Management
Consolidate information and systems with automated processes to focus on innovation, enhance collaboration among all stakeholders and speed time-to-market.

Medical Device companies must manage complexity and change while achieving quality, speed and cost targets.

Collaboration fuels innovation. Only through the open exchange of ideas, knowledge and feedback can companies improve their products and expand their offering. PLM provides a unifying foundation for global teams to easily collaborate and access relevant data in real-time enabling innovation and enterprise agility. The benefits are clear – shorter innovation cycles, increased quality and regulatory compliance, reduced development costs and accelerated time-to-market.

Driving Innovation with Dassault Systèmes Solutions

Dassault Systèmes' PLM solutions are the standard in many of the world's leading Medical Device companies, including four of the top six global brands and in use at nine of the top twenty.

Collaborative innovation
ENOVIA helps companies comply with quality and regulatory guidelines by effectively managing product data and associated project information across the enterprise and throughout the supply chain.

Virtual design
CATIA and SolidWorks accelerate a company's transformation toward a full PLM approach, addressing all manufacturing organizations from original equipment manufacturers (OEMs) and their supply chains to small and medium businesses providing wide and in-depth coverage of mechanical and electrical design and testing solutions.

Digital manufacturing and production
DELMIA speeds manufacturing ramp-up through a range of solutions from process planning to general assembly and factory simulation, allowing complete design and validation of the manufacturing processes in a digital environment.

Realistic simulation
SIMULIA enables designers and engineers to virtually test and optimize the real-world performance of products or packaging via digital prototypes, reducing the cost and need for physical prototypes.
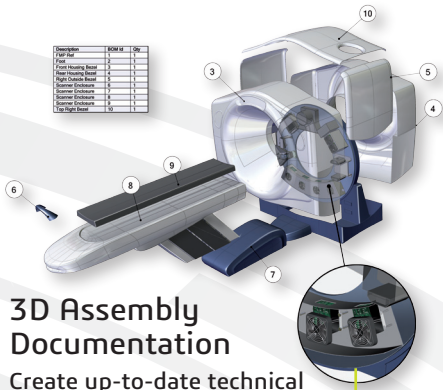
Lifelike Experience
3DVIA Composer revolutionizes product documentation by enabling medical device manufacturers to create easy-to-understand, interactive assembly documentation. 3DVIA Studio offers immersive reality technology for patient care treatment and physician training.

3D Assembly Documentation

Create up-to-date technical documents that are online, easy-to-use and help to eliminate language barriers.

Post-market Activities

Integrate systems to facilitate adequate complaint handling methods in a timely and fully complaint manner, streamlining CAPA and change processes.

Dassault Systèmes Impact on Medical Device Companies:

- **Speed compliance** processes by integrating regulations into product development (design for compliance) and e-submission.

- **Increase business agility** by streamlining design collaboration and managing team activities to be in line with project goals and user requirements.

- **Reduce time to market** through one cohesive solution that allows collaboration of design information and visibility into the complete product development and launch processes.

- **Develop strategic suppliers and partners** by bringing together supplier quality history into the sourcing process.

- **Balance speed versus control** by improving common enterprise processes, then track and measure processes as a basis for improvement.

- **Meet customer needs** by maintaining traceability from ideation to commercialization and obsolescence.

- **Drive part costs down** by publishing part specifications across brands, regions and categories to create efficient procurement processes.

- **Achieve cost savings** through lean and efficient re-use of Intellectual Property (IP).

- **Enable design and manufacturing outsourcing** by creating a centrally managed global virtual work teams and using a single repository to store all product information throughout their life cycle.

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PLM improves productivity and optimizes regulatory compliance for us. The [DS] technology is a big step in our corporate strategy for growing business and introducing innovative life-saving products.
Tim Anderson,
Director of Engineering, Possis Medical

ENOVIA gives us a common and consistent information management process, providing access to product information anywhere, anytime and facilitating collaboration between distributed R&D facilities, factories and sales channels.
Jukka Lehtiranta,
Electronics Design Coach and Project Manager, Datex-Ohmeda

With the realistic simulation solutions from SIMULIA, we have improved device performance, reduced development times, and need fewer physical prototypes than before.
Morten Birkmose
Søndergaard Senior Acoustic Engineer, GN ReSound

With CATIA, our engineers can pay more attention to being creative and implementing new ideas. We can handle more orders. This not only makes our customers happy, but our management as well.
Dawid Drapacz,
Deputy Head, Production Department, Pol-Eko-Aparatura

The key argument for 3DVIA Virtools is the speed at which you can develop [the VR] environments and the fact that you know they will work.
Dr. Stephane Bouchard,
Director, Canada Research Chai in Clinical Cyberpsychology, Université du Québec

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Accelerating Innovation in the Medical Device industry

Dassault Systèmes delivers Product Lifecycle Management (PLM) solutions to Medical Device organizations and their suppliers, accelerating innovative product development while streamlining quality assurance processes for regulatory compliance. Our solutions ensure enterprise-wide visibility of product designs and provide a closed-loop process for proactively managing quality and manufacturing issues.

A world leader in 3D and PLM solutions, DS brings value to more than 115,000 customers in 80 countries across 11 industries. A pioneer in the 3D software market since 1981, DS develops and markets application software for the complete product lifecycle from conception to launch to maintenance to recycling.

Discover why the world's leading Medical Device companies use DS solutions:

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See What You Mean