



MADE TO CURE FOR MEDICAL DEVICE

Manage and improve quality across global regulated operations



IMPROVE VISIBILITY, EFFICIENCY, AND PERFORMANCE OF GLOBAL MANUFACTURING OPERATIONS

Now more than ever, medical device manufacturers require new business strategies to address global regulatory and quality initiatives while improving performance and reducing costs. While many companies rely on paper-based communication and procedures to operate their global manufacturing operations, business line managers are seeing multiple opportunities to reduce compliance risk and improve operating performance. The **Made to Cure for Medical Device** Industry Solution Experience powered by Dassault Systèmes **3D**EXPERIENCE® platform enables medical device companies to take control of quality manufacturing across their global operations, reducing the risk of non-compliance and improving operational performance.

Paperless manufacturing accelerates new product introduction and reduces cost of quality

Medical device manufacturers can now manage complex new product introductions across global supply chains through the use of a synchronized exchange of version-controlled electronic documents, including local market specifications and regulatory testing/inspections. In addition, managers can support the rapid, iterative analysis of production data, parametric measurements, and other quality information in pilot and scale-up phases through the direct connection to plant-floor intelligence, such as supervisory control and data acquisition (SCADA) and smart

measurement systems. Finally, business line managers can help reduce total manufacturing costs (including cost of quality) by eliminating brand damaging non-conformances or regulatory recalls by quickly identifying and quarantining deficient materials for further analysis and disposition.

Manufacturing execution precision and continuous improvement

With Made to Cure for Medical Device, plant operators can enforce enterprise-wide manufacturing best practices with centralized deployment of common procedures for process, assemble, package, and quality execution standards, while supporting local regulatory requirements.

The Industry Solution Experience provides governance, yet rapid adaption to regulatory requirements, and supports continuous improvement initiatives by utilizing actionable KPI metrics. In addition, plant and business line managers can ensure further operational efficiencies through the synchronization of material requirements with production schedules and work orders.

> Made to Cure for Medical Device provides executive dashboards to view global manufacturing operations in real-time.



Manufacturing Operation Real-time Performance

▲72.66%

▼92.25%

Equipment Availability On Time In Full Orders Defects Per Million ▲159

Cost Of Quality ▲ 22.01%

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Key Benefits:

- · Close the loop between master data and the plant floor to analyze non-conformances and deploy process improvements
- · Apply and enforce quality processes with real-time visibility from the plant floor to the executive office
- · Create a global platform to enforce common processes, while adapting to local regulatory requirements
- Synchronize shop floors to ensure that materials and tools are at the right place and the right time for all orders
- · Manage the inbound supply chain with right-quality inspections
- · Achieve UDI traceability with PI information including suppliers

Material Synchronization reduces inventory, increases production throughput, and establishes traceability

With Made to Cure for Medical Device, plant managers can reduce inventory while increasing production by aligning raw materials, components, and semi-finished goods with production, quality inspection, and equipment maintenance processes.

The robust traceability and genealogy supports unique device identifier (UDI) requirements, the product identifier (PI), and supplier materials. In addition, managers can drive consistent operational performance with precise synchronization of materials stocks and production demand, enabled by realtime and actionable visibility to sub-contractor, landed, controlled, work in progress (WIP), and finished goods (FG) inventories.

For more information visit: www.3ds.com/life-sciences

Our **3D**EXPERIENCE® platform powers our brand applications, serving 12 industries, and provides a rich portfolio of industry solution experiences.

Dassault Systèmes, the **3DEXPERIENCE®** Company, provides business and people with virtual universes to imagine sustainable innovations. Its world-leading solutions transform the way products are designed, produced, and supported. Dassault Systèmes' collaborative solutions foster social innovation, expanding possibilities for the virtual world to improve the real world. The group brings value to over 190,000 customers of all sizes in all industries in more than 140 countries. For more information, visit www.3ds.com.

