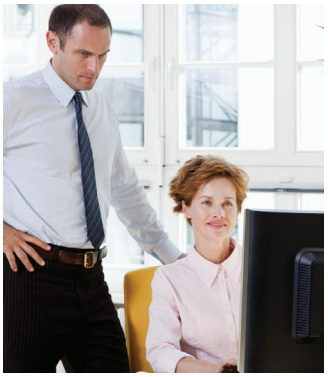
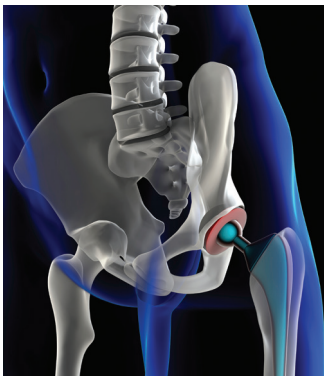
DASSAULT SYSTEMES

3DEXPERIENCE

LIFE SCIENCES
LICENSED TO CURE FOR MEDICAL DEVICE

ACCELERATE THE DELIVERY OF INNOVATIVE, SAFE & FULLY COMPLIANT MEDICAL DEVICES





HOW DO YOU ACCELERATE INNOVATION WHILE ENSURING TOTAL QUALITY AND 100% REGULATORY COMPLIANCE?

Medical Device manufacturers live and die at the hands of innovation. To drive growth today, companies must innovate at an ever increasing rate. And according to the industry analyst group Cambashi, the common challenge is how medical device manufacturers and their suppliers can simultaneously improve financial performance, product innovation and quality while growing at a significant speed.

Dassault Systèmes' **3D**EXPERIENCE platform for the Life Sciences industry provides companies with the solutions that leverage the wealth of information resident in their enterprise to ensure they have the right product, at the right place, at the right time. Our *Licensed to Cure* Experience allows medical device companies to dramatically **accelerate device design and evaluation** with the rigor of an explicit, repeatable and fully traceable creation process for product innovation, regulatory and quality management, and provides a true 360° view of patient and physician requirements.

Product & Process Quality

Successful companies will control information, master product complexity and regulatory compliance and lead the market with breakthrough innovations, while achieving quality, speed and cost targets. Our *Licensed to Cure* Industry Solution Experience ensures a single source of information for design and a fully-transparent and fully-documented change process for both the product, and the process that allows Medical Device manufacturers to be proactive rather than reactive to increasing demands.

High quality and 100% regulatory compliance is assured via a virtual Design History File (DHF) and up-to-date Device Master Record (DMR) that is directly linked to post-market quality assurance business processes such as Complaints, Non-conformance reports (NCR), and Corrective and Preventative Actions (CAPA).

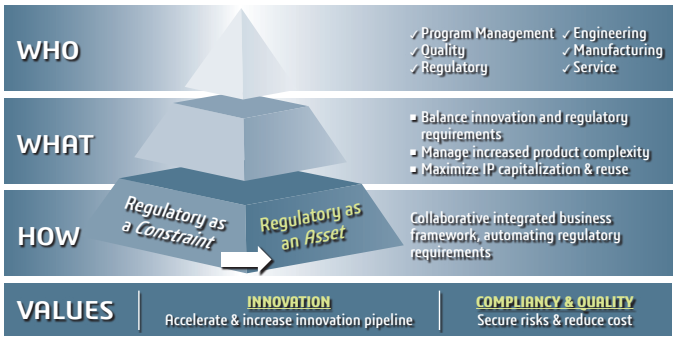
CONTROL INFORMATION, MASTER REGULATORY COMPLIANCE, AND LEAD YOUR MARKET BY CREATING BREAKTHROUGH INNOVATIONS

Regulatory Filing

Successful companies will position themselves to **jump-start projects** by leveraging structured business information based on customer feedback, supplier or internal best practices, while treating regulatory compliance as an asset in the development process, rather than an unwieldy requirement. Compliance and innovation must become complementary rather than conflicting processes.

Pre-market authorization and review process templates speed approvals and collaboration across multiple groups in the enterprise so that breakthrough innovations can reach patients more quickly.

Licensed to Cure for Medical Device



Patient & Physician Requirements

The medical device industry is poised for a sustained period of extreme growth. High consumer expectations for better healthcare and advances in technology that improve quality of life are creating favorable market conditions. Yet rising costs and compliance concerns are forcing medical device companies to proceed with caution – balancing the competitive drive for product innovation and quality with reassuring consumers that what they buy is safe and fairly priced.

Key Benefits

- Integrated framework for compliant innovation and embedding quality and regulatory best practices
- Faster time to market
- Increased quality
- Master regulation compliance
- Maximize IP reuse and select the best value to cost projects
- Optimize resource allocation
- Streamline the regulatory filing process to remove barriers to increasing innovation
- Full traceability and automated reporting and filing

Our *Licensed to Cure* Industry Solution Experience enables you to create a virtual environment for gathering customer feedback and creating requirements that can be managed in a holistic environment with full traceability – visible to all quality, regulatory, and engineering staff – to ensure product safety, accelerate innovation and master regulatory compliance complexity.

EXPERIENCE IT ON YOUR MOBILE

About Dassault Systèmes
Dassault Systèmes, the 3D Experience 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 150,000 customers of all sizes, in all industries, in more than 80 countries.

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