



LIFE SCIENCES LICENSE TO CURE FOR MEDICAL DEVICE

Accelerate the delivery of innovative,
safe, and 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. 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.

Key Benefits:

- Create an integrated framework for compliant innovation and embedding quality and regulatory best practices
- Accelerate time-to-market
- Improve 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
- Achieve full traceability and automated reporting and filing

Dassault Systèmes **3DEXPERIENCE®** platform provides companies in the Life Sciences industry with 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. **License to Cure for Medical Device** Industry Solution 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 a true 360° view of patient and physician requirements.

IMPROVE PRODUCT AND 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. **License to Cure for Medical Device** 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

STREAMLINE REGULATORY FILING

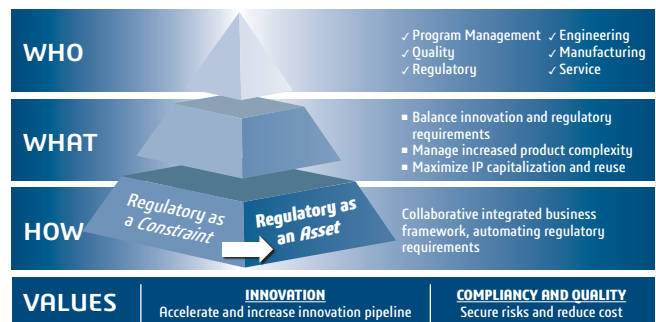
Successful companies will position themselves to jumpstart projects by leveraging structured business information based on customer feedback and supplier or internal best practices, while treating regulatory compliance as an asset in the development process, rather than an unwieldy requirement. Compliance 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.

ENHANCE PATIENT EXPERIENCE

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.

License to Cure for Medical Device enables companies 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 help ensure product safety, accelerate innovation, and master regulatory compliance complexity.



License to Cure for Medical Device

Our 3DEXPERIENCE® 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.



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