DASSAULT SYSTEMES

Beyond compliance

How PLM supports a successful TPLC deployment

Contents

Executive summary

Despite a global recession, medical device manufacturers are facing an unprecedented opportunity for 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 dulling those opportunities, 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.

Successful medical device companies are supporting the U.S. Food and Drug Administration's (FDA) Total Product Lifecycle (TPLC) methodology with technologies, such as Product Lifecycle Management (PLM). TPLC, implemented with a comprehensive PLM suite, enables medical device manufacturers to deliver innovative, compliant-ready products that meet revenue targets and are consumer price-friendly.

Compliance is a necessity throughout the product lifecycle, mandated by increasingly vigilant government agencies. In successful companies, compliance is the outcome of an effective, proactive business strategy that uses an end-to-end PLM system for providing complete product lifecycle traceability while facilitating efficiency and productivity. With PLM enabling better compliance, these companies can achieve strategic, competitive growth initiatives, such as increased quality, more innovative products and faster time to market.

According to the June 2009 ***Total Product Lifecycle Management: Lowering Costs while Increasing Quality*** report by Axendia and Cambashi, "Over 70% (of survey respondents) who improved cost of quality and 79% of those who improved product quality have a TPLC initiative," and are likely to have improved regulatory audit results and time to market.

The FDA believes that TPLC enhances decision making, saving time and money by replacing waterfall design models with a predictive, concurrent approach that drives users to share information collaboratively from concept to obsolescence. End-to-end PLM software enables those TPLC benefits—providing a unifying platform, information-rich and easily accessible by all stakeholders. Compliance, quality and innovation flourish because TPLC and PLM harness the collective intelligence, which encourages design groups to collaborate on design input, share best practices and improve time to market.

Dassault Systèmes (3DS) PLM solutions consist of industry-ready applications, services and methodologies that address the needs of medical device manufacturers, enabling them to improve compliance efficiencies, reduce development costs and focus on innovation.

Coupled with a strong, success-driven services organization and value-oriented methodology, 3DS delivers solutions proven across a diversity of medical device companies including 13 of the top 20 medical device manufacturers in the world.

> *"PLM has helped to drive more efficiency, collaboration and productivity, while providing an environment for innovation and optimized design/build processes. Essentially, PLM solutions help companies to do more with less, while remaining innovative and optimizing their product development processes."*
>
> Product Lifecycle Management Worldwide Outlook, Market Analysis and Forecast Through 2013

Better, faster, cheaper: Medical device manufacturer challenges

Profits in the medical device industry rest on introducing innovative, safe products that are better than last year's release, more reliable than ever before and less costly to produce. As the global population ages and technology enables smarter, smaller medical devices, the current US$220 billion worldwide market will continue to expand. While the market opportunities appear limitless, demand, complexity, regulatory pressures and quality are challenging the medical device industry.

Industry challenges, such as rising medical costs — particularly in the US, effectively the largest market for medical devices — are causing the industry to adapt its survival strategies. To reduce costs, manufacturers are outsourcing specialized functions, such as design and manufacturing, to low cost labor locations, spreading the supply chain thinner and increasing the need for stronger oversight and visibility.

Mergers, acquisitions, spin-offs and new partnerships are creating new companies, hopefully better equipped for a 21st century market. Older business processes that sufficed during less complex times are no longer effective in an environment peppered with regulatory mandates. Staying competitive means medical device manufacturers must manage the complexity of product and process development while achieving quality, speed and cost targets.

Product development processes that emphasize collaboration and central access to accurate information represent one path to achieving those goals. The U.S. Federal Drug Administration (FDA) recommends a concurrent engineering style framework—Total Product Lifecycle (TPLC). TPLC replaces sequential product development frameworks (waterfall) with an iterative approach and enables all stakeholders to provide input early in the design process and on a continuous basis.

Life science advisory firm Axendia and research analyst Cambashi, in conjunction with FDAnews, an independent newsletter provider, evaluated the TPLC transformation process, identifying key results experienced by early adopters. The researchers used a combined online questionnaire and telephone interviews, garnering responses from 212 individuals (80 percent managers, directors and executives), representing more than 185 companies worldwide. Companies like Dassault Systèmes that engage in business with medical device manufacturers funded the study.

In the report, entitled ***Total Product Lifecycle Management: Lowering Costs while Increasing Quality***, Axendia and Cambashi described TPLC as "enabling accelerated innovation, improved product characteristics and better company performance."

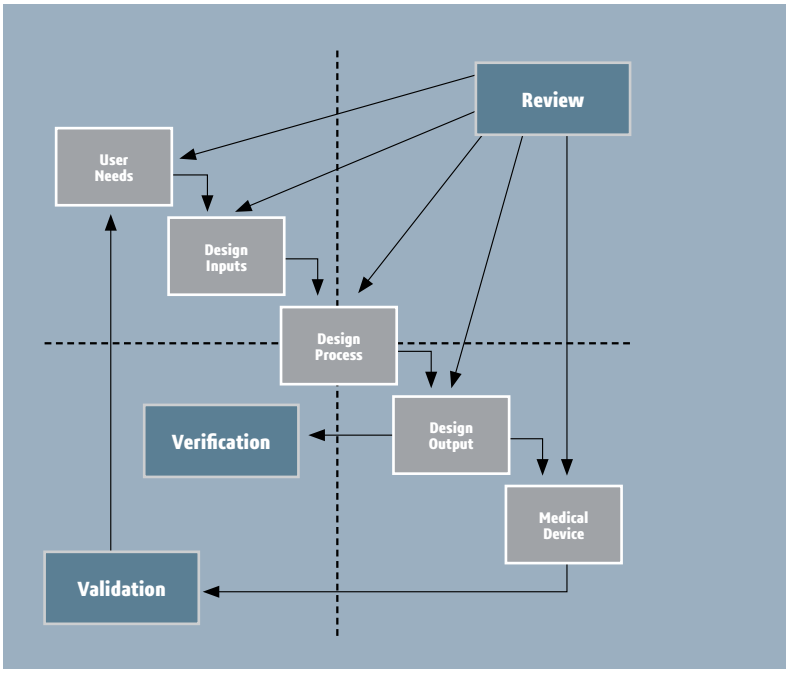

Figure 1: In 1997, the FDA introduced the waterfall design, a product development process that uses logical and sequential steps to produced design controls. Source: FDA CRDH

TPLC: The FDA's practical approach for compliance

Defined by the FDA, TPLC is "an integrated product development scheme and a conceptual framework for assessing a variety of industrial and clinical models."

The Center for Devices and Radiological Health (CDRH), the medical devices regulatory arm for the FDA, implemented TPLC in 2000. The CDRH and the Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) have incorporated TPLC as a global quality and process improvement initiative. By incorporating the TPLC framework as a regulatory philosophy, all phases of the regulatory cycle are integrated, and all stakeholders (e.g., industrial, scientific, marketing and regulatory) share responsibility in efficiently evaluating medical devices. Subsequently, compartmentalization of information, process, and decision making are decreased, and efficiency is optimized.

Today, TPLC is a core element of the CDRH's strategic goals, serving as the global quality and process improvement initiative. The FDA's enthusiasm for TPLC is reflected best in the CDRH vision:

Ensure the health of the public throughout the Total Product Lifecycle (TPLC)

As the FDA points out on the CDRH website, "In a TPLC environment decisions rely on information from the entire product lifecycle. This is achieved by:

- Collaborating across the Center bringing knowledge and experience from each stage of the lifecycle.
- Ensuring that information and knowledge from all stages of the product lifecycle are readily available and used to improve science-based regulations.
- Utilizing information technology to enable rapid communication and sharing among product-centered teams.
- Enhancing scientific decision making through timely collaboration with internal and external experts."

Why iterative is better than sequential

Methodologies promoted by the FDA have a tremendous influence on how the medical device industry develops products. For example, in 1997 the FDA introduced the waterfall design (Figure 1), a product development process that uses logical and sequential steps to produce design controls.

Logical sequencing methodologies, such as the waterfall model or a stage-gate process, remain popular today despite the inherent limitations. Even in 1997, the FDA reported, "Although the waterfall model is a useful tool for introducing design controls, its usefulness in practice is limited. The model does apply to the development of some simpler devices. However, for more complex devices, a concurrent engineering model is more representative of the design processes in use in the industry."

According to the Axendia and Cambashi study, 60 percent of respondents primarily used either a stage-gate or waterfall design process, while 35 percent used a concurrent, agile or other approach that was more in keeping with the intent of TPLC. Their research also revealed that nearly half of the survey respondents indicated TPLC was a priority. This is no surprise since TPLC can play a significant role in stimulating new product introduction—rated the number one opportunity by study respondents.

Unfortunately, despite their good intentions, many of the companies surveyed had not deployed TPLC and, in reality, had not begun the transformation necessary for success. TPLC, like any other framework, has its own challenges.

Roadblocks to TPLC implementation include many of the same challenges faced by the industry as a whole—design changes that delay production, affecting quality and compliance; communication and process challenges along an extended supply chain; and reactions to audit findings.

An iterative methodology, such as TPLC (Figure 2), has the potential of dissolving the roadblocks because it promotes a collaborative environment along the entire product lifecycle. TPLC users validate each component and process design prior to production and design release.

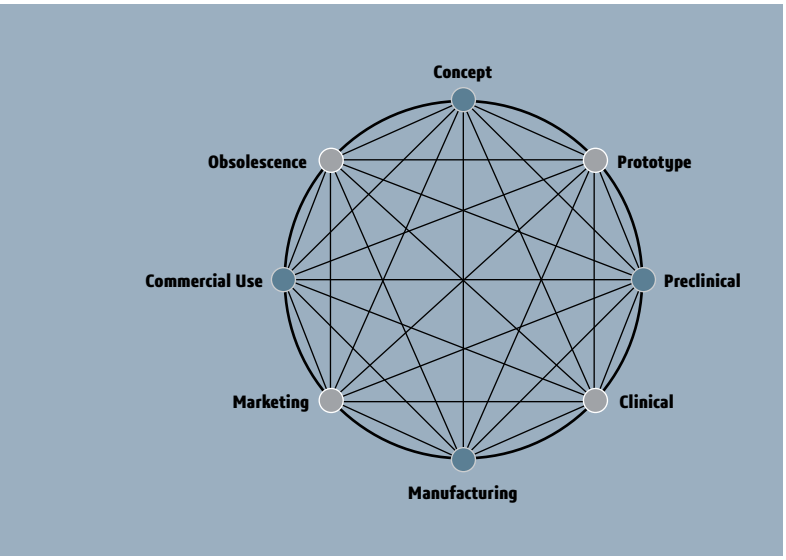

Figure 2: The TPLC model interconnects and maintains pathways to every component necessary to design, build and maintain a product. TPLC users face compliance issues during design, so when engineering changes are necessary, the design is adjusted to meet the regulations. Source: FDA CDRH

Axendia and Cambashi report recommendations

Closed-loop TPLC

The researchers recommend that medical device manufacturers move from a sequential process to TPLC because every stage of the lifecycle feeds into and connects with all others—closing the loop. TPLC creates a collaborative environment that facilitates multi-departmental interaction across the entire product lifecycle.

The interconnected nature of the framework enables stakeholders to have input and access to the information necessary for designing, manufacturing and marketing a safe and effective medical device. The result is better decision making, which logically leads to faster innovation, lower costs and improved quality.

From reactive to proactive

Benjamin Franklin once said, "An ounce of prevention is worth a pound of cure." The same can be said of root-cause analysis, a process often overlooked. Identifying the root causes of problems has enormous benefits, from reducing the number of corrective and preventive actions (CAPAs) to improving cost and quality performance. Although CAPAs are part of a continuous improvement approach, the process is nonetheless reactive, occurring after the product has been designed and built.

TPLC encourages the solving of non-conformance issues early in the product lifecycle—before cost and time issues negatively impact the results. With TPLC, manufacturers can institute CAPAs to plan for adverse events proactively. Key to this process shift are software applications that can gather and analyze the data.

Quality process versus regulatory compliance

Continuing along the theme of "being proactive," the study recommends that manufacturers institute a documented quality process that embeds quality in the lifecycle of every product. The result would be a product that conforms to quality standards as well as business needs associated with costs and compliance.

Value chain visibility

When it works, outsourcing is an effective strategy for reducing costs. Unfortunately, as the study found, most companies had difficulty aggregating data of any type across multiple sites. The study recommended that medical device manufacturers develop a system for internal collaboration that would enable visibility across the value chain.

Single version of the truth

Many companies operate within a siloed environment, unable to communicate across functional lines or distances. TPLC requires collaborative and common systems that increase decision making by accessing relevant and accurate data at any point of the product lifecycle.

The study found that the choice of record keeping for quality issues was that of paper-based, manual setups requiring maintenance and storage. Fewer than 25 percent of the respondents used a Quality Management System (QMS), and for the remaining respondents, the percentage was lower for Enterprise Resource Planning (ERP), Product Lifecycle Management (PLM) or Manufacturing Execution Systems (MES).

The crux of a successful TPLC implementation is access to shared data across the product lifecycle. Medical device manufacturers that want TPLC benefits will need to migrate from a sequential process mindset to one that incorporates a cultural shift from manual to automated processes. Collaborative and common systems are necessary for success.

PLM: Enabling the promise of TPLC

TPLC, enabled with a strategic PLM solution, reduces process complexity, saves time and effectively utilizes resources across the enterprise and throughout the supply chain. PLM applications fulfill the promise of TPLC by helping users to:

- Design market favorable products by capturing the voice of the customer
- Reduce recalls because compliance is built into the design process before manufacturing
- Effectively manage audit requests real-time from a single version of the truth.

With PLM, IT-enabled global teams use a common software environment to access relevant data, tools and processes easily and participate in automated business processes (workflows) over a unifying foundation built on a single platform (Figure 3). The PLM solution makes the massive amounts of information necessary to manage the product lifecycle visible to all stakeholders—eliminating communication bottlenecks. Users no longer need to rely on paper-based processes or home-grown point solutions that fail to communicate cross-functionally and accurately.

PLM supports the end-to-end product development process — from design creation to product analysis; simulation to manufacturing assembly; maintenance planning to operating training; and patient interaction modeling. PLM fills in the product-related gaps that other major enterprise applications, such as Enterprise Resource Planning (ERP), cannot.

By managing quality issues through a single, global, online system, PLM provides medical device manufacturers with insight into their quality systems. Medical device manufacturers can track, investigate and dispose of field complaints, product inquiries and services requests, and be proactive about potential issues. Companies can avoid compliance risk, reduce waste and leverage quality-related information for improving related business processes, such as CAPAs, Nonconformance Reports (NCRs), product complaints and quality audits.

For example, in US facilities, CAPA site leaders can leverage PLM capabilities to determine a request's legitimacy. If further action is necessary, problems can be escalated between categories and tracked. PLM supports the root-cause investigation by linking the information directly to the CAPA. Organizations can respond quicker to market opportunities by streamlining product design, submissions and the production ramp-up—all because PLM enables real-time visibility into initial request, root cause analysis, risk assessment and closure.

PLM also reduces auditing complexity because automatic processes maintain accurate record keeping, tracking auditor requests and providing responses. The responses, such as a manufacturing procedure, are automatically linked to the relevant data in the PLM system. Users can develop an audit schedule to track and plan internal, supplier and external audits.

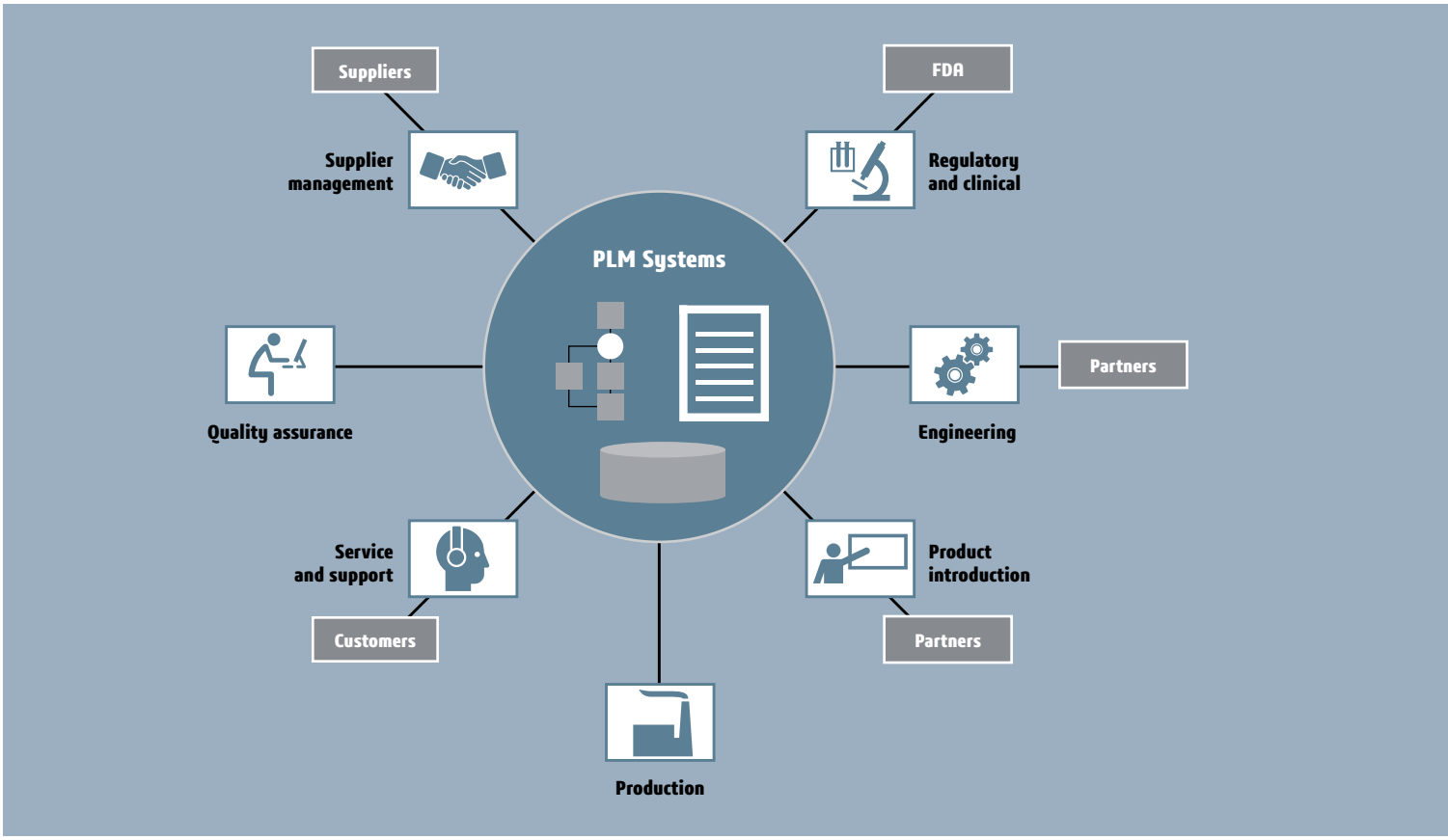

Figure 3: With PLM, IT-enabled global teams use a common software environment to access relevant data, tools and processes easily and participate in automated business processes (workflows) over a unifying foundation—built on a single platform.

Performance improvement: PLM users versus others

Complying with good manufacturing practice (GMP) regulations becomes easier when companies implement a PLM approach that enables a global, integrated closed-loop system for CAPAs. With the tracking of production and non-production issues, audit management and quality monitoring improves as manufacturers shift from a reactive mode to a preventive one.

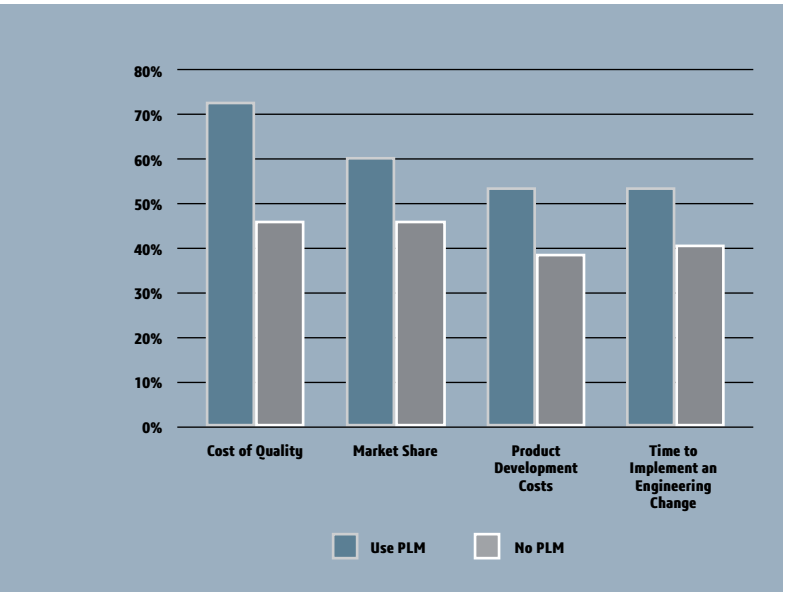

Figure 4: A comparison between medical device manufacturers that us PLM to implement TPLC and those who do not. Source: Total Product Lifecycle Management: Lowering Costs while Increasing Quality. ©2009 Axendia and Cambashi.

By centralizing product development and quality systems processes in a common environment, PLM eliminates organizational silos that foster erroneous information. Organizational silos prevent collaborative communication, leading to poor quality, more recalls and slower time to market. Instead, PLM enables global collaboration for better decision making—from product to process—ensuring compliancy, reducing costs and creating innovative products that meet customer needs and wants.

In a comparison between medical device manufacturers that use PLM to implement TPLC and those who do not, the Axendia and Cambashi study reported that the PLM users group fared much better along cost and quality lines (Figure 4).

Conclusion

The promise of TPLC is clear—shorter innovation cycles, higher quality products and lower costs. In an era of ever-increasing complexity from design to process, TPLC is a proven choice for a success. Combined with a PLM application, the odds for success increase.

Why Dassault Systèmes?

Dassault Systèmes (3DS) provides experiences that are specifically designed to master medical device highly regulated product development challenges and accelerate time to market, collaboratively and efficiently.

The 3DEXPERIENCE platform for Life Sciences is about bringing products to life – connecting innovative virtual 3D designs with patients, physicians, and other research, regulatory, and clinical communities. From concept to patient, medical device manufacturers can create and optimize their product, and manage the delivery to consumers, all while managing and gaining regulatory approvals.

The strategic, end-to-end solution ensures a successful FDA- and ISO-compliant product rollout. Industry-specific applications enable life sciences companies to implement a single, cohesive information source for enterprise-wide visibility into design management and collaboration across the product development process.

The 3DEXPERIENCE platform for life sciences manages product disposition, including approval and verification, assignable cause analysis and immediate corrections.

The solution integrates all new product development processes and interfaces seamlessly with other enterprise applications, such as enterprise resource planning. Audit risks diminish as the closed-loop audit-cycle records findings, recommendations and actions taken.

Medical device manufacturers are able to focus more clearly on innovation by using automation to consolidate information, processes and systems. In addition, product innovation increases as collaboration among stakeholders grows, leading to the delivery of winning products.

Dassault Systèmes 3DEXPERIENCE solutions for life sciences expand virtual universes beyond PLM and allow companies to imagine sustainable innovations capable of harmonizing products, nature and life. Our life sciences solutions leverage the strengths of our brands - CATIA for virtual products, SOLIDWORKS for 3D mechanical design, SIMULIA for realistic simulation, DELMIA for digital manufacturing and production, ENOVIA for global collaborative innovation, EXALEAD for information intelligence, NETVIBES for intelligent dashboarding, 3DSWYM for social innovation, 3DVIA for Online 3D Lifelike Experiences- and can be complemented by offers from our partners.

Coupled with a strong, success-driven, services organization and value-oriented methodology, 3DS brings a complete solution proven across a diversity of medical device companies.

END NOTES

1. *http://www.ameinfo.com/28506.html*
2. *http://www.accessdata.fda.gov/ScienceForums/forum05/0-PO-21.htm*
3. *http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/MedicalDeviceFellowshipProgramCDRH/ucm108143.htm*
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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 150,000 customers of all sizes in all industries in more than 80 countries. For more information, visit www.3ds.com.

Europe/Middle East/Africa
Dassault Systèmes
10, rue Marcel Dassault
CS 40501
78946 Vélizy-Villacoublay Cedex
France

Asia-Pacific
Dassault Systèmes
Pier City Shibaura Bldg 10F
3-18-1 Kaigan, Minato-Ku
Tokyo 108-002
Japan

Americas
Dassault Systèmes
175 Wyman Street
Waltham, Massachusetts
02451-1223
USA

Visit us at
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