DASSAULT SYSTEMES

LIFE SCIENCES

BEYOND COMPLIANCE

Connecting the Dots Between Quality, Engineering, and Regulatory to Increase Innovation & Improve Operational Efficiency

INTRODUCTION

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 innovative products that are clinically and economically relevant. Medical device manufacturers are also facing strict regulatory requirements, and they are now seeing increasing competition and demanding time-to-market pressures, which leads to more emphasis on reducing costs.

In addition, in an effort to capitalize on opportunities in emerging markets, manufacturers must navigate new regulations and quality requirements. They need reliable, adaptable, streamlined, and repeatable processes to cope with shifting regulatory and market opportunities. These external factors stifle business revenue and profits, and leading device manufacturers must adopt new business strategies to address these challenges and stay ahead of the competition. In an effort to accelerate the delivery of innovative, safe, and fully compliant medical devices, companies:

- Strive to provide additional solutions to enhance the patient experience and address patient unmet needs.
- Reduce both time-to-market and development costs.
- Increase outsourcing and externalization.

Within the organization itself, certain issues hinder innovation. Different groups usually conduct product development and regulatory compliance functions in silos, with each group using a different information system and long-established, disjointed manual and paper-based processes. The innovation process slows down when information is hard to retrieve and key decision makers lack a single view of all product- and process-related information. With a Single Source of Truth (SSOT) for all device-related information, all stakeholders have access to relevant information at any time. This type of solution promotes collaboration within the organization to accelerate device design, meet long-term business goals, and achieve operational excellence. By controlling information and making it accessible across an organization, teams can focus on quality, accelerate innovation, and improve operational efficiency while ensuring global regulatory compliance.

MEETING THE CHALLENGE

Patients look to medical device manufacturers to provide solutions that improve and often save lives. The US medical device industry, the world's largest, accounted for an estimated US$82.4 billion in 2004[1] and US$127.1 billion in 2013[2], a 54% increase over a 10-year period. EvaluatePharma predicts that the global medical device market will experience a growth rate of about 4.4% per year and reach US$440 billion by 2018.[3] While there is considerable opportunity for growth, margins for medical device manufacturers are extremely tight—now more than ever.

In addition, extreme competition, especially in high-growth markets like India and China, are forcing medical device manufacturers to focus on exceeding the patient promise—and to concentrate more on innovation with lower pricing. But this cannot be achieved with the burden of additional costs. Increasing internal costs and global expansion compel companies to find new solutions including outsourcing to supply chain partners. However, new suppliers add even more inconsistency in the process and increase quality and regulatory risk if manufacturers do not document and manage processes properly.

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The commoditization of medical devices makes the need for innovation key to a company's remaining competitive. Product upgrades or variations can create regulatory complications. For example, regulatory agencies will cite companies or deliver Warning Letters or Form 483s when a company fails to document product changes accurately. Warning Letters and 483s are posted publicly, resulting in damage to the company's reputation among patients, a loss in corporate revenue, and erosion of shareholder confidence. For most companies, the regulatory filing process is cumbersome and capable of slowing down innovation cycles.

According to the Emergo Group, U.S FDA medical device quality system inspectors have issued Warning Letters to manufacturers at an increasing rate since 2005, and the trend shows no sign of abating (see Figure 1).[4]

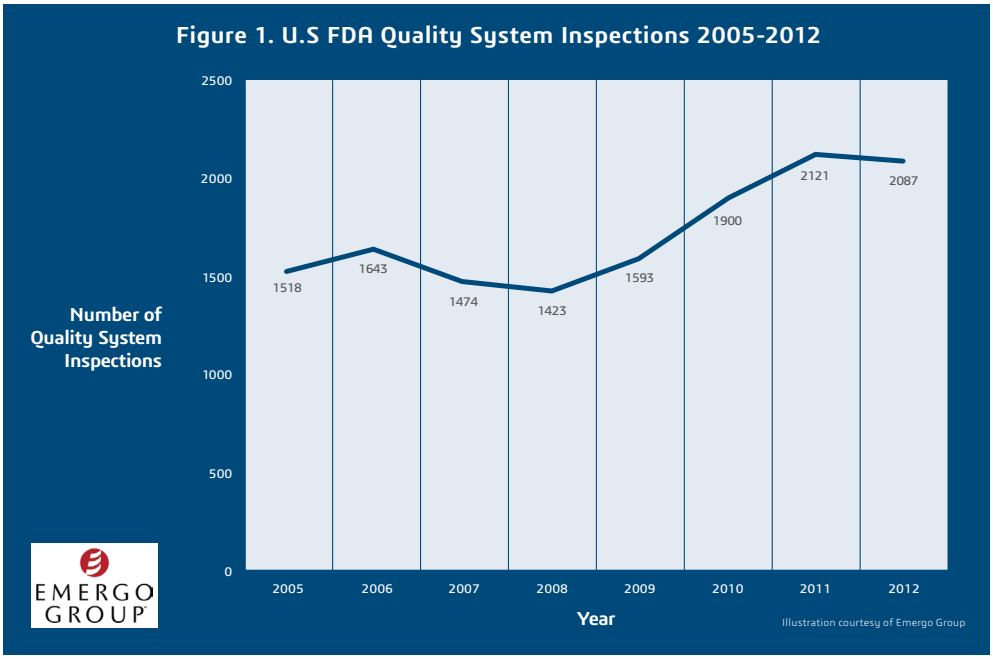

Figure 2. U.S FDA 483s Issued by Category 2012

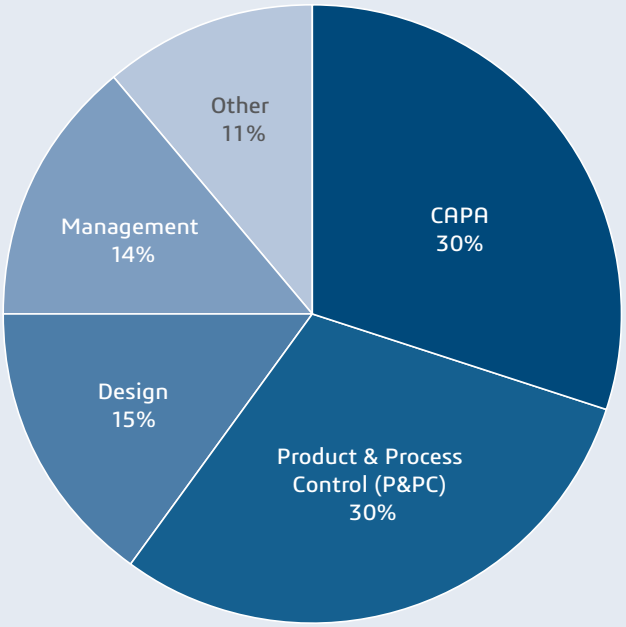

Image courtesy of *FDANews*

FDANews notes that 30% of the 483s issued by the U.S FDA in 2012 were triggered by the agency's inspection of a company's Corrective and Preventive Actions (CAPA) process, by far the most commonly cited deficiency mentioned in U.S FDA Warning Letters (see Figure 2.).[5]

ENABLING MANUFACTURERS TO FOCUS ON QUALITY

A single collaborative system enables a medical device company to connect quality, regulatory, and engineering, to deliver high-quality products, and to facilitate regulatory compliance. This holistic system stores all quality and compliance data centrally, tracks all product changes automatically, and provides necessary audit reports that link directly to a "living" electronic Design History File (DHF), Device Master Record (DMR), and Device History Record (DHR). It also simplifies the management of product engineering Bill of Materials (BOMs) and manufacturing BOM structures such as part versions and revisions, and alternate and spare parts. Quality comes at very little cost when it is done right and allows organizations to truly improve health outcomes by allowing companies to focus on producing advanced medical technologies.

With such a system, Quality Managers obtain data in real time and correlate it with product design information. From the start, Product Managers capture the detailed specifications needed for both product data and quality systems to facilitate closed-loop problem solving. Finally, full access to both a virtual DHF and current DMRs facilitates problem solving for the Regulatory Manager if and when regulatory issues arise.

A single collaborative system enables a medical device company to connect quality, regulatory, and engineering.

Project Leaders can remove the barrier between quality and engineering by organizing all information about a device with a single, global, online system that manages all quality related information including product complaints, non-conformance reporting (NCRs), and CAPAs. Feedback on compliance issues can now become part of the product design process and managed throughout the product lifecycle.

In addition, full traceability and automated reporting and filing removes barriers to increasing innovation. Quality Managers no longer address quality issues, including working with CAPAs and responding to Warning Letters and 483s, alone in isolated silos. Instead, Product Designers share total access to information relevant to quality complaints, including the full compliance process. For example, if a user issues a complaint, then it is linked to the appropriate part of the BOM.

A Change Order (CO) addressing the complaint is automatically associated with that complaint and the CAPA. Such a process leads to early detection of design issues, transforming regulatory compliance into a framework that focuses on improving product quality.

IMPLEMENTING A GLOBAL SOLUTION DRIVEN BY INNOVATION

Implementing a holistic system that connects business processes across the organization ensures early visibility into how products will be designed and built, which helps avoid potential product issues before manufacturing and product launch. Having a system that connects quality issues and field feedback with the same product records used by engineering and design teams allows these teams to have direct access to the "voice of the customer". This information helps engineers make better design choices and ultimately deliver new, high-quality, compliant products with enhanced customer-driven features to market faster.

An end-to-end, SSOT solution allows companies to eliminate scattered processes and data and to embed regulations as an asset, optimizing quality and compliance, while at the same time reducing operational costs and time-to-market. This holistic solution supports all aspects of a medical device company's quality system, regulatory compliance, and ISO-regulated design controls. This single, global, online system provides a flexible solution that streamlines event reporting, reduces recalls, and improves patient safety. All information resides in a comprehensive system, from packaging and unique device identifier (UDI) record to all quality and regulatory data including product complaints, NCRs, Warning Letters, 483s, audits, and CAPAs.

A Single Source of Truth solution eliminates scattered processes and data, optimizes quality and compliance, and reduces costs and time-to-market.

This organized approach to product development and quality management speeds and improves the innovation process and minimizes the risk of non-compliance. Accessibility to one complete source of product information allows a multi-disciplinary approach to design of complex devices. When it is time to create variations of devices or upgrades based on unique patient requirements, knowledge related to quality and compliance can be embedded in the product change processes. Pre-market authorization and review process templates speed approvals and collaborations across multiple groups in the global enterprise and supply chain so that breakthrough innovations can reach patients more quickly.

Medical device manufacturers can become proactive rather than reactive to increasing demands from physicians and patients for safe, fairly priced, and innovative solutions. Product Designers working to address a problem that surfaces in a complaint or CAPA can have instantaneous access to each individual complaint as well as information on the complete compliance process. When making a change in response to an NCR, an engineer simply references it, rather than copying the problem report information from another system. Straightforward and instantaneous access to information ensures that everyone is working with the latest data. In addition, multiple sources of information can spark ideas during new product development. Substantial time savings and improvements in accuracy can be achieved by developing workflows that cross the boundary between product development, regulatory compliance, and quality assurance departments.

ACCELERATING INNOVATION AND IMPROVING OPERATIONAL EFFICIENCY

Accelerating the innovation of new medical devices in the midst of increasing regulatory activity and global expansion requires new business strategies. An end-to-end, collaborative business framework that integrates product design, quality, regulatory, manufacturing, and supply chain information together improves operational efficiency while demonstrating regulatory compliance.

Increasing operational efficiency for medical devices improves the ability of manufacturers to respond to patients' unmet needs, increase patient safety, improve device efficacy, and create a better patient experience with medical devices. The constraints on innovation from quality assurance and regulatory compliance are reduced by a system that harnesses knowledge gained from connecting the dots between quality, regulatory and engineering. In turn, improved product design collaboration reduces product recalls, compliance costs, and time responding to information requests, which allows innovation to flourish.

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Manufacturers need a system to address increasing and extensive regulatory requirements that do not add additional costs or risks to the process. A robust system that connects engineering with quality and regulatory business processes allows companies to proactively manage quality issues before they occur. Reliable, adaptable, streamlined processes that allow reuse of previous analyses help companies comply with inspection requests and improve product quality in the future.

A collaborative holistic system saves money and time by streamlining document change, review, approval and training process, and reducing the time searching for data. As a result, contributors will spend more time focusing on creative solutions that meet patients' needs and less time managing paperwork and responding to regulatory inquiries. Stakeholders will receive a better ROI and employees will experience more job satisfaction when time is spent on making a difference in the lives of patients and less time tracking and resolving issues.

The Dassault Systèmes ***License to Cure for Medical Device*** Industry Solution Experience allows medical device manufacturers to create a virtual environment that increases efficiency within the innovation process. The framework enforces procedures in the workflow by using process templates that embed the regulatory requirements. The ***License to Cure for Medical Device*** Industry Solution Experience provides full traceability that is visible to all members of the quality, regulatory, and engineering staff, providing a Single Source of Truth for engineering, quality, and regulatory information. Access to this integrated and controlled information accelerates product line variation through full IP reuse. Regulatory requirements are directly linked to engineering and quality information, creating an efficient process that brings safe, high-quality, breakthrough innovations to patients that increase their quality of life.

For more information about the ***License to Cure for Medical Device*** Industry Solution Experience, view the product video and read customer testimonials on the Dassault Systèmes website: http://www.3ds.com/industries/life-sciences/license-to-cure-for-medical-device/.

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