At Last: A Single Solution for Controlling CAPA, Nonconformance, Complaints & Documents

Why Top Companies Are Now Moving to a Single, Integral, Closed-loop System to Comply with QSR and ISO Regulations and Develop Innovative Products Faster

There are few industries in the world that face the product development complexities and challenges of the Medical Device industry. It's not enough that you have to continually invent breakthrough new products year after year. But, along the way, you have to comply with complex regulations, which means capturing quality inputs, submitting regulatory notifications, dispositioning nonconforming material, conducting root cause analysis, managing changes associated with CAPAs or quality inputs, and monitoring the effectiveness of corrective and preventive actions.

Historically, accomplishing all of these difficult tasks required a multitude of software and hardware solutions from a host of vendors whose very survival was bent on installing as many applications as possible at as many sites as possible.

The good news is that the game has finally changed. With the emergence of a single, integrated solution for managing CAPAs, Complaints, Nonconformance and all relevant documentation, medical device manufacturers are finally getting their house in order. Below, you'll learn why a single, powerful, closed-loop solution is now the optimal choice for the world's most demanding and most successful medical device manufacturers.

It All Starts with Total Product Lifecycle

The Quality System Regulation (QSR or 21 CFR Part 820) and ISO 13485 (medical devices – quality management systems) govern the methods used in the areas of design, manufacture, purchasing, documentation, production, packaging and labeling for medical devices. Additionally, the regulations include requirements for the traditional Quality Management System processes of Complaints, Nonconformances, and CAPAs.

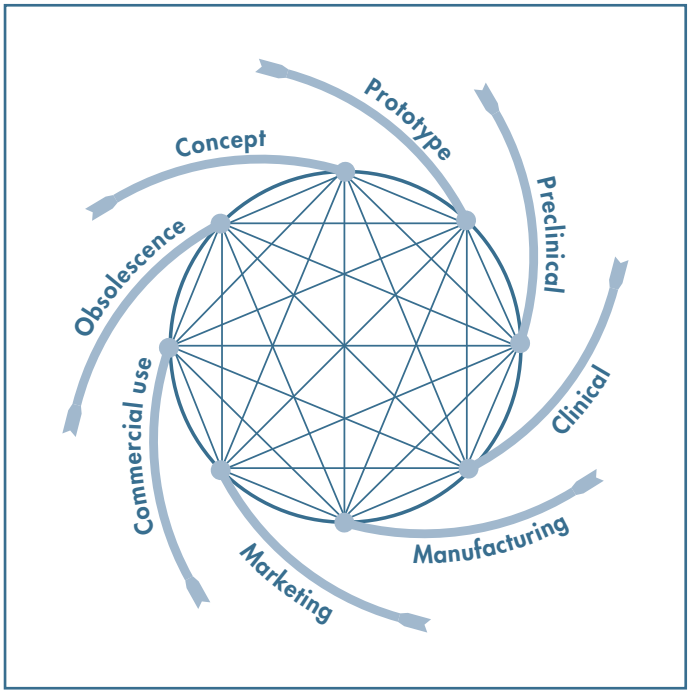

Figure 1: TPLC (Total Product Lifecycle) Model as defined by Dr. David Feigal, CDRH.

Traditionally, different functional departments have been responsible for the business processes described within the QSR, a situation that has resulted in poor communication, misalignment and inconsistent quality. Realizing this problem, the Center for Device and Radiological Health (CDRH) introduced the topic of Total Product Lifecycle (TPLC), which now serves as a cornerstone in its strategic plan.

The TPLC model encourages device manufacturers to use "information technology to enable rapid communication and sharing among product-centered teams." Clearly, the agency is advocating the use of automated systems. However, software alone does not satisfy this guidance, as the information must be able to be accessible to enable shared collaboration. To address this second point, companies must either (a) integrate disparate systems to enable information sharing, or (b) install a single system, at least for the key elements of the QSR.

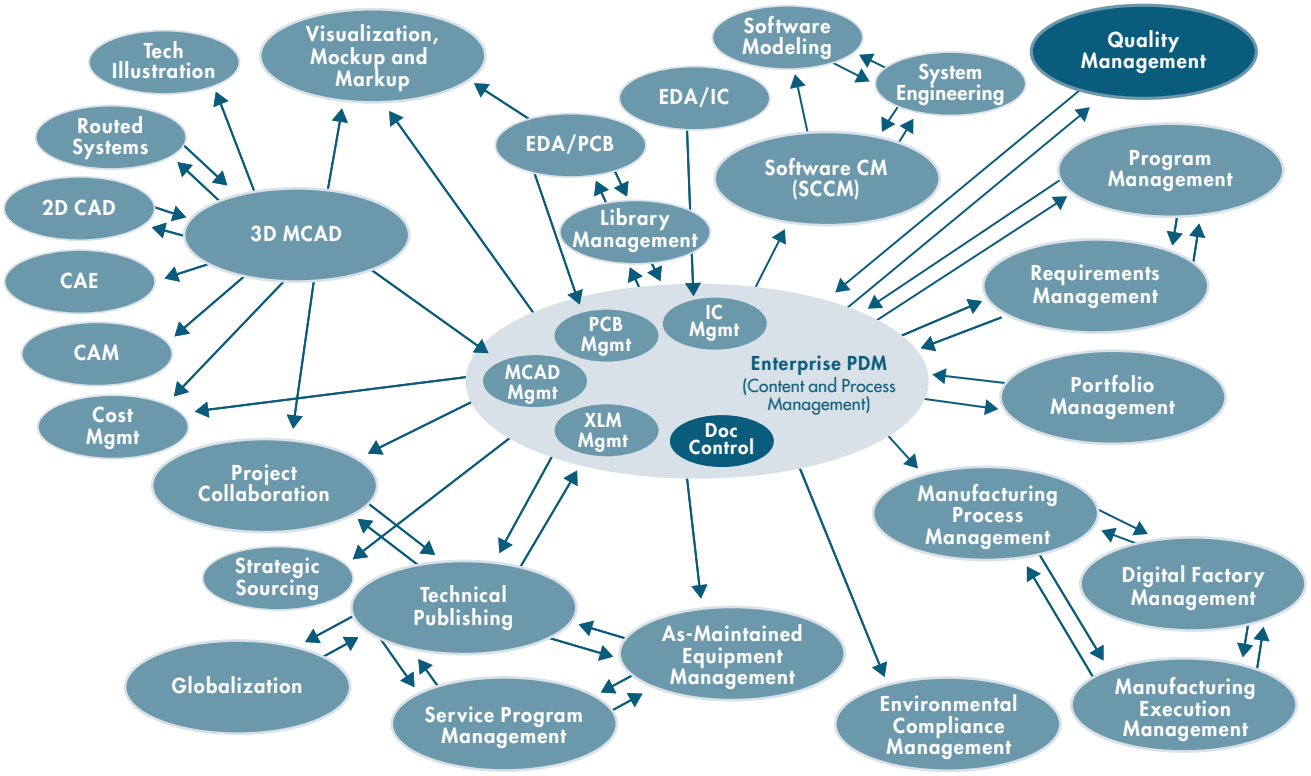

Figure 2: Common IT infrastructure, including disconnected systems for Quality Management and Document Control.

Best-in-Class Solutions vs. Integral Functionality

ISO 9001:2007 requires control of documents and control of products. Similarly, the FDA's QSR and ISO 13485 also have these requirements, as well as requirements for traditional QMS processes, such as CAPA, Complaint handling, and Nonconformance management. Up to now, device manufacturers have been forced to make one of three choices:

1. Implement a manual system and forego automation
2. Purchase a collection of best-in-class point solutions (PLM, QMS and Document Control)
3. Purchase a single, broad, but shallow solution that lacks robust capabilities.

In today's world of complex products, processes, intense regulatory scrutiny, and fierce competition, business automation is now a requirement. However, purchasing a single, broad solution has, traditionally, been unattractive, as no commercially available system could satisfy the many requirements established by functional departments.

Therefore, the vast majority of companies permitted their business units to make individual technology decisions. The result: the more progressive or IT-rich companies frequently attempted some level of system integration, which most often failed to meet its objective due to complex and frequently changing technologies and requirements. In the end, the total cost of ownership for these patchwork systems proved onerous, and the solutions failed to meet the objective of TPLC, as well as the user's own requirements.

The Solution: Broad and Deep Functionality

Much like ERP in the early 2000's, PLM (Product Lifecycle Management) is now recognized as an application consolidator. Manufacturing companies in all industries realize that PLM creates and owns the product data (BOM) required by many departments outside of R&D, including manufacturing, purchasing, quality and regulatory. Therefore, PLM has become the natural vehicle to help device companies implement a TPLC approach, whereby information technology enables rapid communication and information sharing among product-centered teams located anywhere. Robust QMS capabilities contained within PLM will help manufacturers improve quality, reduce cost and shorten time-to-market.

Already an advanced solution for Document Control, Windchill® PLM software now offers robust QMS capabilities that provide true closed-loop operations. With Windchill, Quality inputs (Complaints or Nonconformances, for example) are linked directly to CAPAs, which in turn are linked to change requests. All documents and signatures are electronic, plus all process steps are dictated by automated, repeatable workflow, and all transactions are captured in an electronic audit trail. There's no off-line or manual assignments to worry about – nothing to fall between the cracks.

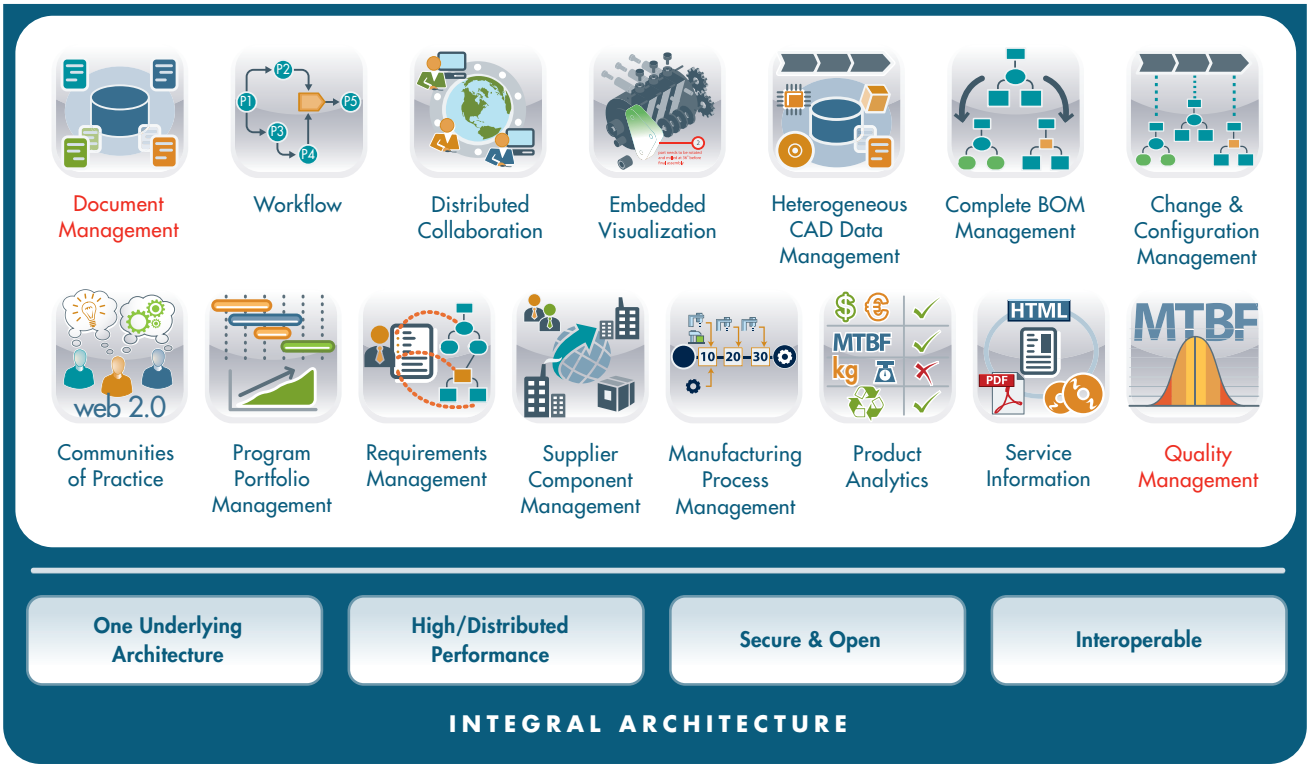

Figure 3: Windchill® PLM system showing integral Document Control and Quality Management.

Windchill's QMS Capabilities: Broad, Deep, Proven

Today, many document control solutions have a "bolt-on" QMS solution, that lacks rich functionality. Windchill's QMS solution has been an industry leading, stand-alone solution for over 10 years. As a result, Windchill's quality solution offers robust functionality, including:

- Wizard-scripted data entry
- Fast entry for light touch users
- Easily configurable fields, drop-down windows and decision trees
- Multi-language user interface
- Advanced, configurable workflows permitting state transitions
- Split lot dispositioning
- Material Review Board (MRB)
- eMDR – initial and incremental
- Ad-hoc and watchdog reporting
- Preventative Maintenance and Calibration
- Internal and External Audit management
- Training Management
- Risk Management

Summary

The FDA strongly encourages device manufacturers to manage the Total Product Lifecycle with automated tools. Windchill is the ideal solution for TPLC because its robust QMS capabilities complement advanced document control and change control processes, thus providing all product stakeholders with instant access to valuable information throughout the organization. Windchill's fast-track validation packages, built with best practices and pre-developed test scripts, accelerate implementation, enabling companies to achieve closed-loop CAPA/Document Control for improved product quality and strict adherence to regulations.

For More Information

To learn how Windchill PDMLink® can help your company execute an effective Document Control process, visit **www.ptc.com/industry/medical-devices.**

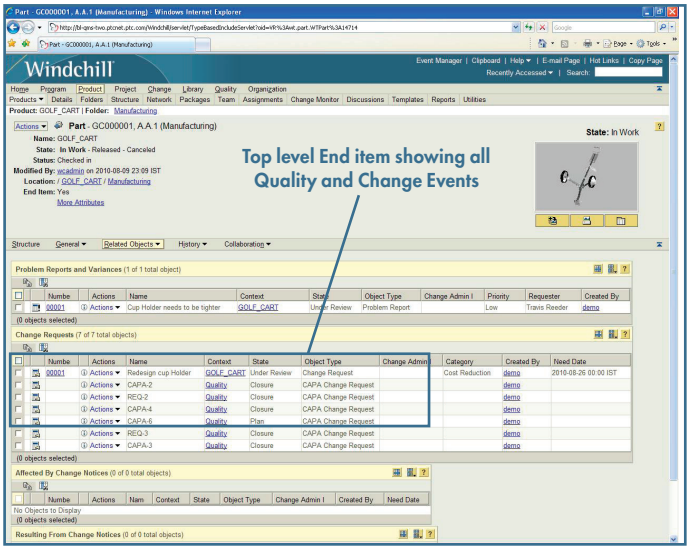

Figure 4: Top level end-items in Windchill reveal all CAPAs, as well as change requests.

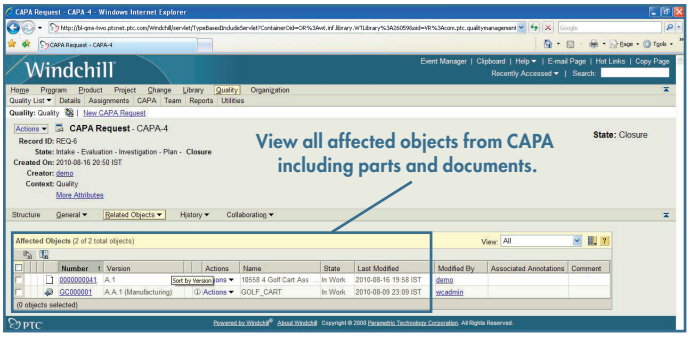

Figure 5: Windchill delivers easy access to relevant information, such as a list of all impacted items from a CAPA.