OPTIMIZING MEDICAL DEVICE DEVELOPMENT WITH FULL REGULATORY COMPLIANCE

OVERVIEW

In today's world, quality has been found to have a major influence on the market success and profitability of any new product. Customers can easily compare products and post opinions on any type of product from a simple sandwich, to a car, or to something as personal and highly regulated as a knee replacement. Assuring quality, reliability, and safety is an integral part of any product development process.

Companies can significantly reduce their time-to-market and costs while delivering the most innovative and compliant products by pursuing a cross-functional product development approach. To be most effective, quality should be managed early in the product development lifecycle and consistently throughout the entire process, using multi-pronged, collaborative methods. Quality information obtained in one lifecycle stage should be readily available to later lifecycle stages. Organizations must have proactive multidisciplinary strategies to strategically leverage regulatory information across the enterprise, mitigate risk and ultimately be innovative by providing sometimes lifesaving solutions to the market. Quality information must be highly visible throughout an organization to ensure that any and all decisions that may require quality data or impact product quality are informed in a timely, efficient, and accurate fashion.

This paper explores how medical device manufacturers, which are highly regulated and whose customers' lives depend on quality, must think beyond the limitations of point solutions for quality management solutions (QMS) and design management. When developing highly complex and regulated product with an increasingly global workforce and widespread network of contractors and suppliers, quality is often sacrificed in the name of profitability, or time to market – sometimes with disastrous results. There is a need to eliminate organizational boundaries in order to accelerate the release of new products to market. Unfortunately, companies often address product quality too late, using disjointed processes and technologies with inadequate cross-functional communication. Achieving product quality is a multidimensional challenge and failure to manage quality in an integrated way throughout the total product lifecycle jeopardizes a company's profitability and reputation.

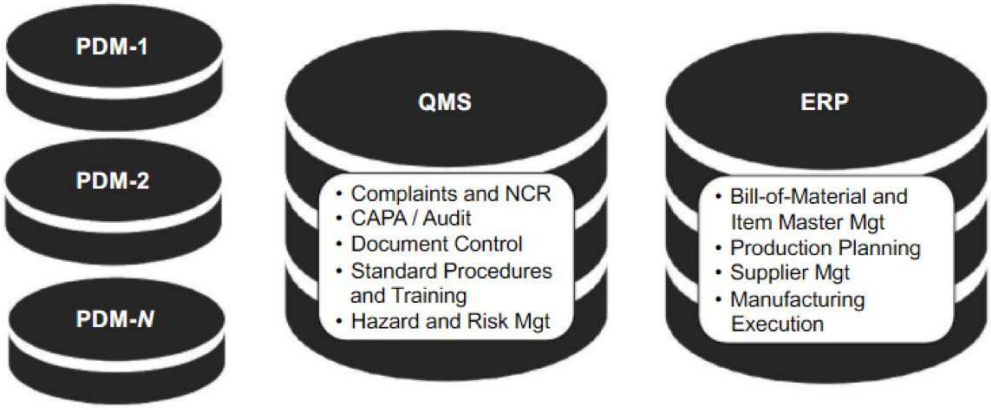

Figure 1:
Disconnected Technology Approach Commonly Found

In a perfect world, with real-time social monitoring solutions and global information platforms, every stakeholder within an organization would have a complete, accurate picture of product development, changes, and quality as it matures throughout the lifecycle. A "single source of truth" would provide insights to all stakeholders and connect top management with the critical information they need to make decisions that impact product development, quality, and reliability while assessing risks. Globally, across the organization, all personnel could clearly understand the product lifecycle status and the impact of their activities on product development and quality.

Integrating a quality lifecycle management solution within an enterprise business platform provides a formalized, systematic approach for managing all aspects of product quality, reliability, and risk. It uses methods that are fully integrated into the total product lifecycle development process and is highly visible to all personnel with a stake in product quality across all lifecycle stages, including:

- ***Optimized design controls*** for early insight into quality, reliability, and risk
- ***Optimized communication and reuse*** of design/device lessons learned

Platform-based PLM for Medical Device Manufacturers

Optimized Design Controls	Optimized Communication and Reuse	Embedded QMS Processes
• Requirements Management	• Reuse Proven Technologies	• Complaints and NCR
• Product Test and Simulation	• xCAD Management	• CAPA / Audit
• Systems Engineering	• xBOM Mgt and Production Planning	• Document Control
• Risk Analysis	• Single Unified Change Management	• SOP - Standard Operating Procedures and Training
	• Automated DHF, DMR, and DHR Reporting	• Hazard and Risk Management

Figure 2:
Medical Device Product Development Processes Covered by a Platform-based PLM Solution

A platform-based product lifecycle management (PLM) solution is an enterprise-wide, cross functional solution that can help ensure product performance, reliability, and safety over the course of a product's life. This unified "platform" approach manages quality, reliability, and risk planning into every part of the product lifecycle. Further, product functional characteristics are tracked systematically throughout development, validation testing, manufacturing, field use, and service to ensure product requirements are met at every lifecycle stage.

OPTIMIZING DESIGN CONTROLS

FDA regulation 21 CFR 820 Subpart C-820.30(c) describes how "design inputs" must be managed in a manner to ensure that "design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient." Importantly, the regulation also states that the "procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements." Therefore, the regulation does not require that requirements are only captured and managed. To fully satisfy this regulation, additional processes must be in place to make sure the requirements are fully verified and validated to optimize the intended application of the device.

Requirements Management for Mass-market and Specialization

Medical device manufacturers often have broad product lines based on a combination of build-to-order and configure-to-order business models (CTO). This means the requirements management process needs to address a combination of traditional product management for the mass market, and more complex sales engineering for custom devices.

Requirements for underlying device technologies need to be identified regardless of the business model. This often starts with an ideation process and some sort of market research that eventually results in formal product requirements. For a CTO device business model, unique customer needs within established technology constraints are usually communicated via a contract. Most companies have requirements management procedures that are appropriate for traditional product management, but are unable to properly handle the increasing specialization of the CTO business model.

As medical device specialization continues to increase, the requirements management procedures must be able to determine how customer needs can be fulfilled by product features that are configured in an end product. These product configuration rules are then exposed to sales engineering staffs, and even potentially to end customers, in order to build a device that perfectly matches the required application.

Requirements Validation through Simulation and Systems Engineering

Medical devices were one of the earliest products to combine all three engineering disciplines – mechanical form, electronics, and computing control – which is collectively referred to as a mechatronic product.

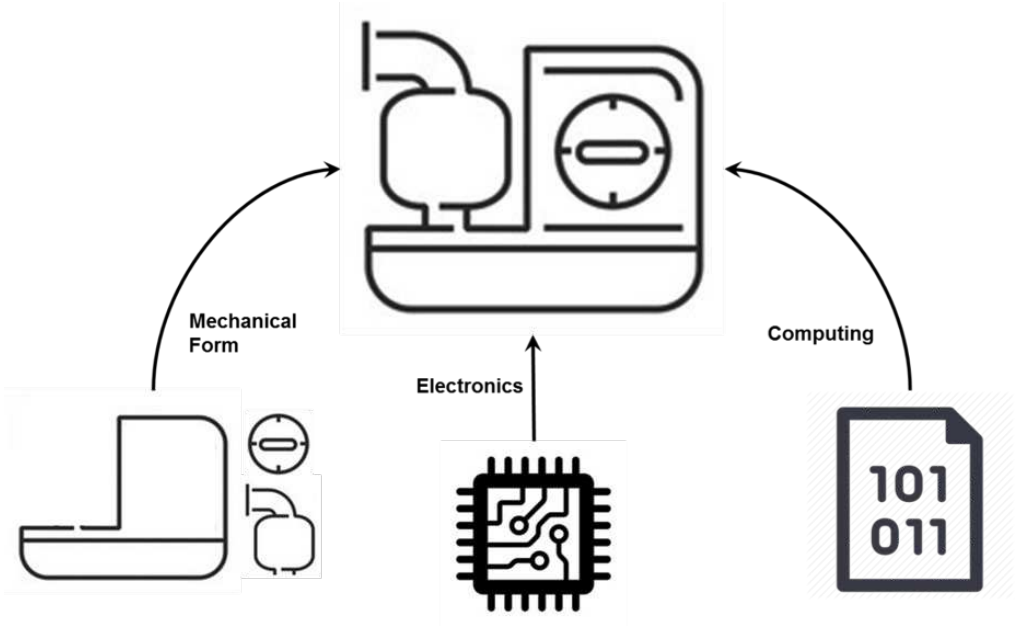

Figure 3:
Mechatronic Product Development

Yet, despite this product complexity, medical device manufacturers have been slow to adopt the simulation and systems engineering processes that define how these disparate design functions should would work together with one another to meet system requirements.

To properly manage product complexity, requirements definition for a medical device must include collaboration with multiple groups across the enterprise. It must be an iterative process with early conceptual design of the system's main functional modules, inputs, and outputs, and include virtual simulations to make sure the identified needs can be met within cost targets. The use of virtual simulations is an important, cost-effective way to repeatedly test and validate that the design is fulfilling requirements. Systems engineering allows the device manufacturer to properly plan how disparate engineering disciplines must interface with one another. Each are important technologies and methodologies that must be included in the medical device product development process.

Another important aspect of this early conceptual design activity is that it establishes traceability for how the customer needs are actually being fulfilled by the engineering design outputs. A platform-based PLM solution maintains data associations between (1) the stated requirement, (2) the product feature which fulfills the requirement, and (3) the actual design delivers the feature's intended functionality. This traceability allows both product management and development to assess the impact of proposed changes. For instance, engineers are able to assess if a proposed design change impacts how well a requirement will be met. In addition, a product manager is able to assess whether a new market or contract requirement causes designs to be re-worked or delay the product's delivery.

OPTIMIZED COMMUNICATION AND REUSE

Reuse Proven Technologies

Perhaps the best way to make sure requirements are fully realized and validated is to reuse past approaches that have been proven to meet the required need. When the traceability (discussed in the previous section) is combined with powerful search tools that use text-based pattern matching, the medical device product manager is able to easily locate past proven solutions and assess their applicability for upcoming product development projects.

Not only does this reuse of proven approaches reduce the risk of failing to meet regulatory and market requirements, the time and effort saved by this approach frees up product development experts to pursue new opportunities that may have been thought too costly to consider. As a result, costs for the "status quo" development activities are reduced, and there is potential to achieve faster market growth and increased revenues.

Optimize Medical Device Designs and Definition

When one thinks of medical device design and definition, the Design History File (DHF) specified within 21 CFR Part 820.30 and the Device Medical Record (DMR) specified within 21 CFR Part 820.40 immediately come to mind. Too often, medical device manufacturers focus on just the delivery of the DHF and DMR and not the underlying processes that generate their content. The consequence is that the regulations may be fulfilled, but the business may still suffer. In addition, standalone quality management solutions (QMS) are not able to sufficiently verify and validate requirements through simulation technology. Standalone QMS tools are deficient in two key areas when designing and defining medical devices:

1. QMS is incapable of properly managing the iterative, in-process designs from all mechatronic disciplines, which compromises how design intent is maintained. As a result, the DHF and DMR submission is a post-development "publishing" function prone to errors and omissions versus a natural result of the platform-based process.
2. QMS does not properly address how quality issues are often resolved through new product designs, which requires coordination between the corrective action preventative action (CAPA) and engineering change processes. A PLM-based platform approach is able to leverage quality issues throughout the product development process.

Maintain Design Intent for Manufacture and Regulatory Filings

As previously discussed, medical devices are complex mechatronic products and this complexity increases the challenge of communicating design intent to the rest of the organization. To properly address this complexity, medical device manufacturers require data and process management tools that span all design disciplines. The best solutions aggregate the different forms of design intent in a single coherent product definition and then extend the product definition with information to prepare for manufacture and service.

An example of how to maintain design intent when preparing for manufacturing is identifying which alternative (or substitute) parts can be used at specific plants to provide the same form, fit, and function of the primary part. For many companies, this could be considered an "ERP" function since it is supply chain related. However, in an effort to achieve high quality products, address product complexity, and deliver innovations more quickly, manufacturing processes must be planned and approved as part of the product engineering sub-process.

Newer technologies even allow medical device manufacturers to start defining their manufacturing routings or work instructions as the design proceeds. The complexity of a manufacturing process combining mechanical, electrical, and computing sub-systems must be addressed early in the development process. Of course, these routings must also include the key quality regulations that must be maintained during the manufacturing process.

Another important consideration for medical device manufacturers is the packaging and labelling of their products. Accuracy is paramount given proper use of these products as they often have life or death consequences. As such, while most industries can treat packaging and labelling as a separate process, the medical device manufacturer must make sure they are properly aligned with design intent.

By having a single system managing the full breadth of the medical device design and its manufacturing approach, it is now possible to assemble the DHF and DMR as product development activities and deliverables are completed. As content is created, vaulted, and reviewed by others, the system can cross-reference the content to be part of the DHF or DMR submission.

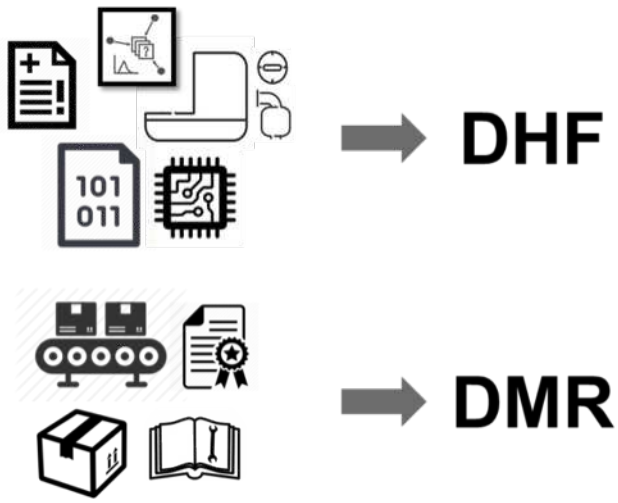

Figure 4:
Managing the Full Breadth of DHF and DMR Content

Unified Document, CAPA and Engineering Change Management

An enterprise-wide PLM platform that manages "change" processes is a mandatory business for every medical device manufacturer. Change managements has often been addressed by implementing a document control system with basic revision and version control. However, there are many limitations to this approach including the lack of product traceability. A QMS tool is sometimes implemented to expand beyond basic document control with basic non-conformance or quality issue identification functionality and then a CAPA process to investigate and resolve the issue. However, again, links to engineering, requirements, and product traceability is non-existent. Finally, a separate system is often implemented to manage design and engineering data. The result is three different technologies managing aspects of delivering a high-quality product to market and unnecessary costs to the organization.

Many medical device manufacturers now realize that their QMS and document control systems have created barriers with the product engineering function, especially when trying to resolve quality issues. To eliminate these barriers, PLM solutions based on an enterprise-wide business platform combine strong document control and CAPA processes with existing engineering change management, product requirement definition and traceability. This provides a "closed loop" quality methodology with a single unified change process that:

- ***Identifies*** the quality issue or non-conformance.
- ***Identifies*** the product changes that must be made to resolve the issue (and allows engineering to make that change within the 3D model within the platform, i.e., a living DMR).
- ***Assesses*** the business impact of making the proposed change.
- ***Monitors*** the product updates that must be made.
- ***Reviews*** the new changes.
- ***Coordinates*** the release of the changes to update standard operating procedures and regulatory documentation as needed.

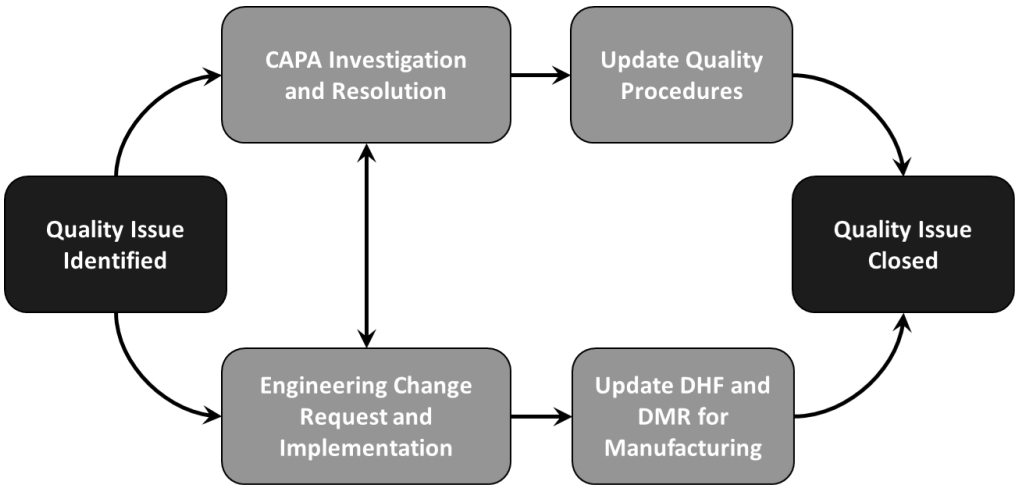

Figure 5:
"Closed Loop" Quality Methodology with a Unified Change Process

CONCLUSION

Medical device manufacturers were amongst the earliest adopters of software technology for managing and optimizing their product development processes. In order to address demanding regulatory guidelines for document control and quality, content management and QMS software was implemented. However, these disconnected systems are unable to evolve to handle the complexity of modern medical technologies and support ever-changing regulatory requirements and growing businesses. As a result, medical device manufacturers are now rethinking their product development approach and are looking for a business platform that supports the full total product lifecycle from ideation through manufacturing and post-market and shares quality information across the enterprise.

A platform-based PLM solution can unify the sub-processes of all stakeholders responsible for developing the medical device and meet quality regulations while delivering operational objectives of growing businesses. Instead of having a product development process hindered by technology silos, the platform breaks down organizational boundaries so companies can achieve the ultimate goal of increased patient safety while delivering innovative healthcare breakthroughs.