Total Product Life Cycle For Medical Device Industry Using Windchill PLM Modules

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Abstract

As a result of intense global competition, Medical Device manufacturers are finding they must boost innovation while facing some new and highly complex business challenges, including global product development, outsourcing of design and manufacturing, and the need to update product development technology. And, while dealing with these challenges, they must continue complying with strict regulatory requirements imposed by governing agencies around the globe.

The FDA's Medical Device Recall Report FY 2003 to FY 2012 shows that there has been a striking 97% increase in the number of recalls (FDA-Recalls). To reverse this trend, medical device companies should adopt new approaches that enable a greater focus on the quality of products; also, FDA's Medical Device Recall Report FY 2010 to 2012 states that recalls were due to design errors as well. Using a collaborative design system that can integrate quality, compliance and engineering teams from their silos and each team can view information more meaningfully for their role; also, this kind of system helps companies to shift from document-centric process to product-centric process.

In the collaborative design environment, there is an increasing demand for the exchange of information and sharing them to reduce lead time and to improve product quality. Software and communication technologies can be a proper approach in this context, for instance, PLM (Product Lifecycle Management) systems. Each product lifecycle development phase has lot of processes & technology and managing this learning can be

placed in a closed-loop system. In this paper, we present a detailed overview of how PTC's product suite (Windchill) helps to achieve the Total Product Lifecycle (TPLC) model product development system considering the medical device manufacturing industry as our case.

Keywords
Product Lifecycle Management, Closed Loop, Total Product Life Cycle, Windchill, and Medical Device.

1. Introduction
A significant problem that many Med Device makers are facing in product development began just two decades back. In 1997, the US Federal Drug Administration (FDA) introduced the 'Waterfall' model as an apparatus for presenting new product design controls. Although it's advantageous, practically speaking is restricted, numerous manufacturers keep on considering Waterfall to be the correct model for making sophisticated products. In recent years, however, these same regulators have encouraged device manufacturers to shift from this rigid model to the more suitable Total Product Life Cycle (TPLC) model.

TPLC encourages the functional and systematic interactions that are now critical in the design of each component and facilitates the cooperation required to break down functional silos. To ensure both business success and regulatory compliance within the TPLC process, however, device manufacturers must consider the use of an integrated Product Lifecycle Management (PLM) and Quality Management System (QMS), which now provides the framework necessary for success.

As the FDA and other regulatory bodies have embraced the idea of managing the total product life cycle (TPLC), Product Lifecycle Management (PLM) has grown to be a vital pillar for the medical device industry, supporting the device lifecycle.

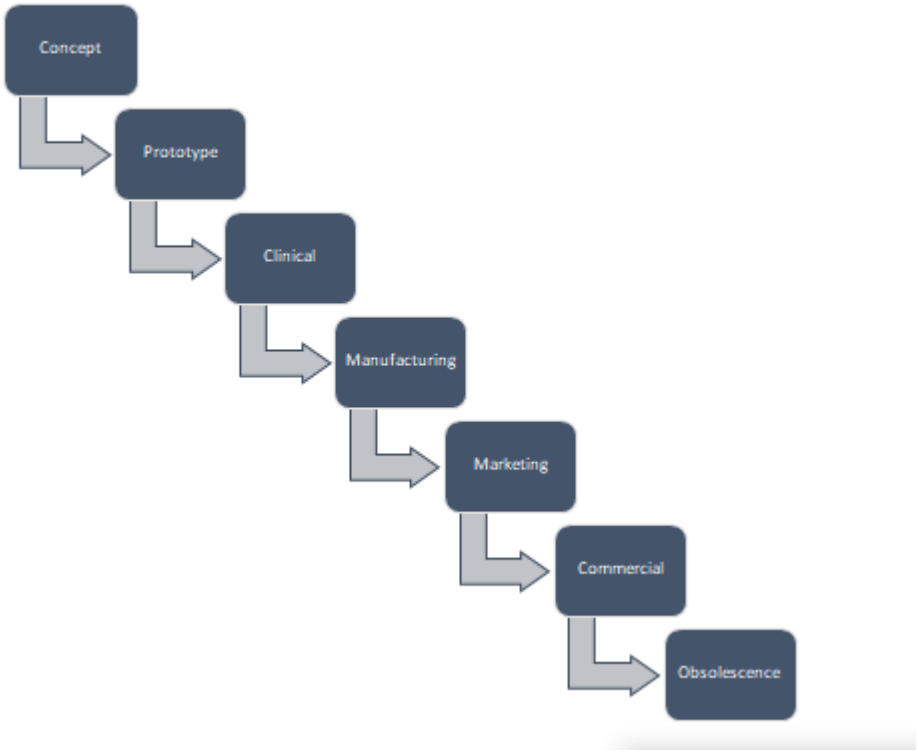

Figure 1. Stage Gate Process

Today many medical device manufacturers have deployed PLM systems. However, in many cases, these systems are regularly used only during the design and engineering phase, and not continued across the complete product lifecycle. PLM systems provide the ability to connect and integrate product information throughout the different stages of its lifecycle: from its design to production & testing, to post-market maintenance to retirement (Hribernik KA, von Stietencron M, Hans C, Thoben K-D), which can cause significant errors at each stage of product development, for example, product design errors due to which there could be several product recalls, from FY 2003 to FY 2012 FDA recall report suggested 97% increase in number of recalls, again during FY 2010 to FY 2012 recalls were due to device & software failures (36%), followed by faulty material or component (26%), errors in process control (17%) and errors in packaging & labeling (13%) (Beckers-Hospital-Review). The below figure shows the recent recalls since year 2013 (MedTech-Recall).

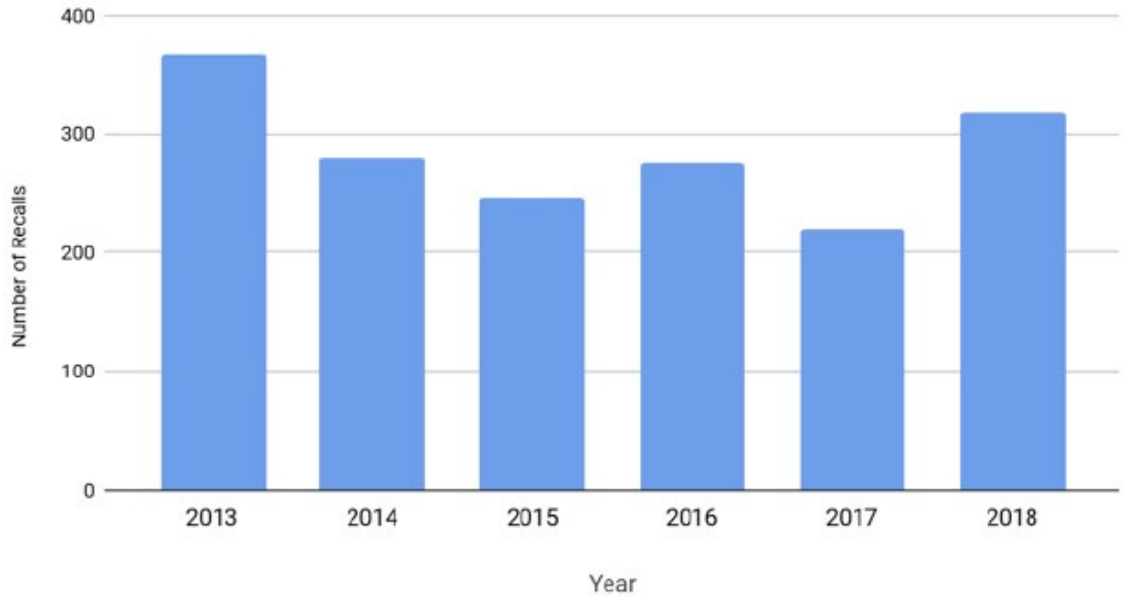

Figure 2. Number of Medical Device Recalls from 2013-2018

PTC Windchill is the smart, connected, and flexible PLM solution which we are considering that can easily integrate with all other PTC software and all primary CAD tools. It can relate to other enterprise systems and core applications and enables real-time collaboration between various teams such as quality, compliance and engineering teams to address the issues during every stage of product development and provide a meaningful context for their role and reduce the number of recalls that have been occurring due to disconnected systems and processes.

This whitepaper gives an in-depth look into the integrated PLM/QMS framework. It suggests how manufacturers can take a proactive approach to their product development at the same time, permitting transparent compliance with quality system and regulatory requirements. Discover how Medical Device manufacturers are enhancing product quality, reducing product and compliance risk, decreasing time-to-market, and improving product performance through an integrated Product Lifecycle Management system.

The paper proposes a TPLC model using PTC's Windchill suite of modules to improve the lifecycle of medical device manufacturing systems (PTC Healthcare & Life Sciences Lifecycle Solutions). Section 2 shows the theoretical background providing brief details on PTC's Windchill modules relevant for the medical device industry, while Section 3 describes the Closed Loop System Benefits. Section 4 presents one customer case study on how Windchill enabled the TPLC model. Finally, Section 5 concludes the paper, highlighting the next steps.

2. Theoretical Background

2.1 Medical Device New Product Development Process (NPD)

As discussed in the previous section, A large portion of a device's total product life cycle is occupied by product development from concept to marketing. The pathway to successful device development is cyclical and iterative as ideas are prototyped, tested, improved, re-tested, optimized and finalized. The device development pathway is a continuum with feedback loops and device modifications (Figure 3). Although portrayed as a compartmentalized process with distinct phases - such as pre-clinical and clinical - steps in device development overlap and portions may need to be repeated as testing and user experience are incorporated into product modifications and the device moves closer to its marketed form. And, product evaluations and modifications continue to occur even after a product reaches the market.

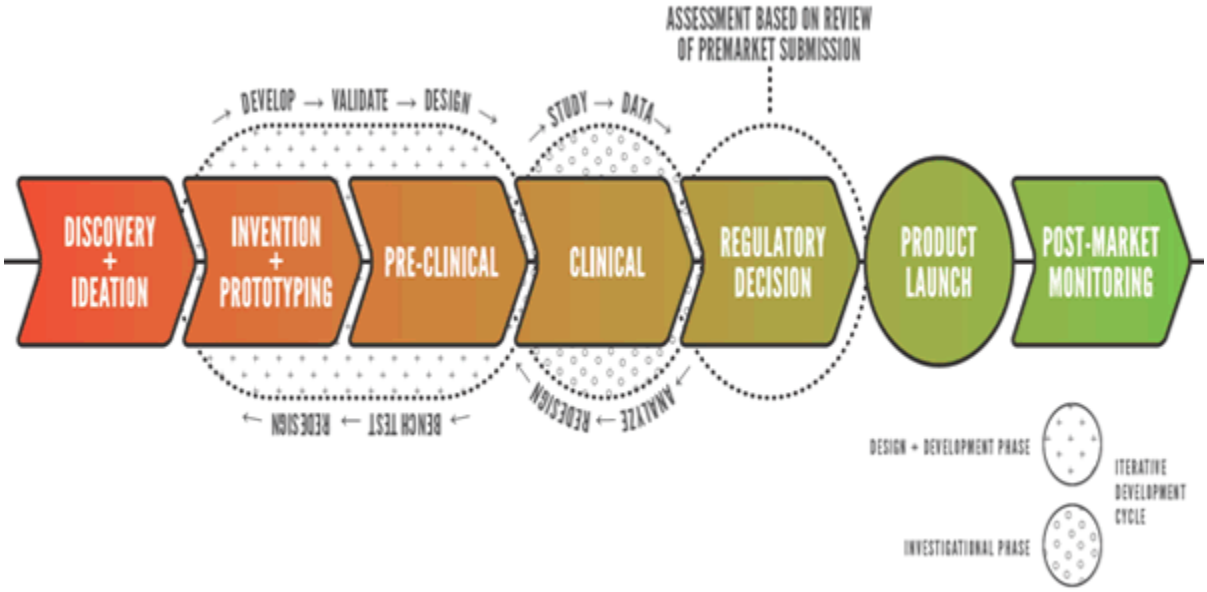

Figure 3. *The medical device development pathway from discovery and ideation to product launch and post-market monitoring is shown. The regulatory process affects a significant portion of the device development pathway and should accommodate the iterative, cyclical nature of device design and development. (FDA-CDRH Innovation)*

The above FDA medical device development pathway can be interpreted, as shown in Figure 4, against the product lifecycle phases and how a perfect close architecture (Jun, H-B. et al. "System architecture for closed-loop PLM.") can be envisioned. The close-loop PLM concept for medical device will have to shift from conventional document-centric to product-centric approach; when product/part and it's data are the foundation to achieve a common view that enables traceability across the product lifecycle from the patient, to requirements to design (Laplante, P.A.), test manufacturing & service, one can achieve more significant focus on product quality, high rate of reuse and reduced regulatory overheads.

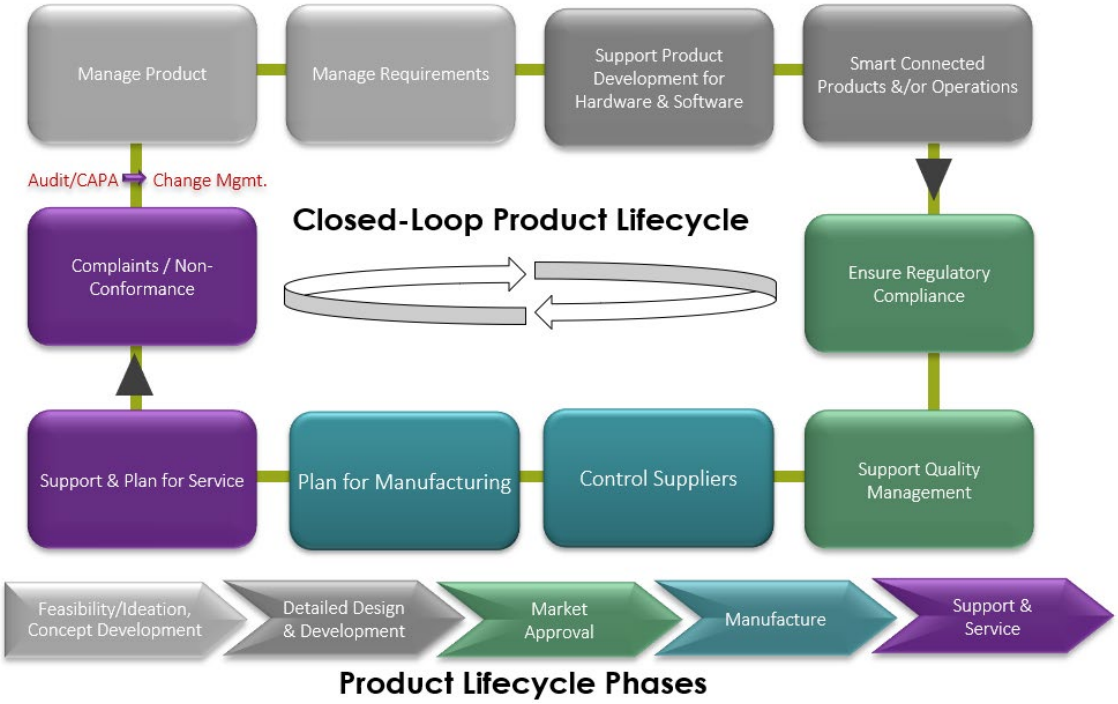

Figure 4. Closed-Loop Product Lifecycle with Lifecycle Phases

2.2 How Windchill Address ISO 13485 (QMS For Medical Devices)

In support of ISO 13485, which defines a closed-Loop lifecycle approach to product design, manufacture & service, PTC has developed industry best practices for the core quality solutions for managing the processes for Doc Control, Design Control, CAPA's, non-conformance, and complaints. Shown in Figure 5. is a partial list of critical capabilities within each process.

Windchill Product Quality is a complete platform for medical engineering innovation and quality. Purpose-built for medical device makers, Windchill Product Quality extends the industry's leading PLM solution with best-practice processes for managing design control, document control and product quality (PTC-Quality-Datasheet).

Designed for rapid time-to-value, Windchill Product Quality is available as a cloud-based SAAS offering with built-in validation. Other deployment models are also available.

Implementing any of these five medical device processes will make a dramatic, positive impact on an organization, and encourage confidence in the transformation along the digital medical engineering journey.

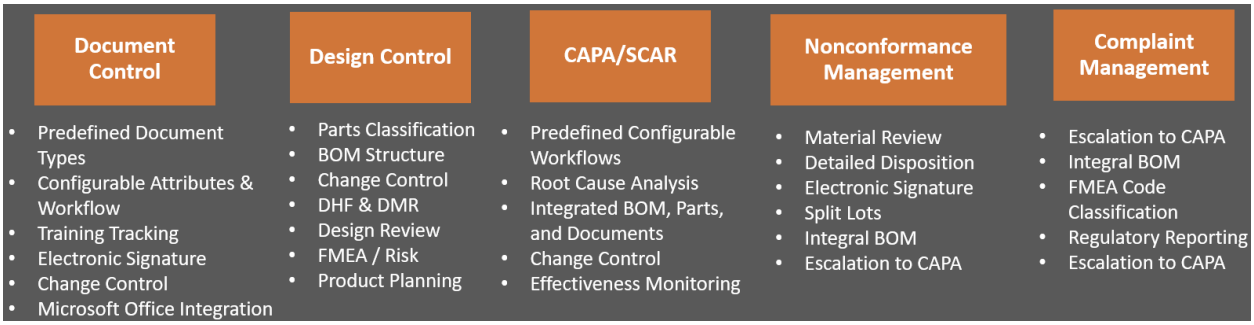

Figure 5. Windchill Regulatory Hub Modules

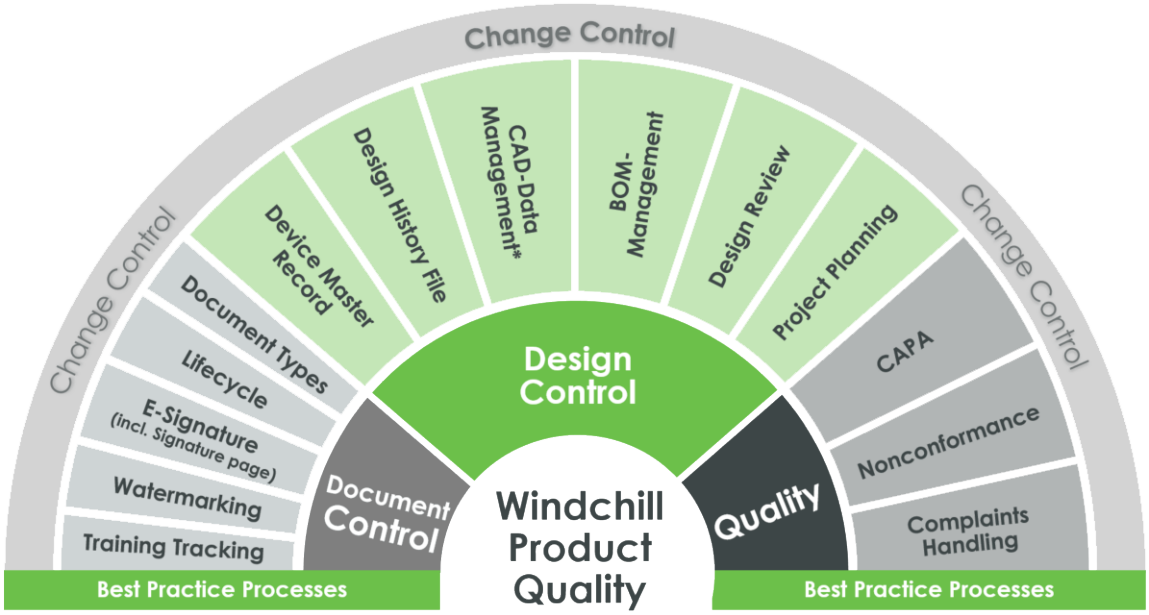

Figure 6. Windchill Product Quality Modules

2.2.1 Document Control

Windchill PLM system's Document Control enables easy creation, control, management and distribution of crucial corporate Standard Operating Procedures and policies in an inherent document control system. It helps ensure access and distribution of correct versions of documents to authorized and responsible entities.

It implements a standard ISO 13485 Document Control Process, 21 CFR Part 11 compliant (FDA Part 11), Provides Management Real-Time access to Reports, Training Records and Dashboards.

2.2.2 Design Control

On March 11, 1997, the FDA issued a document entitled: "Design Control Guidance for Medical Device Manufacturers." (FDA This Guidance document focused on critical issues associated with the Design Control requirements set forth in 21 CFR 820.30 and described the Waterfall Model (Figure 7) as a tool to illustrate the Design Control process.

Concerning the Waterfall Model, the FDA guidance clearly stated: "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."

In the absence of other information from the FDA, many Medical Device manufacturers interpreted the incorporation of the Waterfall Model in the Guidance as "gospel" and implemented their internal product development processes based on this one-dimensional model.

In the Waterfall approach, the design process is a simple sequence of unidirectional phases or stages which assure that each activity or phase has been completed acceptably before the next activity or phase can begin.

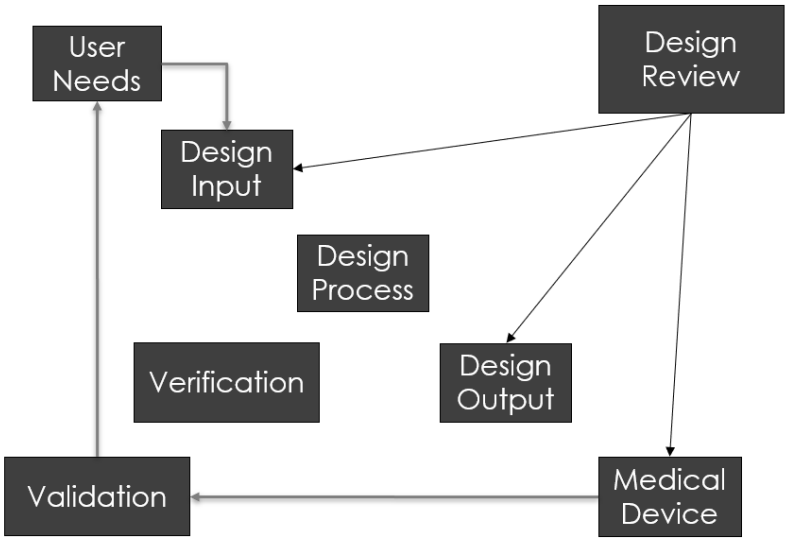

Figure 7. Waterfall Design Process By FDA

Windchill PLM system's Design controls designate the application of a formal methodology to the conduct of product development activities. It is mandatory (by regulation) to implement such practice when designing and developing products within the regulated Medical Device Industry.

Design Controls include most of the core PLM functionalities such as Bill of Information (Parts, CAD and Documents everything that represents/describe a product); some of the main capabilities included in the Windchill PLM system includes Implementing a standard ISO 9001 Risk-Based Design Control Process – NPI/NPD, Design Reviews, Creating & managing Design History File (DHF), Design Master Record (DMR) as per quality standards defined by ISO 13485:2016 using a pre-configured file to collect design information in compliance with 21CFR Part 820.30 Design Controls, Product Planning – Phase Gates, New part Introduction (NPI), Design Review – Formal, Informal and Parts Classification, Change Control, FMEA (Failure Mode Effects, Analysis).

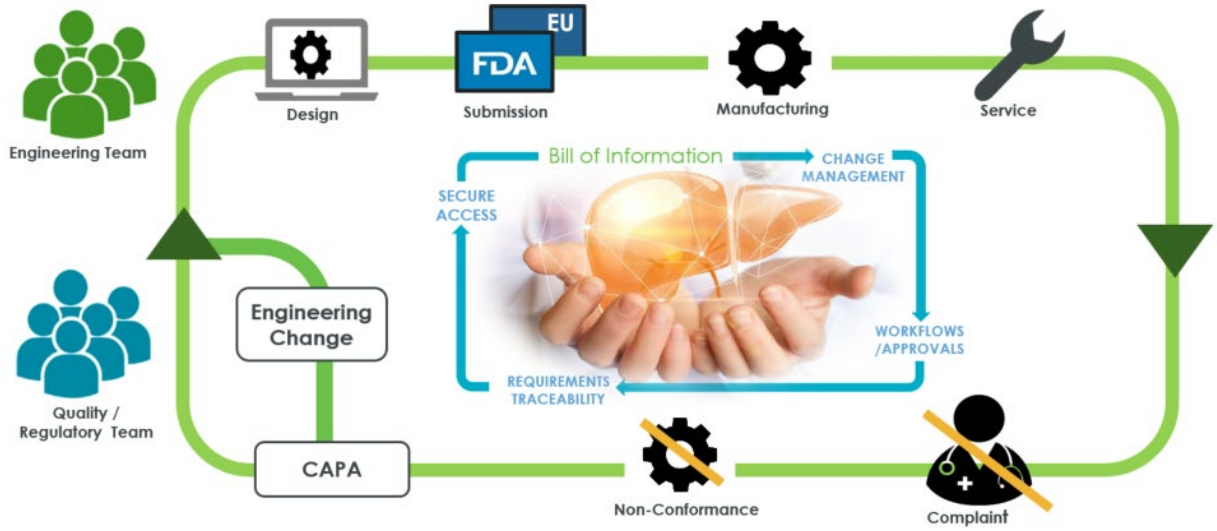

Figure 8. Best-In-Class Design Control Process by PTC

Windchill provides Best-in-class design control for medical device companies (Figure 8) ups the stake with post-market surveillance that is – once again, connected to the Bill of Information.
Post-market surveillance is also associated with the digital Bill of Information. Key benefits are Quality and Compliance records are always in sync– because they are controlled against the Bill of Information, Cross team visibility – all teams share the same information and Connected product performance measurements --quality inputs are collected and included in the full digital product definition.

It also allows companies to create connected medical products that automatically collect information on their performance and provide the design engineer with quality intelligence that enables measurement and accelerates improvement cycles.

2.2.3 CAPA/SCAR

Windchill PLM system provides a standard closed-loop Corrective and Preventive Action (CAPA) / Supplier Corrective Action Request (SCAR) process for the investigation, root cause analysis, corrective/preventive actions (Cline, Brad, and Ken Stillwell.), and close-out of quality issues from across the product lifecycle, ensuring visibility between product data and its associated quality information.

Main capabilities included in the Windchill PLM system related to CAPA/SCAR are Fully integrated with Windchill core Change Control to reduce scrap & reworks, create auditable change records, Rapid entry access for quick CAPA capture, Standard ISO 9001 CAPA process Pre-Configuration (Automatically generate Change Notices, Integrated BOM, Predefined but Configurable Workflows, Part & Documents, Link all quality inputs [design history, Complaints, etc.], Multiple Independent action threads for complex CAPAs and Root Cause Analysis) and Integrated Reporting & Effectiveness Monitoring

2.2.4 Non-Conformance

The Windchill Nonconformance Management best practice is a closed-loop non-conformance (NC) process. A compulsory quality process that enables companies to capture and process all types of internal - product, material and process non-conformances.
The NC procedures shall address the identification, documentation, evaluation, segregation, and disposition of the nonconforming product. The assessment of non-conformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the non-conformance.

Main capabilities included in Windchill PLM system-related Non-conformance are 21 CFR Part 11 compliant "Use as is" (FDA Part 11), Standard ISO 9001 Nonconformance process (Material Review Board [MRB] sub-workflow process, Detailed Disposition [i.e., Scrap, Rework, return to vendor], Split Lot Disposition [i.e., disposition by the portion of the lot], Integrated BOM – attach to any Item in BOM, Capture Immediate Corrections) and Automatic Escalation to CAPA for improvement

2.2.5 Complaints

FDA defines "complaint" as any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution. The ISO 13485:2016 definition is very similar.

Windchill helps customers to Implement a standard closed-loop Customer Experience Management process. Support intake, reporting and capture of external quality information such as customer feedback, field product experiences, and customer complaints.

Main capabilities included in Windchill PLM system related Customer Experience Management module (CEM) are Integrated BOM and FMEA Codes (Classify failures using FMEA Codes against any level of BOM, Record as reported observations using FMEA effects codes, Record as Investigated codes using Failure Modes), Pre-Configured Sub Workflows for Action Steps: (Return Product Analysis, General Follow-up Actions, Regulatory Safety Reporting eMDR, EU Vigilance, Canada, etc.), Automatic Escalation To CAPA and Pre-Configured ISO 13485 Customer Feedback Process.

3. Closed-Loop System Benefits

The benefits of introducing the concept of (total) product lifecycle management to medical device manufacturers are enormous, but in practice, unfortunately, under-estimated. Benefits include Improve product quality, Increase productivity overall, Faster time-to-market, Single source of truth across the complete supply chain, Maximize supply chain collaboration, Manage configurations & version control, Reduce prototyping costs, Lower cost of new product introduction, Lower field maintenance & warranty costs, Simulate field maintenance processes to optimize real sequences & reduce downtime, Streamline regulatory compliance & audits and monitor safety procedures, Insight into critical business processes and Real-time reporting and analytics.

Medical Device manufacturers will need to include and implement PLM features in all aspects of manufacturing including Nonconformance Management, Customer Experience Management (CEM), Corrective and Preventive Action (CAPA), Risk & Reliability / Service Management, Audit Management, Unique Device Identification (UDI)

Certainly, as the regulatory focus shifts from compliance to quality, the reduction of corrective actions in favor of preventative measures is essential to building in quality at the early design stages of the product lifecycle. Failures and root causes must be evaluated to prevent reoccurrences.

In the design and development of medical devices, the FDA's "Case for Quality" (FDA-Case for Quality) initiative calls for manufacturers to ensure the highest levels of device quality and safety throughout product design, manufacture and service. The complex and advanced technology inherent in today's medical devices and their production means that all aspects of the system–including mechanical, electrical, software, and hardware–must be carefully controlled throughout the product development lifecycle in accordance with strict worldwide regulations and standards.

PTC has an array of solutions in PLM / Manufacturing, Digital Transformation, IoT and AR. PTC's PLM solution (Windchill) is combined with the Quality Management System (QMS) capabilities to accelerate product innovation and to maximize product profitability and reduce compliance costs. It delivers a "single source of truth" for business processes, product data and content across enterprise functions and locations. Best practice processes, specifically for medical device manufacturers, are pre-configured in the solution. PTC also has a Validation Accelerator Pack to assist in the software's compliance with FDA regulations for the design and development of safe, effective medical devices.

The value of these types of systems is most effective with closed-loop lifecycle management of the product or the medical device. Research from medical device manufacturers that are using closed-loop processes shows that there is approximately a 75% time-savings in release management. Apart from the benefits mentioned above, such as cost reduction and quality improvement, it is, in the end, the patient that benefits from better outcomes.

Another vital element is that the number of recalls per year can be significantly reduced by using a closed-loop PLM solution to introduce new or updated medical devices into the market. A closed-loop solution provides full visibility, including quality control and product service components from design to operations.

Below is a sample benefit metrics provided by CIMdata based on their research (CIMdata-how to claim the benefits of PLM)

Table 1. Sample Benefit Metrics for PLM

Benefits	Actual Experience
Time to manufacturing	10% to 50% reduction
Engineering change process	10% to 70% reduction
Design review process	50% to 80% reduction
Increased productivity	10% to 20% increase
Product development costs	25% to 40% reduction
New part numbers	5% to 15% reduction
Time to find information	75% to 90% reduction
Design errors	10% to 25% reduction
Time to design	15% to 70% reduction

Travel cost for design	20% to 35% reduction

4. Case Study

The global medical device manufacturing company has achieved a globally harmonized, comprehensive closed-loop solution.

PLM system implemented to support all of the customer's global business units. When fully deployed, the customer estimates its return on investment at $20 million per year. The customer is also a significant IoT user, with over thousands of devices and over 50,000 connections in the market.

Product Lifecycle Management (PLM) is comprised of standard processes, people interactions and an enterprise information system that enables and integrates across the product lifecycle to deliver mature PLM capabilities across the enterprise.

Customer is investing in several strategic platforms to improve innovation capabilities across the global organization. Product Lifecycle Configuration Management, Regulatory Compliance, Innovation Volume and Velocity, and being a Globally Integrated Company are the pillars of the overall effort.

Customers chose PTC as their Single Source of Truth and will consolidate 14 PLM systems into 1 over the course of the next few years.

The strategic decision to use PTC's Medical Device solution is the foundation for future customer success.

5. Conclusion

Medical device manufacturers are focused on developing high-quality products and services aimed at improving patient outcomes. By adopting and correctly implementing a PLM system, businesses can make quicker and better decisions while expediting innovation, which in turn can result in a faster time to market. Due to increased product sophistication and complexity of medical products, closing the production development process loop throughout the development lifecycle has become vital for medical device manufacturers.

Using better products that satisfy the necessities of medical institutions with the growing need for quality, finally benefits the patients!

As the FDA will increase its emphasis on a Total Product Life Cycle (TPLC) model, those Medical Device manufacturers running within an integrated Product Lifecycle and Quality Management infrastructure could be capable of meeting even the strictest requirements for product manufacturing.

Besides, an incorporated Closed-Loop PLM/QMS framework permits companies to take a proactive way for product development while facilitating clear compliance with quality system and regulatory requirements. This integrated framework will permit Medical Device manufacturers to fulfill tomorrow's toughest business challenges while reducing time-to-market, enhancing product performance, and lowering compliance costs.

PTC (www.ptc.com/plm) is one of the leading software vendors providing integrated, internet-based solutions around product lifecycle management and digital 3D design. They provide field-proven IoT and AR solutions, which are bringing together the physical and digital worlds to "reinvent" the way businesses create, manufacture, operate, and service products. PTC has created a new way of deploying Digital Engineering Transformation for more insight into the product lifecycle and better overall outcomes.

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Biographies

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He has vast experience in industries such as Automotive, Consumer Services, Consumer Goods, Electronics/High Tech, Medical Device, Engineering Services. Mr. Srinivas has provided system design and PLM architecture to Ashley Industries, Philips Healthcare, Kohler, CAT, ZF-TRW, Flextronics and Terumo BCT. His areas of interests include PLM process optimization, reliability, manufacturing process optimization, IoT, and lean.

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