# Managing the Total Product Life Cycle

## The Changing Face of Medical Device Product Development

## Executive Summary

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 tough issues, they must continue complying with strict regulatory requirements imposed by governing agencies around the globe.

The most pressing issue that many Med Device makers are facing in product development started just over a decade ago. In 1997, the US Federal Drug Administration (FDA) presented the 'Waterfall' model as a tool for introducing new product design controls. Although its usefulness in practice is limited, many manufacturers continue to see Waterfall as the de facto model for creating complex devices. 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.

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

## Regulatory Framework

To ensure that Medical Devices are designed using practices of the highest quality, the Food and Drug Administration introduced Design Control requirements in its Quality System Regulation (21 CFR Part 820). As a result, Design Controls are irrevocably linked to an organization's quality infrastructure and the Quality Management Systems used to support them.

Design Control principles are at the core of meeting quality system requirements for the design and development of Medical Devices. However, ensuring the necessary level of control during every phase of the product lifecycle (Figure 1) is contradictory to the free flow of ideas typically associated with the development lifecycle.

On March 11, 1997, the FDA issued a document entitled: "Design Control Guidance for Medical Device Manufacturers." This Guidance document focused on key issues associated with the Design Control requirements set forth in 21 CFR 820.30 and described the Waterfall Model (Figure 2) as a tool to illustrate the Design Control process.

With respect to 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 provide assurance that each activity or phase has been completed in an acceptable manner before the next activity or phase can begin.

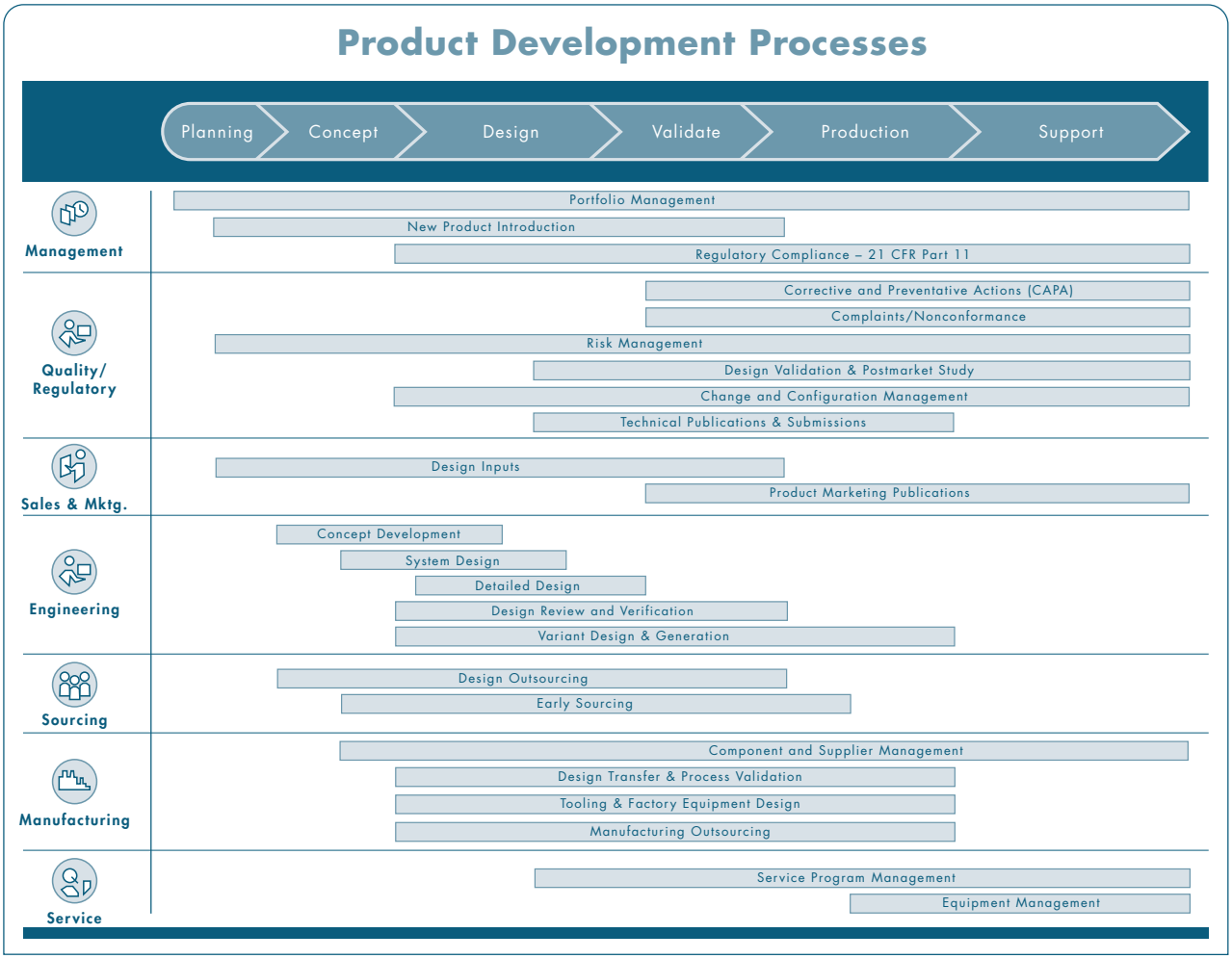


Figure 1. Medical Device Product Development Landscape showing 1) the processes in which most companies engage when developing new products, 2) the stages through which a product advances (horizontal axis on top), and 3) the functional departments responsible for each stage (left vertical column).

Here's how the Waterfall Model works: At the outset of development, requirements are developed and approved. The device is then designed to meet those requirements. Next, the design is evaluated, transferred to production, and finally manufactured and tested to ensure compliance with specified standards. Using the Waterfall Model, the only feedback loops are Design Reviews at the completion of each phase in the process. Unfortunately, Design Reviews are often viewed as obligatory gates to the next phase rather than opportunities to share feedback to improve the product.

In practice, this rigid, sequential and unidirectional model is void of continuous feedback paths for the individuals and departments responsible for each phase. The result: you have a 'reactive' approach to product design, quality and compliance.

In response to this strict adherence to the Waterfall Model, Al Taylor, Director of the Division of Electrical and Software Engineering Office of Science and Engineering Laboratories and a primary contributor to the Design Control Guidance, recently stated :

"Subsequent to publication of the Guidance document, a lot of people have told me that they interpret this diagram as FDA's endorsement of the Waterfall approach to design–this, in spite of the fact that the Guidance document talks explicitly about the use of concurrent engineering and other models of design process."

Despite comments such as these, the industry has continued to follow the Waterfall Model nearly a dozen years after it was first introduced.

At the same time, regulatory scrutiny of device manufacturers is ever-increasing. Companies must demonstrate compliance with the Quality Systems Regulations, which in many instances translates into documenting actions and decisions. Today, the CDRH's Quality Systems Inspection Technique (QSIT) document contains well-defined guidelines for FDA inspectors regarding how to conduct an inspection, with Design Controls and CAPA being two of the four subsystems guaranteed to be interrogated during every visit.

To ensure compliance, Medical Device manufacturers today need a truly closed-loop, integrated change control and quality management system, which will help ensure proper traceability between quality events and engineering activities such as engineering changes and risk assessments.

## Total Product Life Cycle (TPLC)

Another factor contributing to the 'reactive' approach to product design and quality is the existence of 'silo'ed' development processes that are anything but integrated. This problem is compounded by the fact that many departments utilize separate and distinct systems to support their functional needs. These systems include:

- Requirements Management
- Software Source Control Management
- Mechanical Computer-Aided Design (MCAD) Data Management

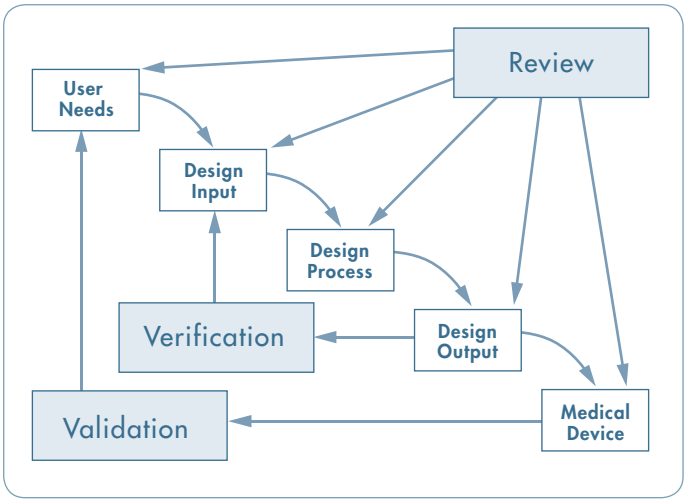


Figure 2. Waterfall Design Process

- Electrical Computer-Aided Design (ECAD) Data Management
- Portfolio Management
- Laboratory Information Management (LIMS)
- Document Management System (DMS)
- Clinical Data Management System (CDMS)
- Submission Management and Publishing
- Quality Management System (QMS)
- Inquiries and Adverse Event Reporting (AERS)
- Learning Management System (LMS)

This plethora of systems, in conjunction with limitations of the Waterfall Model, has necessitated the development of a corrective, action-centric approach to product design and development. When a product doesn't conform to the requirements in this 'reactive' environment, the manufacturer initiates Corrective and Preventive Action (CAPA) and frequently assembles a team of the best and brightest minds within the organization to correct the issue and close the CAPA as expeditiously as possible. These teams frequently implement changes to minimize the incident's recurrence, often in the form of updated procedures or operator retraining.

Although Corrective Actions (CA) are critical in identifying, isolating and resolving the source of an existing non-conformity, CAs are, by definition, reactive in nature. In many companies, the metric for the successful completion of a CAPA is the amount of time it takes to "close" it. In this environment, an open CAPA is viewed as a demerit against the responsible CAPA owner. This focus on closing CAPAs can diminish the intended benefit of the requirement (i.e., getting to the root cause of the non-conformity and preventing its recurrence).

In recent years, regulators have further encouraged device manufacturers to transition away from the rigid Waterfall Model to the more suitable TPLC model (Figure 3), which states that the stages of a product must not only overlap, but they must also be connected. As well, information learned in one stage of one product must be applied to future products that a company develops. TPLC represents the centerpiece of the Center for Devices and Radiological Health (CDRH) Strategic Plan in which the stated vision is: "Ensuring the health of the public throughout the Total Product Life Cycle – it's everyone's business."

### Proactive Product Development

The TPLC model is more representative of a design process in which product development is iterative and incorporates both the required interactions between stakeholders, as well as the contribution and input of every group involved in the development process.

A TPLC approach focuses on sharing information throughout the different product lifecycle stages, and by extension, between different departments. TPLC also encourages the use of Preventative Actions over Corrective Actions, an approach that shifts focus away from rapid event closure in favor of developing solutions that prevent the occurrence of a problem in advance of its manifestation.

Preventive Actions often involve the continuous monitoring of processes that affect the design and production of a product to ensure that they are properly documented, executed and reviewed. Medical Device manufacturers must concentrate on reducing the sources of variability – which lead to Corrective Action – in favor of a proactive approach to product design and quality.

For example, device development teams should conduct DOEs (Design of Experiment) to determine critical process parameters and establish process set points, as well as upper and lower control limits. Next, the team should thoroughly exercise the manufacturing process by producing parts made at the extremes of the process settings to ensure adherence to acceptance criteria. Should the product fail to meet specification, Preventative Actions should be taken to modify either the product or the process until acceptable results are obtained. In the true spirit of TPLC, the knowledge gained during these exercises must be transferred to Manufacturing to help manufacturing engineers and quality engineers better understand the process.

In order to be proactive, device manufacturers must seek out technology solutions that not only archive and manage data, but also facilitate the sharing of product and process data throughout the enterprise, including Development (mechanical design, electrical design and software design), Manufacturing, Sales, Marketing, Quality and Regulatory. It is extremely difficult to assess the impact, and then execute, a change when each department stores important product and process information in separate, disconnected systems.

Quality, clinical and field use data must play a key role in the Product Development process, as well as support Quality by Design initiatives.

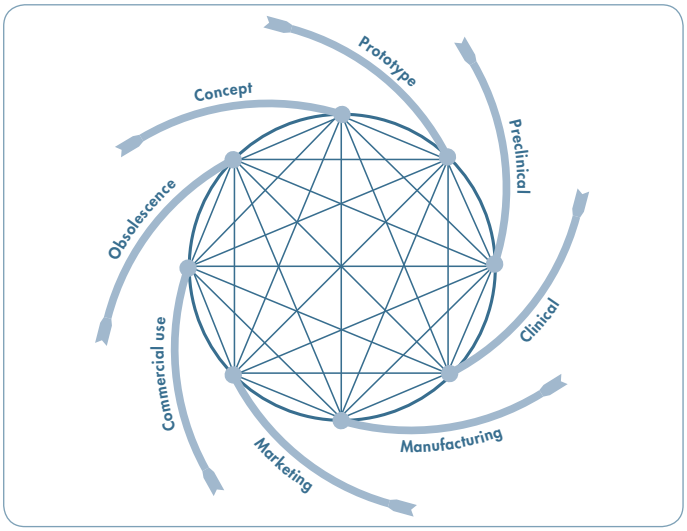


Fig 3 Total Product Life Cycle (TPLC) model created by FDA's Center for Device and Radiological Health (CDRH).

These sources of data provide critical inputs that give designers visibility into variables that are not often available if information resides in isolated quality or study management systems.

Consider a scenario in which a design engineer is tasked with changing a part either to improve performance, add functionality, or reduce cost. Upon accessing the part from the global repository, the engineer can view a complete history of all changes, nonconformances, complaints and CAPAs associated with the part – in the true spirit of TPLC (See Figure 4). No doubt, the new design is sure to incorporate lessons learned throughout the part's life, thus helping to reduce the risk of failure and/or to improve performance. Contrast this scenario with one in which the new design is based solely on a collection of filtered user requirements translated into design inputs. In the former, the additional information, made available to the engineer in an integrated QMS-Product Development System, provides a rich history to aid in the redesign of the item.

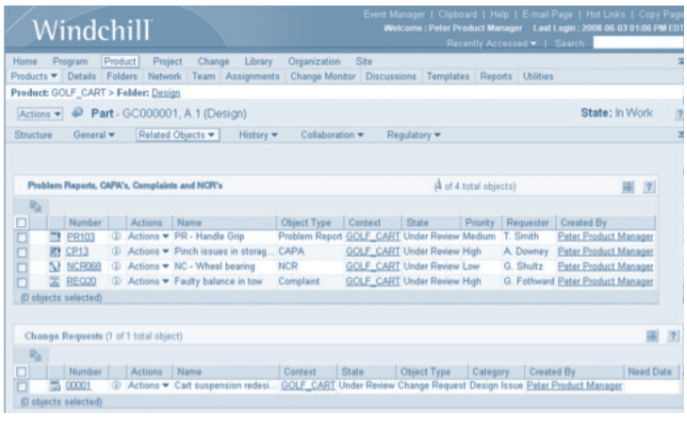


Figure 4. Notice how quality events associated with the object, such as CAPA, Complaint and Nonconformance, are displayed.

## Integrating Systems and People

Today's PLM (Product Lifecycle Management) software systems have become key enablement tools that are helping manufacturers and their suppliers solve design and quality challenges – along with their associated visibility and traceability issues. With the increasing popularity of outsourcing, it is the underlying coordination, integration and visibility that is most critical to how well any given product is designed.

It is difficult, if not impossible, to manage the Total Product Life Cycle using disconnected and unstructured systems and processes, as shown in Figure 5. Without an integrated system that can be accessed from anywhere in the world (that is, web-based), it can be challenging for a product designer to ascertain the impact that an engineering change may have on other components, assemblies or sub-assemblies.

A better solution is to work within an integrated, closed-loop product development and quality system. With the complexity of today's products, and with the rise of outsourcing, Product Lifecycle Management (PLM) systems and the management of data and knowledge, are now critical to Medical Device manufacturing.

With the current move away from "testing quality into products" to a more proactive strategy of "designing quality into products and processes," the ability to control the total product lifecycle process has become a critical factor to ensuring product quality. An integrated Product Development/Quality Systems Management system – as represented in Figure 6 – provides a solid foundation to achieving this goal.

## Implementing TPLC

To reap the benefits of Total Product Life Cycle (TPLC), device manufacturers must implement an integrated Product Lifecycle Management and Quality Management solution. This technology framework enables organizations to bridge rigid process structures and to connect dispersed functional areas into highly efficient, fully integrated teams. Consider the following real-world scenarios using an integrated PLM/QMS solution:

1. **Product Manager creating design inputs.** The Product Manager, responsible for creating design inputs for a product-line extension, is able to produce a report from the Quality Management System that lists all the customer feedback, along with all the product trends to be considered as future design inputs. With this information, the Product Manager can create a more complete and practical set of requirements.
2. **Development Engineer designing next generation device.** In addition to reviewing design inputs from product management, the Engineer must review previously identified complaints, non-conformances, and CAPAs attributed to the current product, in order to improve quality and performance in the new product. Here, the Engineer is able to access results of post-market studies that contain important input from end-users.
3. **Quality Engineer requesting change.** In this scenario, a CAPA has been created in response to a series of nonconformances and complaints. Instead of being forced to "open the loop" and transfer information regarding a required change to a co-worker who, in turn, will initiate a change request, the Quality Engineer can initiate the change request directly from the CAPA system, ensuring the request is made accurately and in a timely manner.
4. **Manufacturing Engineer issues ECN.** When the change control process is completed, the ECN number can automatically be added to the CAPA record, thus ensuring complete, end-to-end traceability.
5. **Supplier Quality Engineer conducts impact assessment.** Upon receipt of a nonconformance describing an out-of-specification situation for a raw material, the Supplier Quality Engineer can immediately run a "where-used" report directly from the QMS system, to quickly assess the impact of the nonconformance and determine if raw materials, WIP or finished goods must be quarantined. Additionally, the Engineer can assess the impact on current design control projects, as encouraged in the TPLC model.
6. **Complaints Manager conducts impact assessment.** Upon receipt of a complaint, the complaints manager searches the product information stored in PLM directly from the QMS system to determine both the effectivity of the particular design, as well as a complete change history for the item.
7. **EVP Quality, Clinical and Regulatory ensures appropriate regulatory reporting of product-adverse events.** Knowing when and what to report to regulatory authorities is often a challenge. An integrated product development, quality and study management system uses decision trees – in conjunction with sophisticated monitoring, tracking and trending algorithms – to ensure accurate and timely regulatory reporting.
8. **IT Director reduces efforts supporting multiple, disparate systems.** A vendor-supported, integrated product development, study and quality management system relieves the IT department's burden of creating, supporting and maintaining expensive custom integrations.

In all these cases, the integrated PLM/QMS solution enables a more rapid, more accurate, and more complete assessment and transfer of information, thus leading to reduced risk and improved quality.

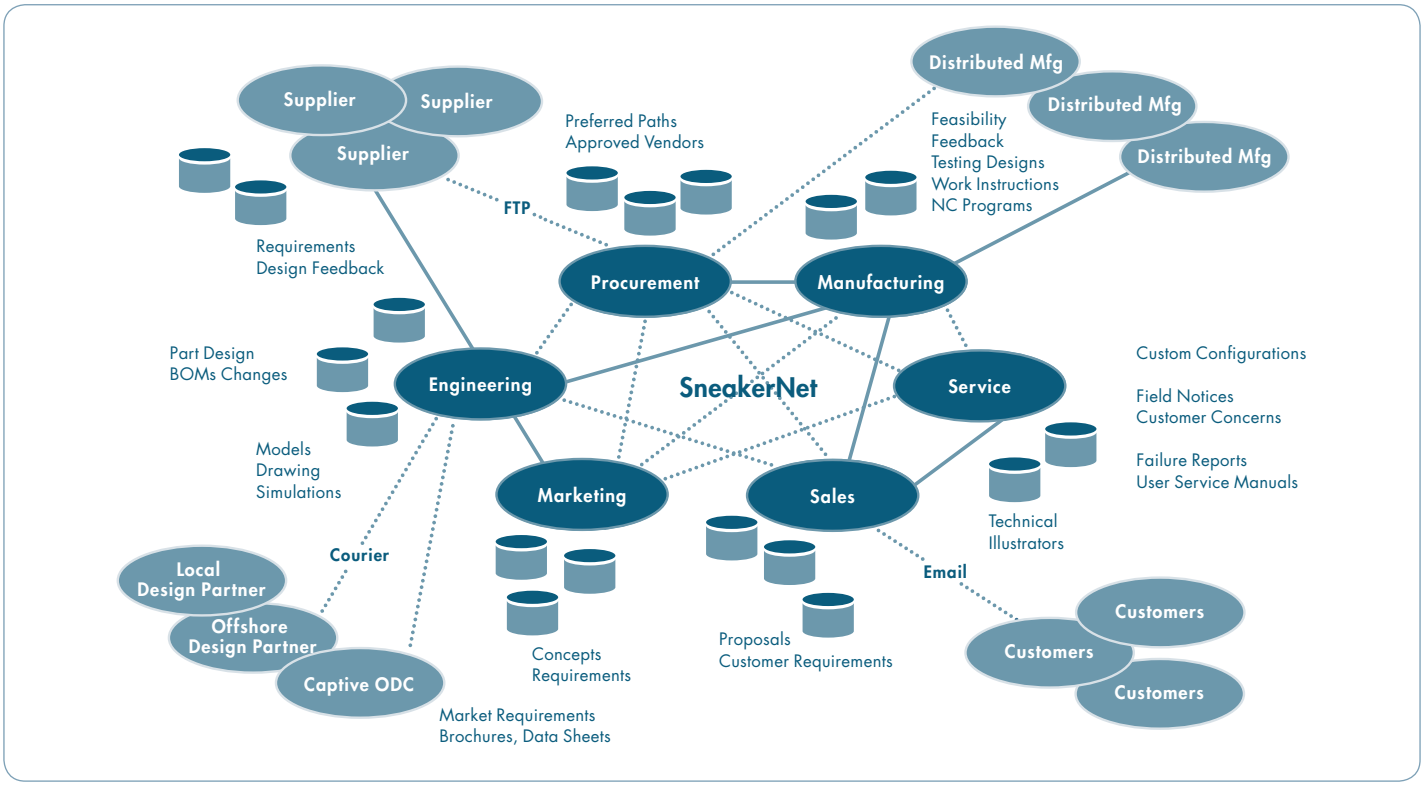


Figure 5


Figure 6

## Conclusion

The rapid pace of advancement in medical technology has thrust product innovation to the very forefront of competitive advantage. As a result, Medical Device manufacturers are faced with a new set of challenges associated with having to develope increasingly complex products while working with antiquated processes and facing intensely competitive markets.

Yet, while manufacturers are pushing the innovation envelope, at the same time they must ensure compliance with strict regulatory requirements imposed by Medical Device enforcement agencies around the globe. Unfortunately, yesterday's rigid and compartmentalized Design Control systems make it difficult, if not impossible, to keep up with the rapid pace of innovation.

By replacing disparate, stand-alone product development applications with a cohesive Product Development System, manufacturers can ensure that the right version of the product data is available to the right people at the right time. This efficient and convenient storage of product information, coupled with the ease of its retrieval, and the ability to better manage changing information, are just a few of the advantages of an integrated platform for Product Development and Quality.

As the FDA increases its emphasis on a Total Product Life Cycle (TPLC) model, those Medical Device manufacturers working within an integrated Product Lifecycle and Quality Management infrastructure will be able to meet even the strictest requirements for product development.

In addition, an integrated PLM/QMS framework enables organizations to take a proactive approach to product development while facilitating transparent compliance with quality system and regulatory requirements. This integrated framework will allow Medical Device manufacturers to meet tomorrow's toughest business challenges while decreasing time-to-market, improving product performance, and reducing compliance costs.

**About PTC**

PTC solutions for life sciences are designed to meet the product lifecycle management requirements of Medical Device manufacturers. PTC solutions, which include a single, global repository for all product and process information that links product development, quality systems management, and study management, help companies hard-wire compliance, improve product quality, and increase speed-to-market.

PTC serves over 500 Medical Device customers, including the top manufacturers across the globe. For additional information on the PTC Product Development System for Life Sciences and Medical Device manufacturers, please visit: **PTC.com**

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