Meeting FDA Standards For Medical Device Quality: An Out-of-the-box PLM Approach

PTC’s Medical Device Value-Ready Deployment™ Offering: Overview
“Companies perceive that the regulatory framework is misaligned with assurance of quality outcomes, in that compliance with regulations does not ensure quality, and that current intervention practices may de-incentivize improved quality.”

“An overwhelming majority of companies interviewed believe that maintaining compliance with FDA regulations does not ensure good product quality”

“An over emphasis on pure compliance versus quality outcomes”

“It is common in medical device companies for only the quality organization to be measured on quality performance; design engineers are commonly measured on time-to-market.”

Source: FDA 2011 - Understanding Barriers to Medical Device Quality
“The medical device industry is approaching a tipping point where the increasing likelihood of a quality event, the rising costs of such events, and the public nature of quality performance will force companies to focus on quality and reliability throughout product design, manufacturing, and marketing.”

- McKinsey & Company

The Business Case for Medical Device Quality, 2013
Key Highlights

- Number of adverse event reports has increased significantly and outpaced industry growth by a wide margin.
- Several factors may contribute to the growth including reporting requirement enforcement by FDA.
- Cardiovascular, IVD and general hospital/surgical devices make up most adverse event report, approx. 60%.
- Radiology (diagnostic imaging) and neurology are the areas growing (~ 24% p.a.) most quickly.

Source: FDA 2011 [https://open.fda.gov/device/pma/](https://open.fda.gov/device/pma/)
TRENDS IN MEDICAL DEVICE RECALLS

Key Highlights

• Recalls have risen slower than adverse events, but have matched industry growth

• In 2009, 40% of adverse even reports were associated with Class III devices vs. 27% in 2003; Conversely, recalls of Class III devices have shrunk from 17% in 2003 to 7% in 2009

• Top 20 most frequently recalled product codes are more heavily focused on radiology devices

Source: FDA 2011

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MEETING THE CHALLENGES: TOP BUSINESS DRIVERS

**Innovation**
- Speed-to-market: first-mover and repeatability
- Decisions: via access to vital data trend
- Quality of new products and processes

**Compliance**
- Global regulations to expand into markets
- Complete supply chain needs to comply
- Traceable throughout the product lifecycle

**Complexity**
- Systems designed for software and hardware
- Lifecycle collaboration across the organization
- Strategic new technologies

**Leverage Lessons Learned**
One source for lifecycle quality & CAPAs

**Govern Product Development**
All product data, processes, and stakeholders

**Meeting the Challenges**

- Innovation:
  - Speed-to-market: first-mover and repeatability
  - Decisions: via access to vital data trend
  - Quality of new products and processes

- Compliance:
  - Global regulations to expand into markets
  - Complete supply chain needs to comply
  - Traceable throughout the product lifecycle

- Complexity:
  - Systems designed for software and hardware
  - Lifecycle collaboration across the organization
  - Strategic new technologies

- Leverage Lessons Learned:
  - One source for lifecycle quality & CAPAs

- Govern Product Development:
  - All product data, processes, and stakeholders

- Closed-Loop Quality:
  - FDA Compliance
  - Product Development
  - Quality Standards
PTC MEDICAL DEVICE
VALUE-READY DEPLOYMENT™ (VRD) OFFERING
**How This Works: Mechanics of a Single Source of Truth**

**Benefits of PTC PLM**
- Creates a single source of truth
- Shifts from Corrective to Preventive
- Enables quality-driven change
- Closes the loop

**PTC PLM Product Lifecycle Management Backbone**

**Documents Backbone**
Manage & Control all key documents / Document Control

**Products Backbone**
Manage and control product information / CAD, BoM, BOO, Change Control, Processes / Workflows…

**Quality Backbone**
Quality, reliability, and risk management is harmonized with engineering & suppliers, across products & processes

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**Product-Based Information:** Design, CAD / Visualization, BoM, Parts, Variants, Change, Workflows

**Document-Based Information:** SOPs, Policies, Quality Manual

**Quality Records associated to products & documents:** CAPAs, NCs, Complaints, Audits, Training…

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**Concept**
- Portfolio Mgmt
- Prod. Requirements
- Design Inputs
- Quality History
- CAPAs
- DHF

**Design**
- CAD
- Risk & Hazards
- FMEA
- Design Validation
- Design Reviews
- CAPAs
- DHF / DMR

**Launch**
- PMA / 510K
- UDI

**Manufacturing**
- Mfg Process Plans
- Nonconformances CAPAs
- Mfg BoM Instructions
- Supplier Mgmt

**Service**
- Service Ticketing
- Warranty
- Inventory Mgmt
- Complaints
- CAPAs

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PTC WINDCHILL: PLM FOR CLOSED-LOOP QUALITY

Ensure Governance via Document Control for SOPs, policies, procedures (quality docs)

Manage Complete Product Definition via Design Control / Design Transfer to connect engineering design (eBoM) to manufacture (mBoM), ensure traceability and change control, enable DHF / DMR

Demonstrate Compliance with Audits, UDI, eSubmissions

Resolve Quality Issues Centrally and leverage lessons learned with one source for CAPAs

PTC Windchill PLM & Quality Backbone

Change-managed Process-driven Secure access

Capture and Manage Internal & External Quality Issues including, Manufacturing and Supplier Nonconformances, Customer Complaints

Design for Quality and Safety with Risk & Reliability Management

Demonstrate Compliance with Audits, UDI, eSubmissions

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A ready-to-deploy services offering to implement proven industry best-practices

• **Proven**
  – Developed with leading Medical Devices Companies

• **Industry Specific and Comprehensive**
  – Based on PTC perspective of ISO 13485 & FDA’s TPLC And 21 CFR Part 820 Regulation for Document Control, Product Realization, Nonconformance, Customer Feedback, CAPA, Audits, UDI

• **Rapid Time-to-Value**
  – Pre-defined Windchill deployment methodology, baseline configurations, validation scripts and adoption program for Medical Device industry

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The VAP offers a complete set of pre-configured validation ready regulatory templates:

- Computer System Validation Plan
- System Requirements Specification (SRS)
- IQ, OQ and PQ Protocols
- Validation Test Scripts
- Requirements to Test Traceability Matrix
- Software Validation Summary Report
Audit Experience

- USDM who provides software validation services to the medical device industry have reviewed our security model and validation accelerator used to enable Windchill FDA Part 11 validation

- Multiple PTC customers are using Windchill and have passed FDA Audits

- Multiple Medical Device Manufacturers have successfully performed vendor audits of PTC resulting in approved vendor status

- Windchill Unique Device Identifier (UDI) has been successfully implemented and validated at numerous sites
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