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

PTC's Medical Device Value-Ready Deployment™ Offering: Overview

May 2016

FDA CASE FOR QUALITY

RELATIONSHIP BETWEEN QUALITY AND COMPLIANCE

"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 OPPORTUNITY TO IMPROVE THE TOTAL QUALITY COSTS

"The Financial Benefit Opportunity is $4.75-$6.0b for the Medical Device Industry" - McKinsey & Company

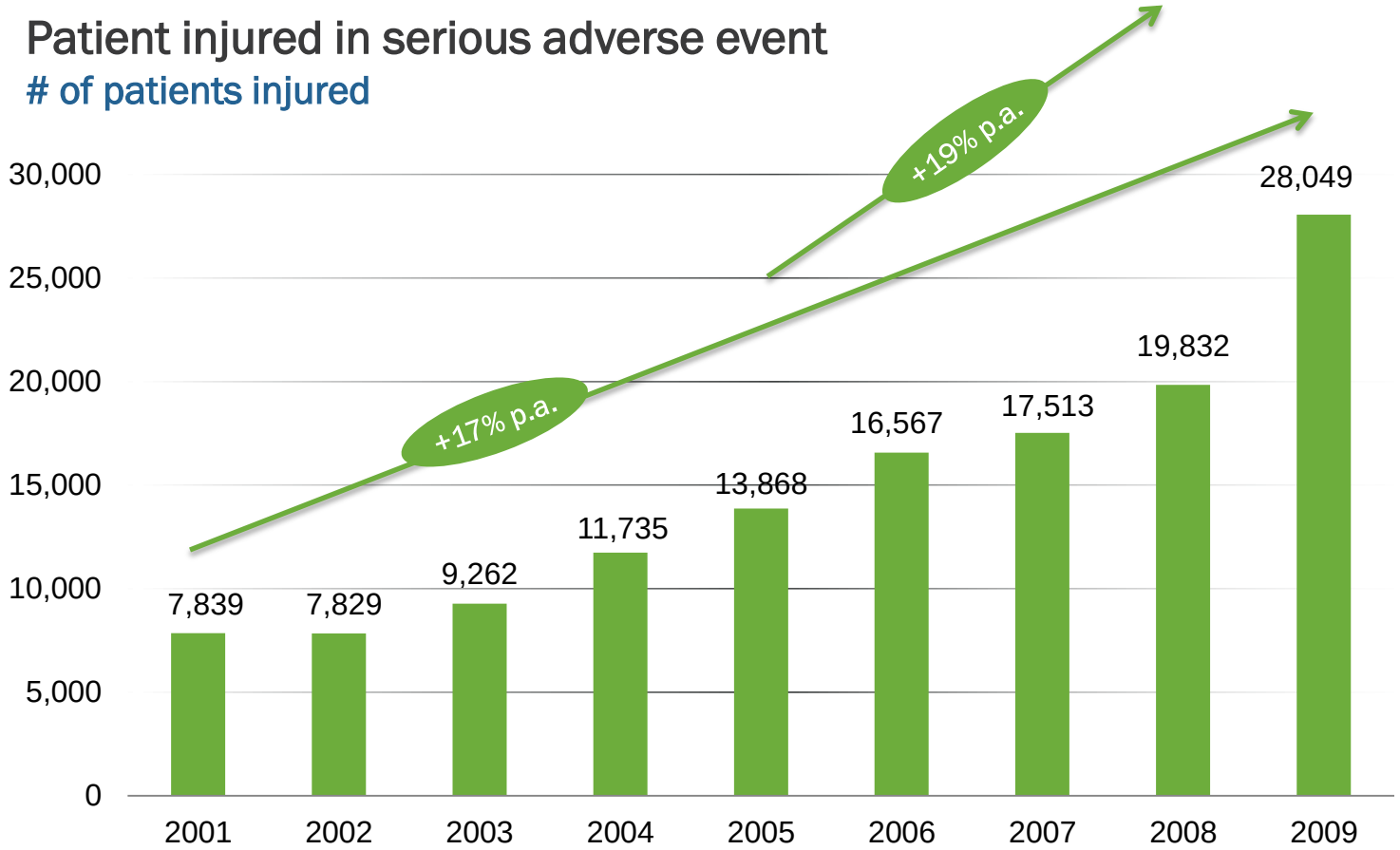
"The medical device industry is approaching a **tipping point** where the **increasing likelihood of a quality event**, the rising costs of such events, and the public nature of quality performance will **force companies** to focus on **quality and reliability throughout product design, manufacturing, and marketing.**"

- McKinsey & Company
The Business Case for Medical Device Quality, 2013

TRENDS IN MEDICAL DEVICE ADVERSE EVENT REPORT

Key Highlights

- Number of adverse event reports has increase 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/

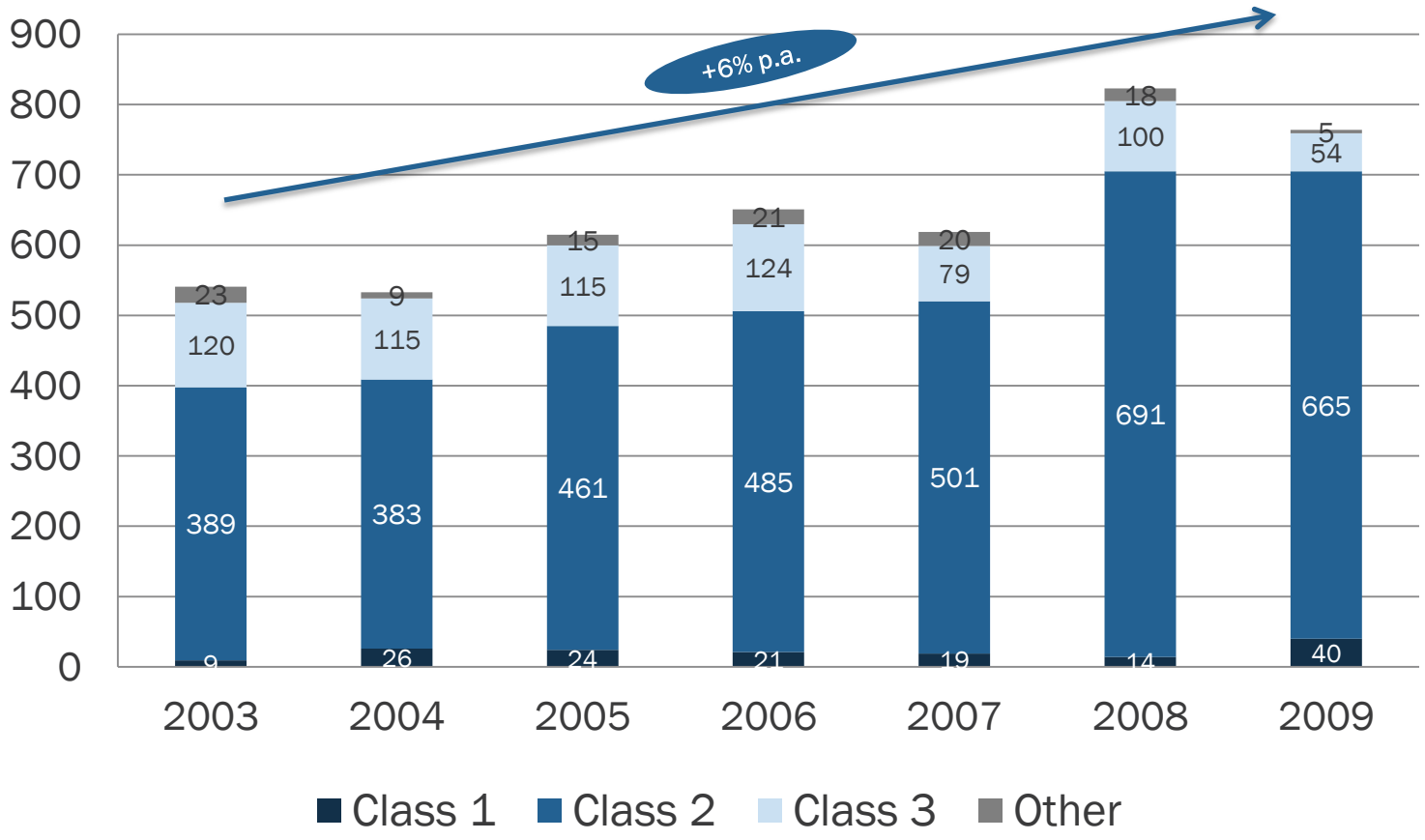
TRENDS IN MEDICAL DEVICE RECALLS

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

Device Recalls (2003 – 2009)

Number of case numbers



Source: FDA 2011

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

Leverage Lessons Learned
One source for lifecycle quality & CAPAs

Govern Product Development
All product data, processes, and stakeholders

Complexity

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

Compliance

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

Meet FDA Requirements
Traceable, easily demonstrable

Reduce Cost of Poor Quality
Single source for design, quality and compliance

Cost

- **Efficiency** in operations and product introductions
- **Insight** into sources of issues and costs
- **Preventive Action** to reduce costs and risk

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

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…*

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

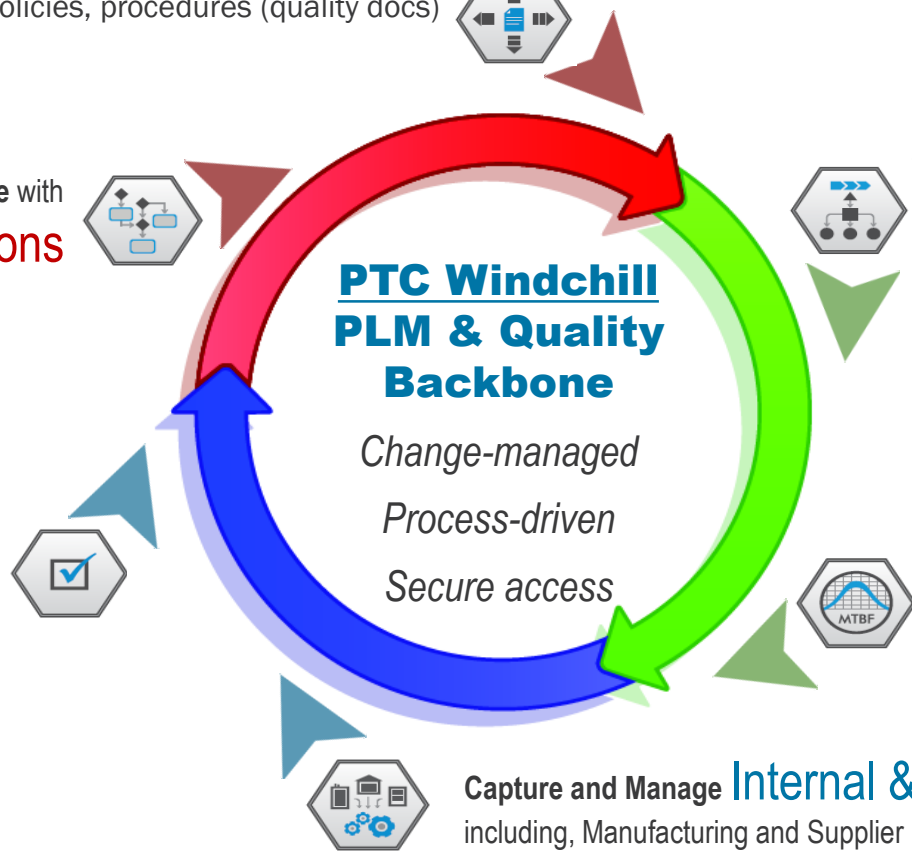
Service
Service Ticketing
Warranty
Inventory Mgmt
Complaints
CAPAs

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



Design for Quality and Safety with
Risk & Reliability Management

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

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

MEDICAL DEVICE INDUSTRY **VALUE-READY DEPLOYMENT ™**

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

Rapid Time-to-Value | Lower Risk | Lower TCO

VALIDATION ACCELERATOR PACKAGE (VAP) FOR PTC® WINDCHILL®

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

PTC VALIDATION EXPERIENCE

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

FOR MORE INFORMATION

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