MEETING ISO 9000 STANDARDS FOR QUALITY IN PRODUCT DEVELOPMENT

Michael Prudhomme and Francois Lamy

June 8, 2016

MEETING ISO 9000 STANDARDS FOR QUALITY IN PRODUCT DEVELOPMENT

- Updates in ISO 9001:2015 emphasize traceability, collaboration, and risk management throughout the product development process. In this session, attendees will learn about harmonized product development processes in PTC Windchill that enable companies in highly regulated industries like medical devices to address ISO 9001:2015 updates (and it's derivative standards) with one PLM solution. With capabilities to manage changes throughout the product lifecycle, to trace the impact of those changes in quality feedback systems, and to address quality issues with not just corrective measures but preventive ones supported throughout the design development and manufacturing processes. PTC Windchill meets the recommendations of the new standard to close the loop on product quality and product development.

AGENDA

- Last Year Refresh – Case for QMS in PLM – CAPA
- The Journey to Connected Quality
- ISO 9001:2015 – Formal introduction of Risk Processes
- Risk Integrated across the Product Life Cycle

AGENDA

- Last Year Refresh – Case for QMS in PLM – CAPA
- The Journey to Connected Quality
- ISO 9001:2015 – Formal introduction of Risk Processes
- Risk Integrated across the Product Life Cycle

CAPA SYSTEMS

- A True CAPA is not an Issue Log
  - Surveillance + Corrective Actions & Preventive Actions = Continuous Improvement
  - CAPA systems create self righting products & processes
- CAPA Corrective Action Preventive Action
  - Corrective Action: Action taken to prevent re-occurrence of a problem
  - Preventive Action: Action taken to prevent the initial occurrence of a problem
- How best to Consolidate CAPA systems
  - Focus on key elements
  - Consolidate using Key elements
- Key Elements – "The Loop"
  - Leverage System Engineering especially Risk and Failure Analysis work
  - Integrated Engineering all the way though
- Ford & Firestone – " A Thought Experiment"
  - Use Historic example to illustrate what is important

FIRESTONE / FORD TIRE CONTROVERSY – OUTCOMES

- Over 240 Deaths [2]

- Over 3,000 serious injuries [3]

Rollover-to-tire failure rates

VEHICLE	TIRE FAILURES	ROLLOVERS	RATE
Explorer	2,450	306	13%
Other Ford SUVs and light trucks	507	24	5%
Other SUVs and light trucks	416	12	3%
Other vehicles	160	4	2%
TOTALS	**3,533**	**346**	

Source: NHTSA Firestone Wilderness AT Investigation Database, Safety Forum

Times art

CENTRALIZED QUALITY MANAGEMENT WITH PLM – "THE LOOP"

Audit Issues

- Create Audit Project from Template
- Assign and Track Audit Checklist Activities
- Lead Auditor Creates Audit Issues Programmatically upon Final Check-in
- Evaluate if Further Dispositions are Necessary
- Escalate to CAPA

Nonconformance

- Enter Nonconformance from Shop Floor or with ERP or MES Integration
- Record Immediate Actions, Segregation, Corrections,
- Perform MRB, Dispositions & Route to Approvals
- Escalate to CAPA

Customer Experience Management

- Issue Capture From all sources, Field Service, Call Center, Sales
- Returned Product Investigation, Failure Investigation
- Quality Investigations, Product Safety & Regulatory Reports
- Escalate to CAPA

Windchill Report Builder , Queries, Reports and Data Monitor

✓ Surveillance Systems use engineering Risk and Failure Data

CAPA/SCAR

- Access Related Quality Inputs
- Identify Root Cause
- Create & Approve CAPA/SCAR Action Plan, Implement Engineering Changes
- Confirm and Verify Effectiveness

✓ All Inputs use same Codes

✓ Root Cause Code FMEA

✓ Integrate Engineering Change & Config Mgmt

✓ Monitor for re-orccurance

BY USING RISK CODIFICATIONS IN SURVEILLANCE

What we effectively do is put the Engineer in the Vehicle

An Engineer who designed the vehicle was riding in it the first time the tread separated

He/She would probably immediately recognize the effect of tire separation

AGENDA

- Last Year Refresh – Case for QMS in PLM – CAPA
- The Journey to Connected Quality
- ISO 9001:2015 – Formal introduction of Risk Processes
- Risk Integrated across the Product Life Cycle

HOW DOES QUALITY INFORM PRODUCT DEVELOPMENT TODAY?

CHANGE Control **RISK** Prevention **EVERY** Stakeholder

Typical state for discrete manufacturers

Many sources for quality data ..


Documents


Nonconformances


Process Quality


Safety, Risk, Reliability


Training and Audits


Customer Complaints


CAPAs

…separated from engineering, mfg, & service:

PLM:
- CAD Data
- Enterprise Parts
- BoM, Options
- Change Mgmnt
- Project Mgmnt

Manufacturing:
- MBoM
- Manufacturing Planning
- Inspections

Service:
- Service Planning
- Field Performance

WHAT ARE THE RESULTS?

High Warranty Costs

High IT / Training Costs

Fewer Resolved Issues

Poor Visibility

Typical state for discrete manufacturers

Many sources for quality data ..

Documents

Nonconformances

Process Quality

Safety, Risk, Reliability

Training and Audits

Customer Complaints

CAPAs

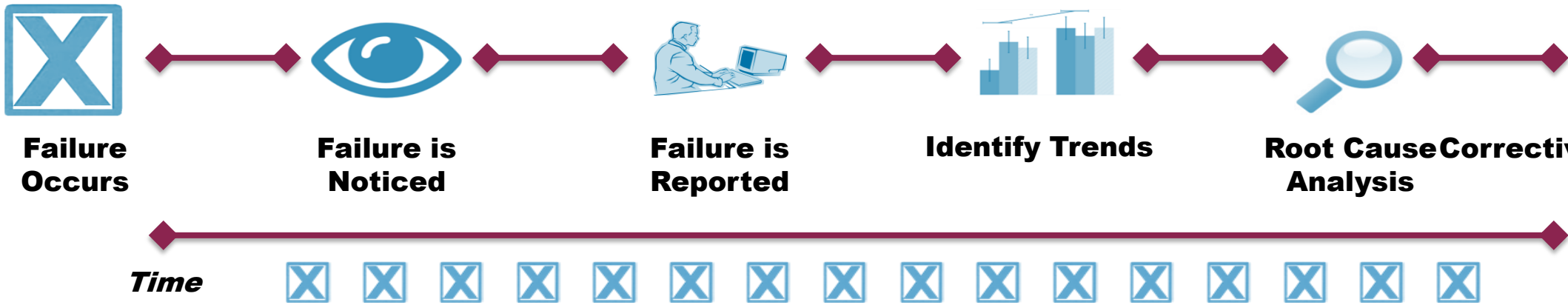
…separated from engineering, mfg, & service:

PLM:
- CAD Data
- Enterprise Parts
- BoM, Options
- Change Mgmnt
- Project Mgmnt

Manufacturing:
- MBoM
- Manufacturing Plannir
- Inspections

Service:
- Service Planning
- Field Performance

BECAUSE THIS LENGTHENS THE TIME FROM *FAILURE* TO *FIX*



Many sources for quality data ..


Documents


Nonconformances


Process Quality


Safety, Risk, Reliability


Training and Audits


Customer Complaints


CAPAs

…separated from engineering, mfg, & service:

PLM:
- CAD Data
- Enterprise Parts
- BoM, Options
- Change Mgmnt
- Project Mgmnt

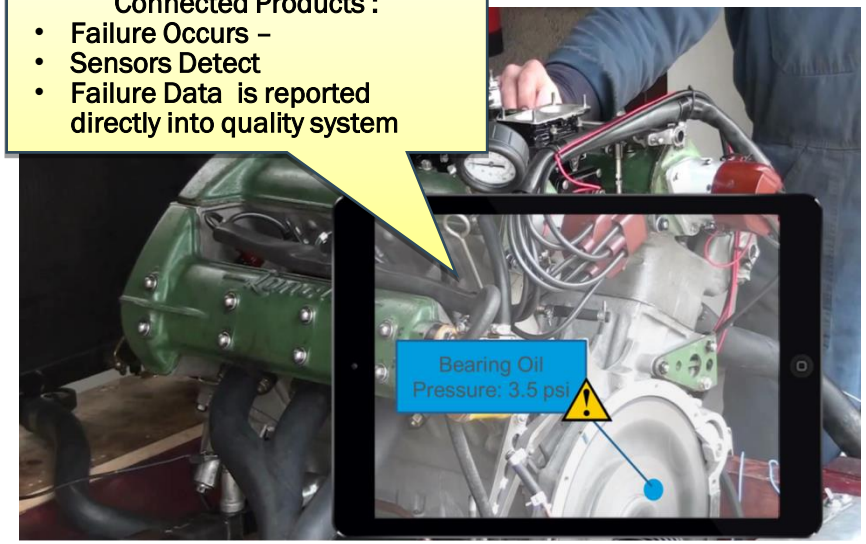
Manufacturing:
- MBoM
- Manufacturing Plannir
- Inspections

Service:
- Service Planning
- Field Performance

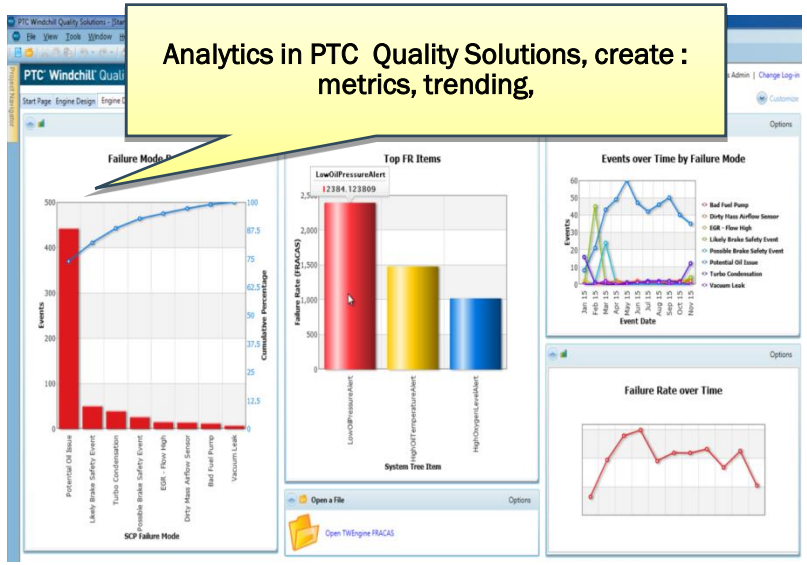
CONNECTED QUALITY

Failure Occurs → **Failure is Noticed** → **Failure is Reported** → **Identify Trends** → **Root Cause Analysis** → **Corrective / Preventive Action**

Connected Products :
- Failure Occurs –
- Sensors Detect
- Failure Data is reported directly into quality system



Analytics in PTC Quality Solutions, create : metrics, trending,



Reduce the Time from Failure to Fix

Prevent the issue in next-generation products

AGENDA

- Last Year Refresh – Case for QMS in PLM – CAPA
- The Journey to Connected Quality
- ISO 9001:2015 – Formal introduction of Risk Processes
- Risk Integrated across the Product Life Cycle

BACKGROUND - ISO 9001 & PLM

- **ISO 9000** - The concepts and Language for a family of standards related to quality management systems.
  - designed to help organizations ensure that they meet the needs of customers and other stakeholders.

ISO 9001 Certification produces "Conformity of Product and Service that meets the needs of the customer"

- The **ISO 9001** Series describes standards for a Quality Management System (QMS) addressing the principles and processes surrounding the **Design**, **Development**, **Delivery** and **Service** of a general product or service. This is the general PLM standard.

BACKGROUND ISO 9001 HISTORY OF CHANGES

"All ISO standards are reviewed every five years to establish if a revision is required to keep it current and relevant for the marketplace."

- ISO 9001:1987
  - Initial - Prescriptive – required documented procedures & records
  - Same as UK Standard BS 5750, with three 'models' for quality management systems
- ISO 9001:1994
  - Prescriptive – required documented procedures & records
  - Emphasized quality assurance via preventive actions and continued to require evidence of compliance with documented procedures.
- ISO 9001:2000
  - Introduction of Process Approach – still required documented procedures & records
  - 'a documented system' not a 'system of documents'
- ISO 9001:2008
  - Process Focus – Concentrate on managing processes less on documentation

BACKGROUND ISO 9001 HISTORY OF CHANGES

- ISO 9001:2015
  - Extends Process Focus managing using Plan-Do-Check-Act
  - Adds focus on Risk as a Backdrop to Process
  - Greater integration with other ISO management standard thanks to a common high-level structure
    - "The new version also provides a solid base for sector-quality standards (automotive TS16949, aerospace AS 9100, medical industries ISO13485, etc.), and takes into account the needs of regulators."
    - http://www.iso.org/iso/home/news_index/news_archive/news.htm?refid=Ref2002

BACKGROUND ISO 9001 - QUALITY IN INDUSTRY

Who

Uses ISO 9001?

1.1M

Companies and their BU's are ISO-certified

2015

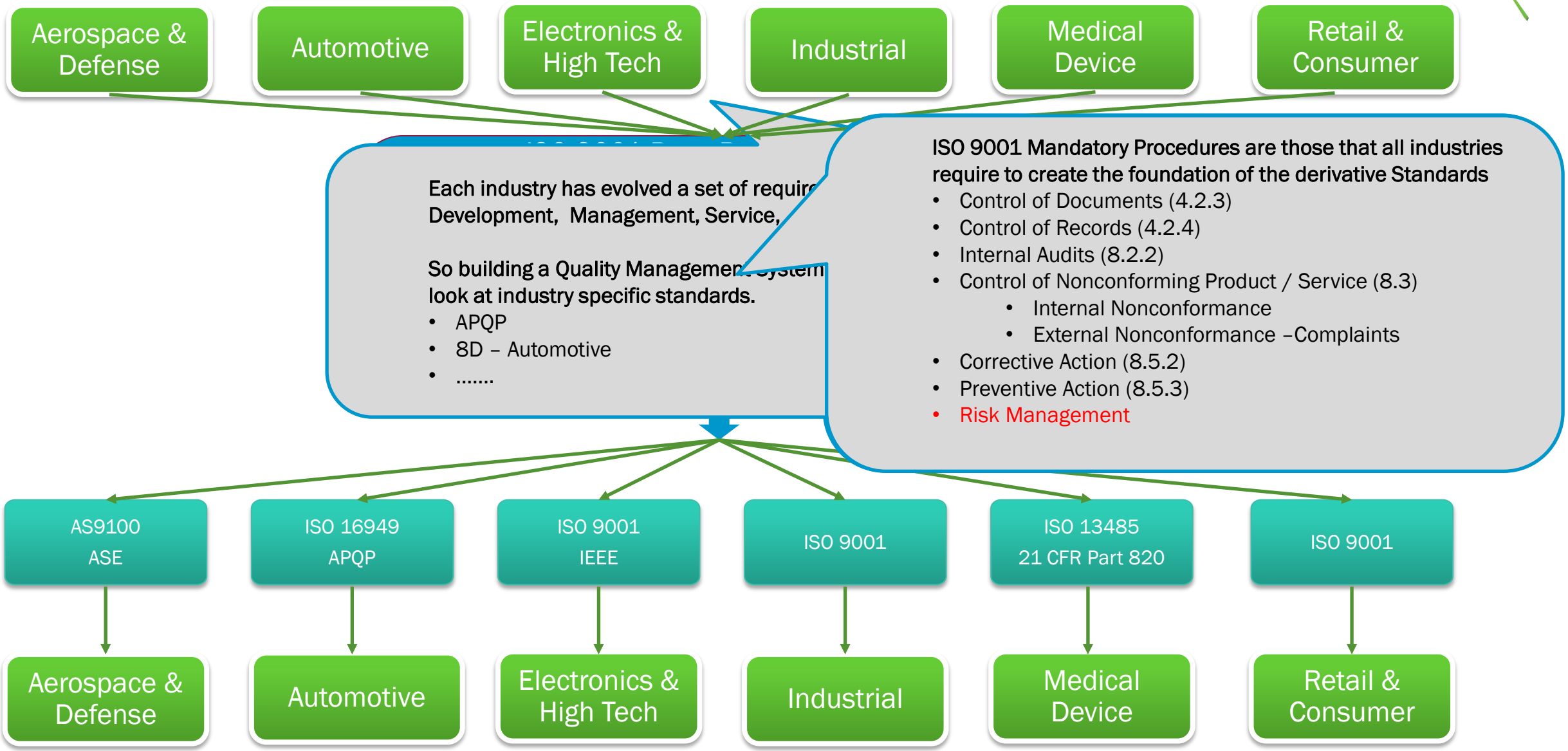
Year of the latest version of ISO 9001

ALL

Industry verticals & sizes of companies

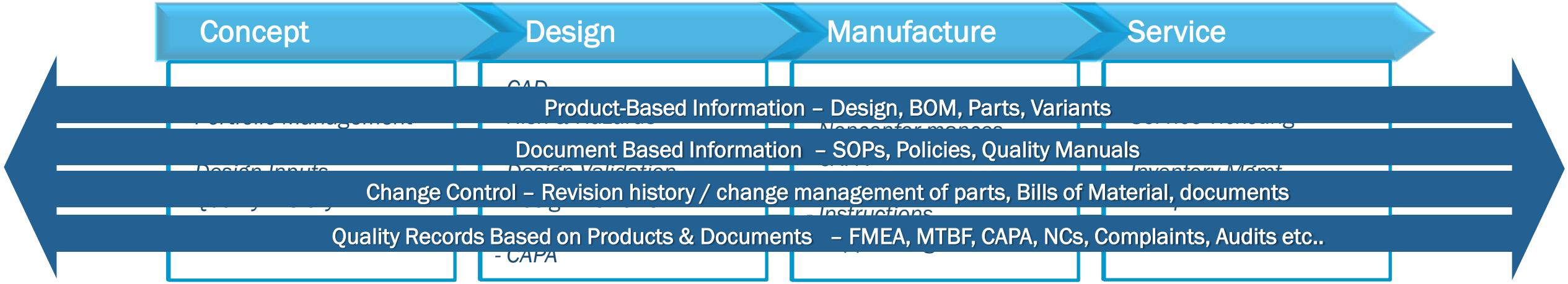
All Industries, Right Now.

COMMON STANDARD - CORE ELEMENTS & DERIVATIVES



ISO & PLM

PLM is the backbone to evolve the complete definition of a product over its entire life:



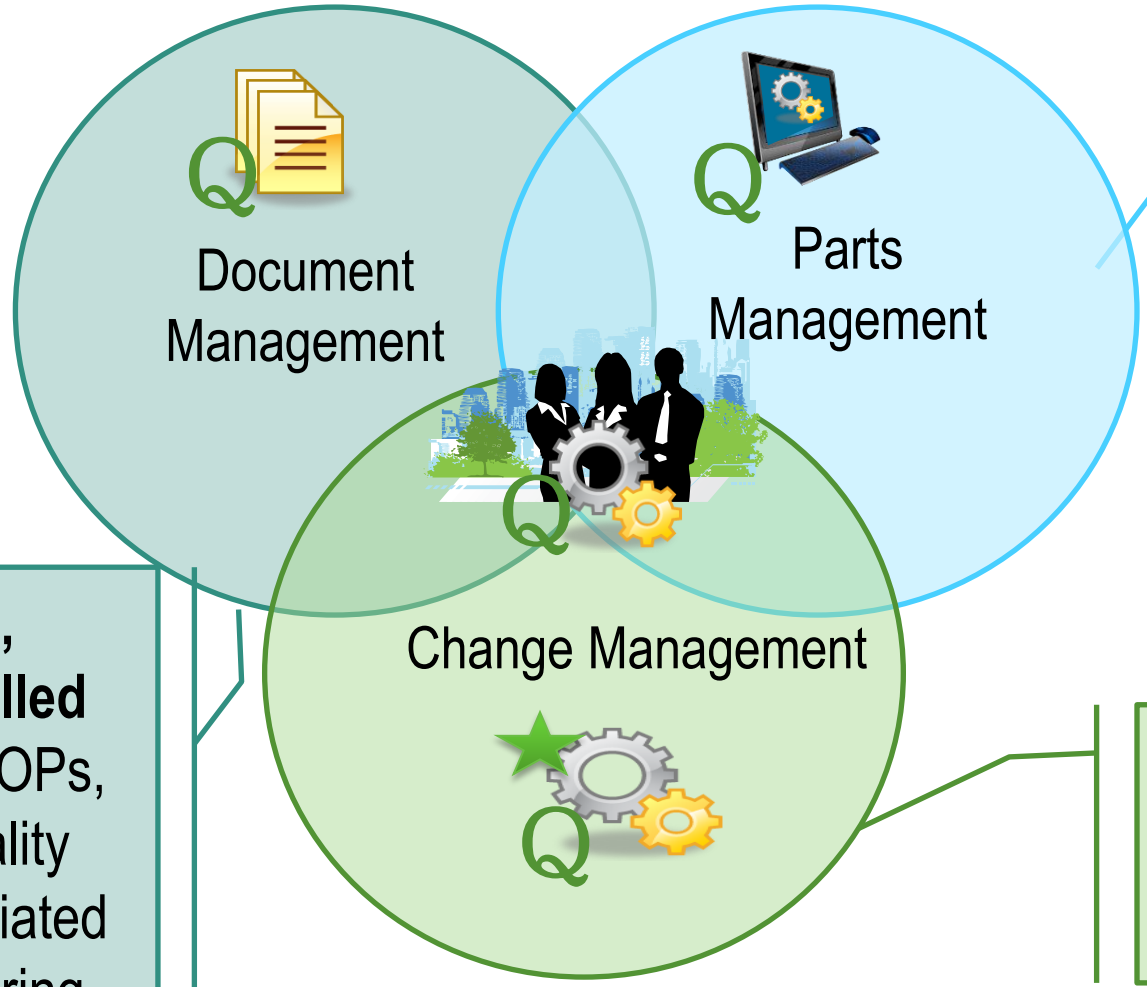
- Products - Provide Control of Product information / CAD Mgmnt, BOM, BOO, history, documentation
- Documents - Manage & Control all key documents, with associativity to related parts
- Change – Manage change process to capture inputs, workflow, approvals and execution of change
- Quality – Quality Activities & Processes interact with the Anchor Points for Products and Processes

Enables:
- Control of Documents (4.2.3)
- Control of Records (4.2.4)
- Internal Audits (8.2.2)
- Control of Nonconforming Product (8.3)
- Corrective Action (8.5.2)
- Preventive Action (8.5.3)

Benefits:
- Supports all ISO 9001 Derivative Standards: ISO 13485 & 16949, AS9100
- Provides a uniform approach
- Speeds implementation – reduces costs
- Provides immediate value

THE **QUALITY** PERSPECTIVE ON INTEGRATION WITH PLM

Integrating **PLM with Quality** leverages change-managed PLM data and functionality



Directly reference Enterprise parts from Quality processes such as Complaints, NCs, CAPAs, Audits

Change-managed, configuration-controlled quality documents (SOPs, work instructions, quality manuals, audits) associated to quality *and* engineering

Drive change directly from quality investigations in the same system from their related quality artifacts

CENTRALIZED QUALITY MANAGEMENT WITH PLM – "THE LOOP"

Audit Issues

- Create Audit Project from Template
- Assign and Track Audit Checklist Activities
- Lead Auditor Creates Audit Issues Programmatically upon Final Check-in
- Evaluate if Further Dispositions are Necessary
- Escalate to CAPA

Nonconformance

- Enter Nonconformance from Shop Floor or with ERP or MES Integration
- Record Immediate Actions, Segregation, Corrections,
- Perform MRB, Dispositions & Route to Approvals
- Escalate to CAPA

Customer Experience Management

- Issue Capture From all sources, Field Service, Call Center, Sales
- Returned Product Investigation, Failure Investigation
- Quality Investigations, Product Safety & Regulatory Reports
- Escalate to CAPA

Windchill Report Builder , Queries, Reports and Data Monitor

✓ Surveillance Systems use engineering Risk and Failure Data

CAPA/SCAR

- Access Related Quality Inputs
- Identify Root Cause
- Create & Approve CAPA/SCAR Action Plan, Implement Engineering Changes
- Confirm and Verify Effectiveness

✓ All Inputs use same Codes

✓ Root Cause Code FMEA

✓ Integrate Engineering Change & Config Mgmt

✓ Monitor for re-orccurance

AGENDA

- ❑ Last Year Refresh – Case for QMS in PLM – CAPA
- ❑ The Journey to Connected Quality
- ❑ ISO 9001:2015 – Formal introduction of Risk Processes
- ❑ Risk Integrated across the Product Life Cycle

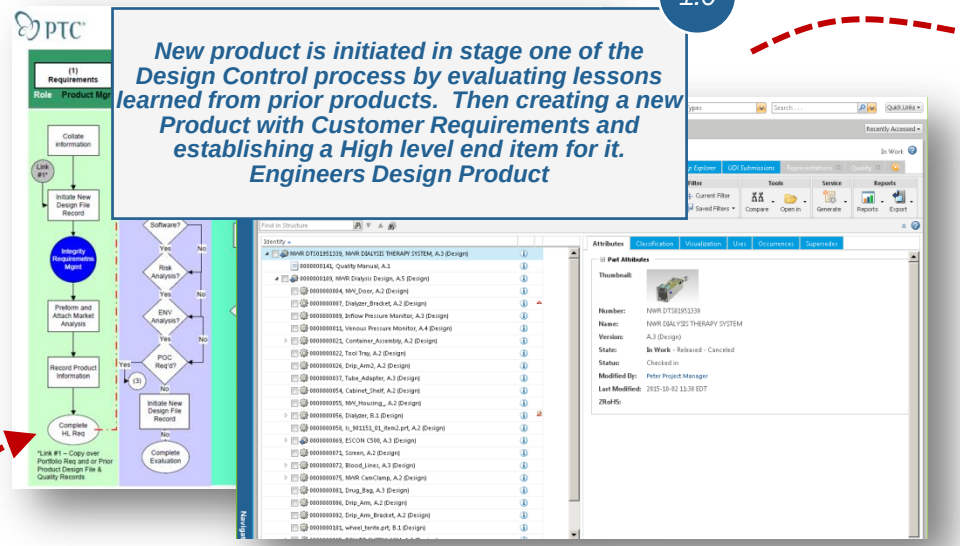
CASE FOR QUALITY – INTEGRAL MED DEVICE SUITE

Corporate Quality

- Start
- 1.0 Initiation New Product from Requirements
- 2.0 Perform Risk Analysis
- 3.0 Generate CTQ, Control Plan and DVP
- 4.0 Initiate Surveillance and Corrective Action
- 5.0 Compare Predicated vs Actual Failure Modes
- 6.0 Management Review, CAPA and Change
- 7.0 Utilize Lessons Learned
- End

1.0

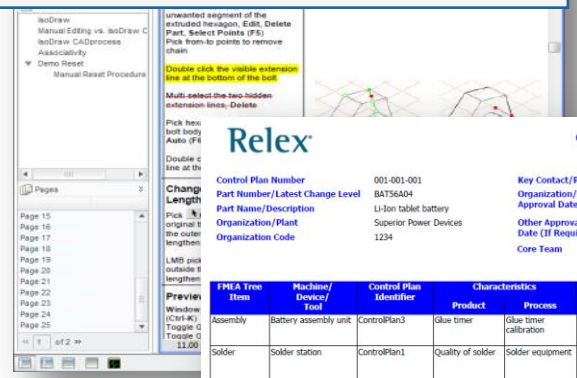
New product is initiated in stage one of the Design Control process by evaluating lessons learned from prior products. Then creating a new Product with Customer Requirements and establishing a High level end item for it. Engineers Design Product



2.0

Preform Risk Analysis to predict Reliability and Identify areas of concern in Design or Manufacturing

First on Functional then Detailed Design Generate CTQs (Critical to Quality Characteristics)



3.0

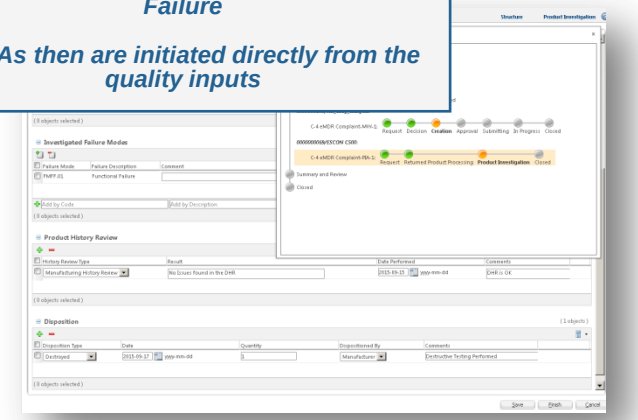
Use CTQ to Create Validation Tests and Generate Control Plans for Manufacturing

Use Failure Mode and Effect Codes to setup Failure Codification for Surveillance Systems FMEA and CTQ

4.0

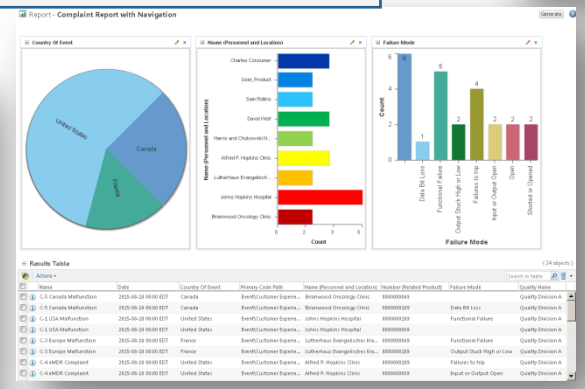
Surveillance & Corrective Action All Quality inputs Use the outcome of engineering process to both quantify and codify any Failure

CAPAs then are initiated directly from the quality inputs



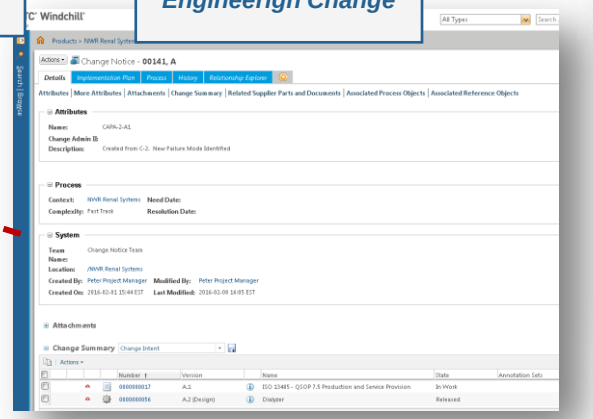
5.0

Compare Predicted versus Actual Failure Modes and Grade Product Performance



6.0

Management Review can Prioritize Corrective Action with Closed Loop Engineerign Change



7.0

Utilize Lessons Learned with New Products