Gestione del ciclo di vita della qualità con Windchill Quality Solutions

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Managing **product quality, reliability, and risk** involves identifying **quality-critical characteristics** early during product planning, communicating them to design teams as **product performance and safety targets**, and connecting them through to test plans, manufacturing controls, and service instructions to ensure they are realized in the finished product. Windchill Quality solutions provides an **end-to-end suite** of **product risk and reliability management modules** connecting system design, part reliability, and risk identification to essential test, manufacture, and service planning activities to support **fully integrated quality management** across the product lifecycle.
Agenda

- Windchill Quality Solutions - Background
- Quality & Reliability Challenges
- PTC Product Approach – Quality Management
- Integrated Risk & Reliability Analysis
- Features & Benefits
- PLM Integration
About NetRM and Relex

- Acquired by PTC in 2007, 2009
- Offering quality solutions for over 25 years
- A presence in multiple industries:
  - A&D, Medical Devices, Electronics & High Tech, Automotive, Industrial

Meet Government and Industry Standards
Ensure Safe and Reliable Products
Achieve High Performance for Complex Systems
Minimize Lifecycle Costs, Warranty / Penalty Costs
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Challenges

- Gaining early insight into product reliability
- Planning for quality and mitigating risk
- Aligning product design with customer requirements
- Optimizing lifecycle costs and profitability
- Leveraging test and field data to communicate best practices

Fragmented Tools & Processes

Consequences of Managing Quality / Reliability Late

- Product recalls
- Undetected risks / hazards
- Decreased consumer confidence
- Increased warranty costs
- Loss of market share
- Escalated cost of changes
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### Product Quality Impacts Every Process

#### PRODUCT DEVELOPMENT LIFECYCLE

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**Notes:**
- Product quality impacts every process across the product development lifecycle.
- The diagram illustrates the integration of various processes and their alignment with the lifecycle phases.
- Key areas include product development, manufacturing, and service, each influencing quality and reliability.

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**Keywords:**
- Engineering Management
- Sales & Marketing
- Sourcing
- Manufacturing
- Service
Quality Management

Plan:
- Reliability Prediction
- Reliability Block Diagrams (RBD)
- Failure Mode & Effects Analysis (FMEA)
- Identify scheduled maintenance needs
- Fault Tree Analysis (FTA)
- Predict Repairs Times
- Markov

Innovate:
- Corrective and Preventive Action
- Customer Experience Mgmt
- Track and Manage Customer Issues
- Analyze Complex Systems
- CAPA
- Manage Corrective Action Processes
- FRACAS
- Weibull

Design:
- Manufacture
- Manage Internal Nonconformances
- Nonconformance
- Identify scheduled maintenance needs
- MSG-3
- Maintainability
- Analyze Accelerated Life Testing Data (ALT)

Test:
- Service
- Life Data Analysis
- Lifetime Cost of Products, Systems
- Life Cycle Cost

Quality Management
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Integrated Risk and Reliability Management Tools

- Analyze reliability, availability, maintainability, and cost together
  - Integrated analyses inform system design

- Integrated top-down / bottom-up risk analysis
  - FMEA effects become FTA top-level events

- Connected risk and reliability analyses
  - Predicted failure rate informs risk analysis
  - Recommended risk controls inform system design

- Collect and analyze failure data
  - Collect and trend in FRACAS, perform deeper statistical analysis via integration with Weibull

- Communicate actual failure data (failure rate, failure modes) to next-gen design
  - Inform next-generation reliability & risk analyses with real-world failure rates, failure modes
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Windchill Prediction

Perform reliability prediction using a comprehensive library of standards

**Why is it Important?**

- Early insight into problem areas
- Design trade-studies without prototype costs
- Meet contractual, industry, market standards

**Common Barriers**

- Getting started… gathering data
- Implementing the methodology
- Understanding the outputs

**PTC Benefits**

- Industry leading libraries, monthly updates
- Science built in… context sensitive screens
- Intuitive, standard reports and graphs
Windchill FMEA (Failure Modes and Effects Analysis)

Identify and control product & process risks

**Why is it Important?**

- Identify and mitigate risks early in design
- Document and quantify risk control measures
- Communicate to cross-functional teams

**Common Barriers**

- Viewed as labor intensive
- Treated as an event rather than a process
- Connect from design through test/manufacture

**PTC Benefits**

- Libraries and automation of data entry
- Standardized process across product teams
- Links CTQ with DVP, Control Plans and V&V
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Access a Single Source of Truth for Product Quality

Execute enterprise-wide quality management

Connect lifecycle activities related to quality

Provide end-to-end visibility into quality issues

Enable iterative quality improvement processes

FRACAS – Change Management Integration

BOM – System Tree Integration

Critical Characteristic – FMEA Integration

Risk and Reliability Analysis

Test, production, and field failures

Enterprise-level quality issues

Next-generation product design

RCA and CA/PA Processes

Iterative product design process

Product BOM

Quality-Related Failures & Incidents
Standardizing Quality with Windchill Quality Solutions
Engineering Process Quality is a key component of delivering products on time while achieving targeted levels of **Performance, Reliability, and Safety**. Many companies, like those in the Medical Devices Industry, have learned the importance of focusing on **standardized, measurable, best practices** to provide safe, reliable products.
Quality Inputs & CAPA: How they Work Together

Nonconformance

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

Customer Experience Management

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

Windchill Report Builder, Queries, Reports and Data Monitor

CAPA

- Access related quality inputs
- Identify root cause
- Create & approve CAPA action plan, Implement ECRs in PLM system
- Confirm and Verify Effectiveness

Initiate New Request
Record data sources
Identify product involved
Evaluate, assign issue
Determine Need for CAPA
Investigate Root Cause
Plan, Perform Corrective Action
Verify Corrective Action
Why is it Important?

- Quickly Record and Process Complaints
- Inquiries and Detailed Quality Investigations
- eMDR and Follow Up Reports

Common Barriers

- Inadequate RCA investigation Capability
- Labor-intensive product safety reporting
- Disconnected Systems, Poor Visibility

Customer Benefits

- Precisely Record Complaints & Investigations
- Integral and robust Safety Reporting
- Management Visibility w Reports & Watchdogs
Thank You