Windchill Quality Management

Closed-Loop Quality for Medical Device Innovators

Windchill Quality Management is purpose-built for medical device makers who seek to accelerate delivery of breakthrough medical devices. It extends the industry's leading PLM platform with best-practice processes harmonized for ISO 13485, EU MDD, and FDA TPLC and 21 CFR Part 820 regulations.

Engineering, quality and compliance. As a medical device maker, you need to excel at all three. Yet for many medical device makers, distributed teams and disconnected data impede innovation and put quality at risk. Windchill Quality Management brings together with a shared view of the medical innovation cycle. So you can focus on what matters most: creating high quality products that improve patient lives and outcomes.

- **Unify engineering, quality and regulatory teams** with a shared, product-centric view of the medical innovation cycle
- **Adopt best practices for Design and Document Control** as an integral part of your product lifecycle
- **Improve quality** with closed-loop Risk, CAPA/SCAR, Nonconformance and Complaint Management
- **Get up and running quickly with SaaS** simplicity and complimentary software validation*

*Cloud only, some restrictions apply

Windchill Quality Management extends the industry's leading PLM solution with best-practices for compulsory ISO 13485 processes. And because these best practices are product-centric – referencing specific products, parts and design details – they close the loop from quality events to engineering insights.

Closed-loop, product-centric quality

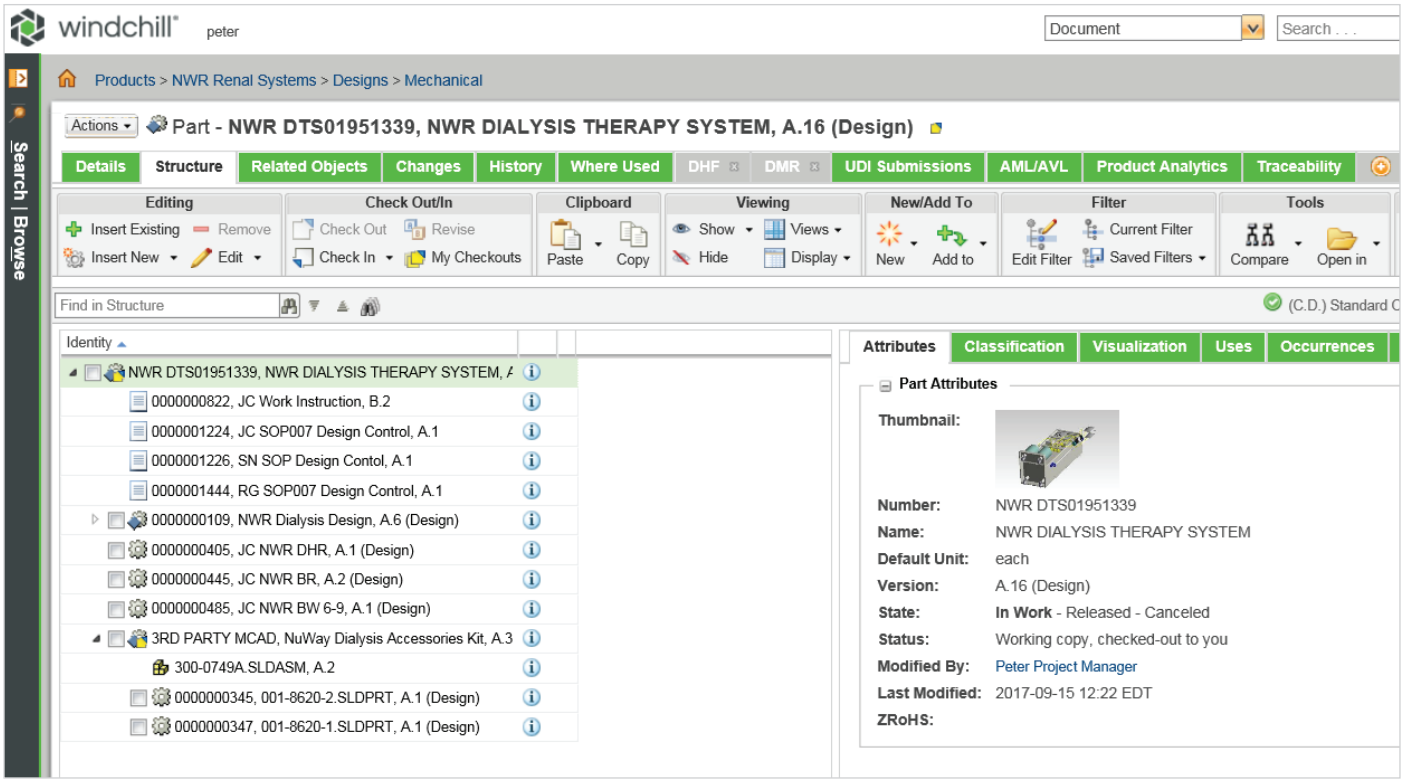
Many medical device makers rely on separate, document-based engineering and quality tracking solutions. These document-centric solutions are inherently brittle and inflexible in the face of continuous change. They are also disconnected from manufacturing and service processes that require detailed design information The resulting errors and omissions add risk to your business. Potentially valuable insights are rarely shared with engineering teams – cutting off a vital source of product intelligence.

Unlike standalone tracking solutions, Windchill Quality Management provides a single source of truth that can be shared across medical engineering, quality manufacturing, supply chain and regulatory teams. It closes the loop on quality, making post-market intelligence available to all teams. And it's built on the trusted, extensible and scalable Windchill platform for team innovation, with more than 1.5 million seats deployed.

A complete innovation and quality platform for medical innovators

Windchill Quality Management processes close the loop from inception through post-market surveillance.

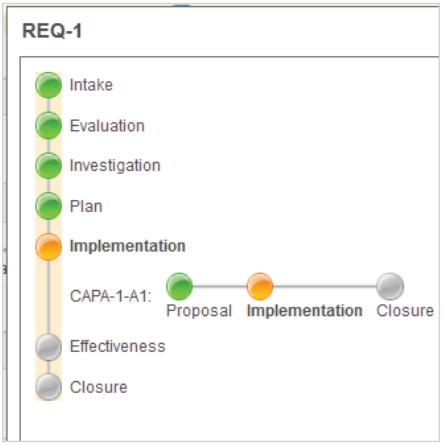
- **Design Control** provides comprehensive Design History File (DHF) and Device Master Record (DMR) capabilities.
  - Adopt a proven, consistent product realization process with integral Parts Classification, BoM Structure, Change Control and Risk Management
  - Generate accurate Design History Files (DHF) and Device Master Records (DMR)
  - Understand status at regulatory milestones – and what has changed
  - Integrate with Microsoft Project to operationalize execution
- **Document Control** enables easy creation, control, management and distribution of key corporate Standard Operating Procedures (SOPs) and policies in an intuitive document control system. It helps ensure access and distribution of correct versions of documents to authorized and responsible personnel.
  - Adopt best practices for 19 med-tech document types
  - Ensure the correct versions of documents are distributed through Qualified Role Access
  - Track SOP notification and training with integrated Learning Management System (LMS)
  - Audit Trail Reports
  - Dashboard Charts
  - Cover Sheet / Signature Page / Watermarketing
- **Corrective and Preventive Action (CAPA)/Supplier Corrective Action Request (SCAR)** provides for the investigation, root cause analysis, corrective/preventive actions, and close-out of quality issues from across the product lifecycle, closing the loop from quality events to engineering inputs.
  - Rapid Entry for quick CAPA capture
  - Gain a holistic view across quality inputs (Deviations, Nonconformances, Complaints)
  - Perform closed-loop root cause analysis



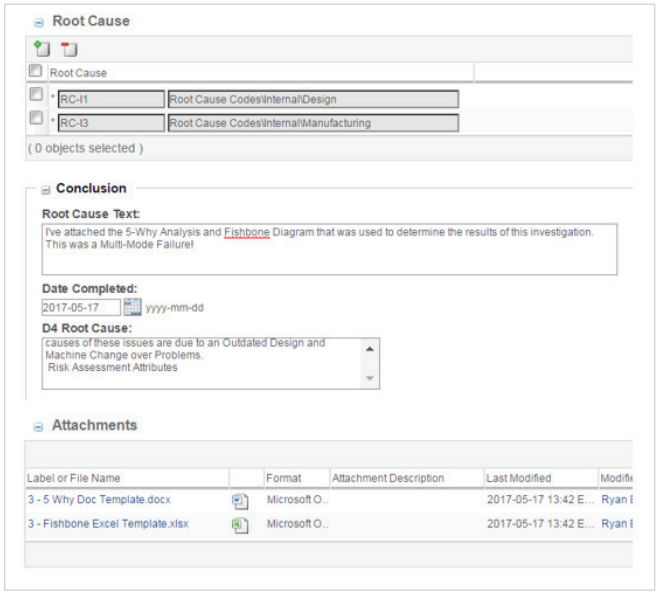
Generate complete, accurate and version-controlled DHF and DMR documentation as you develop your product.

- Integrate with BOM, Part and Documents
- Automatically generate Change Notices
- Access independent action threads for complex CAPAs
- Report status and monitor effectiveness

- **Complaint Management** provides for the intake and tracking of customer complaints to ensure that external sources of quality issues are accurately managed for full-scale correction/prevention.
  - Rapid entry screens and accelerators
  - Pre-Configured Sub Workflows for Action Steps
    - Return Product Analysis
    - General Follow-up Actions
    - Regulatory Safety Reporting eMDR, EU Vigilance, Canada etc.
  - Integrated BOM and FMEA Codes
    - Classify failures using FMEA Codes against any level of BOM
    - Record as reported observations using FMEA effects codes
    - Record as Investigated codes using Failure Modes
  - Easily escalate to CAPA or SCAR



Standardize on robust, well-controlled post-market processes.



Manage a complete, closed-loop CAPA workflow from Intake through Closure

- **Nonconformance Management** captures and resolves internal manufacturing or supplier issues centrally, ensuring roll-up reporting for clear visibility across many potential sources for quality nonconformances, and coordinating root cause investigation with PLM changes for faster, more accurate, and more complete CAPAs.
  - Capture, manage and rapidly resolve manufacturing or supplier issues
  - Get clear visibility across many potential sources of quality issues
  - Coordinate root cause analysis with PLM changes
  - Integrate with ERP and MES* systems
  - Complete nonconformance process
    - Material Review Board (MRB) sub workflow
    - Detailed Disposition (Scrap, Rework, return to vendor)
    - Split Lot Disposition (ie by portion of lot)
    - Integrated BOM – attach to any Item in BOM
    - Capture Immediate Corrections
  - Easily escalate to CAPA or SCAR

Your choice of deployment

Windchill Quality Management is available in two deployment models:

- Windchill Quality Management, Cloud deployment is designed for growing medical device makers who seek world-class capabilities, SaaS simplicity and complimentary validation –at an unbeatable value. Your organization will access a dedicated instance of a single-tenant SaaS solution pre-configured with best practices for medical device makers. Configure your solution to meet your needs.

  The Cloud offering includes a Validation Accelerator Pack from trusted advisors USDM Life Sciences, speeding time-to-value at no cost to you. Your implementation is eligible to be upgraded every two years with the latest software innovations, and includes a complimentary Revalidation.

- Windchill Quality Management, On Premise deployment provides all of the best practice configurations for medical engineering in a custom configured, on premise solution for maximum control over your IT infrastructure, maintenance and security processes. The On Premise deployment model supports hosting of sensitive patient information and data subject to HIPAA regulatory requirements. Validation is required, and is a customer responsibility.

Accelerated validation for rapid time-to-value

For medical device makers who want to get up and running quickly, Windchill Quality Management, Cloud deployment includes a complimentary Validation Accelerator Package developed by USDM Life Sciences, a global leader in software validation. This package enables comprehensive validation of intended use requirements and tests from trusted healthcare validation experts, and includes:

- 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

The Validation Accelerator Package not only saves you time and cost at project inception - it continues to deliver these benefits indefinitely. That's because PTC and USDM will update the Validation Accelerator Pack every two years in alignment with major Windchill Quality Management releases – providing you with easy access to a continuous stream of technical enhancements from the life sciences leader in PLM.

Robust, secure and 21 CFR part 11 compliant

Windchill Quality Management provides secure electronic signature capabilities required to comply with 21 CFR Part 11. Windchill has been successfully implemented and validated to meet the unique needs, configurations and intended use of hundreds of medical device manufacturers. Windchill implementations have undergone multiple FDA audits in support of the Manufacturer's Quality System Regulations.

Extending the world's first smart, connected PLM solution

Medical device innovators benefit from leveraging the unparalleled capabilities of PTC Windchill, the leading platform for medical device innovation. Windchill Quality Management allows you to deliver more product data to more lifecycle stakeholders than ever before.

*ThingWorx Navigate

- Make role- and task-specific PLM data available to all stakeholders in the product lifecycle
- Support rapid innovation and better decision making by unleashing highly dynamic, accurate PLM data throughout the enterprise, providing instant skills to more users

*ThingWorx Navigate available as an add-on

Risk Analysis

- Integrate with PTC Risk and Reliability to understand real-time performance and quality
- Improve speed and accuracy of root cause analysis and corrective / preventive actions to drive critical service activities or engineering changes faster and to improve next-generation products
- Contribute, participate and collaborate
  - Participate in assigned workflow, project and action item tasks
  - Collaborate through topics, discussion postings and problem reports
  - Create, attach and edit Microsoft Office documents with included integration
  - Subscribe to be notified of events on authorized items
- Find and View Product Information
  - Search indexed and non-indexed content
  - Define and execute user-specific saved searches
  - View page content, reports, 2-D and 3-D models and annotations Pan, zoom, rotate, measure, section and explode CAD drawings
- Manage content and control change
  - Create and manage change objects, collaboration projects, and baselines
  - Manage release processes and initiate workflow processes
  - Manage templates and attributes, including documents, parts, projects, teams, lifecycles and workflows
  - Create and manage global searches and reports
- MCAD Data Management
  - Create and manage MCAD models using workgroup managers for all PTC-supported CAD applications including Creo and Mathcad, and for select third-party CAD applications, including SolidWorks, Inventor and AutoCAD
- BoM Management:
  - Unleash the full power of Windchill to manage a complete, multi-dimensional BoM
    - Automatically create and associate BOM items on CAD document check-in
    - Manage product structures and engineering BOMs
    - Manage product structure baselines, instances and products
    - Import BOM structure from Excel
- IP Protection: Secure IP while Increasing Collaboration
  - Protect sensitive data while supporting your global “design anywhere, build anywhere” strategy
  - New security labels improve security throughout the product lifecycle and improve auditability

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