

# Windchill® Nonconformance

CAPTURE, RECORD, AND TRACK INTERNAL PRODUCT NONCONFORMANCES

Windchill Nonconformance manages the intake, evaluation, resolution, and tracking of product and process nonconformances.

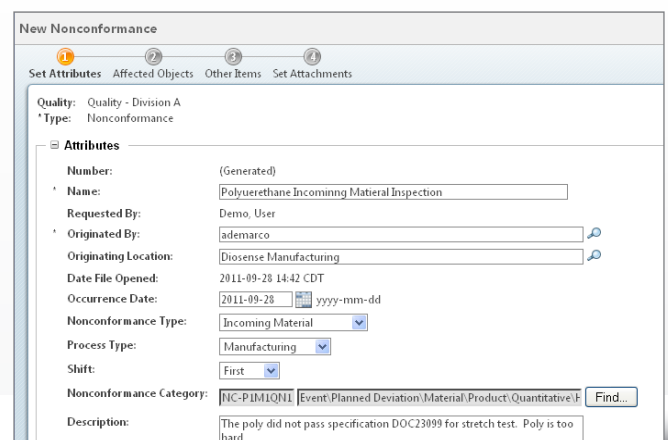
To continuously improve product quality throughout design and development, companies need complete visibility into quality issues that materialize before the product ships. When such internal issues or "nonconformances" arise—wherein a material, product, or process fails to meet the specifications set for it—quality management standards require that the nonconformance be logged, addressed, and resolved in a systematic, documented manner. To be most effective, nonconformance management should be automated, repeatable, and traceable through to resolution, ensuring that quality issues are contained and corrected before they are manifest in fielded products.

Windchill Nonconformance enables the intake, evaluation, resolution, and tracking of internal product, process, and material nonconformances in compliance with industry-driven quality management standards. And by performing these processes in a system that can be seamlessly integrated with CAPA (Corrective Action Preventive Action) processes, product risk and reliability analysis, and change management functionality in a world-class PLM system, Windchill Nonconformance is a key element of an enterprise-wide single source of truth for product and process quality management.

## Key Benefits

### Comply with government and industry quality standards

- Creates a traceable record of quality issue resolution in accordance with quality management standards
- Meet quality standards including 21 CFR Part 11/820, ISO 13485, ISO 9000 / 9001, CMMI, APQP, and Six Sigma
- Reduce the cost of compliance with improved efficiency, while proving measurable continuous improvement



Windchill Nonconformance enables the quick and easy intake, evaluation, resolution, and tracking of internal quality issues

### Enhance cross-functional communication related to quality

- Leverage internal quality information from sources like test results, manufacturing inspections, and supplier lots
- Initiate root cause analysis and corrective / preventive actions in response to nonconformances
- Provide a key source of quantified product performance data to the design team from internal sources
- Communicate lessons learned and design changes to improve next-generation products

### Speed innovation while improving product quality

- Rapid nonconformance capture and processing keeps the assembly line running
- Replaces time-consuming, labor-intensive methods for the intake and resolution of nonconformances
- Improve efficiency by storing all product and quality data together rather than in separate, decentralized systems

- Enable the proactive identification of adverse quality trends before they create costly issues in fielded products
- Root cause analysis addresses and corrects the true cause of an issue, avoiding launch delays and repeat problems

## Features and Specifications

### Automate critical quality processes

- Modular nonconformance investigation with integrated risk and failure qualification
- Process nonconformances against parts and equipment
- Record immediate actions
- Quantify material and product yields and nonconformances
- Material, part, and product disposition, including split lot dispositions and MRB (material review board)
  - Available dispositions include use "as is"
  - Split lot dispositions allow for reuse / rework to reduce costs associated with scrap
- Automate key signature gates in compliance with ISO and FDA standards
- Automated electronic submission and response tracking for medical device compliance data

### Leverage a holistic view of quality across the enterprise

- Quality dashboards provide enterprise visibility into quality issues
- Engineering has complete insight into end-product quality issues
- Intuitive, ad hoc reporting capabilities enable trending and analysis
- Watch dogs and alerts notify key personnel of quality issues

### Create a single source of truth with PLM and CAPA integration

- Capture nonconformances from all product lifecycle stages in one integrated environment
- Access quality records from within workflow tasks
- Many-to-many relationships to associate system components and assemblies with nonconformances

### Preconfigured best practice workflow processes

- Best practice workflow setup to run OOTB (Out of the box) with no additional configuration
- Full audit trail with snapshot reports
- Includes confirmation and effectiveness checks for each action

### Powerful reporting capabilities

- Intuitive trending and data mining reports require no knowledge of object or data structures
- Interactively "drill down" within a report to view detailed record data
- Query across multiple data sets in ways not possible in document-centric quality management systems
- User-defined data queries can be output in a wide variety of formats including: PDF, Text, HTML

### Intuitive, quality-focused user experience

- Easy navigation to quality and product records, designed for both frequent and infrequent users
- Dynamic state diagram provides a quick-reference visual display representing the state of the record
- Access complete quality records directly from workflow tasks – view the task in context of the record
- Easily assign key user roles and groups
- Modular architecture, configurable workflows, and formatting down to the field level allow for adherence to existing business processes
- Capture contact information once and associate with any quality record or any record in Windchill, eliminating redundancy

### For More Information

For more information on Windchill Nonconformance, please visit: [PTC.com/products/windchill/nonconformance](http://PTC.com/products/windchill/nonconformance)

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