PTC® the product development company®

Data Sheet

Windchill® CAPA (Corrective Action Preventive Action)

CLOSED-LOOP MANAGEMENT OF CORRECTIVE/PREVENTIVE ACTIONS

Windchill CAPA provides an enterprise-wide solution for managing the intake, tracking, resolution, and analysis of quality issues.

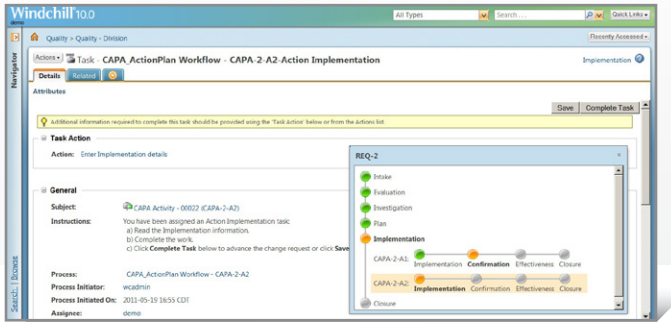
Managing product and process failures across the enterprise is no easy task. Insufficient monitoring of failure reporting and resolution leads to recurring product failures and difficulty complying with industry regulations and quality standards.

Windchill CAPA offers an enterprise-wide solution to track, investigate, and resolve product and process failures. Automated software processes ensure that every reported issue is addressed in a closed loop way with evaluation, root cause analysis, and corrective action planning, execution, and verification. Supplied templates promote compliance with FDA and ISO quality standards and regulations, and robust query and graphing tools enable comprehensive data analysis and trending to track product and process improvements.

Key Benefits

Reduce time to market and product development costs

- Eliminate manual work: Automate CAPA activities using easily configurable software workflows
- Reduce product development time: Use root cause analysis to identify processes that reduce product quality
- Reduce CAPA cycle times: Central visibility and collaboration, plus automated due date-driven workflows, alerts, and escalations help resolve CAPAs in a timely way
- Improve efficiency: Storing all product and quality data together instead of in separate, decentralized systems improves overall quality and enables proactive identification of adverse trends
- Identify new trends early in the product life cycle



Action plan workflows in Windchill CAPA help ensure that all steps are completed in the proper order

Improve products and processes

- Leverage PLM Integration: CAPAs closely inform product development, reducing recurrent issues and costly rework
- Transparent quality improvement processes: Reduce the chances of misidentified and mishandled quality issues

Demonstrate compliance

- Comply with 21 CFR 820, ISO 13485, and ISO 9001 CAPA requirements
- Prioritize CAPAs by risk index to improve compliance with ISO 14971
- Reduce the cost of compliance with improved efficiency, while proving measurable continuous improvement
- Automated electronic submission and response tracking for medical device compliance data

Streamline cross-department activities

- Store product development and quality data together to eliminate system redundancy and boost efficiency
- Enable robust and thorough root cause analysis through a direct connection to product development information
- Automate the intake of product quality data from a PLM system or from Windchill FRACAS
- Leverage risk data during root cause investigation through integration with Windchill FMEA
- Output ECRs from Windchill CAPA to initiate change management in the PLM system
- Improve quality audits with integral document management and change management capabilities

Features and Specifications

Comprehensive BOM integration

- Navigate to and select any top level part, subassembly, or document with CAPA
- Link CAPA instances to BOM parts or documents with a one-to-many or many-to-one relationship
- View and access all associated CAPA records directly from the part or document
- View and access all associated parts or documents directly from the CAPA record

Preconfigured best practice workflow processes

- Best practice workflow setup to run OOTB (out of the box) with no additional configuration
- Allows for a single CAPA to have many simultaneous independent actions
- Full audit trail with snapshot reports
- Best practice workflow 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 CAPA 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 CAPA, please visit:
PTC.com/products/windchill/capa

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