

What's New in PTC Windchill® Quality Solutions 10.2?

NEW FEATURES AND FUNCTIONS IN THE PTC WINDCHILL QUALITY SOLUTIONS 10.2 RELEASE

PTC Windchill Quality Solutions 10.2, released in August, 2013, offers a host of new updates to support product quality, reliability, risk management, and compliance across a wide range of industries.

PTC Windchill Quality solutions 10.2 offers expanded connectivity between other product lifecycle management activities supported by PTC Windchill and the quality-related analysis and feedback supported by the PTC Windchill Quality Solutions suite of products. In addition, the update provides new functionality supporting compliance with Medical Device quality standards, enhanced Global Risk Management across the enterprise with a new, Web-based Fault Tree Analysis module, enhancements to FMEA analysis, new capabilities in support of the MSG-3 civil aviation standard, and much, much more!

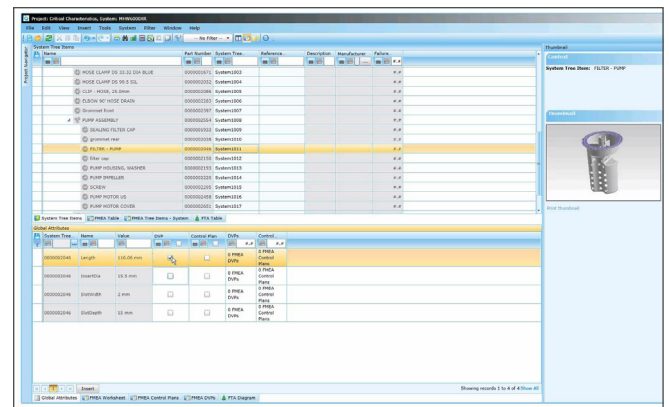
Key Benefits

Quality-Driven Change Management

Building on existing functionality that allows PTC Windchill Quality Solutions to share BOM data dynamically with PTC Windchill PDMLink or MPMLink, so that any changes made in the BOM flow down synchronously into the same system represented in PTC Windchill Quality Solutions, Quality-Driven Change in PTC Windchill Quality Solutions 10.2 offers new capabilities to drive engineering changes from any software module throughout the Quality Solutions suite.

This functionality is enabled by a centralized Problem Table that can be accessed from any module to report a quality issue. As users report incidents from throughout the product lifecycle, these incidents can be associated with related problems that will then

be addressed through changes introduced to the PLM system. From this Problems Table, users can generate an ECR (Engineering Change Request), CAPA (Corrective/Preventive Action) or Problem Report in PTC Windchill that follows established workflows and processes for traceable change management.



In PTC Windchill Quality Solutions 10.2, leverage powerful synchronizations with a PTC Windchill PDMLink or MPMLink Bill of Materials, including Creo thumbnails, Critical-to-Quality characteristics, and Quality-Driven Change Management.

Quality-Driven Change helps improve product quality by enabling users to:

- Drive change from quality problems identified at any stage in the product lifecycle – design through service
- Address quality issues earlier, when fixes are less costly

- Improve the connectivity between test and design teams by driving change from quality issues experienced during test
- Connect quality problems uncovered during manufacturing or service to the design changes necessary to correct them, improving next-generation designs
- Create and manage problems from inside any Global Quality module
- Generate PTC Windchill change objects (ECR, CAPA, Problem Report) associated with a part in a connected BOM

Enhanced Global Risk Analysis Capabilities

New Module: Web-Based PTC Windchill FTA

New, Web-based fault tree analysis in PTC Windchill Quality Solutions 10.2 enables global, enterprise-wide collaboration around risk management processes – a feature mandated by industry-wide requirements like Medical Device Risk Analysis (ISO 14971), Automotive Functional Safety Analysis (ISO 26262), and Civil Aircraft Safety Analysis (ARP4761).

The new, Web-based PTC Windchill FTA offers the complete functionality of the PTC Windchill FTA (Fault Tree Analysis) module, including a full range of analytics, CAFTA converter, dashboards, graphing and reporting, data linking, build from FMEA, library support, built-in toolbar, and so on – in a lightweight, distributable web environment with a robust, intuitive interface. It thereby enables enterprise-wide access to critical Fault Tree analysis, reporting, root cause analysis, and quality improvement functionality.

Web-based fault tree analysis in PTC Windchill FTA delivers the following, industry-critical functionality throughout the organization to enable Global Risk Management capabilities like

- Global Root Cause Analysis (core to CAPA/FRACAS and general problem solving)
- Global Risk Analysis for ISO14971 – a Medical Device Risk Analysis standard
- Global Functional Safety Analysis in support of ISO26262 – an Automotive Functional Safety Analysis standard
- Global Functional Safety Analysis supporting ARP4761 – a Civil Aerospace Safety Analysis
- Global Fault Tree – a common FA&D requirement
- Condition-Based Monitoring Planning

Other new features of PTC Windchill FTA include:

- An easy-to-navigate large fault tree display
- Performance-enhancing long-running task manager
- Support for Multiple Distributions - to model uncertainty and/or variations
- Support for Monte Carlo Simulations - to handle large, dynamic fault trees with repeated events, transfer gates, disjoint events or groups, dependencies, imperfect maintenance, limited repair resources, and very low top-event probabilities
- Specialized gate and event logic in support of ISO 26262 in the Automotive industry
- Enhancements to common (repeated) monitors to detect latent failures across events, in support of ARP 4761 in the Commercial Aerospace vertical
- Long Running Task Manager, which provides the means to continue processing long-running fault tree calculations even when the web application is closed. Calculations take place on the server or can be farmed to multiple servers, with the ability to prioritize, stop, or delete tasks, check on task status and receive notification when tasks are complete

Updates to PTC Windchill FMEA

FMEA enhancements in support of risk management include a customizable risk matrix with an easy, intuitive, and flexible interface; updated user calculations; and failure modes library updates in support of ISO 26262 requirements in the automotive industry. What's more, a brand-new FMEA Actions table helps users track actions taken to address

failure modes and their effects, record the results of these actions, connect them to a common problems table, and – through that connection – launch engineering change requests against system tree parts shared by both PTC Windchill FMEA and a synchronized PDMLink or MPMLink Bill of Materials.

The new Risk Matrix available in PTC Windchill FMEA supports risk analysis activities across a wide range of industries, including Automotive and Medical Devices. It allows for:

- Assignment of High, Medium, and Low risks
- Multiple risk matrices
- 2- and 3-axis matrices
- Easily configurable fields and lists
- An intuitive interface with “painting” available by clicking in cells and customizable colors
- Default risk matrixes may be set for different types of FMEAs, with the risk level automatically set based on the matrix
- Coordination between the risk level graph and the matrix and drill-down capabilities

The newly updated Actions table in PTC Windchill FMEA supports the traceability of actions taken to mitigate risks identified in the FMEA. To mitigate risks identified by the FMEA, analysts typically identify recommended actions and track both Actions Taken and the results of these actions. But because it may take several tries to mitigate a single risk – and there may be several risks associated with the same mitigating action – a robust process must be used to create and track these actions. The new Actions structure provides this robust capability, including features such as:

- Multiple Actions per cause
- Multiple Actions can be associated to a problem, where they are grouped to address the problem with a change artifact
- The results of the change process can be shared out to all associated actions

- With a connection established between the FMEA system tree and the Bill of Materials in either PDMLink or MPMLink, an engineering change order, CAPA, or problem report can be generated as a result of the problem and its associated actions. This item can be traced through established PTC Windchill workflows for change management

Additional FMEA enhancements include:

- Improved worksheet calculations
- An updated IEC62380 Failure Modes Library to support ISO26262 calculations. This improvement leverages the existing connection between Reliability Prediction and FMEA, whereby predicted failure rates flow to FMEA to easily identify the expected frequency with which a part, system, or subsystem is likely to fail, in order to support a quantitative FMEA that meets the requirement of the IEC 62380 specification

New Standards Supported

Medical Devices: eMDR in PTC Windchill CEM

PTC Windchill Customer Experience Management newly supports eMDR (electronic Medical Device Record) submissions to more efficiently comply with 2009 FDA requirements for electronic adverse event reporting.

New eMDR functionality in PTC Windchill CEM works by:

- Populating eMDR fields automatically from customer intake forms in PTC Windchill CEM
- Routing the electronic submission to the right roles throughout the organization for review and approval
- Sending the eMDR via electronic submission to the FDA’s virtual gateway via technology tested and proven with the FDA
- Reducing the time-consuming manual efforts needed to comply with this standard, as well as chances for human error
- Receiving, storing, tracking, and reporting on FDA responses to eSubmissions, helping to reduce instances of noncompliance and audits

- Providing robust internal visibility around compliance with eMDR requirements with dashboard-style reports and charts

Civil Aviation: MSG-3 (Maintenance Steering Group V.3)

New PTC Windchill MSG-3 functionality expands support for the Civil Aviation standard MSG-3 (Maintenance Steering Group Version 3). In addition to the MSI (Maintenance Significant Item) analysis available in previous versions of the tool, PTC Windchill 10.2 adds functionality for the SSI (Structurally Significant Item), Zonal, and L/HIRF (Lightning/High Intensity Radiation Field) analyses also required by the standard.

Structured decision trees for each of these analysis types guide users through the selection of maintenance plans and risk mitigation activities in an easy-to-use, intuitive interface. These robust, logic-guided decision trees are dynamically connected to the tool's FMEA back-end to identify any items whose failure may result in safety, operation, economic, or structural impacts.

Following identification of high-risk items, complete FMEA functionality plus additional, configurable decision tree logic is provided to help the analyst identify maintenance strategies, diagnostics, and tasks that will assist in reducing or eliminating the impact of failures. What's more, the tool offers robust connections to other PTC Windchill Quality Solutions modules, including Reliability Prediction, which supports a quantitative risk analysis by linking to dynamic failure rate data for parts, assemblies, subsystems, and systems; as well as a range of related tools that help to optimize maintenance tasks, costs, sparing, and resources needed in the field.

These new MSG-3 analysis types offer a range of functionality and benefits – beyond the currently available Maintenance-Specific Item (MSI) analysis – to meet the Civil Aviation standard. These include:

- SSI (Structurally Significant Item) analysis, which helps to identify and manage risks to structurally significant items, further enhancing aircraft safety through rigorously structured maintenance needs analysis and maintenance task planning
 - Zonal analysis, which helps to consolidate maintenance tasks by zone: efficiently combining tasks that take place in the same part of the aircraft and within a similar timeframe to maximize aircraft safety and functionality while minimizing maintenance costs through more efficient use of personnel time and effort
 - L/HIRF (Lightning/High Intensity Radiation Field) analysis, which offers an additional level of analysis to safeguard components that are sensitive to L/HIRF impacts, minimizing or eliminating safety risks that could result and introducing mitigating factors – from backup systems and system redesign to inspections and routine maintenance activities – ultimately safeguarding passengers from these effects.
- Other Features and Specifications

Other new features in PTC Windchill Quality Solutions 10.2 include:

- Report Binders, which replace previous Subreports with new functionality supporting child reports, sibling reports, repeated reports, and cascading filters. Report Builder offers a new interface with more robust filter selections, new child- and sibling- options, and red-line data changes, among other myriad features
- Web enhancements, including a project administrators tab added to project properties, the ability to map PTC Windchill PDMLink or MPMLink BOM attributes to PTC Windchill Quality Solutions fields upon import/synchronization, serial number edits, show system folder hierarchy upon file > open, and reserve licenses for web access
- FRACAS team subtables to enable ad hoc Problem security, including creation, reporting/filtering, problem permissions, team permissions by project, add team members to problem table and data definition, find users, import/export, and block incident association and problem modifications for non team members

- Enhancements to the WQS API include support for Parameterized Filters and support for API attachments, including download/upload for multiple attachments via API, attachment deletion via API, and attachment type blacklisting – which prevents certain filetypes from being attached
- Other updates include modified LSAR export as a result of customer feedback, workflow (free-text) email validity check, SDAP library support for all LDAP systems, parent-level record display in reports, enhanced stacking bar charts, and the ability to drill down into charts associated with FRACAS and FMEA groups

For More Information

For more information on PTC Windchill Quality Solutions, please visit: [PTC.com/products/windchill/quality](https://www.ptc.com/products/windchill/quality)

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J2557-PTC-Windchill-WQS-DS-EN-0813