

Siemens PLM Software

Issue Management and Corrective and Preventive Actions (CAPA)

Benefits

- Reduce manual effort by automating your business process through configurable workflows
- Improve problem resolution times and increase executive visibility
- Demonstrate compliance to standards
- Leverage your PLM investment
- Make smarter decisions by reusing knowledge captured and documented within Teamcenter
- Gain insight into deliverables through full traceability and relationships to any issue

Summary

Siemens PLM Software's Teamcenter® software solution for Issue Management and Corrective and Preventive Actions (CAPA) provides an enterprise-wide solution for capturing various forms of complaints, defects and non-conformances providing a formal process to systematically investigate, analyze and resolve these issues while streamlining the definition of measures to prevent future reoccurrences and reporting the results in a simple, intuitive user experience.

In today's competitive environment, companies are challenged to reduce product and operating costs while improving on product quality to help distinguish them in the marketplace. Every effort must be made to improve efficiencies among teams which may be distributed across the globe.

The Teamcenter Issue Management and CAPA solution provides closed-loop issue resolution built on an enterprise-scalable foundation for identifying, analyzing and sharing critical product quality data across your enterprise. Now your design, manufacturing and quality improvement teams can share the same views of the information they need to directly impact Six Sigma and Lean initiatives. CAPA provides visibility into critical product quality characteristics, failures/non-conformances, and resolutions to these issues for smarter decisions across the global, extended enterprise.

Impact the cost of quality

Built on your PLM foundation, Issue Management and CAPA can interrogate the full spectrum of control points including design, production and process, documents, materials, facilities and equipment. This broad information domain allows your

Issue Management and Corrective and Preventive Actions (CAPA)

The screenshot shows the Teamcenter CAPA interface. At the top, the user role is 'capa4 (capa4) - Designer (Engineering)'. Below the navigation tabs, there are icons for 'Create Issue', 'Submit to Workflow', 'Sign off', 'Issue List', 'Refresh', 'Modify', 'Generate Report', 'Derive CAPA', 'Derive CR', and 'Assign Participants'. The main area displays a table titled 'My Issues' with the following data:

Issue No.	Synopsis	Description	Owner	Last Modified Date	Date Created
IR-000041	no exit plans posted	need to know how to get out of the building in case of emergency	capa4	24-Aug-12 10:51:24	24-Aug-12 10:50:50
IR-000016	dimension problem on a t	when taking measurements on the turbine blades, we are noticing the dimensions are not wit	capa4	24-Aug-12 08:56:17	17-Jul-12 14:37:38
IR-000021	cover is easily scratched	customer bought one of the Abcd products, and is complaining that it's very easy to scratch	capa4	24-Aug-12 08:55:22	19-Jul-12 16:17:15
IR-000022	finish on completed cover	the final inspection station, inspection of the final finished product shows the some covers c	capa4	24-Aug-12 08:53:26	19-Jul-12 16:18:15
IR-000031	Measurements are not wi	During ramp up study, measurements are taken after the machining process	capa4	09-Aug-12 10:59:34	09-Aug-12 10:59:34
IR-000020	Brand New synopsis Sprir	this is a long description of the issue which was created in Sprint 7	capa4	07-Aug-12 02:23:44	19-Jul-12 16:14:09
IR-000023	dimensional problem with	the measurements are not within specs again!	capa4	24-Jul-12 14:46:01	24-Jul-12 14:46:01
IR-000017	Generic issue #3	testing the workflow capabilities of anissue	capa4	17-Jul-12 15:52:24	17-Jul-12 15:52:24

Benefits *continued*

- Reduce IT investment by eliminating the need for other systems for tracking issues
- Improve closure results to mitigate the risk of rework on repeat issues

Features

- Intuitive, web-based user experience which can be tailored to your specific needs
- Powerful, easily customizable reporting allows you to present information important to you in your preferred format
- Dashboard with drill down capabilities helps you analyze quality data and identify trends. Powerful, integrated search helps you easily find the information you need, and to create associations to the issues as needed

CAPA teams to find and validate root causes faster without the delays of searching other systems for critical data or the additional risk that can be introduced through manual processes.

Automated workflows streamline the effort of communicating and managing your CAPA process across the extended enterprise. Correlating issues to deliverables and capturing their root causes and resolutions helps to mitigate the risk of rework and improve consistency of execution. This closes the loop between issue capture and final resolution for a positive impact on your cost of quality.

Any result of a corrective or preventive process must be able to demonstrate control through objective measurement of an implemented action. With Teamcenter sophisticated trace links, all deliverables, analysis, documentation and validation results are neatly retrievable for internal or external audits providing added value for engineering and manufacturing teams working on new product programs.

When CAPA activities result in engineering or manufacturing change requests, each change is managed and documented through formal workflows which maintain

the associativity of the entire CAPA investigation. This assures complete documentation throughout the entire process and supports your ability to deliver investigations within consistent processes.

Simple user experience

The Teamcenter user experience supports a wide range of users and the CAPA solution adds to this suite with an extremely simple web-based user interface dedicated to the issue definition and resolution process. The CAPA user interface has been tuned to be very efficient to meet the needs of quality users participating in the issue identification and resolution processes.

Issues and corrective actions and preventable actions

The corrective and prevention process is managed by a CAPA business object. The CAPA object and process manages the resolution of the issue, independent of the issue itself. The advantages of different objects include:

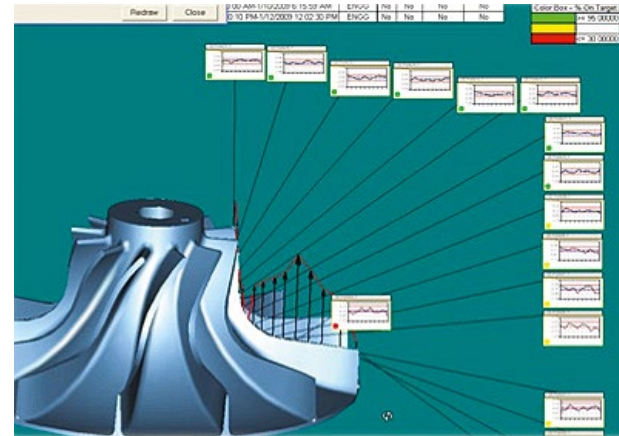
1. Shielding the corrective measures from the issue, if that is desired by your company.

Features *continued*

- Powerful, flexible reporting
- You can view the PLM deliverables, the issues related to the deliverables, and the resolution to the issues in the same environment
- You can use the provided workflows to manage the issue resolution process, or define and execute your own issue resolution processes through the configurable workflows
- Single view for all tasks and sign-offs
- Capture the knowledge of how to resolve the issue within your PLM environment

2. Resolving multiple issues/complaints by a single CAPA, reducing the need to replicate information or duplicate efforts.
3. Addressing a single issue with multiple resolutions, each managed by a separate CAPA business object.

Teamcenter CAPA provides management for both issue and CAPA processes. You may choose to use only one or both, depending upon your business needs.

**Contact**

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