

NetRegulus® NetRM™ Nonconformance Module

Web-based, comprehensive software for Quality management

NetRegulus NetRM Product Architecture

NetRegulus NetRM Software Solutions represent a revolutionary approach to regulatory data management. A series of Study and Quality modules ride atop a powerful relational database that leverages a single data model across all applications, for comprehensive data management. If desired, the modules can be used individually as point solutions, or together as an enterprise system that spans product life-cycles.

NetRegulus NetRM Advantages

Global

Full language localization allows for complete presentation of the UI in the user's preferred language.

Accessible

Authorized users can manage Quality and Study data from any location in the world with a web browser.

Powerful

NetRegulus NetRM Software is built on one of the most sophisticated architectures available today, allowing you to query data across multiple data sets in ways not available in document-centric systems.

Intuitive

User interfaces and workflows are designed by life science professionals to manage the most complicated tasks with a simple-to-use navigation scheme.

Configurable

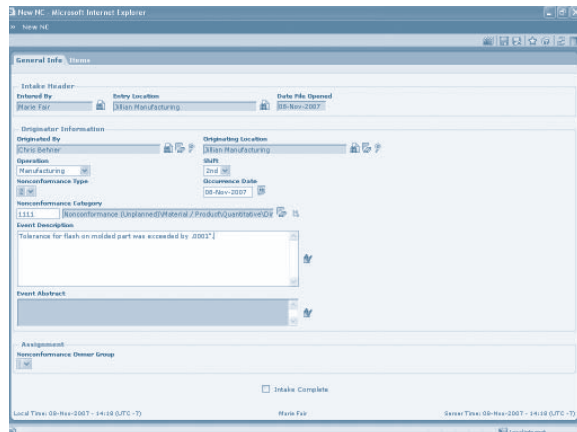
Modular architecture, configurable workflows, control of security zones, formatting to the field level and user-controllable query tools let you design and adapt the system to your environment.

Cost-Effective

The use of standard software components lowers the initial cost of implementation. Plus, a centralized database allows master data to be re-used without the need to reconfigure each time a new study or module is added, lowering the total cost of ownership.

Trusted

NetRegulus solutions are used by some of the most recognized life science companies in the world. See why they trust us to help them manage their mission-critical Quality and Study data.



The Nonconformance module provides comprehensive management capabilities allowing users to initiate, evaluate, assign, monitor and review each NC record.

The Nonconformance Module

The Nonconformance (NC) module is one of a suite of quality management modules that can function either as a stand-alone application or as part of the full NetRegulus NetRM suite of quality management and clinical study management solutions. This module provides comprehensive management capabilities allowing users to initiate, evaluate, assign, monitor and review each NC record. Security and access is controlled by configurable "zones", allowing you as much control over the process as you wish.

As in other NetRegulus NetRM applications, roles are used to enhance and define the user experience. An example of default roles within NC is the NC Evaluator, Investigator, and the record Owner. The Evaluator has the authority to review new NC records to make sure they are accurate and complete and decide if they should continue on in the workflow. The Evaluator can decide if further investigation is necessary and whether or not a disposition requiring approval is required. The Investigator conducts the investigation, performs any required Risk Assessment and makes decisions about whether or not a CAPA is warranted. The NC Owner controls the content of any Approval Packages, using either a default approval matrix of individuals or approval roles, or creating an approval list specific to a given record.

Nonconformance Module Functions

- Manage the intake, evaluation, investigation and resolution of nonconformances
- Maintain information about products, materials, equipment and other items
- Utilize the workflow engine to alert users when and where their involvement is needed
- Configure decision tree elements for Risk Assessments and other key functions
- Associate multiple products, manufacturing sites, vendors or classifications to each nonconformance
- Attach electronic files, test results, photos and other important documents
- Maintain a library of standard text phrases to be used anywhere across the nonconformance record
- Add workflow elements on the fly from a library of optional actions, including corrections, inspections, dispositions, management review and others
- Manage activities, cancel or reassign actions and change due dates. The powerful workflow engine maintains a full audit trail and rationale documentation
- All field labels, tab labels, menu items, form text (warnings, errors, etc) are user/administration configurable to match your own terminology
- Powerful and fully-integrated Reporting Tool lets users generate their own data sets and export to Excel or other commonly used data files
- User configurable reports with e-mail distribution, scheduling and graphing capabilities
- Use electronic signatures to record reviews of material dispositions and other activities
- Easily associate the nonconformance to one or more CAPA records to manage a closed-loop process

Other Quality Modules

Corrective and Preventive Actions (CAPA)

Initiate, evaluate, assign, monitor, review and approve corrective/preventive actions. Link multiple issues from various data sources to each action. Utilize sophisticated "Watchdog" technology to aid in effectiveness monitoring.

Complaints

Manage all activities related to customer complaints. Link complaints to existing or create new corrective actions. Conduct regulatory reporting and other key activities related to risk management.

Audit

Record audit findings, identify respondents, link to specifications and more. Integrates findings into the CAPA module for corrective action.

Summary

For more information on PTC's NetRegulus® NetRM™ Nonconformance Module, please visit www.ptc.com/go/netregulus