

# NetRegulus® NetRM™ Nonconformance Module

Web-based, comprehensive software for global Study and 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 sit atop a powerful relational database that leverages a single data model across all applications, for comprehensive data management, visibility and reporting. If desired, the Study and Quality modules can be used together, allowing organizations to continuously monitor and advance product quality and innovation in a single, integrated solution that spans the total product lifecycle.

## NetRegulus NetRM Key Benefits

### Global

Full language localization allows for complete presentation of the software interface in the user's preferred language, including double-byte characters for languages such as Japanese, Korean and Chinese.

### Accessible

Authorized users can access and manage real-time Study and Quality 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 and trend data across multiple data sets in ways not available in document-centric systems.

### Intuitive

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

### Configurable

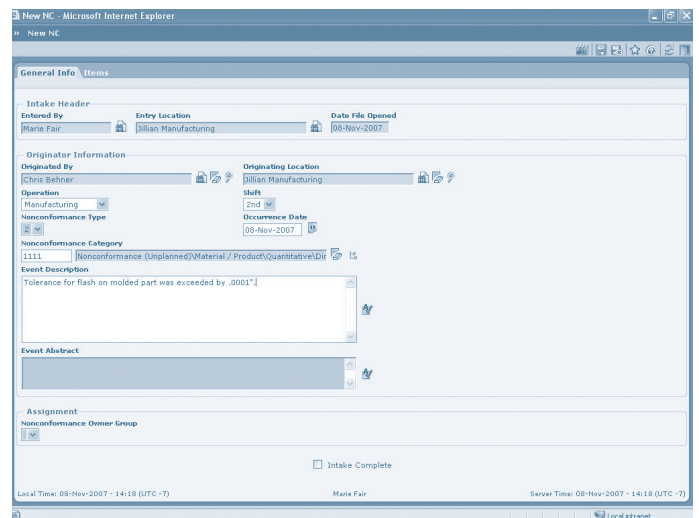
Modular architecture, configurable workflows, control of security zones, formatting to the field level, and user-controllable query tools let you design and adapt the system to your environment.

### Cost-Effective

The use of standard software components lowers the initial cost of implementation and reduces training time. Plus, a centralized database allows master data, reports and other information to be reused without the need to reconfigure or revalidate the system each time a new study or module is added, lowering the total cost of ownership.

### Trusted

NetRegulus solutions are used by some of the largest life sciences companies in the world. See why they trust PTC to help manage their mission-critical Study and Quality data.



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

## The Nonconformance Module

The NetRegulus NetRM Nonconformance module is one in a group of Quality management modules from PTC, which also includes the NetRegulus NetRM Complaints module and NetRegulus NetRM CAPA (Corrective and Preventive Actions) module.

The Nonconformance module is designed to function either as a stand-alone application or as part of the full NetRegulus NetRM suite of Study and Quality management solutions. These solutions provide a single view into the safety, manufacturing and performance trends covering the life of your products.

The Nonconformance module is a highly configurable and comprehensive tool for managing all activities associated with nonconformance record handling in a regulated environment. Users may initiate, evaluate, assign, monitor and review each NC record according to their assigned roles. Users can accomplish tasks faster and more accurately using the software's configurable pull-down menus, smart lookups, intelligent workflows and point-and-click interfaces.

### Nonconformance Module Functions

- Manage the intake, evaluation, investigation and resolution of nonconformances
- Maintain information about products, materials, equipment and other items
- Use 21 CFR Part 11-compliant 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
- Manage activities, cancel or reassign actions, and change due dates while the powerful workflow engine maintains a full audit trail and rationale documentation
- Add workflow elements 'on the fly' from a library of optional actions, including corrections, inspections, dispositions, management reviews, and others
- Utilize the workflow engine to alert users when and where their involvement is needed
- Provide notifications and alerts of pending or overdue items
- 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
- Configure all field labels, tab labels, pull-down lists, menu items, and form text (warnings, errors, etc.) to match your own terminology
- Create data sets and graphs with an easy "point-and-click" interface that also allows users to save and reuse their report templates
- Set up "Watchdog" reports that are sent automatically by the system when an event or user-specified threshold is triggered
- Schedule and distribute reports via email—no need for recipients to log into the system
- Export report data to other commonly used tools for further analysis or processing

### Other NetRegulus NetRM 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 actions, or create new corrective actions. Conduct regulatory reporting and other key activities related to risk management.

#### Study Administrator

Rapidly create and configure electronic or paper clinical, postmarket surveillance, condition of approval, registry, and other types of studies. Oversee the study's progress, including tracking resources, study and site milestones, and financial payment information.

#### Study Data Manager

Conduct all aspects of data collection and management. Enroll study subjects, and manage and track subjects' CRFs and attachments using dynamic workflow tasks configured to your business processes. Also, run reports of CRF data, within or across studies.

#### CRF Builder

Use a "drag-and-drop" interface to design forms used for paper or electronic studies. Create libraries of fields and field groups to rapidly create new CRFs. Embed intelligence for CRFs used in EDC studies. Use "wizards" to publish the forms and to create ad hoc pages for reporting of CRF data within or across studies.

#### CRF Administrator

Manage the company's library of case report forms, and create and schedule automatic processes that validate data entered into one or more CRF fields against quality criteria you define.

### Learn More



For more information on PTC's NetRegulus NetRM Study and Quality modules, please visit our website at:  
<http://single-sourcing.com/products/contentmanager/flavors.html#netregulus>

© 2008, Parametric Technology Corporation (PTC). All rights reserved. Information described herein is furnished for informational use only, is subject to change without notice, and should not be construed as a guarantee, commitment, condition or offer by PTC. PTC, the PTC logotype, NetRegulus, NetRM and all PTC product names and logos are trademarks or registered trademarks of PTC and/or its subsidiaries in the United States and in other countries. All other product or company names are the property of their respective owners.