

NetRegulus® NetRM™ Complaints Module

Web-based, Comprehensive Software for Complaint Management

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 lifecycles.

NetRM Software Features

Global

Full language localization allows for complete presentation of the UI in the user's preferred language, including double-byte characters for languages such as Japanese, Korean and Chinese. Set user language preferences to automatically render the application screens in the supported language sets.

Accessible

Authorized users can manage Quality and Study data from any location in the world with a web browser. Different groups can access data to improve operational efficiencies and product knowledge across an organization.

Powerful

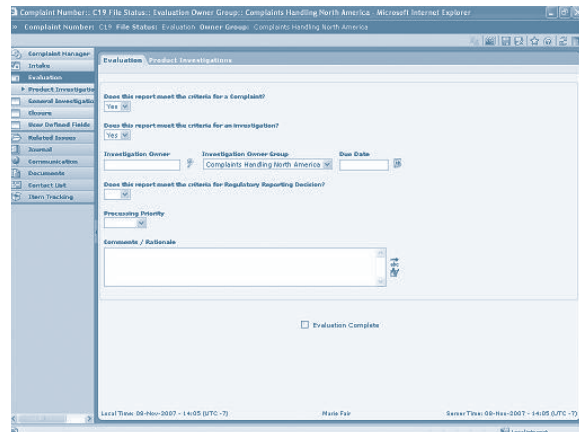
NetRM Software is built on one of the most sophisticated architectures available today, allowing you to query data across multiple data sets in ways not available in document-centric systems.

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

NetRM Software's 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.



The Complaints module allows you to manage investigations, tasks, assignments, regulatory reporting and more.

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.

NetRegulus NetRM Complaints Module

The Complaints module provides a highly configurable comprehensive data management tool for all activities associated with complaint handling in a regulated environment. Manage investigations, tasks, assignments, regulatory reporting and more. Configurable pull down menus, smart look ups and point and click interfaces let users accomplish tasks faster and more accurately.

Complaints Module Functions

- Manage the investigation and resolution of customer complaints
- Maintain customer and product information
- Provide a workflow and review process with issue resolution and system notifications
- Configure decision tree elements for Regulatory Reporting Decisions, Risk Assessments and other key functions
- Generate form letters and regulatory reports using pre-populated templates
- Associate multiple products, manufacturing sites, vendors or classifications to each complaint
- Attach electronic files, photos and other documents
- Generate standard regulatory reports including MedWatch, Vigilance, and Canada PRF
- Support MedWatch Alternative Summary Reporting
- Maintain a library of standard text phrases to be used anywhere across the Complaints record
- Track product movement within the organization
- Add workflow elements on the fly from a library of optional actions, including decontamination, product evaluation, failure investigation, disposition 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

Summary

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