

# NetRegulus® NetRM™ CAPA 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

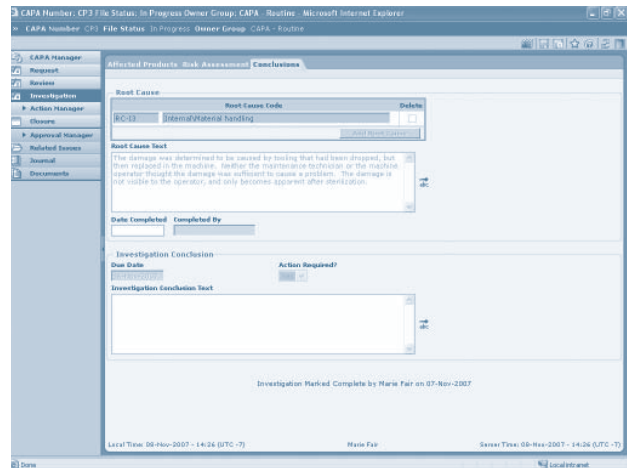
Modular architecture, configurable workflows, control of security zones, formatting to the field level and user-controllable query tools let you design and adapt the system to your environment.

### 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 CAPA module provides comprehensive management capabilities allowing users to initiate, evaluate, assign, monitor, review and approve each CAPA record.

## The Corrective and Preventive Actions Module

The Corrective and Preventive Actions Module (CAPA) 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. 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 a role within CAPA is the CAPA reviewer role, which has the authority to review new requests and return them to the requestor for additional information, or accept the request into the system. The Reviewer can assign the new CAPA to an Owner (or Owner Group) for further investigation. Another role, the Owner, can conduct the investigation and create the Action Plan. The Owner controls the content Approval Package, using either a default approval matrix of individuals or approval roles, or creating an approval list specific to a given record.

This module provides comprehensive management capabilities allowing users to initiate, evaluate, assign, monitor, review and approve each CAPA record.

### **Powerful Reporting**

- Powerful and completely integrated Ad Hoc query tool that provides authorized users the ability to generate their own data sets with an easy to use “point and click” interface
- User configurable query pages and reports with graphing capabilities
- Schedule reports to run at pre-determined intervals and automatically e-mail reports to a distribution list
- Automate standard reporting – quickly compile summaries, change histories, CAPA detail reports and more
- Export report data to other commonly used tools for further analysis and/or processing

### **Comprehensive Process and Record Management**

- Link multiple issues from various sources to each corrective or preventive action including complaints, nonconformances, audit findings and other quality issues
- Design your own classification schema to facilitate trend analysis
- Add multiple classifications to each CAPA record and use data to follow trends
- Includes multiple configurable decision trees/classifications for risk assessment, root causes and effectiveness monitoring
- Generate Corrective/Preventive Action Plans and electronically circulate for Review and Approval
- Create, assign and track multiple optional activities and tasks through closure
- Provide notifications and alerts of overdue items
- Utilize 21 CFR Part 11 compliant electronic signatures where required

### **Configurable Security**

- Configurable security zones allow administrators to set security down to the field level
- Security zones can be applied to users and/or locations to control who can be assigned to activities like Approvals, Investigations, Effectiveness Monitoring and others
- Schedule and distribute reports via email – no need for recipients to log into the system

### **Accessible and Global**

- Full language localization allows for complete presentation of the UI in the user’s preferred language including double byte character languages
- Web-based applications can be accessed from anywhere in the world, from any machine, while still enforcing all the security protocols that the organization applies to their remote users
- Administrative tool kit to configure all labels and user text and provide translations for languages supported by the organization and more

### **Summary**

For more information on PTC’s NetRegulus® NetRM™ CAPA Module, please visit [www.ptc.com/go/netregulus](http://www.ptc.com/go/netregulus)