



PTC Product Focus: A) [CAM Lite – Machining in Pro/ENGINEER Foundation](#)

B) [NetRegulus Quality for Nonconformances, Complaints, and CAPA's](#)

Tips of the Month: A) [Manufacturing Tutorials Available for Download](#)

B) [Access to Product Development Data is Only a Click Away](#)

Announcements: [Most Recent Announcements](#)

Upcoming Events & Training Schedule: [Events & Training Schedule](#)

PTC Product Focus

CAM Lite – Machining in Pro/ENGINEER Foundation

[Click Here To View](#)

[Back To Top](#)

PTC Product Focus

NetRegulus Quality for Nonconformances, Complaints, and CAPA's

The Nonconformance Module

The Nonconformance (NC) module is a highly configurable and comprehensive tool for managing all activities associated with incoming materials and shop floor issues. 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
- 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

Configurable with Labels, Dropdowns, Workflow Packets, and Decision Trees

The screenshot displays the NC Manager software interface within a Windows Internet Explorer browser window. The browser title bar shows "NC Number: NC8 Owner Group: NC Owner Group File Status: Intake Days Open: 328 - Windows Internet Explorer".

The main interface is divided into several sections:

- Left Navigation Panel:** Contains a tree view with items like "Intake", "Evaluation", "Investigation", "Disposition Manager", "Decision", "Disposition", "Approval", "Action", "Closure", "Items", "Approval Manager", "Related Issues", "Journal", and "Documents".
- General Info / Items:** The main form area. It includes fields for "Intake Header" (Entered By, Manufacturer, Date File Opened), "Originator Information" (Originated By, Originating Location, Occurrence Date, Shift), and a "Nonconformance Type" dropdown menu. The dropdown is open, showing options like "Incoming Material", "In Process Mfg", "Final Inspection", "David Rubin NC", and "BQCA New Dropdown". A red circle highlights the dropdown menu.
- Description:** A text area containing the description of the nonconformance: "(The outer diameter of Part #811AA is out of specification.)".
- Additional Details:** A text area containing additional information: "During the final in-process gauging, Screw 811AA measured 0.0002" under the bottom specification limit. Can we still use the screw or should we send this to MRB for review?".
- Parts/Products:** A table listing parts/products associated with the nonconformance.

Select	Product Number	Description	Lot/Serial Number	Supplier Lot/Batch Number	Qua
<input type="checkbox"/>	811AA	A1 Screw	81811		500
<input type="checkbox"/>	811AA	A1 Screw	81812		500
- Other Items:** A table for other items associated with the nonconformance.

Select	Item ID	Description	Unit(s) ID	Quantity	Units	It
-- No Record --						

A red circle highlights the "Additional Details" section. A red arrow points from the "BQCA New Dropdown" option in the dropdown menu to a separate configuration panel on the right.

The configuration panel on the right is titled "Nonconformance Category" and shows a tree view of categories and sub-categories:

- ☒ Event Category-NC
 - ☒ Control limit exceeded
 - ☒ Nonconformance (Unplanned)
 - ☒ Material / Product
 - ☒ Qualitative
 - ☒ Cleanliness
 - ☒ Color
 - ☒ Dimension
 - ☒ Hardness
 - ☒ Quantitative
 - ☒ Other
 - ☒ Planned Deviation

The Complaints Module

The Complaints module is a highly configurable and comprehensive tool for managing all activities associated with complaint handling in a regulated environment. Users may initiate, evaluate and investigate complaints, and when necessary, generate MedWatch and other regulatory reports according to their role assignments. This module is designed to function either as a stand-alone application or as part of the full NetRegulus NetRM suite of Quality management solutions. These solutions provide a single view into the safety, manufacturing and performance trends covering the life of your products.

NetRegulus 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 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 Quality data.

Workflow Automation and Assignment (Includes Status and Due Dates)

The screenshot displays the NC Manager application window. The title bar indicates the NC Number, Owner Group, File Status, and Intake Days Open. The left sidebar contains a navigation menu with options like Intake, Evaluation, Investigation, Disposition Manager, Decision, Disposition, Approval, Action, Closure, Items, Approval Manager, Related Issues, Journal, and Documents. The main content area is titled 'NC Manager' and shows 'Nonconformance Details' for a specific record (NC8). Below this, there's a 'Nonconformance Assignment' section with fields for Assign, Nonconformance, Owner, Owner Group, Due Date, and Cancel. The 'Task Assignments' section is a table with columns for Assign, Task Type, Task Source, Workflow Dependent, Release, Task Owner, Owner Group, Due Date, Status, Cancel, and Reopen. The table lists various tasks such as Intake, Evaluation, Investigation, Disposition, Action, Closure, Correction, Inspection, General Task, and Management Review, each with associated workflow settings and assigned personnel. At the bottom, there's an 'Update Rationale' text area and a 'Planned Disposition Manager' warning section with a 'Create Disposition Manager' button. The status bar at the bottom shows local and server times, the user's name (CAPA Coord), and the server time.

Assign	Task Type	Task Source	Workflow Dependent	Release	Task Owner	Owner Group	Due Date	Status	Cancel	Reopen
✓	Intake	Standard	Yes	Yes	CAPA Coord	NC Owner Group	08-Aug-2009	15		
✓	Evaluation	Standard	Yes	Yes	CAPA Coord	NC Owner Group		15		
✓	Investigation	Optional	Yes	Yes	CAPA Coord	NC Owner Group		15		
✓	Disposition	Optional	Yes	Yes	Quality Supervisor	NC Owner Group		15		
✓	Action	Optional	Yes	Yes	Nonconformance Coord	NC Owner Group		15		
✓	Closure	Standard	Yes	Yes	Nonconformance Coord	NC Owner Group		15		
	Correction	Optional	Yes	No				15		
	Inspection	Optional	Yes	No				15		
	General Task	Optional	Yes	No				15		
	Management Review	Optional	Yes	No				15		

The CAPA Module

The CAPA module is a highly configurable and comprehensive tool for managing all CAPA activities in a regulated environment. Authorized users may initiate, evaluate, assign, monitor, review and approve each CAPA record according to their assigned roles. Users can accomplish tasks faster and more accurately using configurable pull-down menus, smart lookups, intelligent workflows and point-and-click interfaces

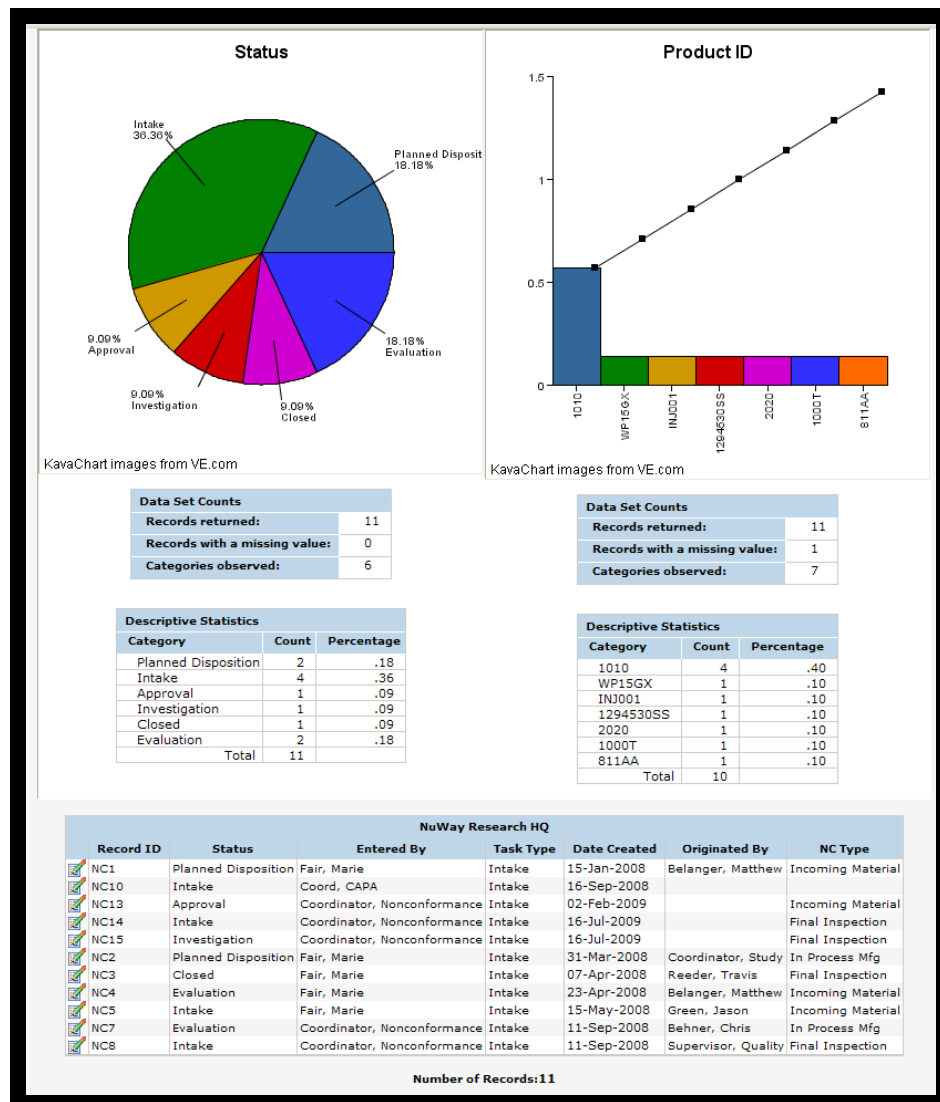
CAPA Module Features

- Initiate, evaluate, assign, monitor, review and approve corrective/preventive actions
- Link multiple issues from various sources to each corrective or preventive action, including complaints, nonconformances, audit findings, and other quality issues
- Use sophisticated “Watchdog” technology to aid in effectiveness monitoring
- Add multiple classifications to each CAPA record and use data to follow trends
- Generate Corrective/Preventive Action Plans and electronically circulate for Review and Approval
- Use 21 CFR Part 11-compliant electronic signatures, where required
- 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 investigation and management review
- Create, assign and track multiple optional activities and tasks through closure

- Utilize the workflow engine to alert users when and where their involvement is needed
- Provide notifications and alerts of pending or overdue items
- Use multiple configurable decision trees/classifications for risk assessment, root causes assignment, and effectiveness monitoring, to facilitate trend analysis
- Configure all field labels, tab labels, pull-down lists, menu items, and form text (warnings, errors, etc.) to match your own terminology

Trending Functionality Includes Easy Drill Down and Watchdogs

- Create data sets and graphs with an easy “point-and-click” interface that also allows users to save and reuse their report templates
- 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 and/or processing



[Back To Top](#)

Tips of the Month

Manufacturing Tutorials Available for Download

[Click Here To View](#)

[Back To Top](#)

Tips of the Month

Access to Product Development Data is Only a Click Away

NetRegulus lets you view any Windchill Data from the Quality Record. These hyperlinks are easily added to critical supporting data such as the Design History File, Where Used, Risk Assessment, Validation and Verification, Intended Use, FMEA, etc. These links are stored under Related Issues/Documents and will assist Quality Assurance (QA) during the Investigation. This will greatly enhance the ability to provide real time feedback to Product Engineers or critical product changes like new Vendor Cut in Lots for QA trending.

1. Simply navigate to the correct location in Windchill and copy the URL.
2. Create a new Related Issue or Document from any Nonconformance, Complaint, or CAPA.
3. Paste the link in under the URL section.
4. Click the blue hyperlink at the top of the page and it will take you directly to the Product Development data.

Quality Links to Any Windchill Data from NC, Complaints, and CAPA

The screenshot displays the NC Manager application interface. The top navigation bar includes links for NC Manager, Intake, Evaluation, Investigation, Disposition, Approval, Action, Closure, Items, Approval Manager, Related Issues, Journal, and Documents.

The main content area shows the "Attachment Internal Reference Documents External Reference Documents" tab selected. Below this is the "External Reference Documents Summary" table:

Date Added	Added By	Title	Process Area	Delete
06-Mar-2009	Nonconformance Coordinator	811 Implant Screw DHF	Investigation	<input type="checkbox"/>
06-Mar-2009	Nonconformance Coordinator	811AA BOM	Investigation	<input type="checkbox"/>
06-Mar-2009	Nonconformance Coordinator	811AA Details Page	Intake	<input type="checkbox"/>
06-Mar-2009	Nonconformance Coordinator	811AA Risk Management SOP	Investigation	<input type="checkbox"/>
06-Mar-2009	Nonconformance Coordinator	811AA Testing Failure Modes	Disposition	<input type="checkbox"/>

Below the summary table is the "External Reference Document Detail" form. The "URL" field is highlighted with a red circle and contains the following text:

```
http://kenterv01.ptc.com/Windchill/servlet/TypeBasedIncludeServlet?
ContainerOid=OR%3Awt.pdmlink.PDMLinkProduct%3A2146426&oid=OR%
```

An arrow points from the "URL" field to a separate window titled "Connect to kenterv01.ptc.com". This window shows a login form with fields for "User name:" (set to "peter") and "Password:", along with a "Remember my password" checkbox and "OK" and "Cancel" buttons.

Utilize the Design History File for Critical Investigations

Quickly Review All Bill of Materials for Containment and Disposition

Title

- [811 Implant Screw DHF](#)
- [811AA BOM](#)
- [811AA Details Page](#)
- [811AA Risk Management SOP](#)
- [811AA Testing Failure Modes](#)

Where Used (2 of 2 total objects)

Number	Version	Name	Context
0000000024	A.1	NTi Screw 811AA	Implant Screw
0000000021	A.1	Implant Screw Kit K00935	Implant Screw

Mitigating Risk to the Customer by Accurately Classifying Each Event

Title

- [811 Implant Screw DHF](#)
- [811AA BOM](#)
- [811AA Details Page](#)
- [811AA Risk Management SOP](#)
- [811AA Testing Failure Modes](#)

Risk Management SOP

Where Used (2 of 2 total objects)

Number	Version	Name	Context
0000000024	A.1	NTi Screw 811AA	Implant Screw
0000000021	A.1	Implant Screw Kit K00935	Implant Screw

Risk Analysis

For each potential hazard identified, a severity and probability index will be assigned to estimate the risk level for each hazard. The following table is established in the VMEDEVOC.

PROBABILITY INDEX	SEVERITY INDEX				RISK INDEX
	A	B	C	D	
1	1A	1B	1C	1D	RISK INDEX
2	2A	2B	2C	2D	
3	3A	3B	3C	3D	
4	4A	4B	4C	4D	

Risk Analysis

For each potential hazard identified, a severity and probability index will be assigned to estimate the risk level for each hazard. Risk Control, Risk Reduction, and Risk Acceptability values will be assigned to each hazard.

Quickly Review All Testing Documentation for Failure Modes

The screenshot displays the PTC Windchill interface. On the left, a list of documents is shown, with '811AA Testing Failure Modes' highlighted by a red circle. The main window shows the details of this document, including its name, state, and a table of iteration history. The iteration history table has columns for Version, File Name, Size, and Date. The first row shows Version A.1, File Name Testing.pdf, Size 1441.9 KB, and Date 10/6/2009. Below the table, there is a 3D model of a dental implant, labeled 'Figure 1. Models of dental implant: a) axisymmetric with part of jaw bone, b) three dimensional with spiral thread.'

Version	File Name	Size	Date
A.1	Testing.pdf	1441.9 KB	10/6/2009

[Back To Top](#)

Announcements

PTC Tips & Techniques Newsletter Archives

Did you miss an issue? Can't find that awesome technique you read about? Fear not, you can click on the link below and go through our Customer PTC E-Newsletter archives.

[Customer Care Zone](#)

PTC Tips & Techniques Webcasts: Work Smarter. Not Harder.

Click below to see regularly scheduled Tips & Techniques technical Webcasts that are designed to provide you with the most popular time-saving tricks that Pro/ENGINEER users of all skill levels will find useful. Get more out of your maintenance dollars!

[Tips & Techniques: Work Smarter Not Harder!](#)

Special Hardware offers for PTC Customers

- <http://www.hp.com/go/ptc>
- <http://www.hp.com/go/ptcworkstation>

PTC Sponsored Events

- <http://www.ptc.com/company/news/events/index.htm>

Explore what is new with the Pro/ENGINEER Wildfire family!

<http://www.ptc.com/go/showcase>

Connect with PTC using the latest Social Networking resources:



Also visit <http://social-product-development.blogspot.com/>

E-PROFILES IS HERE!!

We have been eagerly anticipating the debut of the new electronic version of Profiles Magazine and now it is here! This new web site will supplement the print edition of the magazine and will provide new useful features not feasible with paper media. e-Profiles will provide you with 24x7, worldwide access to key information previously available exclusively in the print version. "Tips & Tricks," a popular feature pioneered by Pro/USER, has also moved to the web and will be expanded as the site matures.

Please take a few minutes to check out this new web site. We don't think you will be disappointed.

<http://profilesmagazine.com/>



[Back To Top](#)

Upcoming Events & Training Class Schedules

Upcoming, 2009 Your local Pro/Engineer User Groups
<http://www.ptcuser.org/rugs/>

June 7 – 10, 2009 Orlando, FL USA
PTC/USER World Event
<http://www.ptcuser.org/>

Events

Our seminars and conferences seek to provide you with relevant information regarding product development trends in your industry as well as innovative software learning experiences. Think of them as a constructive day off where you can share experiences and swap ideas with your peers.

If you can't manage to get away, we'll bring it to you. Check back often for regularly scheduled live webcast events.

[You're Invited to Attend...](#)

Please visit the [PTC Education Services](#) website for the latest training information including course descriptions, schedules, locations, and pricing.

- Attend a course at any PTC Center and receive a **free** copy of Pro/ENGINEER Wildfire Student Edition!

<http://www.ptc.com/services/edserv/index.htm>

Live Instructor-Lead Virtual PTC Training Courses

Virtual Classrooms provide interactive learning with a trained PTC instructor in convenient and manageable sessions that last approximately 4 hours over a series of days. It's easy to join a class right from your desk using a phone or voice-over IP technology.

Sessions are performed just like a traditional ILT (including interactive exercises where you and the instructor can work on lab exercises together) and feature some of our most popular ILT courses. These sessions cover the exact same material as the traditional ILT in-center courses. Also look for some of our most frequently requested mini-topics delivered in the same format that are only an hour - two hours in duration.

If you have any questions about these sessions or would like to see getting other courses, not on this list, on the schedule please feel free to contact me for more details. They are a great way to bring training to you without you having to worry about location or being out from work for long stretches.

You can register for these sessions just as you would for any normal ILT class either by:

1. calling order admin at <http://www.ptc.com/services/edserv/training/registra.htm> or
2. you can go to PTC University directly at <http://www.ptc.com/learning> and submit a registration request directly. All you have to do is search the catalog by typing in “virtual” in the search field and you will see a listing.

PTC

Note: This PTC E-Newsletter will continue to be used for the following:

- 1) Inform you on events related to PTC products (user groups, conferences, training schedules, etc.)
- 2) Educate you on solutions that are available at PTC
- 3) Tips & Techniques using PTC Products

Note: These messages are compiled in the local PTC office and will be distributed via e-mail.

[Back To Top](#)