Oracle® Agile Product Lifecycle Management for Process

Product Quality Management User Guide

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Oracle Agile Product Lifecycle Management for Process Product Quality Management User Guide, Release 6.2.1

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Preface

The *Agile Product Lifecycle Management for Process Product Quality Management User Guide* explains how to use the Product Quality Management (PQM) application to track and manage quality data.

This Preface contains these topics:

- Audience
- Variability of Installations
- Documentation Accessibility
- Related Documents
- Conventions

Audience

This guide is intended for end users who are responsible for creating and managing information in Agile Product Lifecycle Management (PLM) for Process. Information about administering the system resides in the *Agile Product Lifecycle Management for Process Administrator User Guide*.

Variability of Installations

Descriptions and illustrations of the Agile PLM for Process user interface included in this manual may not match your installation. The user interface of Agile PLM for Process applications and the features included can vary greatly depending on such variables as:

- Which applications your organization has purchased and installed
- Configuration settings that may turn features off or on
- Customization specific to your organization
- Security settings as they apply to the system and your user account

Documentation Accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc.

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Related Documents

For more information, see the following documents in the Oracle Agile PLM for Process Release 6.1.1 documentation set:

- *Agile Product Lifecycle Management for Process Getting Started Guide*
- *Agile Product Lifecycle Management for Process Global Specification Management User Guide*
- *Agile Product Lifecycle Management for Process Supply Chain Relationship Management User Guide*
- *Agile Product Lifecycle Management for Process Workflow Administration User Guide*
- A*gile Product Lifecycle Management for Process Release Notes*. Up-to-date Release Notes and other documentation are posted on Oracle Technology Network (OTN) at this location:

  http://www.oracle.com/technetwork/documentation/agile-085940.html#plmprocess

Conventions

The following text conventions are used in this document:

Convention	Meaning
boldface	Boldface type indicates graphical user interface elements associated with an action, or terms defined in text or the glossary.
italic	Italic type indicates book titles, emphasis, or placeholder variables for which you supply particular values.
`monospace`	Monospace type indicates commands within a paragraph, URLs, code in examples, text that appears on the screen, or text that you enter.

1

Introducing Product Quality Management

This chapter provides an overview of Oracle Agile Product Lifecycle Management (PLM) for Process Product Quality Management and includes the following topics:

- Overview
- Getting Started with Product Quality Management

Overview

Product Quality Management (PQM) provides your company with a tool to track and manage data, which translates to (better products) enhanced quality, productivity (lesser time cycles), and reliability. This includes customer feedback, product and manufacturing defects, enhancements, and corrective and preventative measures. PQM closes the support loop by unifying customer service, field sales, manufacturing, and development organizations, and linking the company to its customers and partners.

PQM includes Issues, Actions, and Audits. Issues represent quality incidents. Actions create and manage Corrective and Preventative Actions (CAPA). Audits verify compliance with quality requirements.

Issue

Issues represent quality incidents. An Issue can be typed as a Problem Report (PR) or a Non-Conformance Report (NCR). PRs report general quality incidents and NCRs report material deviations from specifications and other specific quality issues.

Problem Reports

A Problem Report contains a basic description of a quality issue, problem, or incident reported from a customer's perspective. A customer, service representative, or supplier may submit a Problem Report provided they hold the appropriate privilege to process a Problem Report. You need to route a Problem Report through a workflow for inquiry.

Non-Conformance Reports

A Non-Conformance Report can be submitted by a customer, service representative, or supplier to report a basic deviation from specifications or requirements in one or more products. You also need to route Non-Conformance Reports through a workflow for inquiry.

Action

Actions create and manage Corrective Preventative Actions (CAPAs). The CAPA is a formal process of addressing any generic quality problems and analyzing the root cause so you can implement corrective and preventive actions. Actions allow you to aggregate problems into a routable, quality record, perform root-cause failure analysis, and drive the problems to closure using standard CAPA procedures. The CAPA may result in changes to a product, process, or supplier.

Audit

An audit is the pro-active process of verifying compliance with quality requirements. An audit could result in multiple issues.

Getting Started with Product Quality Management

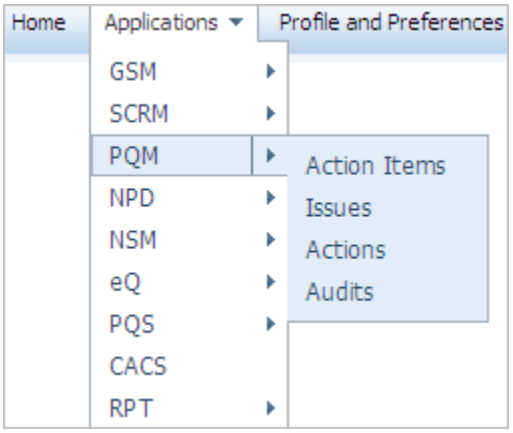
Accessing Product Quality Management

To access the Product Quality Management application, select **PQM** from the left navigation panel as shown in figure 1–1 below or select **PQM** from the Applications menu of the top menu bar, as shown in figure 1–2.

Figure 1–1 The PQM menu from the left navigation panel



Figure 1–2 The PQM menu from the Applications menu on the top menu bar



For general information on using Agile Product Lifecycle for Process software, see the *Agile Product Lifecycle Management for Process Getting Started Guide*.

2

Working with PQM

This chapter describes the capabilities and applied uses of the PQM product. It includes the following topics:

- Creating PQM Objects
- Managing PQM Objects

Creating PQM Objects

All PQM objects have the same creation process in PQM. You can either create a new blank object or an object based on an approved template.

Creating a Blank Object

To create a blank object, you must use the blank option. Users must have the appropriate role to create PQM objects. See the roles appendix in the *Agile Product Lifecycle Management for Process User Group Management User Guide* for a full list of roles.

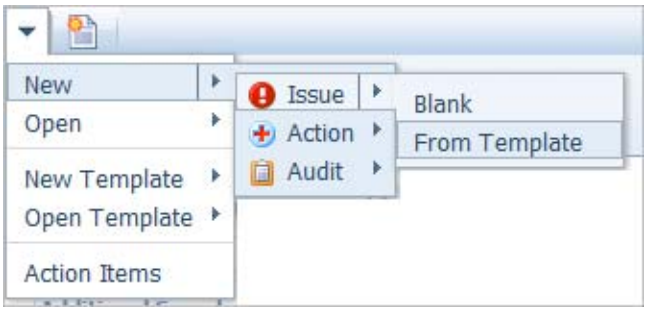
1. On the left navigation panel, click **New > OBJECT TYPE > Blank**. PQM displays a object page with empty fields. If you do not have access to create objects from templates, you will not see the third navigation panel with the blank option. In that case, click on the object type to create a blank object.
2. Follow the guidelines for your desired object type as laid out in the chapter in this manual that specifically addresses that type of object.

Creating an Object from a Template

A user must have the appropriate role, CREATE_FROM_TEMPLATE_<OBJECT TYPE>, to create an object from a template. See the roles appendix in the *Agile Product Lifecycle Management for Process User Group Management User Guide* for a full list of roles.

Users with this role see the **New > OBJECT TYPE > From Template** options in the navigation menu. This menu list your most recently used templates as well as an option to search for templates. Click a most recently used template and the system will create an object based on the template you selected. If you do not see the template you want to use, you can search for templates by selecting the **From Template** header or the **More...** option.

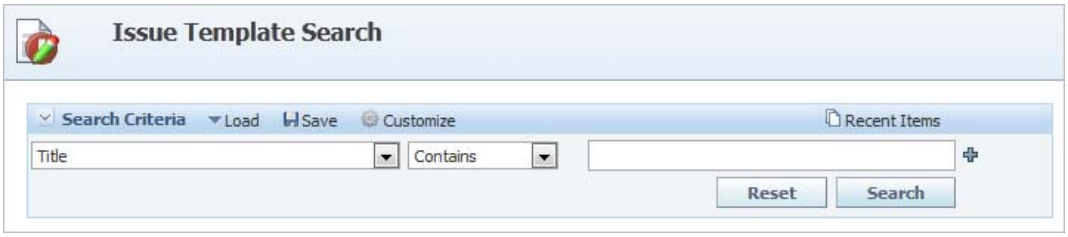
Figure 2–1 New menu and submenu



To create an object using the Template search option:

1. On the left navigation panel, click **New > OBJECT TYPE > From Template**. PQM displays the template search page for that object type.

Figure 2–2 Search page



Use this page to search for the template you would like to use. The template you select automatically creates the new object based on that template and puts it in edit mode. You can preview the template using the view details icon to the left of the template name.

- Click **Recent Items** to display the most recently used templates. Click on any of the most recently used templates to instantly create an object using that template.

2. After selecting a template, complete the object by following the guidelines for the object type as laid out in the chapter in this manual that specifically addresses that type of object.

Managing PQM Objects

All PQM objects are workflow enabled. A workflow is a business process, in whole or in part, during which documents, information, or tasks are passed from one participant to another for action, according to a set of procedural rules. In Agile PLM for Process, workflows are managed using the Workflow Administration (WFA) application.

Action Items

As a document moves through the workflow process, the system generates a to-do list, or "action items," for designated team members. When an object, moves from one workflow status to another, PQM adds an entry to the Action Items list for the current owner of that object.

There are two types of action items:

- PQM object type
- Signature documents

Accessing Your Action Items

You can access the Action Items page in three different ways:

- Click **Applications > PQM > Action Items** on the Application menu in the top menu bar
- Click **PQM > Action Items** on the left navigation panel from the Portal
- From within PQM, click **Action Items** from the action menu

Understanding the Action Items Page

The Action Items page contains a table with the following sortable columns:

RAG Status (not labeled)—This column displays the Red Amber Green (RAG) status of the object. The RAG status is an indicator of compliance with the established service level agreement (SLA) timelines for that document type. SLAs for an object are defined in that object's workflow. When action items are sorted by this column in descending order they will be sorted in Red | Amber | Green sort order listing older red dates first. When items are sorted in ascending order they will be sorted in Green | Amber | Red listing newer green dates first.

Item #—The number of the item.

Title—The name of the item.

Type— The object type of the item.

Status— The workflow step that the object is in (for example, draft, pending, draft (review), requested for certification, and others).

Severity— The severity of the action item. This field only applies to Issues.

Equivalent— The cross reference number associated to the item using the user's preferred Cross Reference settings.

Amber— The date the action item is entering an amber state.

Red—The date the action item will be entering the red state.

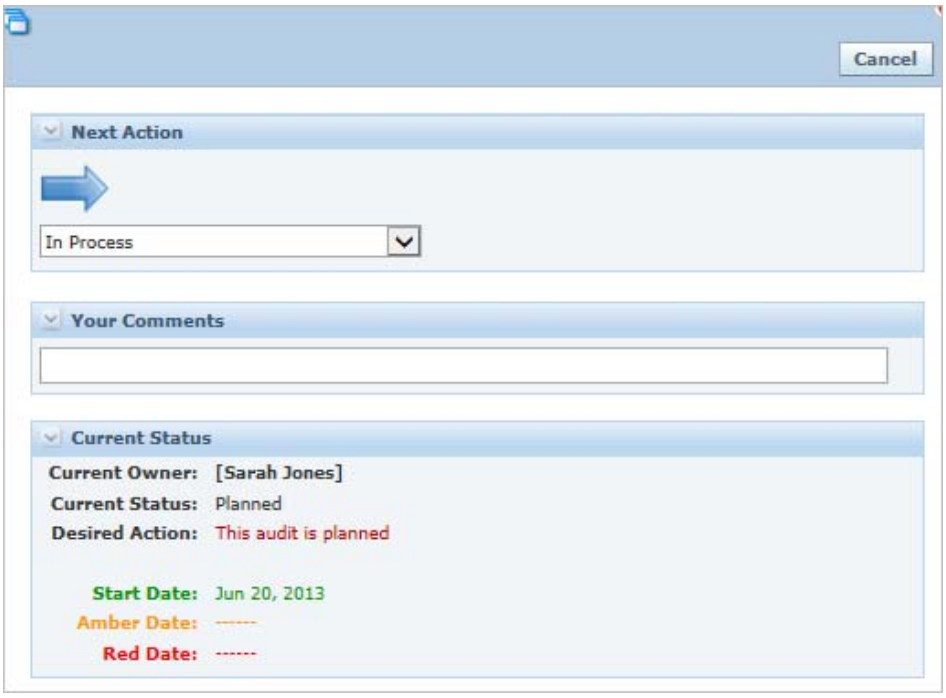
Transitioning a Workflow

Within a PQM object, use the workflow feature to move a document from one workflow step to another.

To move a document in a workflow:

1. Click **Workflow** in the action menu. The Document Workflow dialog box opens, as shown in Figure 2–3. Remember that the buttons and fields that display vary based on the workflow and current workflow step.

Figure 2–3 Document Workflow dialog box



2. Enter comments in the **Your Comments** field (required).
3. Select a step from a drop-down list in the Next Action section.
4. Click the advance workflow icon to forward the object or signature document to the next step in the approval process, or click the move back icon to return it to a prior step. The system updates the workflow status based on your selection.

Selecting Workflow Participants

If the advance workflow icon includes people, in the next dialog box you may have to select workflow participants, such as one or more owners, persons being asked for a signature, or persons being notified. As Figure 2–5 shows, the dialog box may contain preselected data or may prompt you to select one or more participants. Refer to Figure 2–4 through Figure 2–6 for an example of selecting workflow participants.

Figure 2–4 Single select example

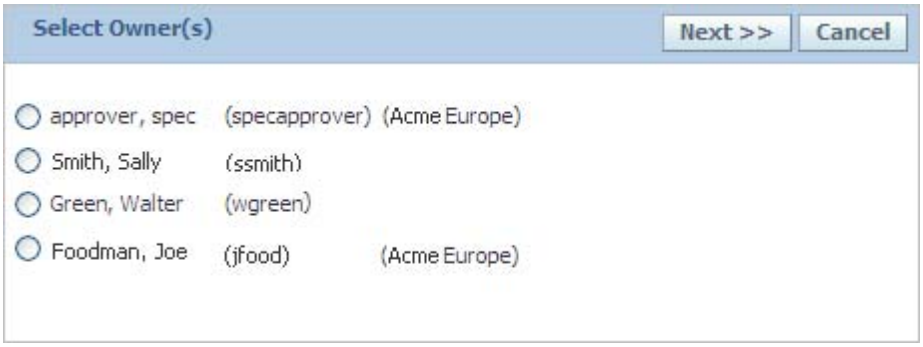


Figure 2–5 Pre-Selected example



Figure 2–6 Multiple select example



Re-Authentication

Depending on workflow configurations, you are sometimes asked to re-authenticate while workflowing an object. You will be asked to enter a passphrase to prove your identity. Your passphrase is managed through profile and preferences. For more information, refer to the *Agile Product Lifecycle Management for Process Getting Started Guide*. For more information around how to configure the re-authentication process, refer to the *Agile Product Lifecycle Management for Process Administrator User Guide*.

Working with Signature Documents

Use a signature document to solicit approval for an object before the object can move to the next step in the workflow. All requested signature documents must be moved to an approved state before the object can move to the next workflow step. When you select a signature document — whether by action item or an email link — PQM displays the signature document page.

The Summary tab shows the object that you have been asked to review. You can follow the link to view the object.

The Approval/Audit Trail tab shows the current status and owner of the signature document, the desired action, assigned dates, and the history of the signature document.

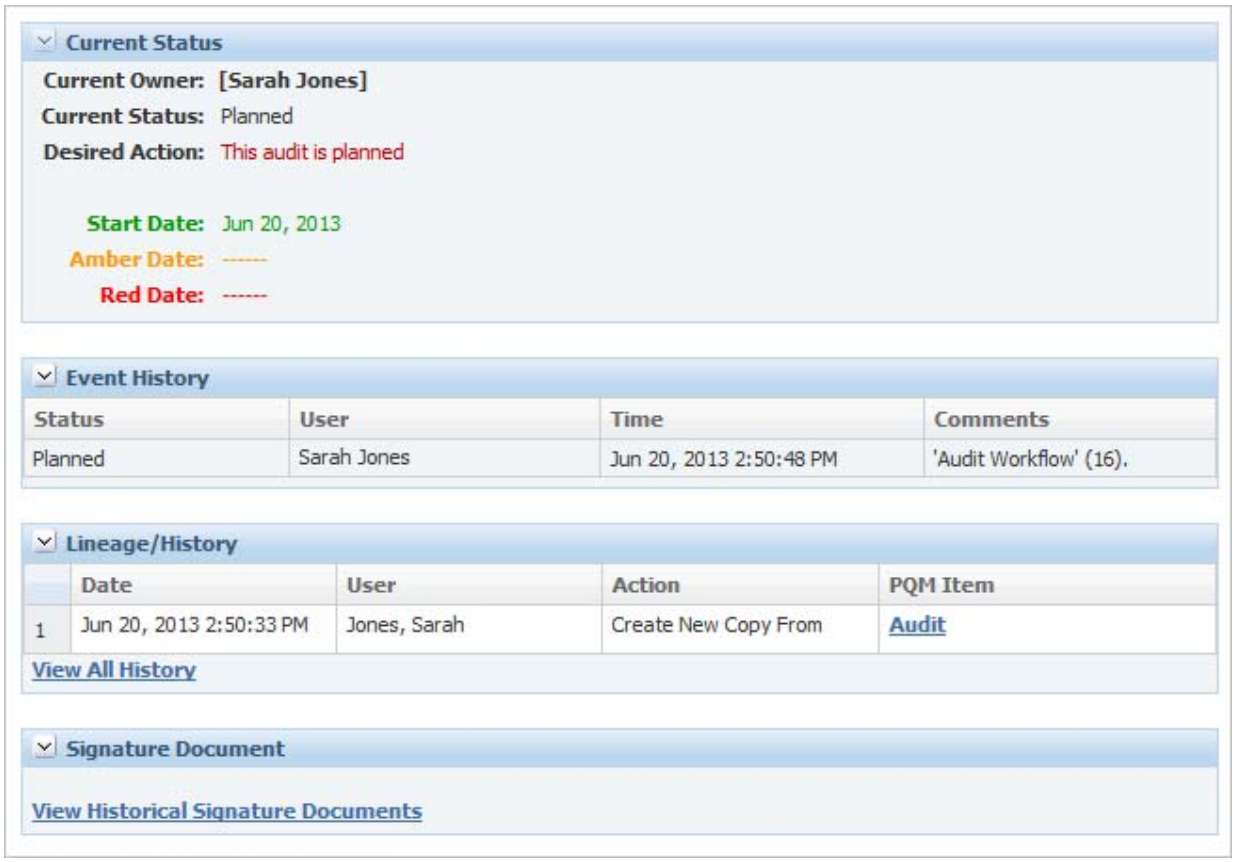
Click **Workflow** in the action menu to take action on the signature document by changing its status to “approved” or “not approved.”

Audit Trail Tab

All workflow-enabled PQM objects contain an Audit Trail tab. This tab contains the data related to the workflow status and history of an object. This page consists of the following system-defined sections:

- Current Status Section
- Event History Section
- Lineage/History Section
- Signature Document Section

Figure 2–7 Audit Trail tab



Current Status Section

The Current Status section contains the workflow data related to an object.

Event History Section

The Event History section contains the list of preceding workflow actions associated with the object.

Lineage/History Section

The Lineage/History section shows a history of where an object was created and updated from.

Signature Document Section

The Signature Document section contains the list of signature documents associated with that step of the workflow. All signature documents associated with an object must be in the approved state before the object can be moved forward in the workflow.

Clicking **View Historical Signature Documents** opens a view of signature documents completed prior to the current stage.

3

Commonly Used Sections

This chapter describes sections that are used in many Product Quality Management objects. It includes the following topics:

- Overview
- Summary Tab
- Ext Data Tab
- Affected Items Tab
- Related Items Tab
- Supporting Documents Tab

Overview

Information in PQM is organized into tabs that are in turn organized into sections. Several sections are common to all or most PQM objects.

Summary Tab

The Summary Tab contains three sections: Summary Information, Suppliers/Facilities, and Cross References

Summary Information Section

The Summary Information section defines basic elements of the object.

Suppliers/Facilities Section

The Suppliers/Facilities section designates which suppliers or internal facilities are associated to the object. For example, after analysis you discover that the problem originated with the supplier, that supplier should be added here. You may discover that the problem was caused by something at an internal facility, in that case, the internal facility would be listed here.

Cross References Section

The Cross References section contains the list of cross-reference numbers for the issue, as stored in external systems. You can use the equivalent value as a search criteria and it can display in object search results. Key fields include:

System Name—The name of the external system.

System ID—A code that identifies an external database. Agile PLM for Process obtains this code from the external system.

Equivalent—The equivalent number designed to identify the issue as it is referenced by other cross-reference systems.

Externally Managed—An indication of whether this data is managed externally or within Agile PLM for Process. If the data is managed externally, you cannot modify the equivalent number from within Agile PLM for Process.

If the cross-referenced database is managed from within Agile PLM for Process, you can modify the equivalent value in the Equivalent field in this table.

Status—The cross reference status of the object.

Note: Only an Agile administrator can turn the Externally Managed flag on or off. For more information on this feature, please see the *Agile Product Lifecycle Management for Process Administrator User Guide*.

Ext Data Tab

Select objects contain custom data. Use custom data to enter customized information, in the form of custom sections.

The custom sections templates are created and maintained by your administrator.

These are represented by the Custom Section on the Ext Data tab, as described below. For more information on creating custom data, see the *Agile Product Lifecycle Management for Process Administrator User Guide*.

Warning: If you remove a custom section, the system deletes the data that you entered. Delete data with caution, because deleted data cannot be restored.

Custom Sections

Custom sections are configurable sets of extended attributes. The custom data that you enter is displayed in a table.

Two roles are associated with custom sections:

- [ADD_CUSTOM_SECTION]—Users with this role can see and use the Add Sections button to add custom sections.
- [REMOVE_CUSTOM_SECTION]—Users with this role can see and use the Remove Sections button to remove custom sections.

Calculated Attributes

Calculated Extended Attributes are supported in PQM.

For more information about custom sections, see the *Agile Product Lifecycle Management for Process Getting Started Guide*.

Affected Items Tab

The Affected Items tab lists items affected by the current issue. A single issue can affect multiple products.

This tab displays all GSM objects related to the Action. You can associate an action to the following GSM objects: Activities, Delivered Material Packing, Equipment, Formulation, Labeling, Master, Material, Menu Item, Nutrient Profile, Packaging Material, Packing Configuration, Printed Packaging, Product, and Trade.

Key fields include:

- **System #** — Number of the related product's specification.
- **Equivalent #** — All cross-references
- **Description** — Display Name and Status of the related product's specification.
- **Rev Found** — The revision number of the affected item in which you found the problem.
- **Rev Fixed** — The revision of the specification in which the problem is fixed.
- **PQM Item #** — The number of the affected item.

Affected Items Section

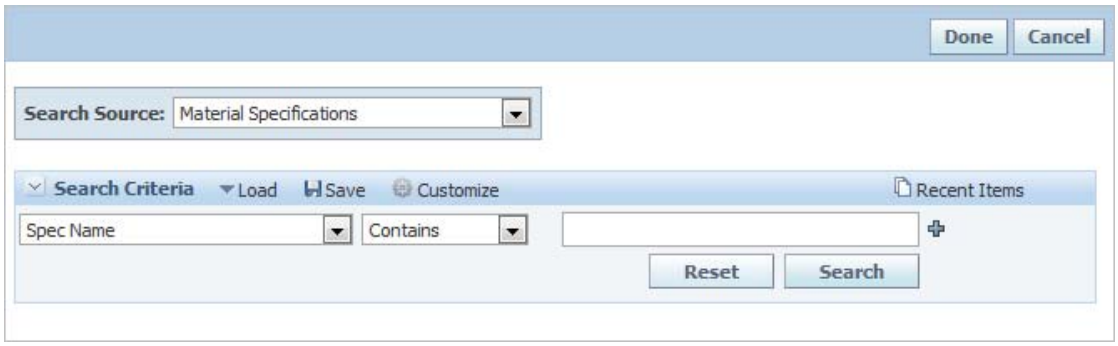
This section represents the actual material that is affected by the issue. For example, if a customer received crushed product, the affected item would be the trade specification they received that was crushed. Depending on your configuration, you can associate an Issue to the following GSM objects: Activity, Delivered Material Packing, Equipment, Formulation, Labeling, Master, Material, Menu Item, Nutrient Profile, Packaging Material, Packing Configuration, Printed Packaging, Product, and Trade.

Adding an Affected Item

To add an affected item:

1. Click **Add New** to display the Search criteria dialog box:

Figure 3–1 Add Affected items search



2. Select the type of GSM object in the Search Source drop down box, enter the search criteria, and click **Search**. A Search Results section appears, with a table of search results.
3. Click the specific item in the search results table. The item is added to the Selected Items section.

4. Click **Done**.

Related Affected Items Section

The Related Affected Items section displays all affected items added to the related issues or actions. For example, if this action is tied to five issues, all affected items added to those issues will be displayed here. This provides the ability for quality managers to see all affected items in one location.

Related Items Tab

The Related Items tab displays other issues and actions related to the object.

Related Issues Section

The Related Issues section displays all issues related to this action.

Adding Issues

Add issues by clicking the **Add Existing** button. If it was an issue you recently created or viewed, you can use the Recent Items option in the search screen to quickly access those items.

Related Actions Section

The Related Actions section displays all actions related to this Action. There is a parent/child relationship between actions, so Actions can be owned by other Actions.

Adding Actions

Add actions by clicking the **Add Existing** button. If it was an action you recently created or viewed, you can use the Recent Items option in the search screen to quickly access those items.

Related Audits Section

The Related Audits section displays all audits related to this Action. If an audit requires action, you would associate it here. Generally, failed audits will also generate issues and those should also be attached on this tab in the Related Issues section.

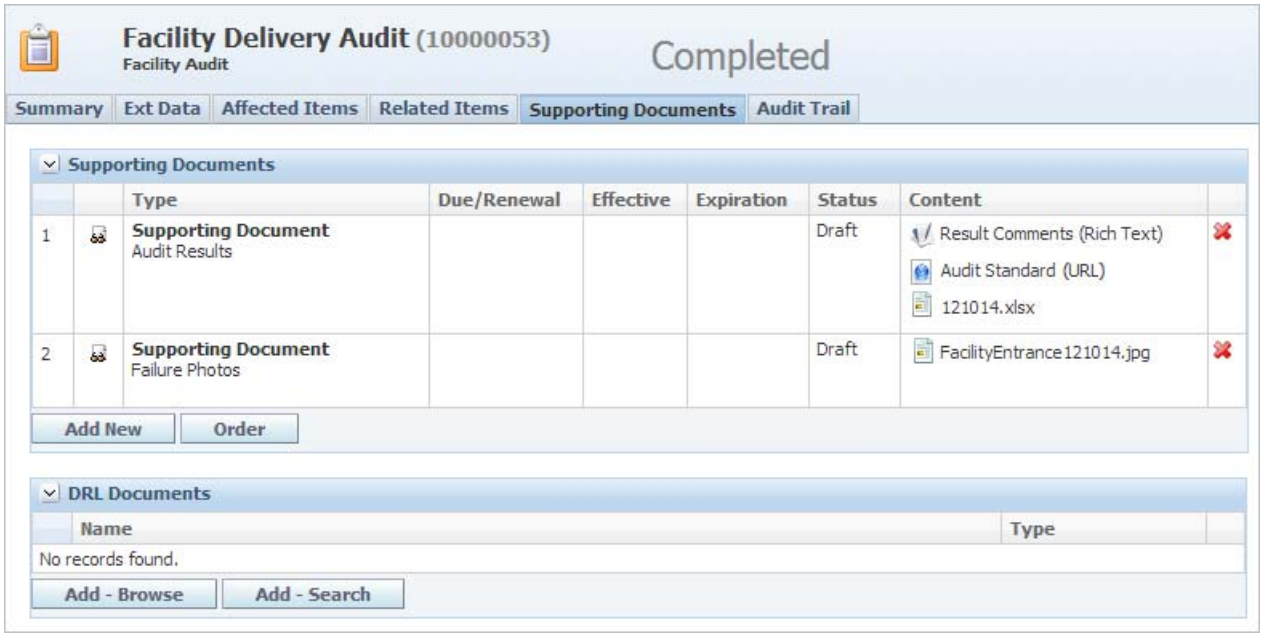
Adding Audits

Add audits by clicking the **Add New** or **Add Existing** button. If it was an audit you recently created or viewed, you can use the Recent Items option in the search screen to quickly access those items.

Supporting Documents Tab

The Supporting Documents section enables you to add unique documents to the object. You can add files, URLs and rich text.

Figure 3–2 Supporting Documents for an audit



Refer to the *Agile Product Lifecycle Management for Process Getting Started Guide* for more information about supporting documents.

4

Working with Issues

This chapter describes how issues are created and used. It includes the following topics:

- Issues Overview
- Summary Tab
- Ext Data Tab
- Related Items Tab
- Supporting Documents Tab
- Audit Trail Tab

Issues Overview

Issues represent quality incidents. An issue can be typed as a Problem Report (PR) or a Non-Conformance Report (NCR). PRs report general quality incidents and NCRs report material deviations from specifications and other specific quality issues.

Problem Reports

A Problem Report contains a basic description of a quality issue, problem, or incident reported from a customer's perspective. A customer, service representative, or supplier may submit a Problem Report provided they hold the appropriate privilege to process a Problem Report. You need to route a Problem Report through a workflow for inquiry.

Non-Conformance Reports

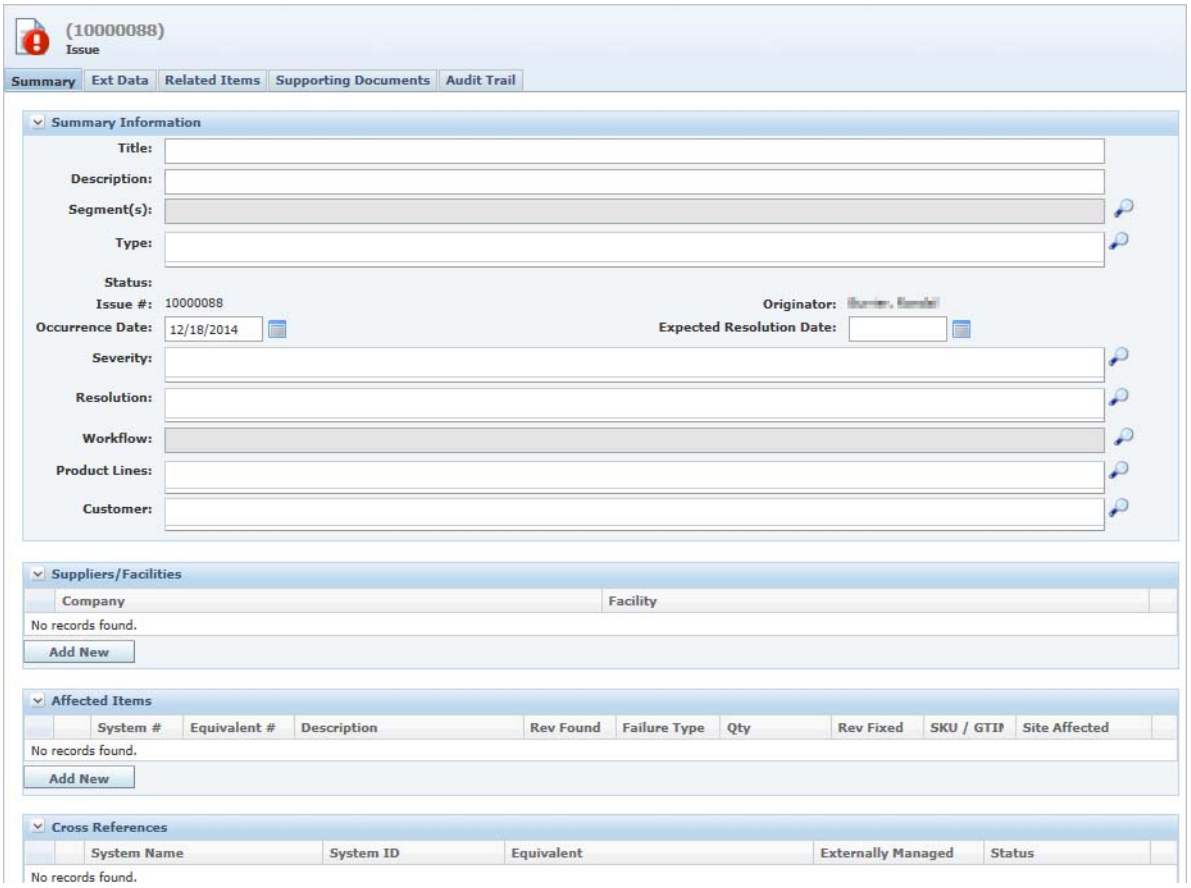
A Non-Conformance Report can be submitted by a customer, service representative, or supplier to report a basic deviation from specifications or requirements in one or more products. You also need to route Non-Conformance Reports through a workflow for inquiry.

Creating Issues

To create an issue:

1. Click PQM > Issues from the left navigation panel. Agile PLM for Process displays the Issue Search page.
2. Click **Create New**. The dialog box that is displayed has five tabs: Summary, Ext Data, Related Items, Supporting Documents, and Audit Trail, as Figure 4–1 shows.

Figure 4–1 New Issue dialog box



Summary Tab

The Summary Tab contains four sections: Summary Information, Suppliers/Facilities, Affected Items, and Cross References.

Summary Information Section

Use this section to define basic elements of the issue. Key fields include:

- **Title** — The name of the issue. This is a required field.
- **Description**— The description of the issue.
- **Segment(s)**— The business segment of the issue.
- **Type —** The type of the issue. This is a required field.
- **Status**— The workflow status of the issue.
- **Issue #** — Number used to identify issues. This number is system generated.
- **Originator** — Auto-populated field that denotes the user who created the issue.
- **Occurrence Date** — Date when the problem occurred. The default date is the origination date, but can be modified.
- **Expected Resolution Date** — Date when you expect the problem to be resolved.
- **Severity** — Severity of the issue.

- **Resolution** — How the issue was ultimately solved. This is critical for auditing and reporting, for example, Packaging Change, Supplier Change, etc.
- **Workflow** — The name of the workflow used to move this issue through the quality tracking process. This is a required field.
- **Product Lines** — The product lines this issue affects.
- **Customer** — The customers associated with this issue.

Suppliers/Facilities Section

Use this section to designate which suppliers or internal facilities are associated to the issue. For example, if the issue is a direct problem with a supplier, the supplier would be selected here. If the issue is a problem with one of your internal manufacturing facilities, you would list that facility here. Key fields include:

- **Company** — The company that is associated to the problem. This can be any SCRM company.
- **Facility** — The facility associated to the problem. When a facility is selected, the company is auto-populated. This can be a specific SCRM facility.

> **Note:** If an issue is associated to a company/facility and published, the supplier will be able to see this issue in Supplier PQM.

To add a new supplier:

1. Click the **Add New** button.
2. Search and select companies/facilities to add as a supplier.

   If an external database is configured, external companies/facilities can also be added as suppliers.

Affected Items Section

This section represents the actual material that is affected by the issue. For example, if a customer received crushed product, the affected item would be the trade specification they received that was crushed. Depending on your configuration, you can associate an Issue to the following GSM objects: Activity, Delivered Material Packing, Equipment, Formulation, Labeling, Master, Material, Menu Item, Nutrient Profile, Packaging Material, Packing Configuration, Printed Packaging, Product, and Trade.

Key fields include:

- **System #** — Number of the related product's specification. This number is independent of revision.
- **Equivalent #** — Select the specific cross referent that applies to this issue. If the issue is a problem with all variants of the material, then leave this field blank.
- **Description** — Display Name and Status of the related product's specification. If a GSM specification was selected, the specification name and status are displayed.
- **Rev Found** — The revision number of the affected item in which you found the problem. If the revision found is unknown, clear the revision found field by selecting the blank option. The corresponding data will still be pulled from the original revision selected, but now it is clear that the specific revision is unknown.

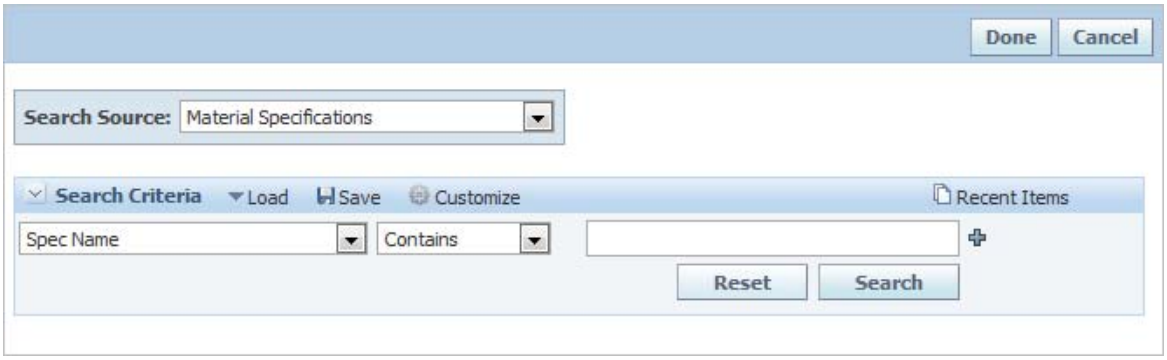
- **Failure Type** — The reason a product failed or did not meet customer requirements. For example, a failure type for the product line Pretzels may be Crushed Product.
- **Qty** — The number of products affected by the issue.
- **Rev Fixed** — The revision of the specification in which the problem is fixed.
- **SKU/GTIN** — The SKU or GTIN of the specification.
- **Site Affected** —The site at which the affected products are having problems.

Adding an Affected Item

To add a new affected item:

1. Click **Add New** in the Affected Items section.
2. From the Search Source drop-down list, select the object type of the affected item, shown in Figure 4–2.

Figure 4–2 Add Affected Items dialog box



3. Use the search form to select the search criteria, then click **Search** to display the items meeting the criteria.
4. Highlight the item in the Selected Items box, then click **Done** to add the item.

Attributes of the Affected Items Section of an NCR

The attributes and operations of NCRs are similar to those of Problem Reports, except for a few additional fields on the Affected Items tab. These fields provide additional information about deviations in one or more products.

An icon is displayed at the end of the row of each affected item. Click the icon to display or manually add additional attributes. The following list details the fields of a process in which the quality assurance team examines incoming materials from a supplier:

- **Conformance Specification** —Reference to the latest specification standard.
- **Serial/Lot Number** — Serial or Lot number of the items of the batch that was defective.
- **Total Quantity Suspect** — Total Quantity suspected of problems. For example, you receive a lot of 500 units, inspect 20 units and find that 5 are defective.
- **Quantity Checked** — The number of inspected items.
- **Quantity Affected** — The actual number of items affected with problems.

- **Containment Actions** — Containment actions taken to dispose material.
- **RMA Number** — Return Merchandise Authorization. The number from the supplier that authorizes you to return defective materials back to the source.
- **Conforming Material Date** — The date when the supplier expects to send materials which conform to specifications.

Cross References

For discussion about this common section, see "Cross References Section" on page 3-1.

Ext Data Tab

The Ext Data tab includes the following sections:

- **Custom Sections**—For discussion of this commonly used section, please see "Custom Sections" on page 3-2.
- **Calculated Attributes**—For discussion of this commonly used section, please see "Calculated Attributes" on page 3-2.

Related Items Tab

The Related Items tab displays actions and audits related to the issue.

Related Actions Section

The Related Actions section displays all actions related to the issue. You can also add new actions from blank or a template.

To add a new action:

1. Click the **Add New** button.
2. Choose **Blank** or **From Template** from the drop down list.

   The Create Action dialog box appears.
3. Complete the required fields to add the action.

Related Audits Section

The Related Audits section displays all audits related to the issue.

Supporting Documents Tab

PQM allows for supporting documents. We support files, URLs and rich text. Refer to "Supporting Documents Tab" on page 3-4 or the Supporting Documents chapter of the *Agile Product Lifecycle Management for Process Getting Started Guide* for more information.

Audit Trail Tab

For discussion of this tab, see "Audit Trail Tab" on page 2-6.

5

Working with Actions

This chapter describes how actions are created and used. It includes the following topics:

- Actions Overview
- Creating Actions
- Summary Tab
- Ext Data Tab
- Affected Items Tab
- Related Items Tab
- Supporting Documents Tab
- Audit Trail Tab

Actions Overview

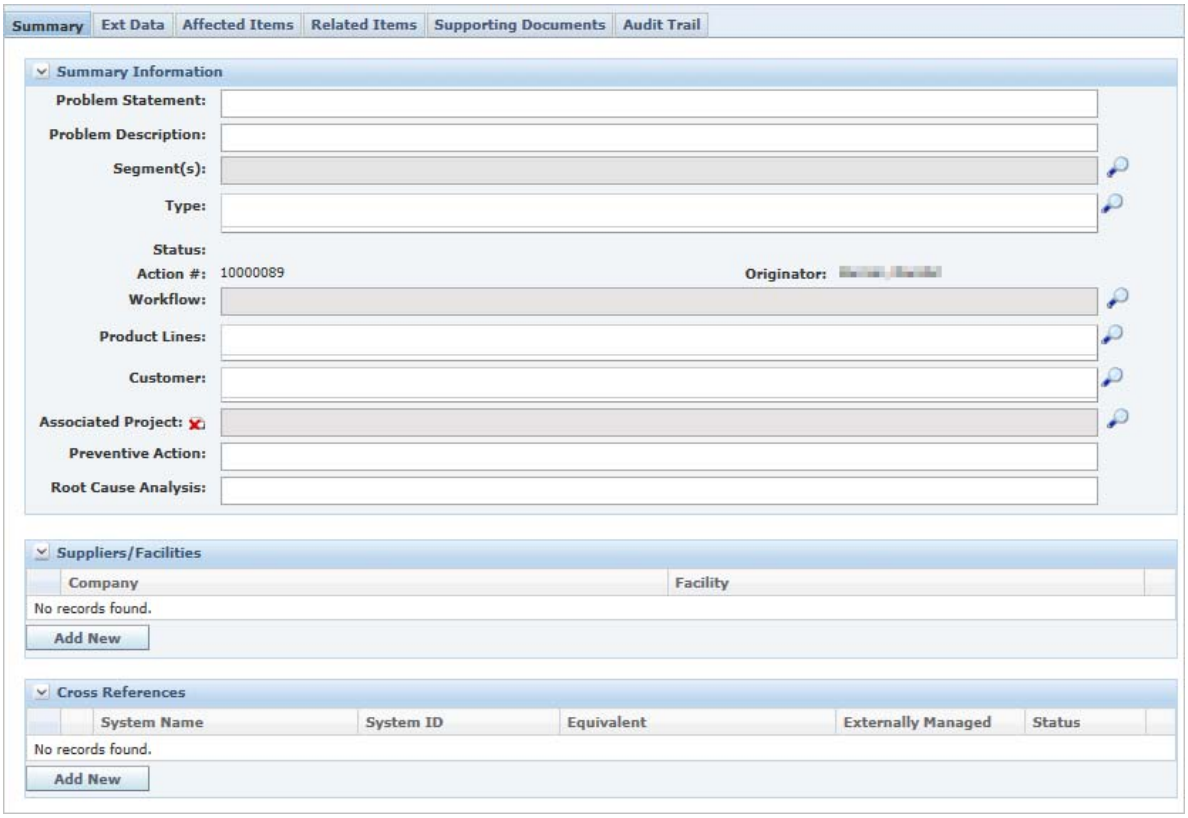
Actions create and manage Corrective Preventative Actions (CAPAs). The CAPA is a formal process of addressing any generic quality problems and analyzing the root cause so you can implement corrective and preventive actions. Actions allow you to aggregate problems into a routable, quality record, perform root-cause failure analysis, and drive the problems to closure using standard CAPA procedures. The CAPA may result in changes to a product, process, or supplier.

Creating Actions

To create an action:

1. Click PQM > Actions from the left navigation panel. Agile PLM for Process displays the Action Search page.
2. Click **Create New**. The dialog box that is displayed has six tabs: Summary, Ext Data, Affected Items, Related Items, Supporting Documents, and Audit Trail, as Figure 5–1 shows.

Figure 5–1 New Action dialog box



Summary Tab

The Summary Tab contains three sections: Summary Information, Suppliers/Facilities, and Cross References.

Summary Information Section

Use this section to define basic elements of the action. Key fields include:

- **Problem Statement** — The description of the action. This is a required field.
- **Problem Description**— The reason for creating the action.
- **Segment(s)**—The business segment of the action.
- **Type —** The type of the action. This is a required field.
- **Status** — The workflow status of the action.
- **Action #** — Number used to identify actions. This number is system generated.
- **Originator** — Auto-populated field that donates the user who created the action.
- **Workflow** — The name of the workflow used to move this action through the quality tracking process. This is a required field.
- **Product Lines** — The product lines this action affects.
- **Customer** — The customers associated with this issue.
- **Associated NPD Project** — When a correction requires an orchestrated project to correct the issue, an NPD project can be used. You would associate the action to

the NPD project here. Generally, an NPD project is needed when the problems span business units and segments, product categories, and requires a lot of individual activities to be performed across groups of users.

- **Preventative Action** — A pro-active action taken to prevent the problem from happening again.
- **Root Cause Analysis** — The root cause of the problem.

Suppliers/Facilities Section

Use this section to designate which suppliers or internal facilities are associated to the action. For example, after analysis you discover that the problem originated with the supplier, that supplier should be added here. You may discover that the problem was caused by something at an internal facility; in that case, the internal facility would be listed here. Key fields include:

- **Company** — The company that is associated to the problem. This can be any SCRM company.
- **Facility** — The facility associated to the problem. When a facility is selected, the company is auto-populated. This can be a specific SCRM facility.

> **Note:** If an action is associated to a company/facility and published, the supplier will be able to see this issue in Supplier PQM.

Cross References

For discussion about this common section, see "Cross References Section" on page 3-1.

Ext Data Tab

The Ext Data tab includes the following sections:

- **Custom Sections**—For discussion of this commonly used section, please see "Custom Sections" on page 3-2.
- **Calculated Attributes**—For discussion of this commonly used section, please see "Calculated Attributes" on page 3-2.

Affected Items Tab

This tab displays all items that are affected by the issue(s) the action is correcting. It contains two sections: Affected Items and Related Affected Items.

Affected Items Section

The Affected Items section represents the actual material that is the true cause of the issue(s) associated to the action. For example, there may be five issues around crushed product. All of them involve a packaging failure. The packaging material that failed would be added here.

Depending on your configuration, you can associate an action to the following GSM objects: Activity, Delivered Material Packing, Equipment, Formulation, Labeling, Master, Material, Menu Item, Nutrient Profile, Packaging Material, Packing Configuration, Printed Packaging, Product, and Trade.

Key fields include:

- **System #** — Number of the related product's specification.
- **Equivalent #** — Select the specific cross reference that applies to the root cause for this action. If the root cause is with all variants of the material, then leave this blank, for example, 5lb, 10lb, and 20lb bags. If the root problem is only with the 20lb bag, then that cross reference should be selected.
- **Description** — Display Name and Status of the related product's specification.
- **Rev Found** — The revision number of the affected item in which you found the problem.
- **Rev Fixed** — The revision of the specification in which the problem is fixed.

Related Affected Items Section

The Related Affected Items section displays all affected items added to the related issues. For example, if this action is tied to five issues, all affected items added to those issues will be displayed here. This provides the ability for quality managers to see all affected items in one location. The key fields are the same as those in the Affected Items section with the addition of the following:

- **PQM Item #** — The number of the affected item.

Related Items Tab

The Related Items tab displays issues, actions, and audits related to the action.

Related Issues Section

The Related Issues section displays all Issues related to this action. Key fields include:

- **Type** — The type of the issue.
- **Issue #** — The system number for the issue.
- **Equivalent #** — The user's preferred cross-reference issue equivalent number.
- **Description** — The title of the issue.
- **Status** — The workflow status of the issue.

Add issues by clicking the **Add Existing** button. If it was an issue you recently created or viewed, you can use the Recent Items option in the search screen to quickly access those items.

Related Actions Section

The Related Actions section displays all actions related to this action. There is a parent/child relationship between actions, so actions can be owned by other actions.

For example, six issues came in regarding cracked plastic lids. When creating the original action, the quality analyst was not sure where the root problem was. Once the action was reviewed by the quality manager, they determined it was a supplier problem. The quality manager would create a new supplier corrective action and associate it to the parent investigative action. The supplier would correct the problem and the quality manager would then close the parent action.

Key fields include:

- **Type** — The type of the action.
- **Action #** — The system number of the action.

- **Equivalent #** — The user's preferred cross reference action equivalent number.
- **Description** — The title of the action.
- **Status** — The workflow status of the action.
- **Relationship** — The relationship of the action, either Parent or Child.

Add actions by clicking the **Add Existing** button. If it was an action you recently created or viewed, you can use the Recent Items option in the search screen to quickly access those items.

Related Audits Section

The Related Audits section displays all audits related to this action. If an audit requires action, you would associate it here. Generally, failed audits will also generate issues and those should also be attached on this tab in the Related Issues section.

Key fields include:

- **Type** — The type of the audit.
- **Audit #** — The system number for the audit.
- **Equivalent #** — The user's preferred cross reference action equivalent number.
- **Description** — The title of the audit.
- **Status** — The workflow status of the audit.
- **Planned Audit Date** — The date the audit is planned.

You can add new audits by clicking the **Add New** button. Select **Blank** or **From Template** from the drop down list, and then complete the required fields in the Create Audit dialog box.

Add existing audits by clicking the **Add Existing** button. If it was an audit you recently created or viewed, you can use the Recent Items option in the search screen to quickly access those items.

Supporting Documents Tab

PQM allows for supporting documents. We support files, URLs and rich text. Refer to "Supporting Documents Tab" on page 3-4 or the Supporting Documents chapter of the *Agile Product Lifecycle Management for Process Getting Started Guide* for more information.

Audit Trail Tab

For discussion about this tab, see "Audit Trail Tab" on page 2-6.

6

Working with Audits

This chapter describes how audits are created and used. It includes the following topics:

- Audits Overview
- Creating Audits
- Ext Data Tab
- Affected Items Tab
- Related Items Tab
- Supporting Documents Tab
- Audit Trail Tab

Audits Overview

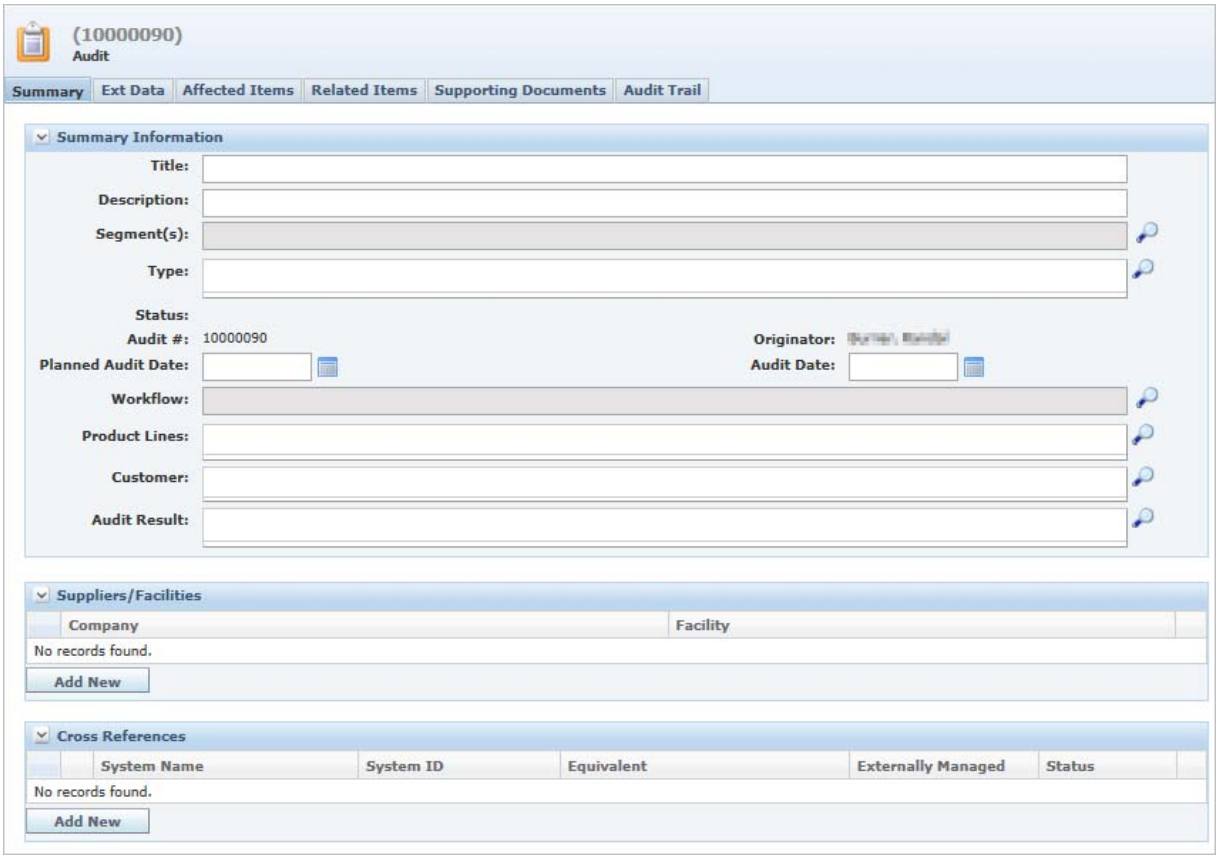
An audit is the pro-active process of verifying compliance with quality requirements. An audit could result in multiple issues. PQM is not intended to be an audit management system or capture every audit result. PQM's intention is to capture only the overall pass/fail result of an audit. PQM should also capture any issues that arise from audits that need to be corrected.

Creating Audits

To create an audit:

1. Click PQM > Audits from the left navigation panel. Agile PLM for Process displays the Audit Search page.
2. Click **Create New**. The dialog box that is displayed has six tabs: Summary, Ext Data, Affected Items, Related Items, Supporting Documents, and Audit Trail, as Figure 6–1 shows.

Figure 6–1 Create New Audit dialog box



Summary Tab

The Summary Tab contains three sections: Summary Information, Suppliers/Facilities, and Cross References.

Summary Information Section

Use this section to define basic elements of the issue. Key fields include:

- **Title** — The name of the audit. This is a required field.
- **Description**— The description of the audit.
- **Segment(s)**—The business segment of the audit.
- **Type —** The type of the audit.
- **Status** — The workflow status of the audit.
- **Audit #** — Number used to identify the audit. This number is system generated.
- **Originator** — Auto-populated field that denotes the user who created the audit.
- **Planned Audit Date** — The date planned to audit the problem.
- **Audit Date** — The date when the problem actually takes place.
- **Workflow** — The name of the workflow used to move this audit through the quality tracking process. This is a required field.
- **Product Lines** — The product lines this audit affects.

- **Customer** — The customers associated with this audit.
- **Audit Result** — The overall result of the audit process, for example, Pass or Fail.

Suppliers/Facilities Section

Use this section to designate which suppliers or internal facilities are being audited. Key fields include:

- **Company** — The company that is associated to the problem. This can be any SCRM company.
- **Facility** — The facility associated to the problem. When a facility is selected, the company is auto-populated. This can be a specific SCRM facility.

> **Note:** If an audit is associated to a company/facility and published, the supplier will be able to see this issue in Supplier PQM.

Cross References

For discussion about this common section, see "Cross References Section" on page 3-1.

Ext Data Tab

The Ext Data tab includes the following sections:

- **Custom Sections**—For discussion of this commonly used section, please see "Custom Sections" on page 3-2.
- **Calculated Attributes**—For discussion of this commonly used section, please see "Calculated Attributes" on page 3-2.

Affected Items Tab

This tab displays all GSM objects related to the audit. You can associate an audit to the following GSM objects: Activities, Delivered Material Packing, Equipment, Formulation, Labeling, Master, Material, Menu Item, Nutrient Profile, Packaging Material, Packing Configuration, Printed Packaging, Product, and Trade.

Key fields include:

- **System #** — Number of the related product's specification.
- **Equivalent #** — Select the specific cross reference that applies to the root cause for this audit. If the root cause is with all variants of the material, then leave this blank, for example, 5lb, 10lb, and 20lb bags. If the root problem is only with the 20lb bag, then that cross reference should be selected.
- **Description** — Description of the object.
- **Rev Found** — The revision number of the affected item in which you found the problem.
- **Rev Fixed** — The revision of the specification in which the problem is fixed.
- **PQM Item #** — The number of the affected item.

Related Items Tab

The Related Items tab displays other issues and actions related to the audit.

Related Issues Section

The Related Issues section displays all Issues related to this audit. For example, a failed audit could result in multiple issues that need to be corrected. These issues would be added here.

Key fields include:

- **Type** — The type of the issue.
- **Issue #** — The system number for the issue.
- **Equivalent #** — The user's preferred cross-reference issue equivalent number.
- **Description** — The title of the issue.
- **Status** — The workflow status of the issue.

Add new issues by clicking the **Add New** button. Choose **Blank** or **From Template** from the drop down list, and then complete the required fields in the Create Issue dialog box.

Add existing issues by clicking the **Add Existing** button. If it was an issue you recently created or viewed, you can use the Recent Items option in the search screen to quickly access those items.

Related Actions Section

The Related Actions section displays all actions related to this audit. The actions in this section should be the actions used to correct a failed audit.

Key fields include:

- **Type** — The type of the action.
- **Action #** — The system number of the action.
- **Equivalent #** — The user's preferred cross reference action equivalent number.
- **Description** — The title of the action.
- **Status** — The workflow status of the action.

Add new actions by clicking the **Add New** button. Choose **Blank** or **From Template** from the drop down list, and then complete the required fields in the Create Action dialog box.

Add existing actions by clicking the **Add Existing** button. If it was an action you recently created or viewed, you can use the Recent Items option in the search screen to quickly access those items.

Supporting Documents Tab

PQM allows for supporting documents. We support files, URLs and rich text. Refer to "Supporting Documents Tab" on page 3-4 or the Supporting Documents chapter of the *Agile Product Lifecycle Management for Process Getting Started Guide* for more information.

Audit Trail Tab

For discussion about this tab, see "Audit Trail Tab" on page 2-6.

7

Creating and Managing Templates

This chapter describes how to create and manage template in PQM. It includes the following topics:

- Overview
- Creating Templates
- Consuming Templates

Overview

PQM templates provide the ability to create objects containing attributes which will be copied when creating issues, actions, or audits. Templates can be created for all object types. Once a template is created, it can be used to create objects. A template must be published before it can be used to create objects.

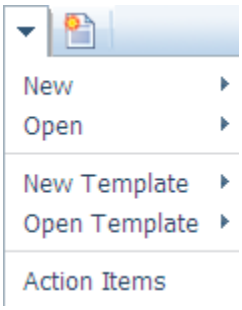
Creating Templates

Roles for Template Creation

A user will need the role of TEMPLATE_CREATOR plus the base PQM object creator role to create templates. For example, a user assigned the PQM_CREATOR_7002 role can create "blank" issues. With the PQM_CREATOR_7002 and TEMPLATE_CREATOR roles, the user can create PQM templates. For a list of PQM_CREATOR_<OBJECT_TYPE> roles, please refer to the *Agile Product Lifecycle Management for Process User Group Management User Guide*.

Users with the appropriate roles see the following options in the navigation menu.

Figure 7–1 Template creation option



New Template—Allows users to select the object type they would like to create and create a new template.

Open Template—Allows users to see templates that have already been created.

Template Attributes

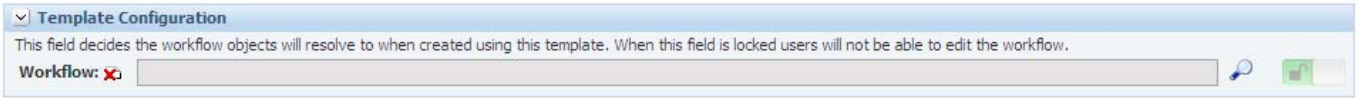
Templates generally have the same attributes available for edit as their corresponding object type. Many values added to these attributes will be copied to the object when a user creates a object from a template.

Templates also have some additional fields which can be found in the Template Configuration section.

Template Configuration

All templates have a Template Configuration section, as shown in Figure 7–2. The template configuration section contains the Workflow field.

Figure 7–2 Template Configuration section



Workflow—The template creator uses the Workflow field to specify an object workflow template. When an object is created from a template, it will automatically resolve to this workflow. If this field is left blank, the object created needs to manually select a PQM workflow.

Locked Fields

Template creators can lock key fields on a template. When these fields are locked they will be un-editable on an object that has been created from this template, unless the user have the TEMPLATE_OVERRIDE role.

The following fields can be locked:

- Type
- Severity
- Product Lines
- Workflow

Locked fields are enabled after the workflow is selected.

Template Access

Templates resolve to WFA workflows. Along with the specific user roles discussed above, workflow controls read and write access to templates. WFA has a resolution criteria of "is Template", allowing templates to resolve to separate workflow templates than objects. See the *Agile Product Lifecycle Management for Process Workflow Administration User Guide* for more information.

Template Availability

Templates for creating objects are not instantly accessible. They must be in a "published" state before general users can start creating objects using them. This setup

allows a template to go through its own workflow and approval process before objects are created based on them. A template is considered published when template is in a status that contains the "Publish Template" workflow tag. See the *Agile Product Lifecycle Management for Process Administrator User Guide* for more information.

Consuming Templates

Once a template is published, users can create objects based on that template. A user must have the appropriate role, CREATE_FROM_TEMPLATE_<OBJECT TYPE>, to create an object from a template. For example, users assigned the CREATE_FROM_TEMPLATE_7003 role can create actions from templates. See the roles appendix in the *Agile Product Lifecycle Management for Process User Group Management User Guide* for a full list of roles.

Users with this role see the **New > OBJECT TYPE > From Template** option in the navigation menu.

The third panel displays the most recently used templates under the "From Template" header. Click on any of the most recently used templates to instantly create an object using that template. You can also click the **More** link or the **From Template** header to open a template search screen.

Use this page to search for the template you would like to use. The template you select automatically creates the new objects based on that template and puts it in edit mode. You can preview the template using the view details icon to the left of the template number.

8

Using PQM as a Supplier

This chapter describes how to use PQM as a supplier. It includes the following topics:

- Overview
- Visibility and Access

Overview

Suppliers can participate in the quality management process using the supplier PQM module. Supplier access is determined by their registrant profile inside Supply Chain Relationship Management (SCRM). Suppliers can be allowed to participate as little or as much as you prefer during the quality management process. For example, suppliers can be given rights to read quality issues that relate to them, edit and workflow supplier corrective actions involving them and create/submit audit results. Trusted suppliers can even be allowed to create issues and actions.

Visibility and Access

Supplier PQM users are treated the same as internal users. For example, the supplier needs to be added to the permissions grid to be given read/write access and the workflow permissions grid to be given workflow permission (see the Supplier Token and Group Membership sections in the *Agile Product Lifecycle Management for Process Supplier Portal Administrator User Guide*) and suppliers need the proper UGM roles to create objects. However, there are a few additional requirements and exceptions for supplier users.

1. Suppliers will only be able to see PQM objects when the following conditions are true:
   - The Issue, Action, or Audit is associated to their company or facility in the PQM Suppliers/Facilities grid.
   - The Issue, Action, or Audit must be in a workflow step on which the tag is set to "Publish to Supplier Portal".

   Note: If a supplier is allowed to create quality objects, remember that the "Publish to Supplier Portal" tag must be in the first step of the workflow used. It is recommended that suppliers are only allowed to create items from templates. The templates available to the supplier should be created specifically for the supplier and include the "Publish to Supplier Portal" tag in the first step.
2. Supplier users are only allowed to associate PQM objects to specifications, companies, and facilities that have been associated to them.

Note: If a published PQM object has been associated to a specification, company, or facility that the supplier is not associated to, then the supplier will still see those rows in the Affected Items and Suppliers/Facilities grids. However, objects listed in the Affected Items and Suppliers/Facilities grids will not be linked. Suppliers are never allowed to access GSM or SCRM objects from supplier PQM. They can only read GSM and SCRM objects through the specification and documents section as described in the *Agile Product Lifecycle Management for Process Supplier Portal Administrator User Guide*.

3. Depending on your configuration, the following fields may be hidden to the supplier: Product Lines, Customers and Associated Project.
4. Custom data that contains the "Do Not Publish to Supplier" tag will not be shown to supplier users.