

## **Agile Product Lifecycle Management**

Getting Started with Agile Management for Pharmaceuticals

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# Preface

Agile PLM is a comprehensive enterprise PLM solution for managing your product value chain.

## Audience

This document is intended for administrators and users of the Agile PLM products.

## 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>.

### Access to Oracle Support

Oracle customers have access to electronic support through My Oracle Support. For information, visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info> or visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs> if you are hearing impaired.

## Related Documents

Oracle's Agile PLM documentation set includes Adobe® Acrobat PDF files. The Oracle Technology Network (OTN) Web site <http://www.oracle.com/technetwork/documentation/agile-085940.html> contains the latest versions of the Agile PLM PDF files. You can view or download these manuals from the Web site, or you can ask your Agile administrator if there is an Agile PLM Documentation folder available on your network from which you can access the Agile PLM documentation (PDF) files.

## Conventions

The following text conventions are used in this document:

Convention	Meaning
<b>boldface</b>	Boldface type indicates graphical user interface elements associated with an action, or terms defined in text or the glossary.
<i>italic</i>	Italic type indicates book titles, emphasis, or placeholder variables for which you supply particular values.

Convention	Meaning
monospace	Monospace type indicates commands within a paragraph, URLs, code in examples, text that appears on the screen, or text that you enter.



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# Introduction to Agile Recipe & Material Workspace

Welcome to the Getting Started with Recipe & Material Workspace. This manual describes the main features and capabilities of Agile Recipe & Material Workspace (RMW) within the Agile PLM application suite. It describes the concepts, actions, and navigational flows that are used in the RMW solution, and should be considered a starting point for new users of the application.

## About this Guide

This manual primarily addresses RMW users who perform various roles within the pharmaceutical drug development process, from early experiments to pilot labs through scale-up. Once the process and recipe is proven, the recipe can be transferred to large scale commercial production. Typical users are Process Scientists, Analysts, Material Managers, Equipment Managers, and others involved in the drug manufacturing processes.

Before you start working in RMW, read this manual to understand the following:

- Concepts and components of RMW.
- Initial actions that you need to perform to begin working with the application, and basic navigation. See also: "[Navigating in Agile RMW](#)" on page 2-1.
- Task and workflow management. See also: "[Workflow Routings](#)" on page 2-15.
- Searching for business objects in RMW. See also: "[Working with Searches](#)" on page 3-1.
- Reporting capabilities. See also: "[Working with RMW Reports](#)" on page 6-1.
- Standards you can create or associate with material or equipment. Standards can be reused and referenced in a recipe.
- Environmental aspects such as environmental conditions for container storage, or room temperature.

## Recipe & Material Workspace Documentation

The complete list of RMW manuals is provided here for the benefit of users and administrators of the RMW solution.

- Getting Started with to Agile Recipe Management for Pharmaceuticals - describes common concepts, basic navigation, searches and workflows. Also covers how to work with reports, standards, and environmental conditions.

- Agile Recipe Management for Pharmaceuticals Administrator Guide - describes all administration and configuration information including Agile PLM integration requirements.
- Agile Recipe Management for Pharmaceuticals Process Management Guide - describes the features of the Process module, covering the creation and execution of projects and campaigns, control recipes, and work requests.
- Agile Recipe Management for Pharmaceuticals Recipe Management Guide - describes the features of the Recipe module, covering the authoring and management of recipes and recipe templates.
- Agile Recipe Management for Pharmaceuticals Material Management Guide - describes the features of the Materials module, covering how to work with material requests, inventory, and allocation. Also covers how to manage analytical activities.
- Agile Recipe Management for Pharmaceuticals Equipment Management Guide - describes the features of the Equipment module, covering equipment qualification, loan, lease, and reservation.
- Agile Recipe Management for Pharmaceuticals Import/Export Guide - describes how to export and import RMW business and administrator objects from a source system to a target system.

RMW is accessed only through the Agile PLM user interface. Refer to Getting Started with Agile PLM along with the Agile PLM Administrator Guide for a thorough understanding of PLM processes. The complete set of Agile PLM documentation, including RMW documentation, is available on the Oracle Technology Network (OTN) Web site <http://www.oracle.com/technetwork/documentation/agile-085940.html>.

## An Overview of Agile RMW

RMW is a Web-based solution provided with the Agile PLM suite to cater to the needs of the pharmaceutical development industry. It is made up of several dimensions such as Recipe (Instructions), Equipment, Material, Analytical (Test and Assays), Environment, Standards and People. These dimensions enable drug manufacturers to conduct the preparation, execution and analysis necessary during the scale-up life cycle of a substance across multiple pilot plants, located in disparate geographic locations. It also helps scale up material production in a systematic and reproducible manner.

### Key Benefits

RMW provides an extensive view of all activities involved in drug manufacturing. It allows aggregation of information over the lifecycle of a drug product and offers the following benefits:

- Information management of Product Development Lifecycle for drug substance and drug product.
- Planning, execution, and analysis of campaigns, process definitions, and work requests.
- Integrated view of processes, materials, equipment, environment, people, and standards data.
- Conformance to business, science, and compliance metrics.

- Easy access to data in order to enable tech transfers, reviews, submissions, collaborations, and distributed operations.
- Consolidated views of lots, campaigns, and so on.
- Product development record, creation of transaction traces (or material chain of custody,) material genealogy archives, and recipe genealogy archives.
- Secure role based access for all.
- Role management that defines various roles for access to the system.
- Efficient streamlining of work using alert management.
- Compliance with Code of Federal Regulations Part 11 through audit trails.
- Custom workflows support.
- Metamodeling ability to define and build a classification hierarchy for the custom object sets for Material, Equipment, and Standards.

## **Output Material Quantity display**

Output Material made in the Process or Work Request displays correctly.

### **Output Material Quantity display is cleaned up**

Output Material (OM) quantities made in a Process Step or Work Request now displays and ensures that:

- Process Step (PS) specifies the number of Control Recipes (CR), as well as planned Output Material quantity for the PS itself in the Output tab;
- Number of CRs specified within the PS is now used to populate the planned Output Material quantity within each Control Recipe of this PS;
- Once the Work Request makes the Output Material, the actual Output Material quantities are correctly displayed in the Work Request and its Control Recipe and associated Process Step; and,
- The view of Campaign Summary at the Project level reflects the Output Material quantities consistently.

### **Ability to add Materials and Equipment directly to a Recipe**

To add Materials and Equipment directly to a Recipe, users previously had to create variables, and then resolve the variables. Now:

- Users can add Materials and Equipment directly onto the BOM and BOE.
- User must indicate which Recipe Action is using that resource.
- Similarly, while editing a Recipe, Process Step, or Work Request, users can edit a Recipe Action instance and add Materials, Equipment, or Standards directly without creating variables.

### **Stability Study view**

The view for a Lot supports Stability Studies:

- Study dates;
- Study environmental conditions; and,
- Results of sample testing.

## Containers on Genealogy tab

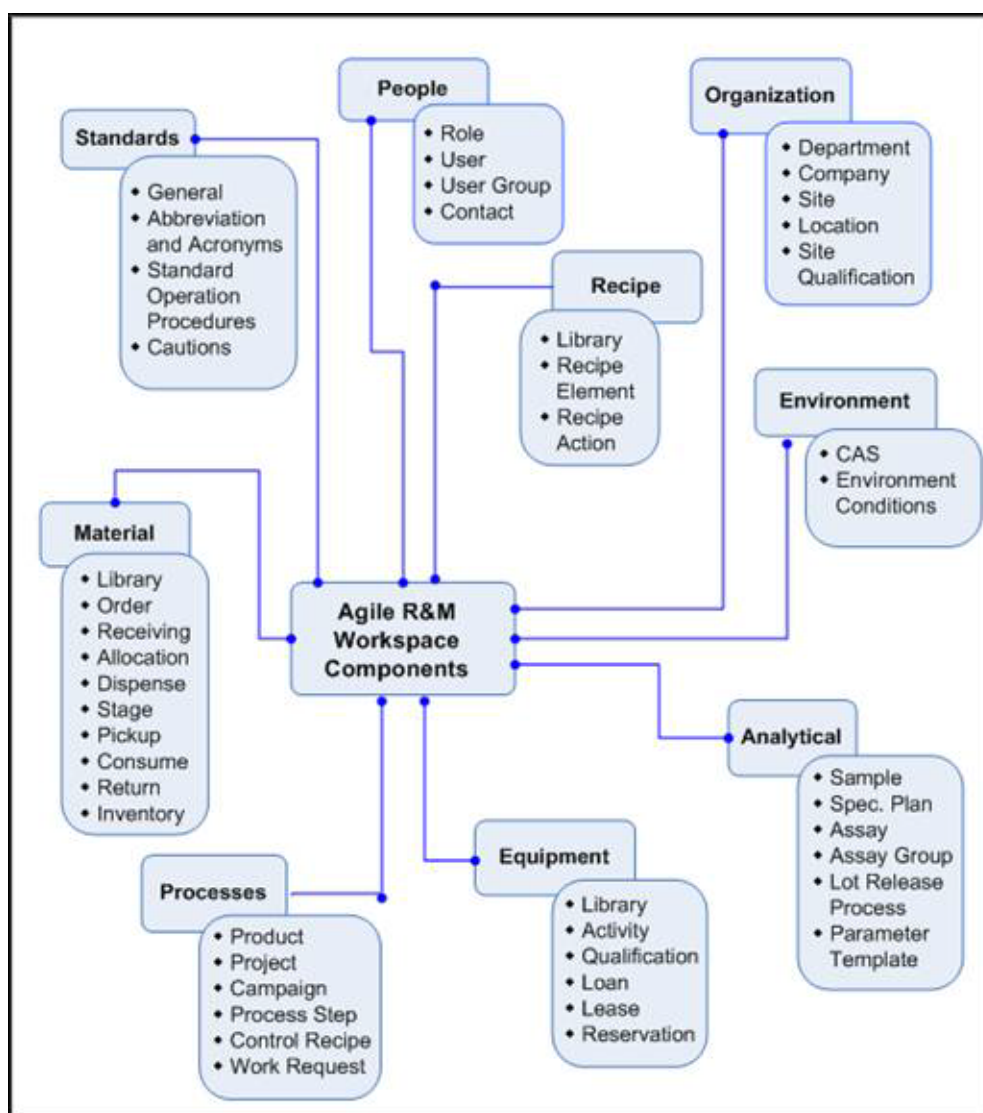
Containers that you consume in a Work Request are displayed, completing the reverse trace (backward genealogy) of how a Material was made.

## Display Parameters and Results

Parameters values that you enter show up while navigating in RMW with other details (For example, Materials consumed, Equipment used) in a Work Request that is closed out. For more details, see the Agile Recipe Management for Pharmaceuticals Process Management Guide.

## RMW Components

RMW covers the entire lifecycle of a drug product from the lab to its commercial launch. The following diagram shows the major components of RMW.



The capabilities of each component are described in the following topic. For detailed information and instructions on how to use these components effectively for your business process, see the relevant user guide of each component.

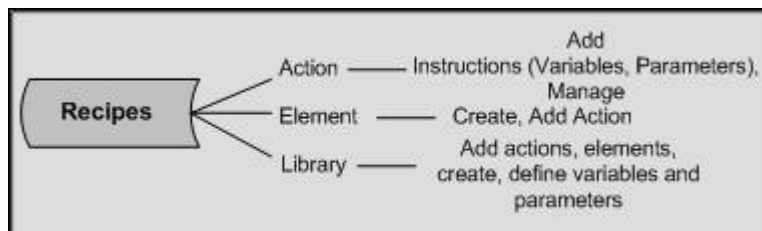
## Notes on RMW Components

Here is a brief description of each component appearing in RMW.

### Recipes

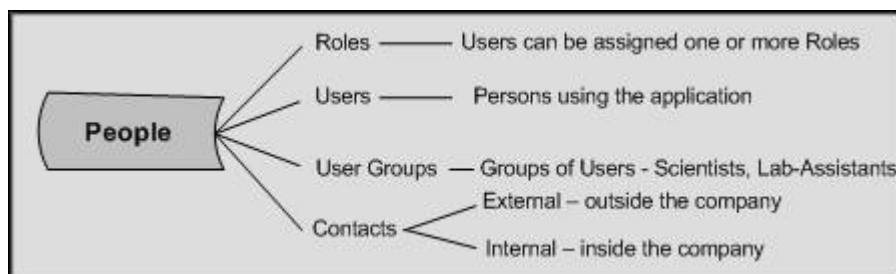
A **Recipe** contains the minimum set of information about the developmental requirements of a specific product. Recipes generally include instructions about gathering and combining raw material, the type of equipment to be used, and processes to be followed to create the target product.

For details, see Agile Recipe Management for Pharmaceuticals Recipe Management Guide.



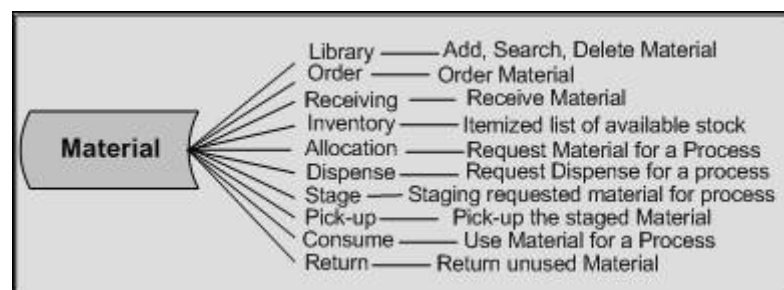
### People

People Management enables you to set up users, roles, user groups, and contacts. This is done by the administrator.



### Material

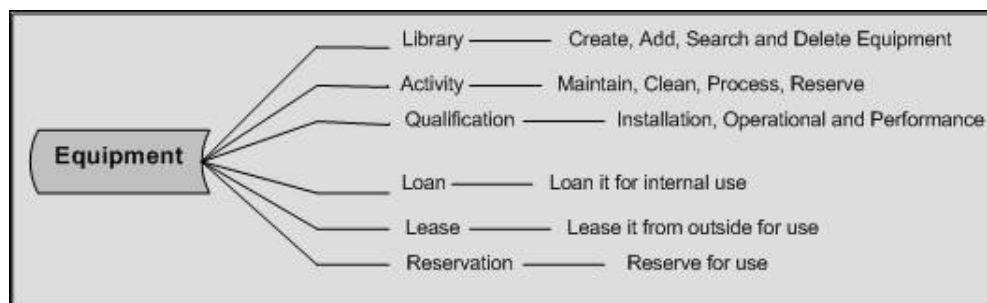
Material Management enables you to classify and organize material used in the development process and track various inventory transactions. The system is similar to an ERP system, tracking resources in a fast-paced, changing development environment. The ultimate goal is to create a recipe which is well proven in a development area, before transferring to commercial operations. For details, see Agile Recipe Management for Pharmaceuticals Material Management Guide.



## Equipment

Equipment Management enables you to add, modify, search, and view equipment. Equipment can have contaminants that can affect the process. It is crucial to track the state of readiness of the equipment by performing various activities on it, such as cleaning, calibrating, and reserving.

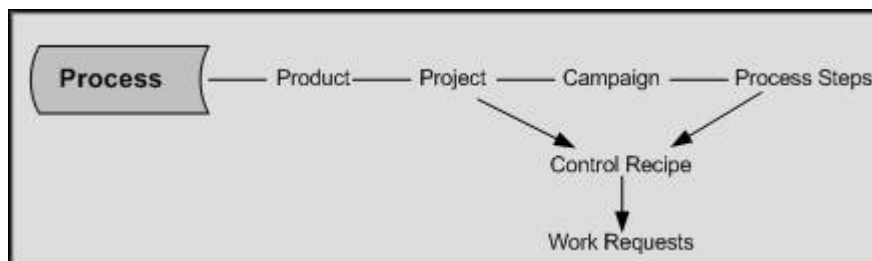
For details, see Agile Recipe Management for Pharmaceuticals Material Management Guide.



## Process

Process Management aims at creating a Work Request, using information derived from a Recipe. A Work Request ultimately results in the material being made and placed into Inventory.

A Process can have several components - Product, Project, Campaign, Process Steps, Control Recipe and Work Request. Within a Project, you can have several Campaigns which are small projects to track and make materials. For each campaign, you can create Process Steps, which can result in several lots being made. Each lot is planned using a Control Recipe and eventually completed with a Work Request. For details, see Agile Recipe Management for Pharmaceuticals Material Management Guide.



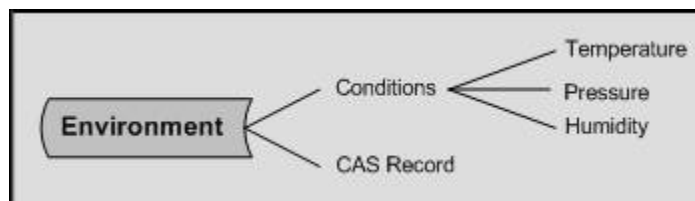
## Standards

Standards enable you to create and maintain a library of predefined statements relating to safety, caution, and other general instructions for a manufacturing process. They can be embedded as variables in the text or instructions within a Recipe Action. You can also resolve these variables to a specific standard based on project or campaign requirement. It also comprises of acronyms and abbreviations used in the industry or organization.

## Environmental

Environmental conditions enable you to track compliance against mandated environmental requirements of regulatory agencies.

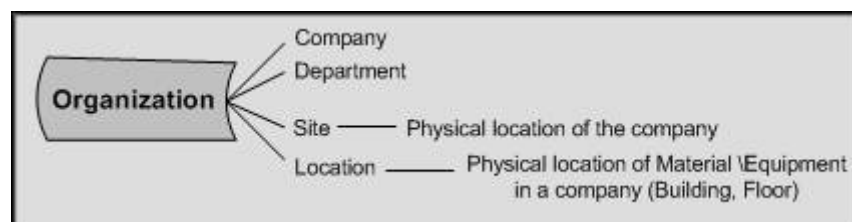
You can use environment conditions to ensure that the container of material is stored as per recommendation. For example, ensuring that material sample is stored in a specified environment to prevent its deterioration.



## Organization

Organization Management enables you to identify and associate RMW objects to geographical entities. An Organization houses multiple Companies, a Company is made of one or more Sites, and one or more Locations make a Site.

Throughout the system, the Site entity is used for receiving materials (into a location), for planning the details within a control recipe (identifying the location from which you can consume material), and completing the work request (identifying the location where you can place the newly made material).



---

## Navigating in Agile RMW

RMW is one of the solutions of Agile PLM. You can access the RMW application if you log in to Agile PLM with the necessary privileges. For details about logging in to Agile PLM, see the chapter 'Navigating in Agile Web Client' in the Getting Started with Agile PLM Guide.

### To access RMW:

1. Log in to Agile PLM.
2. In the left navigation pane, click Tools and Settings.
3. Select Recipe & Material Workspace.

The RMW application appears, displaying the Home page. The Home page includes the Top pane, Navigation pane on the left and the Content pane.

To return to Agile PLM:

1. Click Tools and Settings.
2. Select Product Collaboration. You are back on the Agile PLM Home page.

### To log out of RMW:

1. Click the Logout button on the left navigation pane.

---

**Note:** Logging out of RMW logs you out of Agile PLM as well. To return to RMW, you will have to log in again to Agile PLM.

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## User Access to RMW

A PLM user can access the RMW solution after the PLM administrator assigns the PLM privilege mask called **Recipe & Material Workspace UI Access**.

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**Important:** The tasks below do not indicate anything more than access to RMW solution. End-users must be created in PLM and further configured in RMW.

---

RMW-specific roles and privileges are assigned to users within the RMW solution. For more information, see the chapter "Roles" in the Agile Recipe Management for Pharmaceuticals Administrator Guide.



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**Note:** You may want to create a role for "RMW User", especially if you want to consistently bundle together other PLM privileges for PLM users who will work in RMW.

---

**To give a PLM user access to RMW in Web Client:**

1. All users who will work in the Recipe & Material Workspace solution are first created in Agile PLM (or the company's LDAP system).
2. An Agile PLM user must be assigned the Recipe & Material Workspace UI Access privilege mask. This privilege mask is based on the Recipe & Material Workspace UI Access privilege type.
3. From Agile Web Client's standard interface, a user chooses Tools & Settings > Recipe & Material Workspace to open the RMW user interface.

**For RMW user, to access Product Collaboration from RMW:**

1. In Agile Web Client's RMW interface, choose Tools & Settings > Product Collaboration to return to the standard UI for Product Collaboration and the other PLM solutions.

---

**Note:** You must have the necessary privileges to access Product Collaboration.

---

## My Preferences

You can personalize default settings to suit your requirements and set preferences using the My Preferences button, which appears on the left navigation pane of the Home page. You can view and edit settings in My Preferences. The profile displays in the content pane.

- **General:** General preferences such as company name, date, time, number formats and other basic factors required in setting up and running the application.
- **Home page:** Specify the tables you want to display on the Home page.
- **Preferred Start Page:** The functionality of UI-UI context switching is dependent on the user's Preferred Start Page, which is set on the Preferences tab of the user object in PLM. See also: UI-UI Context Switching

**To set general preferences:**

1. Log in to the RMW application.
2. Click My Preferences on the Navigation pane toolbar.
3. In the General tab, click Change to change the Primary Site. A list of sites are displayed.
4. Select a site from the tree view.

---

**Note:** You can only select one site for this field. By default, the child sites are not selected if you select its parent site.

---

Privilege flag set can be selected for site privilege assignment. In the Tree view, selection of a site is disabled, grayed, or not displayed for the following reasons:

- It is a non-privileged site but is displayed to show the hierarchy of the privilege sites.
  - A site with no child and no privilege does not display on the screen.
1. To change the password, click the Change link next to the Password field. More fields requesting password confirmation appear.
  2. Enter values in the Old Password, Password and Confirm Password fields.
  3. To change Approval Password, fill in the fields as above.
  4. Click the look-up icon to choose a Default Delegate.
  5. Select a user from the search results and click OK.

---

**Note:** The language field is set by the Agile PLM Administrator and you cannot edit it. By default, the preference is set to English.

---

1. Choose the Number Format and Time Zone from the respective menus.

The date format is set by the Administrator in Product Collaboration. The date format by default is dd-mm-yyyy.

1. Select a Button Display from the drop-down list.
2. Select the location to display toolbar buttons from the Display Toolbar Buttons dropdown list.
3. Select the number of columns to be displayed on the Home page.
4. Click OK to confirm, or Cancel to cancel the action.

A confirmation message informs you that you have successfully saved user preferences.

#### To customize the Home page:

The Home page tab displays the Dashboard, My Notifications and Workflow Routings tabs. The dashboard displays tables that you choose in the My Preferences page. You can view and edit the tables appearing on the Dashboard tab.

Example: You select content to display assigned tasks. The Dashboard displays all assigned tasks in the selected view, with the selected display name, either as a Table or Tree Table, in the selected number of rows to be displayed at one time.

1. Log in to the RMW application.
2. Click the My Preferences button in the navigation pane.
3. Click the Home tab.
4. Click Add Rows, select data from the drop-down list or enter values.
5. Click OK. You return to the Home page which displays your latest changes.

A confirmation message informs you that you have successfully customized the RMW Home page.

## UI-UI Context Switching

UI-UIcontext switching allows the user to view an integrated object in RMW, and switch to Agile PLM to see the object's details there (or vice versa). The system

preserves the user's original context object, so that the user can be automatically brought back to the original context in his home location, either RMW or PLM.

---

**Note:** UI-UI context switching is only available for integrated business objects such as Material, Recipe, Manufacturer, and Supplier.

---

The functionality of UI-UI context switching is dependent on the user's Preferred Start Page, which is set on the Preferences tab of the user object in PLM. If the user's Preferred Start Page is "Recipe & Material Workspace", then the user's object context in RMW is preserved. For example, if a user is looking at a material A123 in RMW and then switches to Product Collaboration, the system brings the user to material A123 automatically, assuming the material has been published. If the material does not exist in Agile PLM, then the user is taken to the Agile homepage. The user can move around and visit other objects, but if, and when, the user switches back to RMW, the originally preserved object context will be reloaded, which in this example means that the user will be brought back to material A123.

If the user is not an RMW user and the Preferred Start Page is set to anything other than Recipe & Material Workspace, the user's last location/context object in PLM is saved. If a PLM user is looking at an integrated object in PLM, then switches to RMW, that same object should automatically be opened upon landing in RMW. If the PLM user strays from that object and visits other objects, and then returns to PLM, the user will be brought back to the last saved PLM context.

<b>Agile PLM User</b>		<b>RMW User</b>		
<b>Starting Context Object</b>				
	If the context object exists in both PLM and RMW, when the Agile PLM user switches to RMW . . .	If the context object only exists in PLM, when the Agile PLM user switches to RMW . . .	If the context object exists in both PLM and RMW, when the Agile PLM user switches to PLM . . .	If the context object only exists in RMW, when the Agile RMW user switches to Agile PLM . . .
<b>Material</b>	The user is taken to a search results page in RMW, with the material listed in the results table.  Once the user switches back to PLM, the system automatically takes the user back to the preserved material context object.	The user is taken to the RMW homepage.  Once the user switches back to PLM, the system automatically takes the user back to the preserved material context object.	The user is taken directly to the material object in PLM.  Once the user switches back to RMW, the system automatically takes the user back to the preserved material context object.	The user is taken to the PLM homepage.  Once the user switches back to RMW, the system automatically takes the user back to the preserved material context object.

Agile PLM User		RMW User		
<b>Manufacturer</b>	<p>The user is taken to a search results page in RMW, with the manufacturer listed in the results table.</p> <p>Once the user switches back to PLM, the system automatically takes the user back to the preserved manufacturer context object.</p>	<p>The user is taken to the RMW homepage.</p> <p>Once the user switches back to PLM, the system automatically takes the user back to the preserved manufacturer context object.</p>	N/A	N/A
<b>Supplier</b>	<p>The user is taken to a search results page in RMW, with the supplier listed in the results table.</p> <p>Once the user switches back to PLM, the system automatically takes the user back to the preserved supplier context object.</p>	<p>The user is taken to the RMW homepage.</p> <p>Once the user switches back to PLM, the system automatically takes the user back to the preserved supplier context object.</p>	N/A	N/A
<b>Site</b>	N/A	N/A	<p>The user is taken to the manufacturer / supplier object in PLM. If the manufacturer and supplier have the same name, the supplier is used.</p> <p>Once the user switches back to RMW, the system automatically takes the user back to the preserved site context object.</p>	<p>The user is taken to the PLM homepage.</p> <p>Once the user switches back to RMW, the system automatically takes the user back to the preserved material context object.</p>

Agile PLM User RMW User				
Non-integrated object(ECO)	N/A	The user is taken to the RMW homepage.	The user is taken to the PLM homepage.	N/A
		Once the user switches back to PLM, the system automatically takes the user back to the preserved supplier context object.	Once the user switches back to RMW, the user is taken to the RMW homepage. The object context is not retained in this situation.	

## Unit of Measure in RMW

The Unit Of Measure (UOM) is consistent across RMW and uses the unit that is defined in the "Display UOM" field in the Material Library to drive all transactions.

- For example, if purified water has a Display UOM of Liters in the material library, all transactions in RMW are conducted in Liters.
- Transactions include Order, Receive, Allocate, Dispense, Stage, Pickup, Consume, Return, Dispose, Inventory, Analytical: Sample, and the BOM & Output tabs of Recipes, Control Recipes, and Work Requests.
- All Material Quantity attributes are also displayed in this UOM, for example, Quantity on Hand and Available Quantity.

## BatchML

**BatchML** is an XML using tags specified in S-88. The Import from BatchML feature enables you to integrate Master Recipes authored in RMW with external systems.

Planned Work Request details, Recipes, Control Recipes, and Process Steps stored in RMW include:

- Routings of recipe actions
- Material and Equipment required
- Standards you need to follow
- Assays and parameters you need to measure within the recipe action.

These details can now be executed in other systems by exporting them as XML files.

Listed below are some of the ways you can use the Master Recipes.

1. Details in Work Requests, Recipes, Control Recipes and Process Steps can be executed in other systems by exporting them as XML files. You can also import and store the results of the execution into Agile PLM against the Item/Bill of Material as an attachment.
2. Converting the contents of a recipe into XML files and sending them to Manufacturing Execution Systems (MES) increases the production of the material on a large scale.
3. Working jointly with partners, CMO's, CRO's these files can be outsourced as a collaboration item to companies to manufacture material.

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**Note:** The Import/Export BatchML feature is available through Web Services and application User Interface.

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## Business Objects in RMW

The table below lists and describes objects as they appear in RMW application.

Name	Description	Business Objects
<b>Recipe</b>	<p>A unique set of information that defines the development requirements for a specific product.</p> <p>For details, see Agile Recipe Management for Pharmaceuticals Recipe Management Guide</p>	<p><b>Recipe Action:</b> The lowest level of instruction in a Recipe.</p> <p><b>RecipeElement:</b> RMW allows users to create and manage templates using a set of elements - Phase, Operation, Unit Procedure.</p> <p><b>Library:</b> A centralized repository within the system to retrieve data on recipes.</p>
<b>Process</b>	<p>A sequence of activities intended to lead to a Work Request.</p> <p>For details, see Agile Recipe Management for Pharmaceuticals Process Management Guide</p>	<p><b>Product:</b> A completed dosage form that contains a drug substance.</p> <p><b>Project:</b> Involves a group of inter-related activities that are planned and executed in a certain sequence to create a unique product within a specific time frame.</p> <p><b>Campaign:</b> Planning and executing a set of defined process steps to synthesize a target API material.</p> <p><b>Process Step:</b> A process step defines the processes involved in creating the final drug product.</p> <p><b>Control Recipe:</b> Defines the manufacture of a single batch of a specific product.</p> <p><b>Work Request:</b> Includes materials, equipment, and master recipes that combine to produce one lot of material.</p>
<b>Equipment</b>	<p>A non-depletable resource used in the development process of a product.</p> <p>For details, see Agile Recipe Management for Pharmaceuticals Equipment Management Guide</p>	<p><b>Library:</b> A centralized repository within the system to retrieve data on equipment.</p> <p><b>Activity:</b> Activities (calibrating, cleaning) performed on equipment before using it in a process.</p> <p><b>Qualification:</b> Documented evidence that a process or system consistently and reproducibly performs as intended and does what it purports to do.</p> <p><b>Loan/Lease:</b> Lend equipment for internal use/ lease it for use from external sources.</p> <p><b>Reservation:</b> Reserve equipment for a period.</p>

Name	Description	Business Objects
<b>Material</b>	<p>A substance used in the development process of a product. Materials can be chemicals, excipients, solvents, consumables and so on.</p> <p>For details, see Agile Recipe Management for Pharmaceuticals Material Management Guide</p>	<p><b>Library:</b> A centralized repository within the system to retrieve data on material.</p> <p><b>Order:</b> A request placed for material.</p> <p><b>Receiving:</b> Receipt of Material Lots/Containers from a Supplier.</p> <p><b>Allocation:</b> Reserve material for a process.</p> <p><b>Dispense:</b> Allot/ transfer material as per request.</p> <p><b>Stage:</b> Transferring the quantity to a location from where you can pick up.</p> <p><b>Pickup:</b> Pick up the staged material.</p> <p><b>Consume:</b> Use the ordered material in a process/project/campaign.</p> <p><b>Return:</b> Return unused material.</p> <p><b>Disposal:</b> Disposing material which is contaminated or has exceeded the shelf life. Disposal is done as per EPA rules and regulations, and needs to be tracked carefully.</p> <p><b>Inventory:</b> An itemized list of available stock (Material, Equipment, etc).</p> <p><b>Manage Movement:</b> Movement of Material containers from one location to another. System allows users to track location of containers at all times.</p> <p><b>Manage Shipping:</b> Shipment of Material containers from one location to another. System allows users to ship containers.</p>
<b>Analytical</b>	<p>'Analytical' relates to samples, assays and specification plans. The analytical method is a process used to characterize or detect a chemical or chemical mixture.</p>	<p><b>Assay:</b> Assays are tests that are developed and run to verify the material composition of raw materials, intermediates and final product.</p> <p><b>Parameter Template:</b> Library of parameters (control settings of equipment, material characteristics) that can be stored ahead of time in the system as a library. Process scientists use these templates to create recipe actions quickly instead of re-creating them from scratch each time.</p> <p><b>Specification Plan:</b> A list of tests and/or references to analytical procedures, and appropriate acceptance criteria</p> <p><b>Sample:</b> A portion of a specific material that needs to be analyzed and is evaluated against a spec plan.</p> <p><b>Lot Release Process:</b> Process to gather together samples &amp; results and send it to a group of people for final inspection before the formal release.</p>

Name	Description	Business Objects
<b>Standards</b>	Sets standards to follow while creating chemicals, keeping in mind the hazards that would ensue.	<b>Standards:</b> Predefined statements relating to safety, caution, general instructions in or around a manufacturing process, and the acronyms, and abbreviations used in the industry, and the organization.
<b>People</b>	Internal and external users accessing RMW.	<p><b>Role:</b> Defines responsibilities and actions the User can perform.</p> <p><b>User:</b> Person using RMW and assigned certain roles.</p> <p><b>User Group:</b> Groups which are assigned roles to perform certain functions.</p> <p><b>Contact:</b> People who serve the company directly or indirectly (external or internal).</p>
<b>Organization</b>	An Organization represents the entity that is involved in the development of a product. An Organization can have multiple companies. A company is associated with one or more departments, sites, and locations.	<p><b>Company:</b> A company is the first organizational element. You can have more than one company in an organization. You can associate companies with one or more departments, sites and locations.</p> <p><b>Site:</b> A physical location for a company. It is mandatory to create sites while setting up companies.</p> <p><b>Location:</b> Actual physical location of the Equipment/Material within a site. A location belongs to only one site and cannot be moved from one site to another.</p> <p><b>Department:</b> Specific divisions in a company. A department can be assigned to many users but a user can access only one department.</p> <p><b>Site Qualification:</b> Sites are qualified for certain types of materials, or categories of materials.</p>

## Editing Objects

You can edit objects that appear in the search results, provided you have the appropriate Modify privileges. Use Quick Search to search for a specific object.

### To edit objects:

1. From the search results, select the check box of the object you want to edit. This activates the Edit button.
2. Click the Edit button.
3. Make the necessary modifications and click OK.

A message confirms the modification.

## Duplicating Objects

You can duplicate an object from the object that you have created and save it using a new name. The new object can continue to have all the existing attributes data or you can modify data as required by either deleting existing attribute data or adding new data to the attributes.



**To duplicate an object:**

1. Select an object from the search results.
2. Click the More menu.
3. Select Save As menu option.
4. In the Save As page that appears, enter a new name for the object.
5. To duplicate Notes attached to the object, select Yes. If not, select No.
6. To duplicate Attachments attached to the object, select Yes. If not, select No.

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**Note:** Notes and Attachments are not duplicated by default.

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1. To modify or change existing attributes data, click the Save and Edit button. You can edit/ delete existing data.
2. To save with existing data, click OK. A message confirms that you have successfully saved the new object.
3. To cancel duplication, click Cancel.

## Deleting Objects

You can delete objects that you no longer use in RMW provided you have the appropriate privileges. Once deleted, the deleted object does not show up in the search results.

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**Note:** You cannot delete objects associated with other objects.

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**To delete objects:**

1. In the search results, select the check box of the row you want to delete. The Delete button is activated.
2. Click Delete. The object is deleted. If the object is associated with other objects, a message appears informing you of the association.

**To view deleted objects:**

1. Click the Show Deleted Items icon that appears on the search results table.
2. Search results return a list of objects. The Deleted column displays an icon in the row of the deleted object.

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**Note:** You cannot view details of the deleted objects.

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## Home Page

The Preferred Start Page setting and the roles and privileges assigned to you by the Administrator determine the contents of the Home page. By default, the Home page displays the following:

**Top Pane**

- Home page
- Create menu

- **Search controls**

### Navigation Pane

- **Courtesy Controls** (My Preferences, Tools and Settings, Help, Logout)
- **Navigation Drawers** (Folders and Reports)

### Content pane

The content pane displays tabular data of business objects. Administrator settings govern display in the content pane.

- **Dashboard**
- **My Assignments**
- **Workflow Routings**

### Top Pane

The buttons on the toolbar in the Top pane allows you to perform tasks listed in the following table, provided you hold appropriate roles and privileges.

Name	Description
<b>Home</b>	The Home page displays Dashboard, My Notifications and Workflow Routings (by default) based on settings defined by the Administrator.
<b>Create New</b>	Lets you create objects in all classes for which you have privileges.
<b>Quick Search criteria box</b>	Select a class from the menu and enter the search criteria. Searches all objects listed.
<b>Execute Search</b>	Searches for objects that match the criteria in the text box.
<b>Custom Search</b>	Searches for objects as per the criteria you set in the Custom search page.

### Navigation Pane

The left pane or the Navigation pane contains the Oracle logo, Collapse and Expand buttons.

Name	Description
My Preferences	Displays your preferences.
Tools & Settings	Product Collaboration: Returns you to Agile PLM login page.
Help	Help: Provides access to online documentation (Agile) and Oracle User Productivity Kit. About: Details of License & Version.
Logout	Exits you from the application.

### Folders and Reports



The Folders drawer contains sub-folders of Saved Searches. You can access them if you have the necessary roles and privileges. The folder contains searches that you have created and saved. Click the icon to display and hide all searches. Click the icon to hide the searches. Click to display searches in that folder.

The Reports drawer contains reports which you can access, if you have the required roles and privileges. You can search for reports and save them for use at a later date, and generate reports. Click Expand icon to display all reports. Click the Collapse icon to hide all reports. Click to display reports in that folder.

You can show the Navigation pane using the Expand button and hide the Navigation pane using the Collapse button.

### **Content Pane**

The Home page icon on the Top pane opens displaying the Content pane with tabs the administrator has assigned to you. By default, it displays the following tabs:

- Dashboard
- My Notifications
- Workflow Routings

## **Dashboard**

The Dashboard enables you to quickly view and manage information available in the system, as required by you. You can create a number of dashboard tabs and display content in the form of tables (for projects, campaigns, tasks, reports).

Access to view the dashboard is based on roles and privileges assigned to you by the Administrator. Contact the administrator for details of necessary roles and privileges.

Dashboard tabs are created by the administrator. The user only has privilege to view the tabs assigned by the administrator.

### **Configuring the Dashboard**

The Dashboard tab provides a view of specific data of projects and campaigns and related product information in the form of tables. The administrator creates channels and controls visibility of channels. Only users with the appropriate roles and privileges can view the channels. As a user, you can only select from an existing channel which information can be derived for display and where they appear. You can configure and view the information display, provided you hold appropriate privileges.

For details on configuring the Dashboard tab, see the Agile Recipe Management for Pharmaceuticals Administrator Guide.

#### **To configure the dashboard:**

1. Navigate to My Preferences> Home page tab in the navigation pane.
2. Click Add Rows. Select channels you want to display from the menu.
3. Click OK.

The channels that you have chosen appear on the Dashboard as tabs.

### **Viewing the Dashboard**

The Dashboard tab appears on the Home page of the RMW application along with My Notifications and Workflow Routings tabs.

#### **To view the dashboard:**

1. Click the Home page icon in the top pane to display the **Home** page. The Dashboard displays tabs depending on the roles and privileges assigned to you by the Administrator and the channels you have selected.
2. Click the Dashboard tab.
3. Click the subject link to open and view it.

### Filtering Data on the Dashboard

The Filter icon, which appears on all the Dashboard tables enables you to create customized views of business objects you are reviewing or managing. You can use the options in the dropdown to filter the view and sort data by pre-defined views.

For example: Sort data by different attributes in ascending or descending order.

#### To filter the view of the dashboard:

1. Click the Filter icon. Filter fields display in all the columns along with Filter and Clear buttons.
2. Enter valid data in any one of the fields and click Filter. Data is filtered appropriately.
3. Click Clear to clear the field.
4. Click the Filter icon again and notice that the filter fields disappear.

## My Notifications

The My Notifications tab on the Home page lists alerts sent to your account and items that require action. It provides you with a set of tools that you can efficiently use to manage them. You can sort, select or view rows in the assignment tables. My Notifications tab includes:

- My Notifications
- My Subscriptions
- Possible Subscriptions

### My Notifications

My Notifications displays a list of alerts. For example, if the restock limit alert is triggered, you will receive a notification that stock is below limit. You have to go to the inventory and request for stock. It also informs you of completion of a task, generation of a report, and trigger actions on a workflow.

#### To view a notification:

1. Select a notification from the table. This activates action buttons. Action buttons on the notification include:
  - Delete
  - Mark as Unread
  - Mark as Read
  - Show
  - Refresh
  - Export
  - Compare

2. Click the subject hyperlink. The notification displays the details.

**To delete a notification:**

1. Select a notification from the table.
2. Click Delete.

The notification table displays the following attributes:

- **Is Read:** Specifies if the Notification is read or unread.
- **Priority:** Specifies if the priority level is High, Medium, or Low.
- **Subject:** A link which states the title of the notification. Click the subject link to see details.
- **Type:** Type of notification - Informational or Warning.
- **Time of Alert:** Informs you of the time of alert.
- **Alert Name:** Name of the alert.
- **From Subscription:** The Subscription from which you trigger the alert.

**My Subscriptions**

My Subscriptions lists alerts to which you have subscribed. Notifications are sent to subscribers informing them of alerts for which they are responsible. Alerts are sent to their email address or Dashboards depending on the preference they have set. Refer to My Preferences. Selecting a subscription enables Edit, Unsubscribe, More, Compare, and Export buttons.

**To edit a subscription:**

1. Select a subscription and click the Edit button.

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**Note:** You cannot edit mandatory alert subscriptions.

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**To unsubscribe from a subscription:**

1. Select a subscription and click Unsubscribe to remove yourself from the list of subscribers.

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**Note:** You cannot unsubscribe from mandatory alert subscriptions.

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**To export the subscription:**

1. Click the Export button to export the subscription to any of the following output formats: Microsoft Excel, PDF, HTML, or XML.

**Possible Subscriptions**

Possible Subscriptions lists available alerts to which you can subscribe. Selecting an alert enables the Subscribe, Compare, and Export buttons.

**To subscribe:**

1. Select an alert from the table and click Subscribe.
2. In the Subscription: New page,
  1. Enter Subscription Name. This is a mandatory field.

2. Select a priority level from menu. High, Medium, or Low.
3. Select the Email or Dashboard check boxes to indicate the preferred notification methods.
4. Click Next. Enter condition details.
5. Click Finish.

A message informs you of successful subscription to the alert and it appears in the My Subscriptions table.

## Workflow Routings

The Workflow Routings tab appears on the Home page and lists Workflows tasks and Notifications that requires review or action from you. For example, it may list a Task that you need to take action, a Workflow that you need to approve or a Notification alert.

### Tasks

**Tasks** are specific activities that you can distribute among people in an organization and complete over a specific period of time. Along with helping you manage time and resources efficiently and effectively, they also track progress in your schedule. The tabs that you can view in Tasks are:

- **Assigned tasks:** Lists Tasks assigned to you.
  - Pending: Tasks pending for approval from Approvers/Observers/Reviewers.
  - Delegated: Tasks delegated for action to specified delegates.
  - Completed: Lists completed tasks.
- **Initiated tasks:** Lists Tasks that you initiate and need to track.
  - Pending: Tasks pending for approval from Approvers/Observers/Reviewers.
  - Completed: Lists completed tasks.
- **Search:** Searches for tasks.

### Viewing Tasks

You can view initiated tasks that are in Pending or Completed status.

#### To view initiated tasks:

1. On the Home page, click Workflow Routings > Tasks > Initiated Tasks.
  - Pending tasks display by default.
2. Click Task ID to view task details.

#### To view completed tasks:

1. Click Completed, to view tasks that are complete.
2. Click Task ID to view task details.

### Viewing Assigned Tasks

Tasks are attached to notifications that provide additional information. You can view workflow generated messages that require action and informational messages that do not require action, provided you hold the necessary privileges.

#### To view assigned tasks:

1. Click Workflow Routings.  
Tasks > Assigned Tasks > Pending Tasks display by default.
2. Select the Task ID link you wish to view. The task opens displaying details. The Assigned Tasks tab also lists the following tasks:
  - Delegated
  - Completed

**To take action on tasks:**

1. By default, the Tasks tab displays details of the Pending Tasks assigned to you. The table below describes tabs in the Task: Workflow Status page.

Tabs	Description
Workflow Progress	Displays Completed, Current, and Future states of tasks.
Task Details	Details of the task.
Authorized Parties	Displays the Primary Party and Backup Party who are authorized to take action on the current state.
Opinions	Opinions of users and optional reviewers.
History	Summary of actions taken and modifications made to the task.

The action buttons appearing before the Delegate button depends on the actions you can take in the current state.

Action Buttons	Description of the Actions
Approve	To approve the task. On approval the task moves to the next state.
Reject	To reject the ask.
Submit	To submit the task for approval.
Delegate	To delegate the task to another user.
Get Opinion	For opinion of other users, click Add User and select the user.
Cancel	To return to the search results page.

**Delegating Tasks**

You can delegate tasks for necessary action to a specified delegate. Once you delegate a task, you share all e-mails, notifications, and alerts with the delegate. The person to whom you delegate a task cannot re-delegate the task.

**To delegate a task:**

1. On the Home page, go to Workflow Routings > Tasks. By default the Tasks tab displays the pending tasks assigned to you.
2. Select the Task you want to delegate.
3. Click Delegate. Select the User ID of the person to whom you want to delegate the task.
4. Click OK.

A message confirms successful delegation.

## Workflows

Workflows are a sequence of status changes that an object goes through in a quality control process. The object needs to be in an appropriate status and get approval from the assigned Approvers, Reviewers and Observers before it can move forward. You can create workflows if you hold the necessary roles and privileges. You can view, delegate, un-delegate, activate, deactivate, set status, and search for workflows.

Workflow State is the current status of a workflow at a given point. Standard states include Draft, Release for Review, Approved, Rejected, and On Hold. In addition to these states, you can create your own workflow states.

A component needs to be in an appropriate workflow state before it can move forward. The table below gives you the initial status on creation of workflow for a component and the statuses it can move to.

Menu objects	Active/ Inactive	Initial Status	Possible Statuses	Usable Only if in this State
Recipe	Active	Draft	Draft-Submitted-Approved/Rejected	Any state other than Canceled
Material	Active	Draft	Draft-Submitted-Approved/Rejected	Approved
Equipment	Active	Draft	Draft-Available-Offline-InUse-Hold-ReleaseToProcess-Clean-Retired	Available
Project	Active	Draft	Draft-In Development-In Progress-Completed	In Development

Workflow Actions are actions you can perform on any workflow state. Standard workflow actions include Approve, Need More Info, Reject, and Submit.

The Workflows tab lists the following:

- **My Workflows:** Lists favorite workflows that need approval of Approvers or Reviewers or Observers.
- **Delegated:** Lists workflows you have delegated.
- **Search:** Allows you to search for workflows.

## Lifecycle Phase

Lifecycle phase involves the statuses an object goes through from its creation. Depending on the object, you can move it to the next applicable status. The options in the menu of a lifecycle phase changes according to the current status of the object. Only phases applicable to the object appear in the drop-down list. For example, the lifecycle phase of a material can be changed manually or through a workflow. When you create a material it is in the Draft status. A material can be used in a process only if it is in the Approved status. The system throws up a warning message appears if Materials in the Draft status are used in a process. You can edit material only if it is in the Draft status.

### To change the lifecycle phase of a material:

1. Search Materials > Library and select a material record.
2. Click Change > Lifecycle Phase.
3. Select an appropriate status:
  - **Draft** - by default, the initial state of a new material.
  - **Submitted** - to submit the material for approval.



- **Approved** - to approve the submitted material. You have to first submit a material before it can be approved.
- **Rejected** - to disapprove the submitted material. You have to first submit a material before it can be rejected.

### Viewing Workflows

The My Workflows tab lists workflows assigned to you. You can view workflows assigned to you and also workflows delegated by you.

#### To view workflows:

1. On the Home page, click Workflow Routings> Workflows.
2. By default, My Workflows tab displays a list of initiated workflows.
3. Click Workflow ID link to view details. Selecting a workflow activates the Delegate and Export buttons for that workflow.

### Delegating Workflows

Workflow delegation implies assigning your workflow to a specified delegate to take action. When you delegate a workflow to another user, anytime the object tied to that workflow triggers tasks, the delegated user will receive all tasks assigned to you.

You can delegate a task to multiple users and set a start date and an end date for the workflow delegation. Once you delegate a task, you share all e-mails, notifications and alerts with the delegated user. The person to whom you delegate a task cannot re-delegate the task. You can also set a default user to whom you can delegate the task.

#### To delegate a workflow:

1. On the Home page, go to Workflow Routings> Workflows.
2. Select a workflow and click Delegate.
3. Enter information in the required fields:
  - Delegated User: User ID.
  - Starting Date: The day you delegate the task.
  - End Date: The day the task is automatically delegated back to you.
1. Click OK.

A message confirms the action.

To retain responsibilities on a delegated workflow tasks before the specified end date, un-delegate the workflow task.

#### To un-delegate workflows:

1. In the Home page, go to Workflow Routings> Workflows.
2. Select a workflow and click Un-delegate.
3. Click OK.

A message confirms the action.

### Searching for Workflows

You can search for workflows and take required action on them, provided you have the appropriate privileges to access the task. The Task Details pane displays action buttons when you select the Task ID hyperlink of the workflow.

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**Note:** Action buttons do not appear on the Workflow tab, if you do not hold appropriate privileges.

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#### To perform a search for the workflow:

1. In the Home page, click Workflow Routings> Workflows.
2. In the Workflows tab, click Search. The search results return a list of workflows. See also: Searches.
3. Click the Workflow ID or Workflow Name link to view details.

### Notifications

Notifications can be either informational messages or alerts about actions you need to perform. Alerts also notify you of pending approvals to workflows. Default notifications are sent to Approvers, Reviewers or Observers.

The Notifications tab lists the following:

- **Workflow Notifications:** Notifies you about pending or complete actions that need your attention.
- **Workflow Delegation Notifications:** Notifies you about workflow delegations.

#### Workflow Notifications

##### To view workflow notifications:

1. Navigate to Workflow Routings > Notifications > Workflow Notifications. The Workflow Notifications displays by default. On selecting a workflow notification, several action buttons are activated.
2. Click the Task ID link to view details.

##### To delete workflow notifications:

1. Select a Workflow Notification from the table.
2. Click Delete.

#### Workflow Delegation Notification

##### To view workflow delegation notifications:

1. Navigate to Workflow Routings > Notifications > Workflow Delegation Notifications. On selecting a Workflow Notification, several action buttons are activated.
2. Click Task ID to view details.

##### To delete workflow delegation notifications:

1. Select a Workflow Delegation Notification from the table.
2. Click Delete.

### Views

The Views button allows you to customize how you view objects. You can sort search results by pre-defined views. The drop-down list contains all the views which you have saved. The Views field appears at the top right corner of the search results table.

For example: You want to view Sites pertaining to geographical location. In the **Views** field, enter North America. The search results table returns all sites which are in North America.

## Tables

Search results display data in a tabular format. Tables display data of objects you have sorted initially with either the Default View or Basic View. You can define and add multiple personal views to the table and select any of the views as your default view.

### Viewing Objects in a Table

The table displays search results in a tabular format. The dropdown in the header row contains the Sort Ascending, Sort Descending and Columns buttons.

- To view details of objects in a table by click on the Object ID. The Object ID is generated by the RMW application.
- To sort table choose either Sort Ascending or Sort Descending menus.
- To see the columns available on the table click button. Select the check box to display the column and de-select it to hide the column.

#### To view objects in a table:

1. Hover over the Name/Number ID link in the table. The synopsis view gives you a brief description of the object.
2. Click Close to close the dialog.

### Filtering Table Views

The **Filter** icon appears on all tables and enables you to filter data and create a customized view of data, as per the data entered into the filtered fields. You can use the options in the drop-down list to filter the view and sort data by pre-defined views. For example: Sort data by different attributes in ascending or descending order. If not applicable, you only see a disabled Filter icon.

#### To filter the view on a table:

1. Click the Filter icon. Filter fields display in all the columns along with **Filter** and Clear buttons.
2. Enter valid data in any one of the fields and click Filter. Data is filtered appropriately.
3. Click Clear to clear the field.
4. Click the Filter icon again and notice that the filter fields disappear.

### Sorting Tables

A table is initially sorted by Views - Default View or Base View. You can define additional personal views for each table, and select any view as your default view.

#### To sort a table:

1. Click the column header of the column by which you want to sort. For example, to sort the Equipment table by Equipment ID click the Equipment ID column header. On a search results table, you can sort all columns.
2. Click the column header to sort the table one way and click again to sort it the other way (ascending or descending order).

An indicator in the column header indicates if the table is sorted in ascending order or the descending order. how the table is currently sorted:

**Selecting Rows in Tables**

Selecting rows in tables activates the buttons at the top of the table which allows you to perform various actions on the objects. You can select single rows or multiple rows as required.

- To select a single row, select the check box at the beginning of the row.
- To select multiple rows in a table, select the check box at the left-hand corner of the table.



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## Working with Searches

Searches help you locate objects in RMW. You can perform a search to find specific RMW objects, Attachments, Notes or Workflows. User privileges determine the objects you can search for.

Saved Searches include searches created and saved for future use; global searches created by the administrator and pre-defined searches. The Folders drawer in the Navigation pane contains Saved Searches which contains several sub-folders.

### To view a search folder:

1. Go to the Navigation pane of the Home page and click Folders to display the Search folder.
2. Click the Expand All icon to display all Saved Searches.
3. To view a specific folder, click the icon next to the folder.

---

**Note:** If you do not have the Discovery and Read privileges for an object, it may not appear in the search results. Some objects may not appear in the search results depending on administrator settings, roles, and privileges assigned to you. Contact your administrator for more details.

---

## Types of Searches

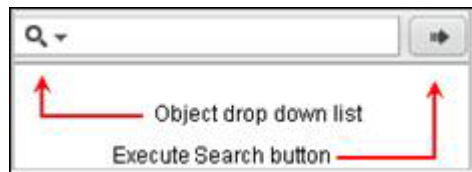
RMW provides you with two types of searches:

- **Quick Search:** Allows you to quickly locate objects. It searches for objects whose name, number ID, or description matches the set criteria.
- **Custom Search:** Opens the Custom Search page which allows you to run a search using parameters defined by Agile Administrator. You can then run an Advanced Search, defining multiple conditions.

## Quick Search

Quick Search helps you locate objects quickly. It searches for objects whose name, number ID, or description matches the set criteria. You require appropriate privileges to search for objects.

The main toolbar on the Top pane contains the Quick Search field. It searches by the specific business object that you select in the menu.

**To execute a quick search:**

1. Select a business object you want to search from the object menu.
2. Enter a wildcard, or a specific name, or number. The search criteria can be a single word or multiple words, a wildcard and a part of a word, or a wildcard and part of a number. Example: It can be \*Mat for Material or \* 0003.
3. Click the Execute Search button. A table displays search results based on the search criteria.

## Custom Search

Custom Search allows you to narrow your search for objects by defining additional conditions and filtering the search results.

The Top pane of the main toolbar contains the Custom Search button along with the Quick Search button.

**To execute a custom search:**

1. Select an object from the menu in the Top pane toolbar.
2. Click the Custom Search button.

For more information click the Search Tips icon. It contains parameters you can use to search for business objects. See also: "[Search Tips](#)" on page 3-5..

1. Select appropriate values from the menu.
2. From the View field, select an appropriate View.
3. Click Search.

Search results display in a table. Placing the cursor over an object link takes you to the synopsis view, from where you can view important details about the object.

## Adding a Favorite Search

Once you search for an object, you can save the search for use at a later stage.

**To save a favorite search:**

1. Click the Custom Search button.
2. Enter details in any field by which you want to search in the Search pane.
3. Click Search.

4. Select a Search from the search results that return.
5. Click Save.
6. In the Save Search As palette,
  - Search Name - Enter a Search Name (mandatory).
  - Public - Select Yes for the search to be global and No for the search to be personal.
7. Click Save.

A message confirms the search is saved successfully.

**To view the saved search:**

1. Click the Custom Search button.
2. In the Search Recipe page, click the arrow in the Load Saved Search field.
3. Select from the list of saved searches.

The search result appears displaying details.

Selecting a row in the table activates buttons, which allow you to perform tasks. You can also use the filter, which allows you to view relevant information by narrowing the search.

## Searching for Records

You can search for a record, save the search criteria and use the saved search.

**To search for records:**

1. In the Search tab, select a search view from the View list.
2. You can search in one of the following ways:
  - Enter search criteria in the field and click Search.
  - Select the required value from the menu provided. Click Search. For details on search values, click Search Tips. The search can be saved for use at a later search. To save the search click Save.
  - Leave all the fields blank and click Search.

You can use the following search expressions to search.

Expression	Description
<b>Wildcards</b>	
*	Matches zero or more occurrences of the character. For example: API* - All items beginning with API. *API - All items ending with API. *API* - All items containing API.
?	Matches zero or one occurrence of the character. For example, specify 'admi?' as your search criteria. The search result is all attributes that have "admi" as a prefix and any one character after that. That is "admin" or "admia"
<b>Individual expressions</b>	



Expression	Description
@	Null
!@	Not null
=	Equal
!=	Not Equal
>	Greater than
<	Less than
>=	Greater than or equal
<=	Less than or equal
	OR
&	AND
' ', '&', ' ', and '&', " ', '!=', '>'	Multipart Expression Examples
&<="(Numerical fields only), "=   =   <	'Red'   'Blue' -> Matches Red OR Blue where 'Red' and 'Blue' are individual expressions.
&>="(Numerical fields only) Character	'Ma*' & 'Mau*' -> Matches 'Mauve' but not 'Magenta' where 'Ma*' and 'Mau*' are individual expressions.
	'Red'   'Ma*' & 'Mau*' -> Matches 'Red' OR 'Mauve' but not 'Magenta' where 'Red' and 'Ma*' and 'Mau*' are individual expressions.
	Jack   Jill -> Matches 'Jack' OR 'Jill'
	!=Jack & !=Jill -> Matches neither 'Jack' nor 'Jill'
	>100 & <=120 -> Matches greater than 100 AND less than or equal to 120
	=135   =125   <122 & >115 - Matches (equal to 135 OR equal to 125 OR (less than 122 AND greater than 115))
<b>Ignoring Expression Characters</b>	
\	Use \ to treat the *, +, or ? characters as an ordinary character. For example, \*.

If any of these characters need to be present in a search string, then they should be specified as an escape sequence as shown in the following table.

Character Sequence	Escaped Character
@	\\@
!@	\\!\\@
=	\\=
!=	\\!\\=
>	\\>
<	\\<
>=	\\>\\=
<=	\\<\\=
	\\
&	\\&
*	\\*

---

?	\\?
---	-----

---

Records/Results display the list of records based on the search.

#### To search for objects:

1. Click the Filter icon to further reduce the scope of search. For each column, text boxes appear.
2. Enter required values.
3. Click Filter. The results appear based on the values.
  - You can sort data in each column on Records/Results in ascending or descending order. Click on the column header.
  - You can also choose the number of records to appear in Results. Select the number from the Results Per Page menu.
  - Buttons on the Records/Results page allow you to perform actions such as Add, Edit, Save As and change status for the record.

---

**Note:** If a search criterion is entered for a numeric field with UOM, user can also select the UOM for the search value from a menu next to the field showing all the valid UOM(s) for the search. The UOM(s) shown in the menu is in the UOMGroup associated with the field and having a simple formula-based conversion. All UOMs having Web service-based conversions will not appear in this menu.

---

## Search Tips

The Search Tips palette suggests search values you can use in the search fields while searching for objects in the database. The palette displays details of values you can use to get the best results while searching for objects.

Blank Field	This field will not be used to limit the results.
Drop-down list set to "(Any)"	This field will not be used to limit the results.
Text field filled with letters or numbers	Only records with this exact value for this field will be shown.
Numerical field (numbers only)	Only records with this exact value for this field will be shown.
"*" character	"*" is a character that can have any value. "A*" will show all records with that field value beginning with "A". "*ide" will show all records with that field value ending with "ide".



---

## Working with RMW Records

This section describes the actions that are common to all types of records, irrespective of the RMW solution and business process.

### Editing a Record

You can modify the content of the record provided you hold Modify privileges.

**To edit a record:**

1. In the search results select the row of the desired record.
2. Click Edit.

Wherever applicable, you can edit a record to save it as Current Version or As New Version.

- Click Edit > Current Version to save current version.
  - Click Edit > As New Version to save new version.
1. Modify the desired fields.
  2. Click OK to confirm changes and Cancel to return to the search results page.
  3. Click OK to return to the search results page.

---

**Note:** RMW does not support editing of notes and attachments in the **Notes and Attachments** tab. To edit notes and attachments, see Working with Notes and Working with Attachments.

---

### Duplicating a Record

You can duplicate a record and save it with a different name. In the duplicated record, you can use all or most of the attributes (data values) of the original record.

**To duplicate a record:**

1. From the search results, select a record.
2. Click Save As from the More menu.
3. In the Save As page, enter a new Name, modify the Name; or click Clear to clear the Name field.
4. To duplicate notes and attachments, select the Yes option. If not, select No.

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**Note:** By default, notes and attachments are not duplicated.

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- Click Save and Edit to modify the desired attribute data.
- Click OK to save the duplicated record. The record retains all existing attributes data.
- Click Cancel, to cancel the duplication process.

## Deleting a Record

You can delete unused records.

**To delete a record:**

1. In the search results, select the record you wish to delete.
2. Click **Delete**.

## Comparing Records

You can compare various records, wherever applicable.

**To compare the records:**

1. In the search results, select two or more records.
2. Click **Compare**. In the Compare Records page, selected records display rows of all fields for comparison in a tabular format.
3. To drop records click **Delete** in the corresponding record.
4. Click **OK**.

## Exporting Records

The **Export** button enables you to export files, folders and object information from RMW into output formats such as Microsoft Excel, PDF, HTML, and XML.

**To export a record:**

1. In the search results, select a record you want to export. Click the **Export** icon.
2. Select the report format and click **Export**.

---

## Working with Notes and Attachments

Notes and Attachments contain additional information or data relevant to the object or process. These can be URLs, relevant documents, images, compressed files etc. All documents attached to RMW objects use Agile's File Vault.

### Adding Notes

You can add notes to any business object.

**To add a note (for the first time):**

1. In the search results, select the desired record.
2. Click the Add Note icon.
3. Enter the Subject.
4. Select the Type of note from the menu.
5. Enter content for the Note.
6. Click OK.

**To add a note from the Notes page:**

1. In the search results, click the **Notes** button of the desired record. In the Notes page, click Add.
2. Enter the Subject.
3. Select the Type of note from the menu.
4. Enter content for the Note.
5. Click OK.

### Deleting Notes

You can delete unused or irrelevant notes.

**To delete a note:**

1. In the search results, click the AddNotes icon of the desired record.
2. In the Notes page, select one or more rows of the Notes records. The Delete button is activated.
3. Click Delete.
4. Click OK.

## Editing Notes

You can edit notes to modify or change content.

**To edit the notes:**

1. In the search results, click the Notes button of the desired record.
2. Select the row of the Notes you wish to edit.
3. Click Edit and modify the content in the Edit Notes page.
4. Click OK to return to the Notes page.
5. Click OK.

## Comparing Notes

Notes attached to business objects can be compared to verify data or to check if data differs in versions.

**To compare notes:**

1. In the search results, select the desired record.
2. Click the object hyperlink.
3. Go to Notes and Attachments tab.
4. In the Notes sub-tab, select two or more rows of the notes you wish to compare.
5. Click Compare. In the Compare Notes page, the selected records display rows of all fields for comparison in tabular format.
6. To drop the Notes you do not wish to compare, click Delete.
7. Click OK to return to the Notes page.
8. Click OK.

## Adding Attachments

You can add attachments to a business object.

**To add an attachment:**

1. Search and select the desired record.
2. Click the Add Attachment icon.
3. In the Attachments page, click Add.
4. In the Add Attachment page, enter Name.
5. Select the Document Type from the menu.
6. Enter Description.
7. Select the attachment Source.
  - If the attachment Source is a File, enter the file path in the File field or click Browse to pick a file from your system.
  - If the attachment Source is a URL, enter the complete URL.
1. Click OK to return to the Attachments page.
2. Click OK to return to the search results page.

## Deleting Attachments

You can delete unused and irrelevant attachments.

### To delete an attachment:

1. In the search results, click the **AddAttachment** icon in the desired record.
2. In the Attachments page, select one or more rows of the Attachment records.
3. Click **Delete**.
4. Click **OK** to return to the search results page.

## Editing Attachments

You can edit the attachment to modify, change or add content.

### To edit an attachment:

1. In the search results, click Attachments in the desired record.
2. In the Attachments page, select a row of the Attachment records.
3. Click **Edit**.
4. In the Edit Attachment page, modify the contents and click **OK** to save.
5. Click **OK** to return to the search results page.

## Comparing Attachments

You can compare attachments associated to a particular record with earlier versions, to verify data.

### To compare attachments:

1. In the search results, click the **AddAttachment** icon in the desired record.
2. In the Attachments page, select one or more rows of the Attachment records.
3. Click **Compare**. In the Compare Attachment page, the selected records display rows of all fields for comparison in tabular format.
4. To drop the attachments you do not wish to compare, click **Delete**.
5. Click **OK** to return to the Attachments page.
6. Click **OK** to return to the search results page.





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## Working with RMW Reports

The RMW application provides you predefined queries to generate reports of various activities in the Environment and Material modules. The output of reports is based on predefined template and is rendered in Excel, PDF, XML, and HTML formats.

The application stores all the reports that you generate. You can view them on-screen, or export them to be stored in your system.

### Generating Reports

You can generate reports for various activities performed in the Environment and Material modules of the RMW application.

**To generate a report:**

1. In the Left Navigation menu, open Reports drawer.
2. Click Material Not Used Report under Reporting > Material. Enter values in mandatory fields.
3. Click Lookup icon to search and select desired values. Enter values in the optional fields.
4. Click Generate Report.
5. Click OK.

---

**Note:** The system records a report request even if you do not complete fields marked mandatory.

---

A Report appears in the Manage Reports page with the request ID along with a confirmation message

### Managing Reports

The RMW application stores all the reports that you generate. You can view these reports on-screen or export them to be saved on your system. For complete details on how to export the reports, refer to Exporting Records. You can access generated reports from Manage.

**To view a report:**

1. In the Left Navigation pane, open the Reports drawer.
2. In Reporting, click Manage.

3. In the Report Request page, select the desired parameters and click Search.
4. In the Results in Report Request, click on the attachment icon of a desired report. File download popup shows up with Open, Save and Cancel buttons.

You can save the report only in Excel format.

**To delete a report:**

1. Search and select the report you wish to delete.
2. Click Delete.

## Environment Reports

The following Environment report can be generated in the RMW application:

Name	Description
SARA 311/312 Report	<p>SARA 311/312 is Section 311 or 312 of Environmental Protection Agency's Superfund Amendments Reauthorization Act. Section 311 requires that hazardous chemicals with Material Safety Data Sheet as prescribed by Occupational Safety and Health Administration (OSHA) be stored in specific environments. A list of such chemicals must be submitted to the concerned authorities. Section 312 requires that the emergency and hazardous chemical inventory form, called Tier II form, is submitted annually. Tier II forms provide the following information for each substance:</p> <p>The chemical name or the common name as indicated on the MSDS.</p> <p>An estimate (in ranges) of the maximum amount of the chemical present at any time during the preceding calendar year and the average daily amount.</p> <p>A brief description of the hazards and manner of storage of the chemical.</p> <p>The location of the chemical at the facility.</p> <p>An indication of whether the owner elects to withhold location information from disclosure to the public.</p> <p>The SARA 311/312 report uses information from RMW Daily Material Inventory. It includes storage details of the chemical. This report lists out all material inventory for the site/location for a given time period.</p>

## Material Reports

The following Material reports can be generated in the RMW application:

Name	Description
Restock Report	Provides details of all materials in the Material Inventory at the selected site where the Quantity Available is less than the Inventory Restock Level. Material Manager uses this report to take decision on restocking of the inventory.
The Material Not Used Report	Used for tracking all the material lots that were not used since a specified date. This report helps the Material Managers to know the materials that are not being used and hence can be freed up from the inventory.

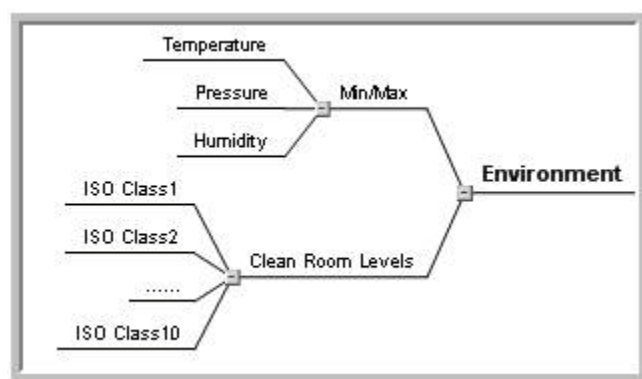
<b>Material Dispensing and Adjustment Report</b>	Provides details of all inventory adjustment transactions, such as dispenses and corrections for each Lot or Container. You have to specify the Lot ID.
<b>Lots without Dispensing Activity Report</b>	Provides details of all the lots that remained without dispensing activity during a specified date range.
<b>Containers without Dispensing Activity Report</b>	Provides the details of all the Containers that remained without dispensing activity during a specified date range.
<b>Daily Inventory Report</b>	Provides the balances of the specified Materials or all the materials in the inventory on a given day. Material field is mandatory.
<b>Daily Inventory by CAS/TPQ Report</b>	Provides the balances of Materials by their CAS (Chemical Abstract Service) and Threshold Planning Quantity.



## Working with RMW Environment

Specifications for the storage environment of a newly created material are of significant importance. These specifications are used to prepare the SARA 311/312 report, where each material's storage condition over a period of time is reviewed and reported. When you create a new material, you need to specify the storage environment, which constitutes of:

- **Ambient Conditions** - Temperature, pressure, humidity and clean room levels.
- **Chemical Abstract Service (CAS) number.**



### Creating a New Environmental Condition

Environment and storage conditions specified at the time of material definition ensure material containers are stored as per conditions specified. You can add new environment conditions as required. RMW records these conditions for verification.

#### To create new environmental condition:

1. From the Create New menu, select Environmental >Condition.
2. In the **General** tab, enter the information.

#### Significant inputs:

- Name
- Clean Room Levels
- Min. Temperature
- Max Temperature
- Min. Pressure

- Max. Pressure
  - Min. Humidity
  - Max. Humidity
3. Click **Finish**.

## Working with Chemical Abstract Service Record

RMW provides recording and retrieval details of Chemical Abstract Services (CAS) of materials. For details, see Recipe & Material Workspace Material Management Guide.

### Creating a New CAS Record

The CAS record indicates the constituents of a material and is a part of material definition.

**To add a new CAS record:**

1. From the Create New menu, select Environmental > CAS.
2. In the General tab, enter the unique Chemical Abstract Service Number of the chemical.

Significant points to note:

- **CAS Number** - Enter a unique number for the chemical.
- **CAS Name** - Enter a unique name of the chemical.
- **Mass Balance Required Flag** - Select Yes if you require Mass Balance report for this material.
- **SARA 312/EPCRA TPQ** - Select Yes if the Inventory quantity limit for the material is set by Superfund Amendments Reauthorization Act, Section 312 regulation.

EPCRA stands for Emergency Planning and Community Right-to-Know Act.

- **Is Tracked By SARA 302** - Select Yes if the material is in Environmental Protection Agency's Superfund Amendments Reauthorization Act, Section 302.
- **SARA 313 Reportable Flag** - Select Yes if the material is listed in Environmental Protection Agency's Superfund Amendments Reauthorization Act, Section 313.
- **OSHA Reportable Flag** - Select Yes if the material is listed in Occupational Safety and Health Administration.
- **OSHA TPQ** - Enter the inventory quantity limit for the material as set by Occupational Safety and Health Administration and select a unit of measurement.
- **OSHA TPQ Alert%** - Specify the percentage of amount in the inventory at which the RMW should send alerts.
- **HAP Flag** - Select Yes if the material is a Hazardous Air Pollutant. If you select Yes this CAS ID appears in the Air Emissions report.
- **CERCLA TPQ** - Enter the inventory quantity limit for the material that is set by Comprehensive Environmental Response, Compensation, and Liability Act.

- **VOC Flag** - Select Yes if the material is a Volatile Organic Compound material.
  - **RCRA** - Enter Resource Conservation and Recovery Act code.
3. Click Finish to save and exit.

You can also create a new CAS in the Safety & CAS sub-tab, while adding a chemical to the Material library. For more details, see Agile Recipe Management for Pharmaceuticals Material Management Guide.





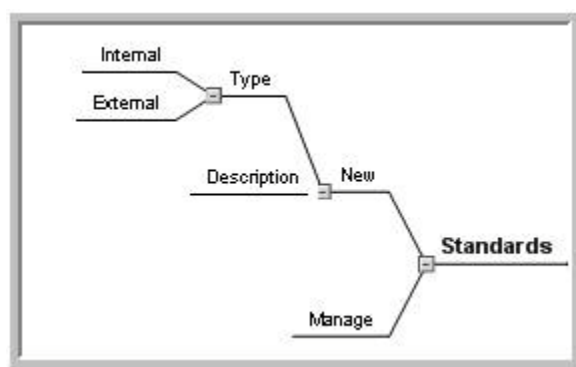
---

## Working with RMW Standards

A Standard is a library of predefined statements relating to the safety & caution of a manufacturing process. It contains general instructions, guidelines and specifications, which you to adhere to while handling equipment and material.

For example, an equipment standard may specify that a certain reactor must be switched on 10 minutes before use, or a material standard may indicate how to handle a particularly hazardous material.

You can attach a Standard to a process, in particular, to a Recipe Action.



### Classification of Standards

A Standard is grouped into one of the following categories:

1. Abbreviations and Acronyms
2. Cautions
  - Hazard Statements
  - Special Notations and Precautions
3. General
4. Standard Operation Procedures (SOP)
  - General Building Procedures
  - General Process Procedures
  - Job Aids

Each Standard has options to indicate where the Standard is displayed when you view and print the Work Request. These Standards are used while authoring Unit Operations and creating Work Requests from the Control Recipe.

You have to enter the summary content of the actual hazard, SOP document or the expanded form of acronym and abbreviations as the description of the document. This is printed along with the Work Request that uses this Standard.

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**Note:** RMW does not store actual hazard or safety documents. It tracks the names and simple descriptions to refer them while authoring a ticket.

---

Versioning of Standards is applicable in RMW. Major versions are incremental on approval, while the minor versions are incremental at the creation or at first edit after each approval of these Standards.

You can browse, search, edit, duplicate, and set status for a Standard. You can also add attachments or notes to provide more information, compare records of two or more Standards and export the records to either an Excel or PDF file. You can add Standards directly to the BOS of a Recipe, while you are editing a Recipe Action instance.

## Creating a New Standard

**To create a new standard:**

1. From the Create New menu, select Processes > Standard.
2. In the Preface tab, select a category under which you wish to place this standard.
3. Click Next.
4. In the General tab, enter Name and select the Operating Mode.
5. Click Finish.

---

**Note:** You can also create a new Standard when you perform a search on standards. In the search results, select a standard and click **Save As** to duplicate the existing standard.

---

## Editing a Standard

Editing of a standard is possible only when the standard record is in the Draft, rejected, or Approved status.

**To edit a standard:**

1. Run a search and from the search results select a Standard record. For information on search, see Searching for Records.
2. To edit the Standard as current version, click Edit > Current Version. To edit the Standard as a new version, click Edit > As New Version.
3. In the General tab, modify the desired data and click OK.

A message confirms the modifications in the Standard record.

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**Note:** RMW does not support the editing of notes and attachments in the Notes and Attachments tab. To edit the notes and attachments, see the chapters [Working with Attachments](#) and [Working with Notes](#).

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## Browsing the Standards

When you perform a search, you can use the Browse tab to locate Standards relating to each category. To view records of a specific category only, select the desired category from the Standards tree.

## Deleting a Standard

**To delete a standard:**

1. Run a search and from the search results select the records of Standards you wish to remove.
2. Click Delete.

For information on search, see ["Searching for Records"](#) on page 3-3.

## Managing Associations to a Standard

Standards represent cautions you need to comply with to ensure quality and safety. Using Equipment or Material which does not conform to standards can be hazardous to health or result in contamination of the end product.

For example:

- Not wearing gloves while handling chemicals can be harmful.
- Presence of moisture in the equipment can contaminate material.

You can associate the following to a Standard:

- Equipment Category
- Equipment
- Material Category
- Material

**To associate equipment category and equipment to a standard:**

1. Run a search and from the search results select a Standard.
2. Click Manage Associations.
3. In the Equipment tab, click Add Category under Associated Equipment Categories.
4. Select the desired Equipment Categories you wish to associate to the selected Standard.
5. Click OK.
6. From Associated Equipment, click Add Equipment.
7. Select the desired Equipment you wish to associate to the selected Standard and click OK.
8. Click OK.

**To associate material category and material to a standard:**

1. Run a search and from the search results select a Standard.
2. Click Manage Associations.
3. In the Material tab, click Add Category under Associated Material Categories.
4. Select the desired Material Categories that you wish to associate to the selected Standard and click OK.
5. Under the Associated Material, click Add Material.
6. Select the desired Material you wish to associate to the selected Standard and click OK.
7. Click OK.

**To disassociate equipment category and equipment from a standard:**

1. Run a search and from the search results select a Standard.
2. Click Manage Associations.
3. In the Equipment tab, select the Associated Equipment Categories that you wish to delete.
4. Click Delete.
5. Select the desired Associated Equipment that you wish to delete and click Delete.
6. Click OK.

**To disassociate material category and material from a standard:**

1. Run a search and from the search results select a Standard.
2. Click Manage Associations.
3. In the Material tab, select the Associated Material Categories that you wish to delete.
4. Click Delete.
5. Select the Associated Material that you wish to delete and click Delete.
6. Click OK.

## Changing the Workflow Status of a Standard

If a Standard has a workflow associated to it, and you have the access permission assigned to your role and user ID, you can change the workflow status of a Standard.

**To change the workflow status of a standard:**

1. Run a search and from the search results select a Standard.
2. Click Change > Workflow Status > and select the applicable status.

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**Note:** If the selected object does not have an active workflow, you cannot change the status.

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## Purging Revisions of a Standard

A Standard has minor intermediate revisions, until you approve and release a revision as the next version. These minor revisions of the Standard can be deleted from the

database when one version is finalized (approved for release). You cannot delete a revision, if an active workflow is associated with it.

**To purge revisions of a standard:**

1. Run a search and from the search results select a standard with revisions which you want to purge. Ensure the selected standard is in the Approved status.
2. Click More> Purge Revisions.

## Changing Status of a Standard

A **Standard** can be in one of the following states:

- **Draft** - when the standard is created.
- **Submitted** - when the standard is submitted for approval.
- **Approved** - when the standard is approved.
- **Obsolete** - when the standard is not in use.

**To manually change the status of the standard:**

1. Run a search and from the search results select a Standard record.
2. Click Change > Lifecycle Phase and select the applicable status.

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**Note:** For a newly created standard, the lifecycle phase shows only 'Submit' option. When the standard is in 'Submitted' state, the lifecycle phase displays other applicable options.

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