

## **Product Lifecycle Management**

Agile Recipe Management for Pharmaceuticals Process  
Management Guide

Release 9.3.3

**E39302-01**

October 2013

E39302-01

Copyright © 2010, 2013, Oracle and/or its affiliates. All rights reserved.

Primary Author: Usha Pereria

Contributing Author:

Contributor:

This software and related documentation are provided under a license agreement containing restrictions on use and disclosure and are protected by intellectual property laws. Except as expressly permitted in your license agreement or allowed by law, you may not use, copy, reproduce, translate, broadcast, modify, license, transmit, distribute, exhibit, perform, publish, or display any part, in any form, or by any means. Reverse engineering, disassembly, or decompilation of this software, unless required by law for interoperability, is prohibited.

The information contained herein is subject to change without notice and is not warranted to be error-free. If you find any errors, please report them to us in writing.

If this is software or related documentation that is delivered to the U.S. Government or anyone licensing it on behalf of the U.S. Government, the following notice is applicable:

U.S. GOVERNMENT END USERS: Oracle programs, including any operating system, integrated software, any programs installed on the hardware, and/or documentation, delivered to U.S. Government end users are "commercial computer software" pursuant to the applicable Federal Acquisition Regulation and agency-specific supplemental regulations. As such, use, duplication, disclosure, modification, and adaptation of the programs, including any operating system, integrated software, any programs installed on the hardware, and/or documentation, shall be subject to license terms and license restrictions applicable to the programs. No other rights are granted to the U.S. Government.

This software or hardware is developed for general use in a variety of information management applications. It is not developed or intended for use in any inherently dangerous applications, including applications that may create a risk of personal injury. If you use this software or hardware in dangerous applications, then you shall be responsible to take all appropriate fail-safe, backup, redundancy, and other measures to ensure its safe use. Oracle Corporation and its affiliates disclaim any liability for any damages caused by use of this software or hardware in dangerous applications.

Oracle and Java are registered trademarks of Oracle and/or its affiliates. Other names may be trademarks of their respective owners.

Intel and Intel Xeon are trademarks or registered trademarks of Intel Corporation. All SPARC trademarks are used under license and are trademarks or registered trademarks of SPARC International, Inc. AMD, Opteron, the AMD logo, and the AMD Opteron logo are trademarks or registered trademarks of Advanced Micro Devices. UNIX is a registered trademark of The Open Group.

This software or hardware and documentation may provide access to or information on content, products, and services from third parties. Oracle Corporation and its affiliates are not responsible for and expressly disclaim all warranties of any kind with respect to third-party content, products, and services. Oracle Corporation and its affiliates will not be responsible for any loss, costs, or damages incurred due to your access to or use of third-party content, products, or services.

---

---

# Contents

<b>Preface</b> .....	v
Audience .....	v
Documentation Accessibility .....	v
Related Documents .....	v
Conventions .....	v
 <b>1 Introduction to Process Management</b>	
About this Guide .....	1-1
Recipe & Material Workspace Documentation .....	1-1
Process in RMW - An Overview .....	1-2
Process Structure .....	1-2
 <b>2 Working with Projects</b>	
Creating a Product .....	2-1
Editing Product Details .....	2-1
Product Tabs .....	2-2
Creating a Project .....	2-2
Editing Project Details .....	2-3
Project Tabs .....	2-3
Changing Lifecycle Phases of a Project .....	2-3
Alerts Associated with a Project .....	2-4
 <b>3 Working with Campaigns</b>	
Creating a Campaign .....	3-1
Editing Campaign Details .....	3-2
Campaign Tabs .....	3-2
Changing Lifecycle Phases of a Campaign .....	3-2
Alerts Associated with Campaign .....	3-3
 <b>4 Working with Process Steps</b>	
Creating a Process Step .....	4-1
Editing a Process Step .....	4-4
Process Step Tabs .....	4-4
Changing Lifecycle Phases of a Process Step .....	4-4

Validating the Process Step for Control Recipe Creation .....	4-5
Creating Control Recipe from a Process Step .....	4-5
Deleting a Process Step .....	4-5

## 5 Working with Control Recipes

Creating a Control Recipe.....	5-1
Editing a Control Recipe.....	5-2
Control Recipe Tabs.....	5-2
Requesting Inventory from Control Recipe.....	5-3
Reserving Equipment from Control Recipe.....	5-3
Creating Recipe Template from Control Recipe .....	5-4
Auditing Control Recipe.....	5-4
Deleting Control Recipe .....	5-5
Changing Lifecycle Phases of a Control Recipe.....	5-5

## 6 Working with Work Requests

Creating a Work Request.....	6-1
Editing a Work Request .....	6-2
Work Request Tabs .....	6-2
Requesting Inventory from Work Request .....	6-3
Reserving Equipment from Work Request .....	6-3
Consuming Inventory from Work Request.....	6-3
Recording Parameter Values in Work Request.....	6-4
Adding Material to Inventory.....	6-4
Recording Equipment Activity from Work Request.....	6-6
Viewing Equipment Usage from Work Request.....	6-6
Auditing Closeout of Work Request .....	6-6
Closing Out a Work Request .....	6-6
Changing Lifecycle Phases of Work Requests .....	6-7

---

---

# 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.

---

# Introduction to Process Management

The Process Management module within the Agile PLM Recipe & Material Workspace (RMW) solution allows you to manage the processes involved in the development process of a chemical product.

## About this Guide

This guide provides information on all the features and functionality of the RMW Material Management module. It also covers instructions on how to use the various menus and commands available on the RMW User Interface to create and manage material objects. The features that are visible to you on the interface are determined by the access privileges assigned to you by an administrator.

## 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 Recipe & Material Workspace - describes common concepts, basic navigation, searches and workflows. Also covers how to work with reports, standards, and environmental conditions.
- Recipe & Material Workspace Administrator Guide - describes all administration and configuration information including Agile PLM integration requirements.
- Recipe & Material Workspace Process Management - describes the features of the Process module, covering the creation and execution of projects and campaigns, control recipes, and work requests.
- Recipe & Material Workspace Recipe Management Guide - describes the features of the Recipe module, covering the authoring and management of recipes and recipe templates.
- Recipe & Material Workspace 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.
- Recipe & Material Workspace Equipment Management Guide - describes the features of the Equipment module, covering equipment qualification, loan, lease, and reservation.
- Recipe & Material Workspace 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>.

## Process in RMW - An Overview

The following business processes are enabled through the Process Management module:

- Creating new Projects to track material being made in pilot plants or development areas.
- Associating recipes to Campaign or process steps within a Project and resolving resource placeholders to resources that are available at specified facility or site.
- Managing Bill of Processes (BOP), Bill of Material (BOM) and Bill of Equipment (BOE), and Bill of Standards (BOS) which are auto-created from a copy of recipe, to be carried over to the Control Recipe and the Work Request.
- Capturing all work completed in the work request, including materials made, materials consumed, control parameter settings and in-process measurements of materials.
- Releasing all material coming into Inventory from the Work Request using a formal Lot Release process.
- Completing Work Requests using a structured approach with re-usable Projects and Campaigns.

## Process Structure



- **Project** - Plan what products are to be developed and set time lines.
- **Campaigns** - Identify target material, site for campaign execution, specify environmental impact and then eventually initiate the work request via the control recipe.
- **Process Step** - Specify Recipe with BOP, BOE, BOM, BOS specify environmental impact of process step, resolve resource variables, reserve and allocate material and equipment, and auto-create Control Recipes and/or Work Requests.
- **Control Recipe** - Resolve resources; create/manage inventory requests for BOM, reservation requests for BOE or Suite.
- **Work Request** - Resolve resources; and close out - Amount made as product or by-products is placed into inventory, results captured against materials made, equipment used (start and end time) and actual quantities of materials used.



---

## Working with Projects

A Project tracks all the activities required to successfully complete the making of a product which can either be a molecule or an API or a drug product. Development teams use projects to investigate the processing or manufacturing of a new drug.

You have to define a product in the application before you can begin project planning. A product is the base point for process management in the Agile RMW application. A project targets one or more products, usually variants of the same base molecule to synthesize an API or a drug product for a specific indication. You initiate a project to keep track of all activities related to developing the product.

A Project consists of one or more campaigns. The campaign summary tab of a **Project** reflects all the activities involved in a project.

### Creating a Product

A product is the end result that pharmaceutical companies plan to develop after conducting comprehensive research and selecting a form that is safe to manufacture. It can include target molecules or drug products. A molecule has the potential to treat and cure a disease.

**To create a new product:**

1. Go to Create New menu, select Processes > Product.
2. In the General tab, enter a unique Product ID.
3. Select Type:

**Drug Formulation** - the end product which is examined and analyzed through research and development before moving to the manufacturing stage and eventually marketed.

**Target Molecule** - represents the molecule you are examining.

4. Click Finish.

### Editing Product Details

In the Edit Product page you can only modify the type of the product and the description provided.

**To edit product details:**

1. Go to Processes > Products and run a search. From the search results, select a product.
2. Click the Edit button.

The Product ID is unique and cannot be modified.

**To edit product details after you save it with new ID:**

3. Go to More > Save As to save the product with a new ID.
4. Enter Product ID and select the Yes button to duplicate all Notes and Attachments of the earlier project.

To further modify the new product, click Save and Edit.

To save the new product ID, click OK.

To return to the search results page, click Cancel.

## Product Tabs

The tabs on the Product Details page include:

- **General:** Details of the type of the product and description of the product.
- **Notes and Attachments:** Notes/attachments providing additional information.
- **History:** A detailed account of all events that occurred in the process of creating a product.
- **Changes:** Records changes that a product undergoes from its initiation.

## Creating a Project

Creating projects help you track all the activities related to developing and manufacturing a product.

**To create a new project:**

1. Go to the Create New menu, select Processes > Project.
2. In the General tab, enter the required information.

**Significant inputs:**

- **Project ID** - unique identification of the project.
  - **Therapeutic Area** - clinical condition in which you intend to use the product.  
For example: Diabetes, Oncology
  - **Indication** - signs of how the therapeutic area manifests itself or what is apparent to the patient.
3. Click Next.
  4. In the Product tab, click Add Row(s) to add a product for which the project is created.
  5. Click the Lookup icon. From the search results, select a product.

**Candidate Selection Date** - the date on which you select a candidate for the project.

**Project Lifecycle** - stage of development.

§ To add more than one product, enter the desired number in the box adjacent to the **Add Row(s)** button and click **Add Row(s)**.

6. Select a **Status** - Active, Parked, Terminated.
7. Click **Finish**.

---

---

**Note:** To set permissions to access the Project, refer to Recipe & Workspace Management Administration Guide.

---

---

## Editing Project Details

You can edit the project details provided the project is in Draft, in Deployment or Parked status and not when it is in the Canceled or the Completed status.

### To edit project details:

1. Go to Processes > Project and run a search. From the search results, select a Project.
2. Modify the details you have provided in the General and Product tabs. The Project ID is unique and you cannot modify it.

### To edit a project after you save it with new project ID:

1. Click More > Save As to save the Project with a new name and ID.
2. Enter Project ID and select Yes to duplicate all the Notes and Attachments of the earlier project.

Click Save and Edit to further modify the new project.

Click OK to save the new project.

Click Cancel to return to the search results page.

## Project Tabs

The tabs on Project Details page include:

- **General:** Lists details of the Project.
- **Product:** Lists details of the product associated with it.
- **Campaign Summary:** Displays all the activities involved in a project. It lays out the actual and planned quantities of the target material at all levels - Campaign, Process Step, Control Recipe and Work Request.
- **Notes and Attachments:** Notes/attachments providing additional information.
- **History**

Status Transition: Lists all the transitions the object undergoes from its initiation.

Workflows: Lists the statuses a Project workflow.

Changes: Records changes a Project undergoes from its initiation.

## Changing Lifecycle Phases of a Project

A Project goes through the following phases:

- **Draft** - indicates the initial status of a newly created project.
- **In Development** - indicates that the project is in use.
- **Completed** - indicates that the project is completed.

---

---

**Note:** You cannot change a project state to Completed if the associated campaigns are not in Completed or Canceled status.

---

---

- **Parked** - indicates that the project is put on hold and can be taken up again in future. You can also cancel any further work on the parked project.

---

**Note:** You cannot park a project if the associated campaigns are not in Completed or Canceled status.

---

- **Canceled** - indicates that the project is called off.

**To change the lifecycle phase of a project:**

1. Go to Processes > Project and run a search. From the search results select a Project.
2. Click Change > Lifecycle Phase and select an appropriate lifecycle phase.

---

**Note:** You can change the lifecycle phase of the project to Cancelled or Parked, if the associated campaign, control recipe and work request are in the Completed, Parked, Canceled or Rejected status.

---

## Alerts Associated with a Project

While deploying the RMW application you can set up the following alerts for a project:

Name	Type	Triggered
New Project Alert	Non-mandatory	When you create a new Project and its status is in Development.
Canceled Project Alert	Mandatory	To warn all the associated contacts that the project is canceled.
Parked Project Alert	Mandatory	To warn all the associated contacts that the project is temporarily on hold.

All the alert messages contain details such as Project ID, Project Name, Product, Therapeutic Area, Indication, Candidate Selection Date and Status.

---

## Working with Campaigns

A Campaign describes a series of structured activities and processes required to produce a defined quantity of intermediate or final material and the Active Pharmaceutical Ingredient (API) used in a drug product.

There can be many campaigns in a project and you usually associate one campaign to one intermediate/API. You can also have one campaign associated with multiple intermediates/API.

You can have one or more campaigns associated with a product, while associating a campaign with a target material. Campaigns consist of many process steps and each process step in a campaign, tracks the making of several lots of materials within it. Process Step or a Recipe need not always make materials; it can represent other activities in the campaign such as cleaning, or equipment setup/dismantling.

### Creating a Campaign

While creating campaigns, you need to associate it to a Product and a Project. The **Project** must be in the In Development status and ensure that the Project-Product is in Active status.

---

**Note:** The system displays a warning to proceed if the Project is in Draft status. Also, ensure that the Project-Product is in Active status.

---

#### To create a new campaign:

1. Go to the Create New menu, select Processes > Campaign.
2. In the Characteristics sub-tab under General tab, enter the required information.

#### Significant inputs:

- **Project Product** - indicates the Product and Project ID for which you are creating this campaign. Click the Lookup icon, from the search results and select a product. The project ID associated with it is automatically filled up.
- **Target Material** - select a Target Material ID for the Campaign.
- **Planned Campaign Site** - The ID of the Site where you plan to execute this campaign.
- **Process Route** - Defines the route a Process takes.
- **Stage of Work** - A state in the work lifecycle of the campaign. For example: During Phase 3.
- **Environmental Regulation Summary (ERS)**. Select:

**At Campaign Level** - if the regulations are applicable only at campaign level.

**At Process Step Level** - if regulations are applicable only at process step level.

**N/A** - If ERS is not applicable.

- **Initiating Order** - The ID of the associated material order, if any.
  - **Planned Quantity** - The quantity of the material you plan to make.
3. Click Next.
  4. In the Objectives sub-tab under the General tab, select Campaign Objective to identify the purpose of the campaign.

---

**Note:** You can assign more than one objective to a campaign.

---

5. Click Finish to save the campaign.

## Editing Campaign Details

You can edit a campaign provided it is in Draft, Approved, or In Progress status and not when it is in Submitted, Completed, Parked, Canceled, or Rejected status.

## Campaign Tabs

The tabs and sub-tabs on the Campaign - View Details page include:

- **General:** Lists details of the campaign.
  - Characteristics: Lists the characteristics of the campaign
  - Objectives: Identifies the purpose of the campaign.
- **Notes and Attachments:** Notes/attachments provide additional information.
- **History:** A detailed account of all events that occurs since its initiation.
  - Status Transition: Lists all the transitions the object undergoes from its initiation.
  - Workflows: Lists the workflows a campaign passes through.
  - Changes: Records changes that a campaign undergoes from its initiation.

## Changing Lifecycle Phases of a Campaign

A **Campaign** goes through the following phases:

- **Draft:** the state of a newly created campaign.
- **Submitted:** when the campaign is submitted for approval.
- **Approved:** when the campaign is approved.
- **Parked:** when the campaign is put on hold.
- **In Progress:** when the campaign is in use.
- **Completed:** when status of the campaign is manually set as complete.
- **Rejected:** when the campaign is rejected.
- **Canceled:** when the campaign is called off.

**To change the lifecycle phase of a campaign:**

1. Go to Processes > Campaign and run a search. From the search results select a campaign.
2. Click Change > Lifecycle Phase and select the applicable lifecycle phase.

---

**Note:** For a Campaign to be Completed, all the control recipes associated with it must be in the Final status.

---

## Alerts Associated with Campaign

Alerts inform you of actions you need to take.

Name	Type	Triggered when
New Campaign Request Approval Alert	Non-Mandatory	You approve a new campaign request.
Cancel Campaign Request Alert	Mandatory	You cancel a new campaign request.
Campaign Modification Alert	Mandatory	You modify any one of the following campaign properties: Quantity Requested Requested Delivery Date

All the alert messages contain details such as Project ID, Project Name, Product, Campaign Name, Campaign Leader, Material Name Requested, Material Item ID Requested, Quantity Requested and Delivery Date Requested.





---

## Working with Process Steps

A Process Step defines the processes involved in creating the final drug product. Each process step can contain several control recipes; and each control recipe tracks the making of a single lot or several lot of material within it. A Process Step need not always refer to making material; it can represent other activities such as cleaning, setting up, or dismantling equipment, standards or cautions it is associated with, etc.

A Process Step specifies the number of control recipes and also the planned quantity of the target material. The planned target quantity per control recipe is also populated within the process step.

### Creating a Process Step

Since a Process Step defines the processes involved in creating the final drug product, you can add a Process Step to a Campaign. Each process step in a campaign, tracks the making of several lots of material within it. A process step or a recipe need not always make materials; it can represent other activities in the campaign such as cleaning, or equipment setup/dismantling.

A Process Step contains several control recipes; each control recipe making a single lot or batch.

#### To create a process step:

1. Go to Create New menu > Processes > Process Step. A New Process Step page appears.
2. In the Recipe tab, use the Lookup icon and associate a recipe to the Process Step. An existing recipe is associated with a Process Step. The Name and Version fields are automatically populated with the data from the recipe you selected.
3. Select a campaign using the Lookup icon.
4. Click Next.
5. In the Details sub-tab under the Process Step Details tab, all the fields are updated automatically with data from the recipe you selected.
6. Click Next.

#### Bill Of Processes (BOP) > Instructions

- a. In the Instructions sub-tab under BOP tab, select the recipe record and click Edit SFC to create a sequential flow chart of process. The edit SFC button helps you to add recipe actions and recipe elements.
- b. In the right pane of SFC Editor, click on the Start Is Complete object and click Delete.

- c. Click New > Recipe Element from Template. You can also right-click in the right pane of the editor and select the same option from the menu.
  - d. Select a Recipe Element Template and click OK.
  - e. Click anywhere in the right pane to add the recipe element object. For complete details on how to use SFC Editor, see Working with SFC Editor in the Recipe & Material Workspace Recipe Management Guide.
  - f. When you add a recipe element template, the recipe action templates associated with it are added automatically. If you wish to add more recipe action templates, click New > Recipe Action Template and select the desired templates.
  - g. Click OK.
  - h. In the Instructions tab, a table listing the recipe and associated recipe elements and recipe actions appear. The instructions that you entered in the recipe action template appear in the right column.
  - i. To edit a recipe element template or a recipe action template, select the desired record and click Edit.
  - j. To save the recipe BOP as a template for future use click Save As Template.
7. Click Next.

The Parameter tab displays a list of parameters associated with the Recipe with details. To edit a parameter, select the desired record and click Edit.

8. Click Next.

#### **Bill of Material (BOM)**

In the Materials sub-tab under the BOM tab, a list of material variables appears. You can resolve the unresolved variables, view sample information of the material to which a variable is resolved. You can add, delete, and edit the variables.

- a. For each material, enter the Planned Quantity to Consume and the Display Order, in which the items must appear in the recipe list.
  - b. Select a material variable and click View Sample Information to view the information of a material sample. The Sample Information page appears, displaying the Lot ID and other details from which the selected material was sampled.
  - c. To add a new material directly to the BOM, click More > Add Material.
9. Click Next.

In the Consumables sub-tab under BOM tab, the list of material variables of the type Consumable appears. You can resolve the unresolved variables, and add, delete and edit the variables.

- a. To add a new consumable material directly to the Consumable sub-tab under BOM tab, click More > Add Material.
- b. For each material of the type Consumable, enter the Planned Quantity to Consume.

---

**Note:** The Unit of Measure of the material is Unit.

---

10. Click Next.

The Specification Plans sub-tab of the BOM tab lists specification plans associated with the recipe. You can add new specification plans or delete the inapplicable plans.

**11. Click Next.**

The Equipment sub-tab lists equipment variables. You can resolve the unresolved variables, view disposition of equipment, and also add, delete or edit equipment variables.

**Bill of Equipment (BOE)**

- a. To add new equipment, click More> Add Equipment.
- b. In the Search Equipment Page, select the Recipe Action associated with it.
- c. Enter a value in any field and run a search. Select Equipment from the search results and click OK.
- d. To resolve an unresolved equipment variable, select a variable record and click Resolve Variable.
- e. To view the disposition of equipment, select an equipment variable record and click View Equipment Disposition. The Equipment Disposition page displays the equipment name, its availability status, etc. It also contains the OK, Reservations and View Last CleaningActivity buttons.
- f. Click OK to return to the BOE page.
- g. Click Reservations to see the reservations made on the equipment. You can also create new reservations/ edit reservations from this page.
- h. Click View Last Cleaning Activity to see the last cleaning activity performed on the equipment.

**12. Click Next.**

**Output**

The Output tab, lists output material variables defined in the Instructions tab of recipe action templates. You can edit these variables, add new material variables and resolve the unresolved variables.

1. To add material, click More > Add Material.
2. In the Search Material page, select the Recipe Action associated with it.
3. Enter a value in any field and run a search. Select a material from the search results and click OK.
4. Enter Output Quantity. Select the appropriate UOM from the drop-down list.
5. Select the Type of the output.
6. To resolve an unresolved output variable, select a variable record and click Resolve Variable.

**13. Click Next.**

**Bill of Standards (BOS)**

The BOS tab lists standards defined in the instructions entered in recipe action templates. You can edit these standards add new standard variables and resolve the unresolved variables.

To resolve an unresolved variable, select a variable record and click Resolve Variable.

**14. Click Next.**

The Cautions tab displays the caution type standards associated with resolved materials and equipment.

**15. Click Finish.**

A message appears confirming the creation of the Process Step.

## Editing a Process Step

You can edit a Process Step only when it is in the Draft status. While editing a Process Step, you can edit the Recipe Action associated with it and add Material, Equipment or Standards directly to the BOM, BOE or BOS without creating a variable.

## Process Step Tabs

A The tabs and sub-tabs on the Process Step View Details page includes:

1. **General:** Lists details of the Process Step.
2. **Bills of ...:** Displays the BOP, BOM, BOE, BOA and BOS sub-tabs.
  - **Bill Of Process (BOP):** A collection of approved Unit Operations.  
 Instructions: Lists recipe and associated recipe elements and recipe actions.  
 Includes a view of the Sequential Flow Chart (SFC).  
 Parameters: Displays the parameters values that were entered and the results.
  - **Bill Of Materials (BOM):** A list of materials, which are required to produce the target material.  
 Material: List of material variables.  
 Consumables: List of consumable material variables.  
 Specification Plans: List of specification plans associated with the recipe.
  - **Bill Of Equipment (BOE):** List of equipment required / used in the process step.
  - **Bill of Assay (BOA):** List of assays associated with the process step.
  - **Bill of Standards (BOS):** List of applicable standards.  
 Standards: List of standards applicable to the process step.  
 Cautions: List of cautions used in the process step.
3. **Output:** List of final material you wish to produce.
4. **Notes and Attachments:** Notes/attachments providing additional information.
5. **History:** A detailed account of all events that occur since the initiation of a Process.  
 Status Transition: Lists all the transitions the object undergoes from its initiation.  
 Workflows: Lists the statuses of a Process workflow.  
 Changes: Records changes that a process step undergoes from its initiation.  
 Print: Lists print details.

## Changing Lifecycle Phases of a Process Step

A Process Step goes through the following phases:

- **Draft:** the state of a newly created process step.
- **Submitted:** when the process step is submitted for approval.
- **In Progress:** when the process step is in use.
- **Parked:** when process step is put on hold.
- **Approved:** when the process step is approved.
- **Completed:** when status of the process step is manually set as complete.
- **Canceled:** when the process is called off.

**To change the lifecycle phase of a process step:**

1. Go to Processes > Process step and run a search. From the search results select a process step.
2. Click Change > Lifecycle Phase and select the applicable phase.

## Validating the Process Step for Control Recipe Creation

Validation of a process step helps in checking if all variables in the BOP have been resolved.

**To validate a process step for creation of a control recipe:**

1. Run a search and select a process step.
2. Click More > Validate for Control Recipe Creation.

The Validate for Control Recipe Creation page appears, displaying the following:

- List of exceptions, if any
  - Problems encountered during creation with error messages. For example: Containers not in Evaluated status or equipment not in Available status.
  - The problems describing the reason for exception.
3. Click OK.

## Creating Control Recipe from a Process Step

You can create a control recipe from an approved process step of an approved campaign.

**To create a control recipe from a process step:**

1. Go to Processes > Process Step and run a search. From the search results, select a process step.
2. Click More > Create Control Recipe. The Control Recipe- New page appears.

The application automatically selects Process Step of Campaign option for Control Recipe Belongs To, and populates the Process Step fields.

3. To create a control recipe, see Creating a Control Recipe.

## Deleting a Process Step

You can delete a Process Step only when it is in the Draft, Canceled or Rejected status and not when it is in the Approved status.



---

## Working with Control Recipes

A Control Recipe constitutes data that you collect and define to create a Work Request. It is associated with a process step and represents a chemical reaction that produces a product and by-product(s) or waste.

A Control Recipe is released as a template which in turn is used to create Work Requests.

### Creating a Control Recipe

A control recipe is created keeping in mind the process steps that are defined to create a product and hence associated to a process step of a campaign or a project.

**To create a control recipe:**

1. Go to Create New menu, select Processes > Control Recipe.

---

**Note:** The RMW application generates the Control Recipe ID automatically.

---

2. In the Preface tab, enter the required information.

**Significant inputs:**

- **Control Recipe Belongs To** - A control recipe can be associated to a process step of a campaign or it can be a part of a project. Select one of the below options.
- **Process Step of a Campaign** - Search for process steps using the **Lookup** icon. From the results, select the process step to which you wish to associate the control recipe. Once you select the process step, the system automatically fills the campaign ID to which the process step belongs.
- **Project** - Search for the Project and Recipe using the Lookup icon.

3. Click Next.

4. In the Attributes sub-tab of the General tab, enter the required information.

**Significant inputs:**

- **Operating Mode** - Select one of the modes it is going to be used for: Clinical or, Development and Not Applicable if either does not apply.
- **Scale Factor** - The number used to scale Variable Quantities in recipes that are marked as scalable.

- The Implementation Site, and the Planned Start and End Dates are automatically picked up from the Campaign or Project details. However, you have the option to change them.
5. Click **Finish**.

---

**Note:** The information contained in the BOP, BOM, BOE, BOS and Output tabs is copied from the Recipe from which the Control Recipe is derived. To modify information in these tabs, click Next.

---

---

**Note:** For complete details on these tabs, refer to Agile Recipe Management for Pharmaceuticals - Recipe Management Guide.

---

## Editing a Control Recipe

You can edit a Control Recipe only when it is in the Draft status. Once a Control Recipe is in the Submitted status, you can edit only the Work Request associated with it. You cannot create a Control Recipe for a Canceled, Rejected, Parked or Completed Process Step.

## Control Recipe Tabs

The tabs and sub-tabs on the Control Recipe - View Details page include:

1. **General:** Lists details of the Control Recipe
2. **Bills of ...:** Displays the BOP, BOM, BOE, BOA and BOS sub-tabs.
  - **Bill Of Process (BOP)** - A collection of approved Unit Operations.  
Instructions: Lists recipe and associated recipe elements and recipe actions. Includes a view of the Sequential Flow Chart (SFC).  
Parameters: Displays the parameters values that were entered and the results
  - **Bill Of Materials (BOM)** - A list of materials, which are required to produce the target material of the control recipe.  
Material: List of material variables.  
Consumables: List of consumable material variables.  
Specification Plans: List of specification plans associated with the recipe.
  - **Bill Of Equipment (BOE)** - List of equipment required / used in the control recipe.
  - **Bill of Assay (BOA)** - List of assays associated with the control recipe.
  - **Bill of Standards (BOS)** - List of applicable standards.  
Standards: List of standards applicable to the control recipe.  
Cautions: List of cautions used in the control recipe.
3. **Outputs (or Output)** - List of final material you wish to produce.
4. **Notes and Attachments** - Notes/attachments providing additional information.
5. **History** - A detailed account of all events that occurs since the initiation of the Control Recipe.



Status Transition: Lists all the transitions the object undergoes from its initiation.

Workflows: Lists the workflows a control recipe passes through.

Changes: Records changes that a control recipe undergoes from its initiation.

Print - Lists print details.

## Requesting Inventory from Control Recipe

You can carry out the following material transactions from a control recipe:

- New Allocation Request
- New Dispense Request
  - By Materials
  - By Allocation Requests
- Material Pickup
- Material Consumption
- Material Return

All these transactions are valid for the material inventory.

### To request inventory from a control recipe:

1. Go to Processes > Control Recipe. From the search results, select a control recipe.
2. Click More > Request Inventory.

The Requests page appears with a list of materials associated with the Project.

3. To view the list of material associated with other levels of the process (Campaign, Process Step, Control Recipe and Work Request), select the desired option.

The corresponding list of materials appear in a table.

4. Select the required materials and click the action button for material transactions (New Allocation Request, Pickup, etc).

---

**Note:** For complete details on how to carry out Material Transactions, refer to Agile Recipe Management for Pharmaceuticals - Material Management Guide.

---

## Reserving Equipment from Control Recipe

You can reserve equipment associated with a recipe from the control recipe. You can either reserve the entire Bill of Equipment (BOE) or individual equipment listed in the BOE. While reserving the equipment through BOE, RMW displays the estimated start and end date for the reservation duration by default. You can change the reservation dates at the BOE level or for individual equipment. Each of these reservations is for a single site.

### To reserve equipment from a control recipe:

1. Go to Processes > Control Recipe and run a search. From the search results, select a control recipe.
2. Click More > Reserve Equipment. The Equipment Reservation: Add page with the Preface tab appears.

**Significant inputs:**

- The reservation purpose is automatically set to Process; however you have the option to select any one.
- If Equipment is already associated with the control recipe, these appear in the Equipment tab. You can add more equipment or delete the ones you do not require.
- In the Equipment tab, you are required to enter reservation period, the Start Date and End Date, for each equipment record.

---

**Note:** For complete details on how to carry out Equipment transactions, refer to Agile Recipe Management for Pharmaceuticals - Equipment Management Guide.

---

## Creating Recipe Template from Control Recipe

You can use a control recipe as a recipe template; which can be at the General, Site or Master Level.

**To create a recipe template from control recipe:**

1. Go to Processes > Control Recipe and run a search. From the search results, select a control recipe.
2. Click More > Save as Recipe Template.
3. In the Preface tab, enter the Name for the new recipe template and select its Recipe Level.
4. Click Next.
5. In the General tab, use the Lookup icon and select
  - Company name, if you selected the Recipe Level as General.
  - Site of Execution, if you selected the Recipe Level as Site or Master.
6. Select Yes to duplicate all Notes and Attachments.
7. Click Finish.

## Auditing Control Recipe

Once you create a control recipe, you can validate it for work request creation. You can validate the BOM, BOE and BOP specified in a control recipe and generate a consolidated list of errors, if any.

A warning message appears if:

- Equipment or materials used on the BOE/BOM are in Non-qualified status.
- Status of the equipment is Unavailable or Non-qualified.
- Variables used in the control recipe are not associated to any equipment or material. In addition, a dialog box appears, displaying variables, equipment and material, allowing you to match the variables with the correct equipment or material.

**To audit a control recipe:**

1. Go to Processes > Control Recipe and run a search. From the search results, select a recipe.
2. Click More > Audit Recipe.

In the Audit Recipe page, you see one of the following:

- A message indicating successful validation of the control recipe.
- An Exceptions Table listing the objects and the problems that resulted in unsuccessful validation.

## Deleting Control Recipe

You can delete a control recipe if:

- a Work Request is not created for the control recipe.
- a Material Allocation Request is not made for the control recipe.
- an Equipment reservation is not made for the control recipe.
- it is not in the Completed state.

---

---

**Note:** You cannot delete a control recipe if it is in Approved, Canceled, Submitted or Completed status.

---

---

## Changing Lifecycle Phases of a Control Recipe

The lifecycle phase of a **Control Recipe** can be changed manually or through a workflow. A control recipe has the following lifecycle phases:

- **Draft:** the state when you create the control recipe.
- **Submitted:** when you submit the control recipe for approval.
- **Approved:** when the control recipe is approved.
- **In Progress:** when the control recipe is in use.
- **Rejected:** when it is not approved for use.
- **Canceled:** when it is put out of use, even though approved.
- **Completed:** when all the associated work requests are in their final lifecycle phase.

**To change the lifecycle phase of a control recipe:**

1. Go to Processes > Control Recipe and run a search. From the search results, select a Control Recipe.
2. Click Change > Lifecycle Phase and select the applicable lifecycle phase.



---

## Working with Work Requests

A Work Request is a record of all BOP, BOM, BOE, BOS and tests performed to produce a Target Material or a Lot of a particular material. Work Requests are automatically created from Approved Control Recipes or manually from Approved Recipes. Work Requests derived from control recipes, also inherit the material and equipment (which can be modified) associated with it.

There are three types of Work Requests in each phase:

- Cleaning
- Processing
- Other

There are two operating modes for Work Requests:

- Clinical Supply
- Development

---

**Note:** Work Requests once created, can only be Aborted or Canceled and not Deleted.

---

Once a Work Request creates the Output Material, the actual output quantities are displayed in the Work Request, Control Recipe, and Process Step and in the campaign summary at the Project level.

### Creating a Work Request

Work Requests are created in two ways:

- From a Recipe
- From an approved Control Recipe.

---

**Note:** You can create Work Requests only from ApprovedControl Recipes or Approved Recipes.

---

**To create a work request from a recipe:**

1. Go to Recipes > Library and run a search. From the search results, select a Recipe.
2. Go to More> Create Work Request. In the Create Work Request from Recipe page, enter the required information.

**Significant inputs:**

The application automatically creates a Control Recipe from the given recipe, and approves it internally. Operating Mode, Implementation site, Scale Factor Planned Start and End Date.

- **Project** - The ID of the project you wish to associate with the work request.
- **Target Quantity** - Amount of end product to be produced.
- **Target Yield** - Net amount of actual produce expected.

**To create a work request from an approved control recipe:**

3. Go to Processes > Control Recipe and run a search. From the search results, select a control recipe.
4. Change the lifecycle phase of the control recipe to 'Approved'.

Once you approve a Control Recipe, RMW generates a Work Request ID associated to that Control Recipe. A message displays the Work Request ID and the Control Recipe it is associated with and also confirms that the Control Recipe is in the Approved status. For example: Work Request ID for Control Recipe 'CR303' is: 'WR53'.

## Editing a Work Request

Work Requests can be edited when they are in the In Progress status. While editing a Work Request, you can edit the Recipe Action associated with it and also add Material, Equipment or Standards directly to the BOM, BOE or BOS without creating a variable.

## Work Request Tabs

The tabs and sub-tabs on the Work Request Details page include:

1. **Control Recipe:** Lists details of the Control Recipe.
2. **Bills of ...:** displays the BOP, BOM, BOE, BOA and BOS sub-tabs.
  - **Bill Of Process(BOP)** - A collection of approved Unit Operations.  
Recipe: Displays associated recipe element and recipe action templates.  
Parameters: Displays the parameters values that were entered and the results.
  - **Bill Of Materials (BOM)** - A list of materials, which are required to produce the target material of the work request.  
Material: List of material variables.  
Consumables: List of consumable material variables.  
Specification Plan: List of specification plans associated with the work request.
  - **Bill Of Equipment (BOE)** - List of equipment required / used in the work request Equipment.
  - **Bill of Assay (BOA)** - List of assays associated with the work request.
  - **Bill of Standards (BOS)** - List of applicable standards.  
Standards: List of standards applicable to the control recipe.  
Cautions: List of cautions used in the control recipe.
3. **Outputs:** - List of final material you wish to produce.

4. **Notes and Attachments:** Notes/attachments providing additional information.
5. **History:** A detailed account of all events that occurred in the process of making the work request.
  - **Status Transition:** Lists all the transitions the object undergoes from its initiation.
  - **Changes:** Records changes that a work request undergoes from its initiation.
  - **Workflows:** Lists the workflows the work request passes through.
  - **Print:** Lists print details.

## Requesting Inventory from Work Request

You can raise inventory requests for carrying out material transactions from the work request. The process is the same as that for raising requests from a control recipe.

For complete details on how to request inventory, see Requesting Inventory from Control Recipe. Also refer to Recipe & Material Workspace Material Management Guide.

## Reserving Equipment from Work Request

You can reserve equipment from a work request. The process is the same as that for reserving equipment from a control recipe.

For complete details on how to reserve equipment, see Reserving Equipment from Control Recipe. Also, refer to Agile Recipe Management for Pharmaceuticals - Equipment Management Guide.

## Consuming Inventory from Work Request

You can consume an inventory on ad-hoc basis. This ad-hoc consumption does not require you to carry out any material transactions, that is, requesting material allocation, raising dispense request, staging of material by the material manager, and so forth.

**To consume inventory on an ad-hoc basis from work request:**

1. Go to Processes > Work Request and run a search. From the search results, select a Work Request.
2. Click More > Consume Inventory.
3. In the General tab, enter the required details.

**Operating Mode** - Select one of the modes you are using it for - Clinical, Development, or Not Applicable.

The **Work Request** field is automatically populated with the work request ID from which you initiated the consume inventory action.

4. Click Next.
5. In the Containers and Quantities tab, enter the Quantity Consumed and the Consumed Date.

The Quantity Consumed should not be more than the Quantity on Hand.

6. To add the IDs of additional containers manually from which you wish to consume inventory:

- a. Click Enter Manually.
  - b. In the Enter Manually page, enter the Container ID and Quantity to Consume values.
  - c. To add more records, click Add Rows and enter the required details.
  - d. Click OK to save and return to the Containers and Quantities tab.
7. To add more containers from the inventory records from which you wish to consume inventory:
    1. Click Lookup From Inventory > Entire Inventory.
    2. From the search results, select the Containers and click OK.
  8. To delete the containers from which you do not wish to consume any material, select the container records and click Delete.
  9. Click Finish.

## Recording Parameter Values in Work Request

Results of every parameter defined in the recipe instructions have to be recorded in the RMW application. These results are the actual values of the parameters recorded during the execution of the work request. The Parameters and Results are displayed in a work request that is closed out.

### To record the results of a parameter in the work request:

1. Go to Processes > Work Request and run a search.
2. Select a work request from the search results.
3. Click More > Record Parameters.
4. Select a parameter to add a result.
5. Click New Result. In the Results window, enter the required information and click OK.

### Significant inputs:

- **Recorded Value** - The quantity of material and its unit of measurement.
- **Test Result** - Whether the execution passed or failed the tests, unless not applicable.
- **Notebook Reference** - The Reference ID of the recording medium.

### To edit a record:

1. Select the result record and click Edit Result.
2. Modify the record and click OK.

## Adding Material to Inventory

You can add the output material in to the material inventory from the work requests. The output materials are defined in control recipe. These are by-products, secondary products and final target material.

The output materials are defined using the output variables. Resolve the Output variable to Material before you add the output material to the inventory.

### To add material to inventory from work request:



1. Go to Processes > Work Request and run a search. From the search results, select a Work Request.
2. Click More > Add To Inventory.
3. Select the output material you wish to add to the material inventory.
4. Click Add To Inventory.
5. In the Lot tab, enter or modify the required information.

**Significant inputs:**

The Add to Inventory action lets you define:

- **Target Material Lot** - Target Material Lot number is auto generated Number by default. You can change it to Manual Entry and assign a new Lot number, manually.
  - **Number of Containers** - This field is automatically populated by the application, however, you can change this value.
  - **Quantity** - Specify the amount of output material and its applicable unit of measurement.
  - **Final Form** - Select Yes if the output material is in its final form.
  - **Crystal Form** - The form of the material, whether it is in crystals.
  - **Stability Study** - Select Yes if any stability study was carried out on the material. If you select No, you will need to enter details in the Reason Not On Stability.
6. Click Next.
  7. In the **Containers** tab, enter or modify the required information. You can enter the details of the container in which you wish to store the output material.

**Significant inputs:**

- **Container ID** - Generated by the application.
  - **MOC** - Selects the material of construction of the container.
  - **Container Size** - Overall capacity of the container in volume units.
  - **Container Type** - Selects the shape of the container.
  - **Gross Quantity** - Total Weight (mass) of the material and container, including packing.
  - **Net Quantity** - Weight of the material in the container. This is equal to the difference of gross weight and tare weight.
  - **Tare Quantity** - Mass of an empty container including all fittings and appliances associated with that particular type of container on its normal operating condition.
  - **Storage Location** - The location of the container to store the output material. This field is mandatory.
8. Click Finish.

## Recording Equipment Activity from Work Request

Resolve the equipment variables in BOE to specific equipment from the library. In record Activity, set the Start Time, End Time and the equipment Status after Activity. You can also delete the activities from the list.

**To record the equipment activity from a work request:**

1. Go to Processes > Work Request and run a search. From the search results select a Work Request.
2. Click More > Record Activity.
3. In the Record Activity page, change the Start Time and End Time to the actual recorded activity times.
4. Select the new status of the equipment from Status after Activity.
5. To delete an equipment activity record, select the desired row and click Delete.
6. Click OK.

## Viewing Equipment Usage from Work Request

At any time during the execution of a work request, you can view equipment related activities.

**To view equipment usage from a work request:**

1. Go to Processes > Work Request and run a search. From the search results, select a Work Request.
2. Click More > View Equipment Use.

A table displays the list of equipment and recorded activities.

## Auditing Closeout of Work Request

Before you closeout a work request, you need to audit if the objects in the work request encountered any problems during execution. You cannot close a work request until all the exceptions are resolved. It can be due to various reasons; the variables and parameters that you defined in recipe action template were not resolved to any objects from the library; a container status remains "to be evaluated", and so forth.

The Audit Closeout action in RMW allows you to see the problems that objects encountered before creation of a work request.

**To audit a work request for closeout:**

1. Go to Processes > Work Request and run a search. From the search results select a Work Request.
2. Click More > Audit Closeout.

A table lists objects and describes the problems encountered.

## Closing Out a Work Request

After you execute the work request and production is complete, you can **Close Out** the work request. 'Closing out' a work request is possible when its lifecycle phase is In Process. Ensure to generate a lot number for the work request before you close out the record.

**To close out a work request:**

1. Go to Processes > Work Request and run a search. Select the work request you want to close out from the search results.
2. Click More >Close Out.
3. Enter the required information.

**Significant inputs:**

- **Production Status** - indicates whether the work request was successfully Finished or Aborted because of failures.
- **Target Material Was Produced** - indicates whether the target material was successfully produced or not.
- **Lot Release Process** - select the process used for releasing the final Lot.

---

**Note:** A table lists exceptions associated with the objects in the work request, below the close out form.

---

4. Click OK.

## Changing Lifecycle Phases of Work Requests

You can change the status for a Work Request manually or through a workflow. A Work Request has the following lifecycle phases:

- **Canceled:** when the work request is not in use.
- **In Progress:** when the work request is in use.
- **Completed:** when the work request is executed.

**To change the lifecycle phase of a work request manually:**

1. Go to Processes > Work Request and run a search. From the search results, select a work request.
2. Click Change > Lifecycle Phase and select the applicable lifecycle phase.

