Agile Product Lifecycle Management

Recipe & Material Workspace Process Management Guide

v9.3.2

Part No. E28692-01
December 2012

Copyright and Trademarks

CONTENTS

Preface

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.

Note	To read the PDF files, you must use the free Adobe Acrobat Reader version 9.0 or later. This program can be downloaded from the Adobe Web site http://www.adobe.com.

The Oracle Technology Network (OTN) Web site http://www.oracle.com/technetwork/documentation/agile-085940.html can be accessed through **Help** > **Manuals** in both Agile Web Client and Agile Java Client. If you need additional assistance or information, please contact My Oracle Support (https://support.oracle.com) for assistance.

Note	Before calling Oracle Support about a problem with an Agile PLM manual, please have the full part number, which is located on the title page.

TTY Access to Oracle Support Services

Oracle provides dedicated Text Telephone (TTY) access to Oracle Support Services within the United States of America 24 hours a day, 7 days a week. For TTY support, call 800.446.2398. Outside the United States, call +1.407.458.2479.

Readme

Any last-minute information about Agile PLM can be found in the Readme file on the Oracle Technology Network (OTN) Web site http://www.oracle.com/technetwork/documentation/agile-085940.html.

Agile Training Aids

Go to the Oracle University Web page http://www.oracle.com/education/chooser/selectcountry_new.html for more information on Agile Training offerings.

Accessibility of Code Examples in Documentation

Screen readers may not always correctly read the code examples in this document. The conventions for writing code require that closing braces should appear on an otherwise empty line; however, some screen readers may not always read a line of text that consists solely of a bracket or brace.

This documentation may contain links to Web sites of other companies or organizations that Oracle does not own or control. Oracle neither evaluates nor makes any representations regarding the accessibility of these Web sites.

Chapter 1

Introduction to Process Management

This chapter includes the following:

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 Guide* — 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 Equipmen**t (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 byproducts is placed into inventory, results captured against materials made, equipment used (start and end time) and actual quantities of materials used.

Chapter 2

Working with Projects

This chapter includes the following:

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:

1. Go to **More > Save As** to save the product with a new ID.
2. 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.
   - **Candidate Selection Date** - the date on which you select a candidate for the project.
   - **Project Lifecycle** - stage of development.
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.

   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 Development* 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 workflows a Project passes through.
  - **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*, *Cancelled* 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.

Chapter 3

Working with Campaigns

This chapter includes the following:

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.
   - **Stage of Work** - A state in the work lifecycle of the campaign. For example: During Phase 3.
   - **Process Route** - Defines the route a Process takes.
   - **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** - 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.

Chapter 4

Working with Process Steps

This chapter includes the following:

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

   1. 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.
   2. In the right pane of SFC Editor, click on the Start Is Complete object and click **Delete**.
   3. 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.

4. Select a **Recipe Element Template** and click **OK**.
5. 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*.
6. 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.
7. Click **OK**.
8. 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.
9. To edit a recipe element template or a recipe action template, select the desired record and click **Edit**.
10. To save the recipe **BOP** as a template for future use click **Save As Template**.

7. Click **Next**.
   1. The **Parameter** tab displays a list of parameters associated with the Recipe with details.
   2. To edit a parameter, select the desired record and click **Edit**.
8. Click **Next**.

   Bill of Material (BOM)

   1. 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.
   2. For each material, enter the **Planned Quantity to Consume** and the **Display Order**, in which the items must appear in the recipe list.
   3. 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.
   4. To add a new material directly to the **BOM**, click **More > Add Material**.
9. Click **Next**.
   1. 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.
   2. To add a new consumable material directly to the Consumable sub-tab under **BOM** tab, click **More > Add Material**.
   3. 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**.
    1. 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)

    1. To add new equipment, click **More> Add Equipment**.

2. In the Search Equipment Page, select the **Recipe Action** associated with it.
3. Enter a value in any field and run a search. Select **Equipment** from the search results and click **OK**.
4. To resolve an unresolved equipment variable, select a variable record and click **Resolve Variable**.
5. 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 Cleaning Activity** buttons.

- Click **OK** to return to the BOE page.
- Click **Reservations** to see the reservations made on the equipment. You can also create new reservations/ edit reservations from this page.
- 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 dropdown 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.

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

14. Click **Next.**
    1. 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

The tabs and sub-tabs on the **Process Step View Details** page include:

- **General**: Lists details of the Process Step.
- **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.
- **Output**: List of final material you wish to produce.
- **Notes and Attachments**: Notes/attachments providing additional information.
- **History**: A detailed account of all events that occurs since the initiation of the Process.
  - **Status Transition**: Lists all the transitions the object undergoes from its initiation.
  - **Workflows**: Lists the workflows a process step passes through.
  - **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 on page 17.

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.

Chapter 5

Working with Control Recipes

This chapter includes the following:

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 *Recipe & Material Workspace 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:

- **General**: Lists details of the Control Recipe
- **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.
- **Outputs (or Output)** - List of final material you wish to produce.
- **Notes and Attachments** - Notes/attachments providing additional information.
- **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 *Recipe & Material Workspace 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 *Recipe & Material Workspace 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
   1. **Company** name, if you selected the **Recipe Level** as **General**.
   2. **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.

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.

Chapter 6

Working with Work Requests

This chapter includes the following:

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:

1. From a **Recipe**
2. From an approved **Control Recipe**.

Note You can create **Work Requests** only from *Approved* **Control 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:

1. Go to **Processes > Control Recipe** and run a search. From the search results, select a control recipe.
2. 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:

- **Control Recipe**: Lists details of the Control Recipe.
- **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 work request.
    - Cautions: List of cautions used in the work request.
- **Outputs**: - List of final material you wish to produce.
  - **Material**: List of material variables.

- **Notes and Attachments**: Notes/attachments providing additional information.
- **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.
  - **Workflows**: Lists the workflows the work request passes through.
  - **Changes**: Records changes that a work request undergoes from its initiation.
  - **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 on page 19. 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 on page 19. Also, refer to *Recipe & Material Workspace 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:
   1. Click **Enter Manually**.
   2. In the *Enter Manually* page, enter the **Container ID** and **Quantity to Consume** values.
   3. To add more records, click **Add Rows** and enter the required details.
   4. 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** - 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** - 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 progress.* 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.