



Agile Product Lifecycle Management

Recipe & Material Workspace Process Management Guide

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CONTENTS

Oracle Copyright.....	ii
Chapter 1 Introduction to Process Management.....	1
About this Guide	1
Recipe & Material Workspace Documentation.....	1
Process in RMW - An Overview	2
Process Structure.....	2
Chapter 2 Working with Projects.....	3
Creating a Product	3
Creating a Project.....	3
Editing Project Details	4
Changing Lifecycle Phase of a Project	4
Alerts Associated with a Project.....	5
Chapter 3 Working with Campaigns	7
Creating a Campaign	7
Editing Campaign Details	9
Managing Process Steps from Campaign.....	9
Adding New Process Step.....	10
Changing Lifecycle Phase of a Process Step.....	10
Validating the Process Step for Control Recipe Creation.....	10
Creating Control Recipe from Process Step.....	11
Changing Lifecycle Phase of a Campaign	11
Alerts Associated with Campaign.....	11
Chapter 4 Working with Control Recipe	13
Creating a Control Recipe	13
Requesting Inventory from Control Recipe	14
Reserving Equipment from Control Recipe	15
Creating Recipe Template from Control Recipe	15
Auditing Control Recipe.....	16
Deleting Control Recipe	16
Changing Lifecycle Phase of a Control Recipe.....	16
Chapter 5 Working with Work Requests.....	19
Creating Work Requests	19
Requesting Inventory from Work Request	20

Reserving Equipment from Work Request.....	20
Consuming Inventory from Work Request	20
Recording Parameter Values in Work Request	21
Adding Material to Inventory.....	21
Recording Equipment Activity from Work Request	23
Viewing Equipment Usage from Work Request.....	23
Auditing Closeout of Work Request	23
Closing Out a Work Request.....	24
Changing Lifecycle Phase of Work Requests	24

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) <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) <http://www.adobe.com>.

The [Oracle Technology Network \(OTN\) Web site](http://www.oracle.com/technetwork/documentation/agile-085940.html) <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.

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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) <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) http://www.oracle.com/education/chooser/selectcountry_new.html for more information on Agile Training offerings.

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Introduction to Process Management

This chapter includes the following:

▪ About this Guide	1
▪ Recipe & Material Workspace Documentation	1
▪ Process in RMW - An Overview	2

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 Export/Import Guide* — Describes how to export and import
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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 the *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) <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), 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, 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.
-

Working with Projects

This chapter includes the following:

▪ Creating a Product.....	3
▪ Creating a Project.....	3
▪ Editing Project Details.....	4
▪ Changing Lifecycle Phase of a Project.....	4
▪ Alerts Associated with a Project	5

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.

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.

Creating a Project

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 — the clinical condition in which you intend to use the product.
 - Indication — the type of therapeutic area related to Symptomatology; indicating 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 — the 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 and 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 the project permissions, refer *Recipe and Workspace Management Administration Guide*.

Editing Project Details

You can edit a project provided it is in *Draft*, *In development* or *Parked* status of the lifecycle phase.

Note You cannot edit a Project when it is in either the *Canceled status* or the *Completed status*.

Changing Lifecycle Phase of a Project

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:
 - 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.

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.

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

- Canceled - indicates that the project is called off.

Note You can change the lifecycle phase of the project to *Canceled* or *Parked*, if 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 several alerts. Given below are alerts you can set up for a project:

- New Project Alert — a non-mandatory alert triggered when you create a new project and the status of the newly created project is *In Development*.
- Canceled Project Alert — a mandatory alert triggered to warn all the contacts associated with project that the project is canceled.
- Parked Project Alert— a mandatory alert triggered to warn all the contacts associated with project that the project is temporarily on hold.

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

Working with Campaigns

This chapter includes the following:

▪ Creating a Campaign	7
▪ Editing Campaign Details	9
▪ Managing Process Steps from Campaign	9
▪ Changing Lifecycle Phase of a Campaign	11
▪ Alerts Associated with Campaign	11

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 associate a campaign with a target material and you can have one or more campaigns associated with that product. Campaigns consist of many process steps. 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.

Process step contains several control recipes, each control recipe making a single lot or batch. Control recipes are also commonly called Planned Batch Record if they are making a lot of material.

You use the Control Recipe to create one or more Work Requests and the data is automatically used to create those Work Requests.

Each campaign has at least one process route which can be selected within a campaign, and can be entered to represent the eLN process route ID.

Creating a Campaign

You can add a campaign for a project, only if the project is in the *In development* status. Also, ensure that the Project - Product is in *Active* status.

While creating a new campaign, select the project and the associated product.

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 - The Product and Project ID for which you are creating this campaign. Click the look-up from the result, select a product. The project ID associated with it is
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automatically filled up.

Note Ensure that the selected project is in the *In Development* status.

- Target Material - select 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 will take.
 - Environmental Regulation Summary (ERS). Select:
 - At Campaign Level, if the regulations are applicable at campaign level only.
 - At Process Step Level, if the regulations are applicable only at the level of process steps.
 - N/A - If ERS is not applicable.
 - Initiating Order - The ID of the associated work order, if any.
3. Click Next.
 4. In the Objectives sub-tab under the General tab, select the Campaign Objective to identify the purpose of the Campaign.

You can assign more than one objective to a campaign.
 5. Click Next.

You can optionally click Finish to save the campaign at this stage and enter the process steps later.
 6. In the Process Steps tab, click New.
 1. In the *New Process Step* page, enter the Process Step Name.
 2. Click Associate With Recipe to add the Recipe from the library.

Later on, you can create a control recipe or several control recipes for a process step. Each control recipe represents a lot being made.
 3. In the Recipe tab in the *New Process Step* page,
 4. Click the Lookup icon.
 5. Select a recipe from the search results that appear.

The values in the Name and Version number fields are updated by the application, with data from the recipe you selected.
 6. Click Next.

In the Details sub-tab under the Process Step Details tab, all the fields are filled up automatically. The data in these fields is updated automatically with data from the recipe you selected.
 7. Click Next.

If you selected ERS option At Process Step Level in the Characteristics sub-tab under the Details tab, the ERS tab appears.
 8. In the ERS tab, click Add Material.

This is required to report planned environmental impact. It tracks whether the material (and its by-products) you are producing in the process step is emitted into the air, or disposed of
-

as waste into a waste disposal system.

9. Select the desired material and click OK.

Note The Material should contain CAS.

10. Enter the required details.

Significant inputs:

- Material Use - The usage of the material. For example: Material can be used as Solvent.
- Total Quantity Used Per Lot (predicted) - The total quantity of material that will be used per Lot.
- Total Quantity Disposed Per Lot (predicted) - The quantity of unused material that will be disposed per Lot.
- Disposal Method - The method of disposing of unused material.
- WSIS# or other Information - Additional information pertaining to the option you selected as Disposal Method.
- RCRA Code - Indicates the RCRA Code.

11. Click Finish to save and return to the Process Steps tab.

7. Click Finish to save the campaign.

Editing Campaign Details

You can edit a Campaign only when it is in *Draft*, *Approved* or *In Progress* status.

Note You cannot edit a Campaign that is in *Submitted*, *Completed*, *Parked*, *Canceled* or *Rejected* status.

Managing Process Steps from Campaign

Process steps are created under a campaign from recipes. The process step takes a *copy* of the recipe, which contains the automatically generated BOM and BOE. The BOM and BOE are also carried over as *copies* to control recipe and work request. You can change the BOP/BOM/BOE at any level; from creating a campaign to work requests.

To manage process steps from a campaign:

1. Go to Processes > Campaign and run a search. From the search results, select a campaign.
2. Click More > Manage Process Steps.

In the *Campaign* page, you can carry out the following steps:

- Add new process steps.
 - Edit and delete a process step.
 - Change the lifecycle phase of a process step.
 - Print a process step.
 - Validate a process step for control recipe creation.
 - Reserve equipment from process step.
-

- Request inventory from process step.
- Create a control recipe from process step.

Adding New Process Step

To add a new process step in the campaign:

1. Click New to add a new process step.
2. In the Recipe tab,
 - Click the Lookup icon.
 - Select the recipe from which you wish to create process steps.
3. Click Next.
4. In the Process Step Details tab, modify the required information, if needed.
This data is copied from the Recipe you selected.
5. Click Finish.

Changing Lifecycle Phase of a Process Step

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
 - The errors in which the problems were encountered. 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 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 from Campaign option for Control Recipe Belongs To, and populates the Process Step fields.

3. Follow the instructions given in [Creating a Control Recipe](#) on page 13.

Changing Lifecycle Phase of a Campaign

A campaign goes through the following phases:

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

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 their *Final* status.

Alerts Associated with Campaign

Alerts inform you about actions you need to take. While deploying the RMW application, you can configure and set up various alerts for a campaign.

- New Campaign Request Approval Alert — a non-mandatory alert triggered when you approve a new Campaign request.
 - Cancel Campaign Request Alert — a mandatory alert triggered when a Campaign request is canceled.
-

- Campaign Modification Alert — a mandatory alert triggered when 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, Target Molecule, Campaign Name, Campaign Leader, Material Name Requested, Material Item ID Requested, Quantity Requested and Delivery Date Requested.

Working with Control Recipe

This chapter includes the following:

▪ Creating a Control Recipe	13
▪ Requesting Inventory from Control Recipe	14
▪ Reserving Equipment from Control Recipe	15
▪ Creating Recipe Template from Control Recipe	15
▪ Auditing Control Recipe	16
▪ Deleting Control Recipe	16
▪ Changing Lifecycle Phase of a Control Recipe	16

A Control Recipe constitutes data that you collect and define to create a Work Request regardless of the location, site or personnel. 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. These templates are used to create Work Requests.

You cannot create a Control Recipe for Canceled, Rejected, Parked or Completed Campaigns.

A Control Recipe consists of the following sections:

1. Bill Of Process (BOP) - A collection of approved Unit Operations.
2. Bill Of Materials (BOM) - A list of materials, which are required to produce the target material of the control recipe.
3. Bill Of Equipments (BOE) - List of equipments required / used in the control recipe.
4. Output - List of final material you wish to produce.

Creating a Control Recipe

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 name and Recipe using the Lookup icon.
3. Click Next.
 4. In the Attributes sub-tab under the General tab, enter the required information.

Significant inputs:

- Scale Factor - The number used to scale all parameters (belonging to any recipe action or variable) 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 to save and exit the control recipe.

Note The information contained in the BOP, BOM, BOE 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 *Recipe & Material Workspace Recipe Management Guide*.

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 appears 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 the 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 each 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.

Note For complete details on how to carry out the 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. This template can be at 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 if you wish to duplicate all the Notes and Attachments.
-

Auditing Control Recipe

You can validate a control recipe 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 displaying the Objects and the Problems that resulted in unsuccessful validation.

Deleting Control Recipe

You can remove the control recipe if:

- you have not created a work request for a control recipe.
- you have not made Material Allocation Request for a control recipe.
- you have not made an Equipment reservation for a control recipe.
- the control is not yet in *Completed* state.

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

Changing Lifecycle Phase of a Control Recipe

You can change the lifecycle phase of a Control Recipe manually or through a workflow. The lifecycle of a control recipe has the following 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.
-

Note Approved Control Recipe can be moved to *In Progress* status when at least one Work Request is in *In Progress*, *Completed* or *Close-out In Progress*.

- 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

This chapter includes the following:

▪ Creating Work Requests.....	19
▪ Requesting Inventory from Work Request	20
▪ Reserving Equipment from Work Request	20
▪ Consuming Inventory from Work Request	20
▪ Recording Parameter Values in Work Request	21
▪ Adding Material to Inventory	21
▪ Recording Equipment Activity from Work Request	22
▪ Viewing Equipment Usage from Work Request.....	23
▪ Auditing Closeout of Work Request.....	23
▪ Closing Out a Work Request	24
▪ Changing Lifecycle Phase of Work Requests.....	24

A Work Request is a record of all BOP, BOM, BOE and the tests to be 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

Creating Work Requests

You can create a work request only from an approved Control Recipe.

To create a work request:

1. Go to Recipes > Library and run a search. From the search results, select a Recipe.
2. 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.

- Project - The ID of the project that 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.

Note The RMW application generates the Work Request ID.

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 14. 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 15. 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 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.
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 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 Look Up 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 OK.

Recording Parameter Values in Work Request

For every parameter defined in the recipe instructions, their results 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.

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

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

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.
6. If you want to edit any result that you recorded, select the result record and click Edit Result.
 7. 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. All the output variables must be resolved before you can 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.
-

You can also select only the Lots or only the Containers of the output material for adding to the inventory.

4. Click Add To Inventory.
5. In the Lot tab, enter or modify the required information.

Significant inputs:

The table displays the output material name and the list of Lots and Containers that you defined in the recipe. The Add to Inventory action lets you define:

- Target Material Lot - This field is automatically populated by the application only when the output material is a final product. However, you can change it and assign a new Lot number.
- 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 - This is generated by the application.
- MOC - Look up and select the material of construction of the container.
- Container Size - Overall capacity of the container in volume units.
- Container Type - Select the shape of the container.
- Gross Quantity - Total Weight (mass) of the material and container, including packing.
- Net Quantity - The 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.

8. Click Finish.

Recording Equipment Activity from Work Request

When you resolve the equipment variables to specific equipment from the library, any activity performed on the equipment are logged automatically. After you have executed your work request, you can record the actual activities, that is, Start Time, End Time and the equipment Status after Activity. And 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. If you wish 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 the activities related to all the equipment.

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 displaying the list of equipment and recorded activities appears.

Auditing Closeout of Work Request

Before you can close out a work request, it is required 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 helps you to see the problems that the objects encountered.

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 displaying the list of objects and the problems appears.

Closing Out a Work Request

Once you execute the work request and production is complete, you can Close Out the work request. You can close out a work request only when its lifecycle phase is in either *In-progress* or *Approved* status. Ensure that you generate a lot number for the work request before you close out the record.

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

Significant inputs:

If there were any exceptions associated to the objects in the work request, a table displaying the list of objects and problems appears below the close out form.

- Production Status - Indicates whether the work request was successfully Finished or Aborted due to any failures.
- Target Material Was Produced - Indicates whether the target material was successfully produced or not.
- Lot Release Process - Lookup and select the process used for releasing the final Lot.

4. Click OK.

Changing Lifecycle Phase of Work Requests

You can change the status for a Work Request manually or through a workflow.

The lifecycle of a Work Request has the following phases:

- Draft — the state of a newly created work request.
- Submitted — when the work request is submitted for approval.
- Approved — when the work request is approved for use.
- Canceled — when the work request is put out of 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.