



Agile Product Lifecycle Management

Recipe & Material Workspace Material Management Guide

v9.3.1

Part No. E16511-01
September 2010

Oracle Copyright

Copyright © 1995, 2010, Oracle and/or its affiliates. All rights reserved.

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

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

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

U.S. GOVERNMENT RIGHTS

Programs, software, databases, and related documentation and technical data delivered to U.S. Government customers are "commercial computer software" or "commercial technical data" pursuant to the applicable Federal Acquisition Regulation and agency-specific supplemental regulations. As such, the use, duplication, disclosure, modification, and adaptation shall be subject to the restrictions and license terms set forth in the applicable Government contract, and, to the extent applicable by the terms of the Government contract, the additional rights set forth in FAR 52.227-19, Commercial Computer Software License (December 2007). Oracle USA, Inc., 500 Oracle Parkway, Redwood City, CA 94065.

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

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

This software and documentation may provide access to or information on content, products and services from third parties. Oracle Corporation and its affiliates are not responsible for and expressly disclaim all warranties of any kind with respect to third party content, products and services. Oracle Corporation and its affiliates will not be responsible for any loss, costs, or damages incurred due to your access to or use of third party content, products or services. The RMW product includes software developed by the Visigoth Software Society.

CONTENTS

Oracle Copyright	ii
Introduction to Material Management.....	1
About this Guide	1
Recipe & Material Workspace Documentation	1
Overview	2
Working with Material	3
Adding Material in the Material Library	3
Setting the Material Stock Level.....	6
Activating or Deactivating Material	7
Changing Material Lifecycle Phase	7
Ordering Material	8
Creating a Material Order	8
Editing a Material Order.....	9
Changing Material Order Lifecycle Phase.....	10
Receiving Material	10
Adding a Material Receipt	11
Editing the Material Receipt.....	13
Changing Material Receipt Lifecycle Phase	13
Working with Material Inventory	15
Lots	15
Containers.....	16
Adjusting Material Quantity	17
Disposing Material	17
Planning Material Disposal.....	18
Disposing the Material Planned for Disposal	18
Moving Material.....	19
Changing Lifecycle Phase of Lots	19
Splitting Containers.....	20
Merging Containers	20
De-allocating Material.....	21
Monitoring Inventory Level.....	22
Material Inventory Alerts	22

Working with Material Requests.....	23
Allocating Material	23
Creating an Allocation Request.....	24
Allocating Material.....	25
Changing Lifecycle Phase of Allocation Request.....	25
Viewing Allocation Status.....	26
Dispensing Material	26
Creating Material Dispense Request.....	27
Changing Lifecycle Phase of Dispense Request	28
Staging Material	28
Staging Inventory.....	29
Picking up Staged Material	30
Staging Additional Containers	31
Consuming Material.....	31
Adding Consumed Material Details.....	31
Consuming All Staged Material.....	32
Returning Unconsumed Material.....	32
Managing Analytical Activities	35
Working with Assays	35
Creating a New Assay	35
Creating a New Assay Group	36
Changing the Lifecycle Phase of an Assay or Assay Group.....	36
Activating or Deactivating an Assay	36
Working with Parameter Templates	37
Creating a Parameter Template	38
Working with Specification Plans.....	39
Creating Specification Plans	40
Changing Lifecycle Phase of Specification Plans.....	41
Purging Revision of Specification Plans.....	42
Specification Plan Alerts.....	42
Working with Samples.....	42
Creating a New Sample.....	42
Changing Lifecycle Phase of a Sample	43
Entering Results for a Sample.....	43
Splitting a Sample	44
Working with Lot Release Process	44

Creating a New Lot Release Process.....	44
Changing the Lifecycle Phase of a Lot Release Process	45

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.

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) <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.

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.

Introduction to Material Management

This chapter includes the following:

▪ About this Guide	1
▪ Recipe & Material Workspace Documentation	1
▪ Overview.....	2

The Material Management module within the Agile PLM Recipe & Material Workspace (RMW) solution enables you to manage material usage within the development process of a chemical product.

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

- Creating new material - chemical, excipients, buffer, media, solvents, consumables and so on.
- Creating and managing lots and containers.
- Allocating, dispensing, staging and consuming material.
- Viewing and using raw materials, intermediates, and consumables through Work Requests.

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 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>.

Overview

RMW allows you to manage three broad functional areas:

- **Material Library** - Enables you to manage materials within the RMW library. You can add new material objects, place material requests or dispense material.
- **Material Inventory** - Enables you to add and manage lots and containers for materials, as well as dispose, move and ship material.
- **Material Requests** - Enables you to place requests for allocating, dispensing, staging and consuming material.
- **Material Analysis** - Enables you to add and manage assays, samples, and specification plans for material testing.

A typical material workflow consists of the following steps:

1. Engineer sends a request for material allocation from the library to the Material Manager.
2. Material Manager allocates material from local inventory, if material is available. Material Manager requests inter-plant transfer or orders the material from an external source, if it is not available.
3. Warehouse clerk receives the ordered material and enters the record in RMW. Material Manager allocates the received material to the engineer.
4. Engineer creates a Dispense Request on allocated Lots.
5. Material Manager takes material from containers, weighs and places material at a location. (This is called Staging.)
6. Engineer performs assays on materials, qualifies the lots, and enters the assay results in RMW. Then ships the lots.
7. Pilot Plant Technician picks up material, consumes material (executes work requests), keeps or returns the remaining material, and submits finished product to storage

Working with Material

This chapter includes the following:

▪ Adding Material in the Material Library	3
▪ Setting the Material Stock Level	6
▪ Activating or Deactivating Material	7
▪ Changing Material Lifecycle Phase	7
▪ Ordering Material	7
▪ Receiving Material	10

The RMW application maintains records of materials used for clinical supplies. These records are stored in the Material Library. You can add, edit and search for materials in the material library.

Every material that is added to the library must be associated with a category. The material categories are created before you add a new material. Contact your RMW administrator for creating the required material categories.

Adding Material in the Material Library

A material that is to be used in RMW has to be entered in the material library first. When you add a new material to the library, RMW automatically generates a unique Item ID for it.

To add a material in the library:

1. In the **Create New** menu, select **Materials > Library**.
2. In the **Preface** tab, select **Material**.
Select **Chemical** if you are adding a chemical material.
3. Click **Next**.
4. In the **General** tab, enter required information.

Significant inputs:

- **Item Code** — Unique Number or Code given to the material according to which you arrange the material in your catalog for corporate identification.
- **Material Type** — The type of material. Select:
 - **Raw Material**, if it is raw material.
 - **API**, if it is Active Pharmaceutical Ingredient.
 - **Intermediate**, if it is an intermediate product during the production of an API.
 - **Consumable**, if it is a consumable. If you select **Consumable**, you can mention its receiving unit in the **Characteristics** tab.
 - **Final Product**, if it is the end product.
- **Compound Number** — The identification number of the material compound.

5. Click **Next**.
6. In the **Characteristics** sub-tab under **Details** tab, enter required information.

Significant inputs:

- The following fields appear only if you have selected **Chemical** in the **Category** tab. Skip these fields, if you added a non-chemical material.
 - **Density** — The density of the chemical in numbers. This is used when converting the UOM from Liters to KG while storing in the system.
 - **Physical State** — Physical state of the chemical; Solid, Liquid or Gas.
 - **Molecular Weight** — Molecular weight of the chemical in number.
 - **Molecular Formula** — Molecular formula of the chemical.
 - **Min Purity Level** — Lower purity level of the chemical, in percentage.
 - **Max Purity Level** — Upper purity level of the chemical, in percentage.
 - **Lower Explosion Limit** — Lowest concentration needed for the chemical to ignite and explode, in percentage.
 - **Upper Explosion Limit** — Upper most concentration needed for the chemical to ignite and explode, in percentage.
 - **Average Boiling Point** — Average boiling point of the material.
 - **Average Melting Point** — Average melting point of the material.
 - **Average Freezing Point** — Average freezing point of the material.
 - **Vapor Pressure** — Pressure at which the vapor of the new chemical is in dynamic equilibrium with its non-vapor phases.
 - **Auto Ignition Temperature** — Lowest temperature at which the new chemical will spontaneously ignite.
 - **Sampling Exemption Flag** — Indicates if the new material requires sampling. Selecting **Yes** implies the material is exempted from sampling.
 - **Consumable Receiving Unit** — This field appears only if you have selected **Consumable** in the **General** tab. Specify the unit of measurement for receiving the consumable.
7. Click **Next**. **Safety & CAS** sub-tab appears if you have selected **Chemical** in the **General** tab. Skip the following two steps, if you have selected **Consumable**.
 8. In **Safety & CAS** sub-tab, enter required information.

Significant inputs:

- **DEA Controlled Substance Flag** — Select **Yes** or **No** to specify if the chemical is regulated by the Drug Enforcement Administration.
- **EU Controlled Substance Flag** — Select **Yes** or **No** to specify if the chemical is regulated by the European Union.
- **SEVESO Controlled Substance Flag** — Select **Yes** or **No** to specify if the chemical is regulated by the Seveso Directive.
- **Cyanide Substance Flag** — Select **Yes** or **No** to specify if the chemical is a cyanide substance.
- **DOT Regulated Flag** — Select **Yes** or **No** to specify if the chemical is regulated by the Department of Transportation.
- **MSDS URL** — Enter the location of material safety data sheets.
- **Too Dangerous to Test** — Select **Yes** or **No** to specify if the chemical is dangerous to be tested.

9. In **CAS Composition**, click **Add Rows**.
10. Search and select the Chemical Abstracts Service (CAS) number for the material.
11. Click **OK**. The page returns to CAS Composition and the selected CAS number appears in the field.
12. In **Percentage**, specify the percentage of CAS contribution to the material composition. All the CAS percentage for a material must add up to exactly 100%.

Note You can add a CAS record also from **Environment > CAS**. For more information, see Working with Environment in *Getting Started with Recipe & Material Workspace Guide*.

13. Click **Next**.
14. In the **Storage and Handling** sub-tab under the **Details** tab, enter the required information.

Significant inputs:

- **Safety Storage Condition** — Type of safety storage condition to indicate if the material should be segregated for safety purpose.
- **Moisture Sensitivity** — Indicates if the material is sensitive to moisture.
- **Air Sensitivity** — Indicates if the material is sensitive to air.
- **Handling Precautions** — Provide specific instructions if the material requires additional caution during handling.
- **Peroxide Forming Flag** — This field appears if you have selected **Chemical** in the **General** tab. Select **Yes** or **No** to specify if the chemical is a peroxide forming substance.
- **NFPA H** — Denotes the level of possible injury as per National Fire Protection Association standards.
 - Select **0**, if exposure under fire conditions would offer no hazard beyond that of ordinary combustible material.
 - Select **1**, if exposure would cause irritation but only minor residual injury.
 - Select **2**, intense or continued but not chronic exposure could cause temporary incapacitation or possible residual injury.
 - Select **3**, if short exposure could cause serious temporary or residual injury.
 - Select **4**, if very short exposure could cause death or major residual injury.
- **NFPA F** — Denotes the susceptibility of material to burning as per National Fire Protection Association standards.
 - Select **0**, if the chemical does not burn.
 - Select **1**, if the chemical must be pre-heated before it burns.
 - Select **2**, if the chemical must be moderately heated or exposed to relatively high ambient temperature before it burns.
 - Select **3**, if the chemical is a liquid or solid that can burn under almost all ambient temperature conditions.
 - Select **4**, if the chemical either rapidly or completely vaporizes at atmospheric pressure and normal ambient temperature, or if it is readily dispersed in air and burns readily.
- **NFPA R** — Denotes reactivity of the chemical with water as base as per National Fire Protection Association standards.
 - Select **0**, if the chemical is normally stable, even under fire exposure conditions and is

not reactive with water.

- Select **1**, if the chemical is normally stable, but can become unstable at elevated temperatures and pressures.
- Select **2**, if the chemical readily undergoes violent chemical change at elevated temperatures and pressures or reacts violently with water or form explosives mixtures with water.
- Select **3**, if the chemical is capable of detonation or explosives decomposition or reaction but requires a strong initiating source or which must be heated under confinement before initiation or which reacts explosively with water.
- Select **4**, if the chemical is capable of detonation or explosives decomposition or reaction at normal temperatures and pressures
- **NFPA S Carcinogen** — Indicates that the user requires special protective gear while using the chemical.
- **NFPA S Suspect Carcinogen** — Indicates that the user requires special protective gear while using the chemical.
- **NFPA S Allergen** — Indicates that the user requires special protective gear while using the chemical.
- **NFPA S Reproductive Hazard** — Indicates that the user requires special protective gear while using the chemical.
- **NFPA S Highly Potent** — Indicates that the user requires special protective gear while using the chemical.
- **NFPA S Water Reactive** — Indicates if the chemical reacts when exposed to water.
- **NFPA S Oxidizer** — Indicates if the chemical is an oxidizer or not.
- In **Acceptable Containers MOC**, click **Add Material of Construction** to look up the material acceptable for the container in which the material is stored or handled. Select the material of construction and click **OK**.

When a new material is made, and placed into a container, this acceptable containers MOC definition is used. You will be warned if the MOC definition is different from the MOC of the container in which the material is being stored. For more information, see *Recipe & Material Workspace Administrator Guide*.

15. Click **Finish**.

Setting the Material Stock Level

You have to define and maintain the stock levels for materials in various sites from time to time.

To set the stock level for material:

1. Search **Materials > Library** and select a material record.
2. Select **More > Set Stock Level**.
3. Click **Add Site** to search and select the sites whose stock levels you wish to set. You can select one or more sites to set the stock requirements.
4. Click **OK**.
5. For each site that you added, enter the following:
 - **Inventory Restock Level** - The level of the inventory quantity at which restocking is required.

- **Quantity Adjustment Threshold** - The inventory adjustment limit for a lot or container in percentage.

6. Click **OK**.

Activating or Deactivating Material

You can activate or deactivate a material in the material library to indicate that a particular material is available for use or not. You can use a material only when it is in active state in the material library.

When you perform transactions on an inactive (deactivated) material, a warning is issued. You can also remove the inactive material and add another active material.

To activate or deactivate a material record:

1. Search **Materials > Library** and select a material record.
 2. Click **More**, and:
 1. Select **Activate** to activate the material.
 2. Click **OK**.
- Or
3. Select **Deactivate** to deactivate the material.
 4. Click **OK**.

Changing Material Lifecycle Phase

The Lifecycle Phase of a material can be changed manually or through a workflow. A material can be used in a process only if it is in the **Approved** state. You can edit a material only if it is in the **Draft** status.

To change the lifecycle phase of a material:

1. Search **Materials > Library** and select a material record.
2. Click **Change > Lifecycle Phase**.
3. Select an appropriate state:
 - **Draft**, to add a new material.
 - **Submitted**, to submit the material for approval.
 - **Approved**, to approve the submitted material. You have to first submit a material before it can be approved.
 - **Rejected**, to disapprove the submitted material. You have to first submit a material before it can be rejected.

Ordering Material

RMW Management allows you to record the purchase or transfer order details. When you do not have a material in stock, or when there is an immediate Allocation Request for a particular material that is out of stock, you can order it from an external vendor or you can do an inter-plant transfer.

You can:

- Add details of a material ordered from an external vendor or for an inter-plant transfer.
- Locate an order by its Purchase Order Number.
- Locate all the material purchased through a single order
- Modify an order
- Change the status and cancel an order

Once an order is fulfilled, that is the ordered materials are received, it is entered into RMW inventory. Each time a received quantity is entered into RMW, the corresponding order status is also updated.

An order can have any of the following states:

- **Pending** — order is added, but the ordered material have not been received.
- **In Progress** — some material has been received.
- **Completed** — all the ordered materials and their quantities have been received. The order status is automatically changed to *Completed*.
- **Canceled** — order has been canceled. You can only cancel an order, if the order is in *Pending* state.

You cannot change the status of an order from *Pending* to *In-Progress* or from *In-progress* to *Completed* manually.

The status of the order changes from *In Progress* or *Pending* to *Complete* when you have received all the materials of that order. The status changes from *Pending* to *In-progress* when the order is partially fulfilled.

Creating a Material Order

When there is a need to replenish the inventory, or when there is an immediate Allocation Request for a material that is not available in the inventory, you can place purchase orders.

You can place orders in one of the following ways:

- Add Order for consumables or non consumables
- Add Order from Inventory
- Add Order from Allocation Request
- Add Order from Library

A newly added order is in *Pending* state.

To create a new order for material:

1. In the **Create New** menu, select **Materials > Order**.

Note You can also create a new order from:
Search **Materials > Library**, select the desired material and click **More > Order**.
Search **Materials > Inventory**, select the desired material and click **More > Order**.

Note Search **Materials > Allocation**, select the desired material and click **More > New Order**.

2. In the **General** tab, enter required information.

Significant inputs:

- **Is Consumable** — Check this box if the material is used as a consumable.
- **Purchase Order Number** — The purchase order number to identify the receipt of materials. This number cannot be changed once the order is in **In Progress** state.
- **Vendor** — The vendor or the source site. If the **Order Type** is **Inter Plant**, you need not fill this field.

3. Click **Next**.
4. In the **Material List** tab, click **Add Material**.
5. Select the material from the list and click **OK**.

If you selected **Is Consumable** checkbox in the **General** tab, make sure that you add only consumable material from the list. If you select a non-consumable material, the application will throw an error.

Note When you do not place the order through **Create New** menu selection of **Material > Order**, the material details you entered earlier in the application appear automatically in the fields.

6. To remove one or more material from the list, select those records and click **Delete**.

Note You should leave at least one material in the list.

7. Click **Next**.
8. In the **Order** tab, enter **Total Quantity Ordered** and select the unit of measurement.
9. Click **Finish**.

Note If you add inactive or unapproved material, the application issues a warning , You can proceed to place the order by clicking **OK**.

Editing a Material Order

Once an order is placed, you edit the order details. You can only edit orders that are in *Pending* or *In Progress* status.

You can change the purchase order number, expected arrival date, source site, add or remove materials and the change total quantity of the material on the order. However, you cannot change the order ID, order type and order date.

When you edit an *In-Progress* order, the total ordered quantity for any material in the order cannot be less than received quantity for that material. You cannot edit the Purchase Order Number for an *In Progress* order.

Note If the order has an associated Allocation Request, a tree view with the material and the corresponding Allocation Request ID is listed in **Materials**.

Changing Material Order Lifecycle Phase

When you create a material order, it is in *Pending* state of its Lifecycle Phase. Once the material is received, the order automatically moves to *Completed* state. If the material is received partially, the order remains in *In Progress* state.

You can cancel orders only in *Pending* state. You cannot use a canceled order in any of the processes.

To cancel a material order:

1. Search and select a material order.
2. Click **Change > Lifecycle Phase > Canceled**.

Receiving Material

When you receive a material, you have to add a receipt for it in the RMW application. The material inventory is created mainly through the receiving process. You can record details for:

- Externally received material — materials that are received from external vendors
- Internally received material — materials that are received through inter-plant transfers

You can:

- Add material lots and container that are received through external vendors or inter-plant transfers into RMW inventory.
- Modify details of the received material
- Print a label for the received lots or containers

When you enter a received item into the RMW, the corresponding order status is also updated. The status of the order changes from *In Progress* or *Pending* to *Completed* when you have received all the materials in that order. Also, the status changes from *Pending* to *In Progress* when you receive some materials in the order.

- If the status is *In Progress*, the source ID is generated. You can only cancel or edit the receipt.
- If the status is *Completed*, all materials associated with the source ID have been received.
- If the status is *In Progress* or *Complete*, the received lots are added into inventory.
- You can only cancel the receipt record, if the object status is *In Progress*.
- You cannot receive any container for a lot that is disposed.

When the ordered material is received, you have to add a receipt to the RMW inventory. Each received material can have lots from multiple manufacturers.

Lot that is received can be a new lot or an existing lot. If it is an existing lot, you can enter the details for the newly received containers that are a part of that lot.

You have to enter details for each lot and the container received for a lot.

The container quantity sums up to the received quantity of the lot.

Once you enter a receipt for a material that is received, the RMW automatically increases the "Quantity On Hand" of the received material in the inventory by the Received Quantity. The order status for the order item is also updated when the material is received.

You can only receive one consumable material container at a time.

Adding a Material Receipt

You can add a new receipt for an order, either for a consumable or non consumable. You can also add an ad-hoc receipt, without creating an order in RMW.

You can receive a consumable material, one container at a time. For a consumable material, the container level tracking is turned off, by default. Consumable receiving will capture Consumable Quantity instead of Container Net Weight.

To add a material receipt:

1. In the **Create New** menu, select **Materials > Receiving**.

Note You can also add a material receipt from:

Note Search **Materials > Receiving**, select a material Order and click **New Receiving**.

2. In the **General** tab, enter required information.

Significant inputs:

- **Is Expendable** — If the material can be used completely for consumption.
- **Order** — The order ID for which you are receiving the material.
- **Vendor** — The ID of the Site from where you receive the material. This has to be a qualified site and it should be different from the Receiving Site.
- **Bill of Lading** — The verification document that comes along with the shipment.
- **Receiving Site** — The ID of the Site where the order is received. It should be different from the Vendor Site ID.

3. Click **Next**.

4. In the **Materials** sub-tab under **Details** tab, enter the **Number of Lots** in for each Material.

The Material table lists the material that was ordered in the selected Order. This Order number is automatically populated in the **Purchase Order Number** field.

5. To receive any material other than that is received against the given Order, click **Add Material**.
6. Search and select material and click **OK**.
7. Enter the **Number of Lots** in which the total quantity of material is received.

Note If you want to fill the same value in this field across multiple records, use Fill Down function. For complete details, see *Getting Started with Recipe & Material Workspace Guide*.

8. Click **Next**.

9. In the **Manufacturer** sub-tab under **Details** tab, enter required information.

Significant inputs:

- The number of rows that appear under each material correspond to the **Number of Lots** you specified in the **Materials** sub-tab.
- **Manufacturer Lot** - The identification number assigned to each Lot by the manufacturer. This field is mandatory.
- **Internal Lot Number** - This is generated by the application.
- **Manufacturer Same As Vendor** - Select **Yes** or **No** to indicate if the manufacturer and the vendor are the same.
- **Manufacturer** - Search and select the manufacturer name.

10. Click **Next**.

11. In the **Lot Details** sub-tab under **Details** tab, enter required information.

Significant inputs:

- **Quantity Received** - The quantity of material received. Note that the quantity received in the current Lot can be less than the quantity ordered.
- **Number of Containers** - The number of containers used for shipping the given Lot.
- **Status** - The status of the material in the given lot after inspection and initial verification.
- **COA** - Indicates if the list of the analytical tests, acceptance criteria and results made on the lot, is available or not.
- **TSE** - Indicates if the Transmissible Spongiform Encephalopathy Certificate, which is used for denoting the presence of animal products in the lot, is available.

12. Click **Next**.

13. In the **Container Details** sub-tab under **Details** tab, enter the information.

Significant inputs:

- **Package Verified** - The result of verification or inspection of the package.
- **Container Type** - This field appears for non-consumable receipt.
- **MOC** - Material of construction of the container.
- **Gross Quantity** - Total Weight (mass) of the material and container, including packing. This field appears if the material received is non-consumable.
- **Tare Quantity** - Mass of an empty container including all fittings and appliances associated with that particular type of container on its normal operating condition. This field appears if the material received is non-consumable.
- **Net Quantity** - The weight of the material in the container. This is equal to the difference of gross weight and tare weight.

Note Sum of net weight for all received containers should be same as the Quantity received for the lot.

- **Status** - The status of the container.
- **Import Status** - The status of the material when it was imported into the United States of America.

14. Click **Finish**.

Editing the Material Receipt

You can edit receipt details and also:

- Add or remove material items
- Add or remove lots/containers

You can edit the details for a received lot or container only if it has not been allocated. However, the edited quantity should not be below the allocated quantity. The container status has to be *In Progress* for you to edit its details.

You can remove a lot or a container only if no transactions have taken place on any of the lots or containers. When you remove a material from the receipt, all associated lots and containers are also removed.

If a received container has not been allocated at all, it can be edited or removed. Also, if no container from a received lot is allocated, the received lot can be edited or removed.

You can also edit details such as Receiver User ID, Date of Receipt, Receiving Site ID, Vendor Site ID and Purchase Order Number.

Changing Material Receipt Lifecycle Phase

You can set the status of the receipt details to any one of the following:

- **In Progress** — when the request is in progress.
- **Completed** — when the request is completed.
- **Canceled** — when the request is canceled.

To change the lifecycle phase of material receipt:

1. Search and select a material receipt.
2. Click **Change > Lifecycle Phase** and select the applicable state.

Working with Material Inventory

This chapter includes the following:

▪ Adjusting Material Quantity	17
▪ Disposing Material	17
▪ Moving Material	19
▪ Changing Lifecycle Phase of Lots	19
▪ Splitting Containers	20
▪ Merging Containers	20
▪ De-allocating Material	21
▪ Monitoring Inventory Level	22
▪ Material Inventory Alerts	22

The RMW Material Inventory helps you manage the details of Lots and Containers that handle material. You can manage disposal, movement, shipping, consumption and return of lots and containers in the material inventory.

Lots

RMW records the following details for a lot:

- **Lot Number** — The identification number of the lot.
- **Status** — The status of the lot. A lot, like a container, can have the following status:
 - *To Be Evaluated* — This is the default status. The lot or container is yet to be evaluated and approved or rejected. You cannot use a To Be Evaluated lot or container in a Clinical Supply process. You can use a To Be Evaluated lot or container in a Development process, but you receive a warning message.
 - *In Production* — The lot is being manufactured internally through a Work Request.
 - *Rework* — The internally manufactured lot may need further refinement before use.
 - *Evaluated* — The lot has at least one Approved and current submission.
 - *Planned for Disposal* — The lot is planned for disposal.
 - *Rejected* — The lot is rejected and not fit due to some reason.
 - *Quarantined* — The lot was approved, but is now set aside for further analysis for some reason. You cannot use a Quarantined lot or container in a Clinical Supply process. You can use a Quarantined lot or container in a Development process, but you receive a warning message.
 - *Hold* — The lot or container is held from usage. You cannot use it in any process.
 - *Disposed* — The lot is no longer available for use. The quantity of material on hand for this lot is set to zero.
- **Manufacturer** — The company which manufactured the lot. If the lot is manufactured in-house, it automatically appears with the lot.

- **Manufactured Date** — The date of manufacturing the lot. If the lot is manufactured in-house, this date is the Actual End Date of the associating Work Request.
- **Import Status** — The status of the material when it was imported to the United States.
- **Final Form** — This detail indicates if the lot is in final form. If the lot is manufactured in-house, it automatically appears with the lot.
- **TSE Certificate** — This detail specifies if the Transmissible Spongiform Encephalopathy Certificate to indicate the absence of animal products in the lot, is available on file.
- **Supplier Lot Number** — The Identification number of the supplier of the lot.
- **Responsible Person** — The person responsible for the Work Request that produced the lot. If the lot is manufactured in-house, it automatically appears with the lot.
- **Expiration Date** — The date on which the lot of material expires.
- **Stability Study** — This detail indicates if a sample of the lot has been put on stability testing.
- **Storage Site** — The location to store the lot.
- **Contact Person** — The person in charge to make decisions regarding the lot of material.
- **Number of Container** — The number of containers inside the lot.
- **Date of Receipt** — Date the lot was received or added to a site
- **Certificate of Analysis** — The list of the analytical tests, acceptance criteria and results made on the lot.

Containers

A container can be of any size and shape. It can be manufactured from a variety of materials. It can have different Gross Weight, Tare Weight and Net weight.

The RMW facilitates recording of the following details for a container:

- **Container ID** — The identification number of this container.
- **Material of Construction** — The material used for constructing this container.
- **Size** — The capacity of the container.
- **Gross Weight** — Total weight of the container, including the material.
- **Tare Weight** — The weight of the container without the material.
- **Storage Location** — The location to store the container.
- **Comments** — Additional comments regarding the container.
- **Manufactured Date** — The date of manufacturing the container.
- **Original Quantity** — The quantity of material in the lot when it was received.
- **Quantity on Hand** — Quantity of material in the container.
- **Quantity Available** — Quantity of material available for use in the container.

Note Lot status is always the default status of the container.

Adjusting Material Quantity

You can adjust the inventory for consumables and non consumables, if the Quantity on Hand does not match the Quantity Available. There is a threshold limit up to which you can adjust the inventory. This Inventory Adjustment Threshold is calculated in percentage.

If you exceed this limit while adjusting the inventory, RMW sends an alert to the Material Managers and other subscribers. At this point, RMW resets the value of the Total Quantity Adjusted to Zero. Also, the adjustments requested are applied to the lots/container simultaneously.

Low inventory level is the lowest stock limit. If the Quantity on Hand is lesser than the Low inventory level, the material manager receives an alert to restock the inventory.

To adjust the material quantity:

1. Search and select an Inventory.
2. Click **More** and select **Adjust Quantity**.
3. In **Reason For Adjustment**, enter reason for changes.
4. In **Adjustment Date**, by default the current date appears. Click within the field and select the date of adjustment. You cannot update this date later.
5. In **Adjusted by**, by default the current user's ID appears. Search and select the name of the user. You cannot update this name later.
6. Click **OK**.

Disposing Material

The material may be disposed for the following reasons:

- Material shelf-life has exceeded (for vendor-supplied materials, found in material specification).
- Contamination or breakage.
- Project place in *Parked* status.

To dispose a material you have to first plan the disposal. You can select one or more lots/containers and enter a planned disposal date.

Once a lot/container has been disposed, RMW resets or decrements the inventory for the container and also changes the site for the container to the disposal site.

A disposed material has the following states:

- Plan for Disposal — When planned disposal date is entered, the lot/container is in the *Plan for disposal* status.
- Disposed — When actual disposal date is provided, the lot/container is in the *Disposed* status.

If a lot/container is planned or confirmed for disposal, it can still be used until it is actually disposed. The actual disposal date and time should not be earlier than the last transaction date and time.

You cannot receive any container for a lot that is disposed.

Effect of disposing material on inventory

Once a lot or container is disposed, RMW resets or decrements the inventory for the container and also changes the Site for the container to the disposal site.

RMW decrements a material's quantity from the inventory in four situations:

- When a material is consumed for a process.
- When the material is dispensed to another plant/or for consumption.
- When the material is disposed.
- When the material is allocated.

Total inventory quantity for each lot is the summation of both quantity on hand and available quantity of associated containers.

Planning Material Disposal

To plan a disposal for the inventory:

1. Search **Materials > Inventory** and select desired material.
2. Click **More > Plan Disposal**.
3. Enter the following information for each container:
 - **Planned Disposal Date** — Specify the scheduled disposal date. This cannot be a past date.
 - **Comments** — Enter any additional information.
4. Click **OK**.

Disposing the Material Planned for Disposal

Once a material inventory is in *Planned for Disposal* state, you can dispose the material. A disposal plan can contain one or multiple lots/containers of different materials.

When you have selected a lot for disposal, only the comprising containers that are in inventory is disposed. Containers currently out of inventory are not affected by the disposal plan.

To dispose the material planned for disposal:

1. Search **Materials > Dispose** and select a planned disposal record.
2. Click **Dispose**.
3. Enter required information.

Significant inputs:

- **Actual Disposal Date** — The actual date when the inventory has to be disposed. The actual disposal date and time should not be earlier than the last transaction date and time.

- **Disposal Method** — The method used to dispose the inventory.
 - Select **Incineration** to burn the waste.
 - Select **Sewer** to send the waste to sewage pipes.
 - Select **Sent to Waste Mgmt Company**, if you send the waste to any Waste Management Company.
 - **Waste Stream ID** — The ID of the waste stream.
 - **Site of Disposal** — The location where the inventory has to be disposed.
 - **Disposed By** — The ID of the user who disposed the material.
4. In the **Inventory** table, change the **Disposal Location**, if required.
 5. Click **OK**.

Moving Material

You can move material from one location to another.

To move material:

1. Search **Materials > Inventory** and select material.
2. Click **More > Move**.
3. In **Move** page, enter the following:
 - **Moved On** — By default, the present date appears in the field. Change the date, if required.
 - **Moved By** — By default, the logged-in user's ID appears in the field. Search and select the user who moves the material.
 - **Reason for the Move** — Enter the reason for moving the material.
4. In the **Inventory** table, for each container in the lot, search and select the **To Location** where the material has to be moved.
5. Click **OK**.

Changing Lifecycle Phase of Lots

You can change the status of a lot. When you change the status of a lot, the status of all containers associated with that lot also changes.

To change the lifecycle phase of a lot:

1. Search and select the lot.
2. Click **Change > Lifecycle Phase** and select an appropriate state.
 - **To be Evaluated**, lots which need evaluation.
 - **Rejected**, if you have evaluated and found the lot unsuitable to be used.
 - **Quarantined**, if the lot has been quarantined for some reason.
 - **Evaluated**, lots which are evaluated.
 - **Approved**, if you have evaluated and found the lot suitable to be used.

Splitting Containers

You can transfer material from a single container to other new or existing containers. Ensure that total inventory balance before and after split transaction remains the same. The status of the new container is same as that of the parent container.

To split a container:

1. Search **Materials > Inventory** and select the container.
2. Click **More > Split**.
3. In **Target Containers** table, enter the number of containers required for the transfer and click **Add Rows**.
4. For each container, enter required information.

Significant inputs:

- **Container Gross Weight** - Total Weight (mass) of the material and container, including packing.
- **Container Tare Weight** - Mass of an empty container including all fittings and appliances associated with that particular type of container on its normal operating condition.
- **Container Net Weight** - The weight of the material in the container. This is equal to the difference of gross weight and tare weight.
- **Import Status** - The status of the material when it was imported into the United States of America.
- **Material of Construction** - Select material of construction of the target container from the drop-down list.
- **Container Size** - Enter Container Size and select a unit of measurement.
- **Container Type** - The type of the target container.
- **Container Status** - The status of the target container.
- **Container Location** - The current location of the container.

5. Click **OK**.

Merging Containers

You can transfer a quantity of material from multiple containers to a new or existing single container. Ensure that total inventory balance before and after merge transaction remains the same. The containers chosen to be merged must belong to the same lot.

To merge containers:

1. Search **Materials > Inventory** and select two or more containers.
2. Click **More > Merge**.
3. In the **Source Containers** tab, enter **Quantity To Merge** for all the containers.

This is the quantity of material that is taken from each of the source containers and merged into the Target Container.

4. Click **Next**.
5. In the **Target Containers** tab, enter required information.

Significant inputs:

- **Container Type** - The type of the target container.
- **Package Verified** - Select the result of the verification of the package
 - **Accepted**, if the package is approved.
 - **Damaged**, if the package is found damaged.
- **Import Status** - The status of the material when it was imported into the United States of America.
- **Gross Weight** - The gross weight of the target container.
- **Tare Weight** - The tare weight of the target container.
- **Net Weight** - The net weight of the target container.
- **Container Status** - The state of the target container.
- **Container Size** - The size of the container.
- **Material of Construction** - The material of construction of the target container.
- **Container Location** - Search and select the current location of the container.

6. Click **Finish**.

De-allocating Material

To fulfill a critical request for a material that is not immediately available in inventory, you may want to free up that material from another existing Allocation Request. This can be done through the process of De-allocation.

RMW displays the Available Quantity (Qty on Hand - Quantity Allocated) for all the containers of a selected Allocation Request material item, from which you can decide on the quantity to be de-allocated for each.

Once a container is de-allocated from an allocated material list, an alert is sent to the associated people. Also, the Available Quantity for the lot/container is updated, thus freeing up some more material from the allocated list which you can allocate to another user.

Even after a lot or container is relieved from an allocated list, RMW maintains a log of previous owner and project assigned to the lot/container.

You can de-allocate material from an Allocation Request in *Completed* status. You can de-allocate material from an Allocation Request in *In Progress* status, if the material is not used anywhere else. De-allocation cannot be done on allocation requests that are in the *Draft* or *Submitted* or *Approved* status.

To de-allocate material:

1. Search **Materials > Inventory** and select a material record.

Note You can also de-allocate material by searching **Material > Allocation** and selecting material.

Note The Allocation Request should be in *In Progress* or *Completed* status and it should not have reference to any Dispense Request.

2. Click **More > Deallocate**.
3. In **Quantity to Deallocate**, enter the quantity to be de-allocated for each container. This quantity should not be more than the allocated quantity.
4. Click **OK**.

Monitoring Inventory Level

The RMW allows you to monitor the material inventory level at site level and ensure that the material is not less than the restock levels. You need to ensure that the material is always stocked at a required minimum level.

If inventory level is less than the restock limit, a mandatory alert is initiated to warn the Material Manager that the inventory needs to be restocked. The alert message contains the details of the material to be restocked such as the material name, common name, item ID, item code, restock limit and quantity on hand.

Material Inventory Alerts

The following alerts are triggered at various stages of processing the inventory:

- **Lot/Container Quarantined Alert** — This is a mandatory alert that is sent when a lot or container has been quarantined.

The alert message contains details such as lot number, quarantined date, quarantined by and reason for quarantining.

If an entire lot has been quarantined, the alert message displays the lot number. If only a container has been quarantined, then the container and its associated lot are displayed in the alert message.
- **Expiration Alert** — This is a mandatory alert that is sent on the expiration date of a lot. The alert message contains details such as lot number, material name, item ID and expiration date.
- **Exceed Adjustment Threshold Limit Alert** — This is a mandatory alert that is sent when the inventory adjustment exceeds the adjustment threshold limit. The alert message contains details of the lot that has exceeded the inventory adjustment threshold.
- **Restock Limit Alert** — This mandatory alert that is sent to warn the Material Manager that the inventory needs to be restocked. The alert is sent when the quantity on hand of a material at a site is equal to the restock limit. The alert message contains the details of the material to be restocked such as the material name, common name, item ID, item code, restock limit and quantity on hand.
- **OSHA TPQ** — This alert is sent when the amount in inventory for that material reaches the amount specified in the OSHA TPQ attribute set for that material. This is not a mandatory alert.

You can also configure custom alerts to suit your requirements. Contact your RMW administrator.

Working with Material Requests

This chapter includes the following:

▪ Allocating Material	23
▪ Dispensing Material	26
▪ Staging Material	28
▪ Consuming Material	31

Material requests are transactions that are carried out on material inventory. An engineer raises request for allocating, dispensing, staging and consumption of material.

Allocating Material

When you require material for your project, you send an Allocation Request to the material manager. If the material is available in the inventory, the material manager allocates it to you. If not, the material manager sources it from vendor or another site and allocates it to you.

Sourcing is of two kinds. The material manager can either purchase the material through an external vendor, or make the material available through an inter-plant transfer.

Allocation process involves:

- Creating an Allocation Request, modifying and canceling it.
- Sourcing the material to fulfill the Allocation Request. The methods include:
 - Purchasing material through an external vendor
 - Inter-plant transfer
 - Allocating from existing inventory
 - Locating Allocation Requests
 - De-allocating the material

The Allocation Request process entails:

1. Engineer request for material.
2. Manager gets material from local inventory.
Or
3. Manager decides to Order material.
 1. Manager orders material from outside.
 2. Manager requests for Inter-plant transfer.
4. Manager receives material and adds to the library.
5. Manager allocates material to Engineer.

A newly created Allocation Request is in the *Draft* status. Allocation Request cannot be fulfilled until the request is in *Approved* or *In Progress* state. The status of an Allocation Request changes as the associated workflow state changes. You can also change the status of an Allocation Request manually. You can create Allocation Requests based on the access permission assigned to your role and user ID.

All the materials that are added to the Allocation Request have to exist in the Material Library. You cannot specify the lots or containers when you create the Allocation Request. You can create Allocation Requests for API or non API substance. But, you cannot create Allocation Requests for consumable material.

Note An Allocation Request can be saved in *Draft* state and submitted later.

Creating an Allocation Request

When you do not know in which work request the material is going to be consumed, but you want a list of materials to be allocated for the project, you create an Adhoc Allocation Request. The RMW prompts you to enter the corresponding project name when you are creating an Adhoc Allocation Request.

To create an allocation request:

1. In the **Create New** menu, select **Materials > Allocation**.

Note You can also allocate material from:
Select **Materials > Allocation**

Note Search **Materials > Library**, select a material record and click **More > Create Allocation Request**.
Search **Materials > Inventory**, select a Lot and click **More > Create Allocation Request**.

2. In the **General** tab, enter required information.

Significant inputs:

- **Choose One** — Select any one of the names or IDs to identify a Project, Campaign, Process Step or Work Request associated with the Allocation Request.
- **Responsible Person** — The ID of the person responsible for the Control Recipe.
- **Operating Mode** — Select the operating standard for the allocation.
 - **Clinical Supply**, if you request the material for clinical trials.
 - **Development**, if you request the material for experimental development.
 - **Not Applicable**, if you do not wish to associate an operating mode with the request.
- **Allocation Site** — The ID of the site to which the material manager allocates the material.

Note The site ID cannot be changed once the Allocation Request gets approved.

3. Click **Next**.
4. In the **Material List** tab, click **Add Material**.
5. Search and select the material and click **OK**.

Note You should select at least one material for the Allocation Request.

6. For each material you add, enter **Original Requested Quantity** and **Need By Date**.
7. Click **Finish**.

Allocating Material

You can fulfill an Allocation Request that is in the *Approved* or *In Progress* or *Completed* states.

Initially, you search for the Allocation Request that is to be fulfilled and select the material items in the request. For each selected allocation material item, RMW displays the lots/containers that have Quantity on Hand as greater than zero.

The allocation ID, comprising the material items, lots and containers are all displayed as a hierarchical tree with the container at the lowest level. You can select the Quantity On Hand, Quantity Allocated and Quantity Available for each container before you fulfill the request. You select a container and enter the Allocated Quantity to record an allocation transaction in RMW.

For each Allocation Request material item, if the Allocated Quantity is equal or greater than the **Current Requested Quantity**, then the status of the Allocation Request Line Item is **Fulfilled**.

The requested material items can be completely fulfilled or partially fulfilled depending on the quantity allocated. The partially allocated material item is in *Pending* state and the partially fulfilled Allocation Request is in *In Progress* status.

An Allocation Request can be allocated only if it has inventory in the allocation site. When you allocate a material from the inventory, the available inventory quantity is updated. Once an allocation is completed for a line item, Agile RMW updates its status to *Fulfilled*.

To allocate material according to an allocation request:

1. Search **Materials > Allocation** and select **Allocation Request**.
2. Click **More > Allocate**.
3. In **Select Container Stored at**, select the sites to be displayed in Allocation table.
 - Select **Allocation request site or its descendant sites** to show materials in the allocation site.
 - Select **All Sites** to show materials in all the sites.
4. Enter the quantity allocated for each container in **Allocated Quantity**.
5. Click **OK**.

Changing Lifecycle Phase of Allocation Request

To change the lifecycle phase of an allocation request:

1. Search **Materials > Allocation** and select an Allocation Request.
2. Click **Change > Lifecycle Phase** and select applicable state:
 - **Draft**, to add a new Allocation Request. You cannot allocate any material items in this request, until it moves to *In Progress* or *Approved* status.
 - **In Progress**, if any requested line item in the Allocation Request is partially allocated.
 - **Completed**, if all the material items are allocated.
 - **Canceled**, to cancel an Allocation Request.

- **Submitted**, to submit the Allocation Request. When you submit an Allocation Request through workflow task, it automatically moves to the *Submitted* state.
- **Approved**, if the request is ready to be fulfilled.
- **Rejected**, to disapprove the Allocation Request.

3. Click **OK**.

The status of the comprising line items in an Allocation Request affects the status of the Allocation Request itself.

An Allocation Request material item can have the following status:

- **Requested** — When you create a new Allocation Request, the material items that comprise the Allocation Request are in this state, by default.
- **Pending** — When a material item is partially allocated, it is in the "Pending" status.
- **Fulfilled** — When the allocated quantity of the line item is equal to or greater than the current requested quantity, then it is in the "Fulfilled" status.

Viewing Allocation Status

To view the status of an allocation request:

1. Search **Materials > Allocation** and select an Allocation Request.
2. Select **More > View Allocation Status**.

You can view the status of the Allocation Request according to the display preference set in **Display**.

Dispensing Material

Dispensing is making the material available to the users. The Dispensing component in RMW automates the process of dispensing an allocated material, staging, pick-up, consumption and return of the picked up material.

When you, as the engineer/requester, submit a Dispense Request to the material manager, the material manager stages the dispensed material. You pick up the qualified material for consumption, consume it and return the unconsumed material, if required. You can only create a Dispense Request for a material that is already allocated to you.

The Dispense Request process entails:

1. Engineer request for material by raising an Allocation Request.
2. Manager allocates or reserves material.
3. Engineer creates Dispense Request for shipping or point of use.

The Dispense Request can be created with Allocation Request.

4. Manager Stages the material for Engineer to Pick-up.

You can make a Dispense Request once the Material Manager allocates a lot or container to you. Dispense Requests can be created only for allocation requests with partially or completely fulfilled

material items. You can also dispense without a lot or container allocated to you.

Once a dispensing transaction for a material is completed, an alert message is sent to the users with the material ID, lot number and container number.

Types of Dispense Requests

Dispense Requests are of the following types:

- Dispense Request from Allocation Request — When you make a Dispense Request from Allocation request, fields such as Project, Campaign and Responsible Person automatically take values from the Allocation Request.

A Dispense Request from an Allocation Request can be either for raw materials and intermediates or APIs. Once an Allocation Request is in *In Progress* or *Completed* status, it can be used for creating Dispense Request.

- Adhoc Dispense Request — Dispense Requests without Allocation Requests are called Adhoc Dispense Requests. Adhoc Dispense Request can be either for raw materials and intermediates or APIs.

Creating Material Dispense Request

To create a material dispense request:

1. In the **Create New** menu, select **Materials > Dispense**.
2. In the **General** tab, select one of the following:
 - **Point of Use** - to use the material for a work request or a development project.
 - **Shipping** - use the material for an internal customer or external contact. If you select **Shipping**, two additional fields, **Planned Shipper** and **Planned Ship Date**, appear in the form.

3. Enter the required information.

Significant inputs:

- In Choose One section, select project, campaign, process step, control recipe or work request associated with the Allocation Request. Search and select the required ID or name, as applicable.
- **Operating Mode** - Select
 - **Clinical Supply**, if you request the material for clinical trials.
 - **Development**, if you request the material for experimental development.
 - **N/A**, if you do not wish to associate an operating mode with the request.
- **Fulfillment Site** - The ID of the site where the material will be received.
- **Responsible Person** -
 - If you selected Point of Use, specify the ID of the person responsible for the Control Recipe.
 - If you make Shipping Dispense Request, specify the ID of contact person.
- **Planned Shipper** - This field appears only if you selected Shipping option. Select the company responsible for the delivery of the material, from the drop-down list.
- **Planned Ship Date** - This field appears only if you selected Shipping option. It is the date on which you want the material to be shipped.

- **Point of Use** - This field appears only if you selected Point of Use option. It specifies the location where the material is to be dispensed.
 - **Purpose** - The purpose for which you need the material.
 - **Purpose Details** - Enter any additional details for the selected purpose. This becomes a mandatory field only if you select **Other** in **Purpose**.
4. Click **Next**.
 5. In the **Associated Allocation Requests** tab, click **Add Allocation Request** to add allocation requests.

Note You can associate an Allocation Request for the Dispense Request only if you created it from **Create New** menu. If you created the Dispense Request from an Allocation Request, this step is not required.
 6. Select an **Allocation Request** and click **OK**.
 7. In the **Dispense Details** tab, click:
 - **Add Material** to add materials to the Dispense Request. Select the material and click **OK**.
 - **Add Lot** to add lots to the Dispense Request. Select the lots and click **OK**.
 - **Add Container** to add containers to the Dispense Request. Select the containers and click **OK**.
 - **Delete** to delete the materials, lots or containers from the Dispense Request.
 8. Click **Finish**.

Changing Lifecycle Phase of Dispense Request

To change the lifecycle phase of dispense request:

1. Search and select a Dispense Request.
2. Click **Change > Lifecycle Phase** and select an appropriate status.

Note The options in Lifecycle Phase drop-down list change according to the current state of dispense request. Hence, only the applicable states appear in the list.

Staging Material

A dispensed material goes through the process of staging, picking up, consuming and returning.

Staging is the act of moving a lot / container from an inventory location to a staging area. A stage area is a location where the entire container or a portion is weighed out.

RMW supports two types of dispensing:

- **Central Dispensing** – The Material Specialist weighs out the requested portions of the material into new containers that will be picked up by the Requester.
- **Distributed Dispensing** – The Request picks up the entire container to a new location (plant or development lab), weighs out portions and consumes the material and later returns the original container to inventory.

You can track the process of staging the inventory to the consumption location. Once you have created a Dispense Request in RMW, the Material Manager stages the material. This can be done only for dispense requests that are in *Approved* or *In Progress* status.

If the Dispensing Request contains specific lots or containers or both, you can select and stage those lots/containers that match the requested inventories. When all the requested material items and quantities have been staged, the dispensing request status is *Completed*.

The person requesting the material picks up the requested lots and containers from the staging location. After picking up the material, it is either consumed, partially or fully, or it is returned to the inventory, partially or fully.

RMW uses web services to integrate with various types of weighing equipment.

If the quantity on hand or the quantity available is greater than the quantity requested to be dispensed, you may want to add new containers and add only the requested quantity or the quantity that you want to stage. Hence, for partial staging, you have the option to create a new container for the material to be dispensed, select the container's material of construction and other details. Once you create a new container, RMW adds this new container into the corresponding lot inventory.

The Material Staging process entails:

1. Engineer requests for material by raising an Allocation Request.
2. Manager stages the material for the engineer to pick up.
3. Engineer picks up the material.
4. Engineer consumes the material to make new material.
5. Engineer either retains the unconsumed material, if any or returns it.

Staging Inventory

To stage the requested material:

1. In the **Create New** menu, select **Materials > Stage**.

Note You can also create a new material staging from

Note Search **Materials > Dispense**, select a Dispense Request and click **More > Stage**.

2. In the **Preface** tab, search and select **Dispense Request**.
3. In the **Requested Inventory** tab, enter the container number for the material requested in the Dispense Request as follows:
 1. Click **Scan Container Bar Code**, if you have a bar code reader attached to your computer system.
 2. Click **Add From Inventory** to add container from material inventory. Search and select the container.
4. In the **Requested Inventory** table, select inventory record and click **Add to Staging List**.
5. Click **Next**.
6. In the **Stage** tab, select **Yes** or **No** for **Stage Whole Container?** to indicate if you need complete or partial staging.

If you select **No** for **Stage Whole Container?**, enter the number of new containers needed for partial staging in **Number of New Containers**.

7. Click **Next**.

In the **Staged Containers** tab, additional fields become active based on your selection for the field **Stage Whole Container?**.

If your selection was **Yes**, only one field is active.

- **Staged Location** - Location to stage and dispense the material.

If your selection was **No**, the following fields are active:

- **MOC** - Material of Construction of the new container.
- **Container size** - The volume size of new container.
- **Gross Quantity** - Total Weight (mass) of the material and container, including packing.
- **Tare Quantity** - Mass of an empty container including all fittings and appliances associated with that particular type of container on its normal operating condition.
- **Net Quantity** - The weight of the material in the container. This is equal to the difference of gross weight and tare weight.
- **Container type** - The type of container, such as box, bottle, etc.

8. Click **Finish**.

Picking up Staged Material

A picked up item can have the following status:

- Picked Up
- In Progress
- Completed

To pick up the staged material:

1. Search **Materials > Stage** and select staged material.

Note You can also pick up the staged material from:

Note Search **Analytical > Sample**, select a sample and click **Pickup Sample**.

2. Select **More > Pickup**.
3. Select the container for which you want to enter the pickup transaction details.
4. In **Destination Location**, for each container, search and select the destination to specify the location where the lots or containers have been moved after pick up.
5. Click **OK**.

Staging Additional Containers

To stage additional containers:

1. Search **Materials > Stage** and select staged material.
2. Select **More > Stage Additional Containers**. Follow the instructions given in [Staging Inventory](#) (on page 29).

Consuming Material

You can enter the consumption details of picked-up material in RMW. Material consumed must be from a qualified site.

To add a consume transaction on a picked up material, the status of the picked up material should be *Picked up* or *In Progress*. When the material is first consumed or returned for a pickup ID, its status changes from *Picked up* to *In Progress*. When the entire quantity picked up is either consumed or returned, the status changes from *Picked up*, or *In Progress*, to *Completed*.

Once you enter a consume transaction in RMW, the *Quantity on Hand* is reduced by the amount consumed.

Adding Consumed Material Details

To add details of the consumed material:

1. In the **Create New** menu, select **Materials > Consume**.
2. In the **General** tab, enter required information.

Significant inputs:

- **Consumed by** - The ID of the user who consumed the material.
 - **Operating Mode** - Select
 - **Clinical Supply**, if the material is consumed for lab or testing purpose.
 - **Development**, if the material is consumed for production purpose.
 - **N/A**, if the material is was consumed for any other purpose, such as, cleaning, maintenance, etc.
3. Search and select one of the following:
 - Process Step
 - Work Request
 - Campaign
 - Control Recipe
 - Project
 4. Click **Next**.
 5. In the **Containers and Quantities** tab, enter the consumptions details.

You can enter the details either manually or by searching and selecting from the inventory.

6. To enter the details manually, click **Enter Manually**.
7. In the *Enter Manually* page, specify the **Container IDs** from which you have consumed the material and the **Quantity** of material consumed.

You must remember the correct ID of the Containers. If the Container ID that you enter does not exist in the library, the system will throw an error.

Note To fill the same values for multiple fields, use Fill Down action. For complete details on how to use the Fill Down action, see *Getting Started with Recipe and Material Workspace Guide*.

8. To select the containers from the inventory, click **Look Up From Inventory > Entire Inventory**.
9. Select the Containers from the list.
10. In the *New Consume* page, enter the **Quantities consumed** and **Consumed Date** against each container.
11. Click **Finish**.

Consuming All Staged Material

To consume all the staged material:

1. Search **Materials > Stage** and select the staged material.
2. Click **More > Consume All**.
3. Enter required information.

Significant inputs:

- **Pickup Location** — The location where staged the material will be picked up from.
- **Work Order** — The ID of work order. This is a mandatory field if operating mode is Clinical Supply.
- **Operating Mode** — Select:
 - **Clinical Supply**, if you request the material for clinical trials.
 - **Development**, if you request the material for experimental development.
 - **N/A**, if you do not wish to associate an operating mode with the request.
- **Consumed By** — The consumer of the transaction. By default the logged in User ID appears.
- **Consumed On** — The date of consumption. By default, the current date appears.

4. Click **OK**.

Returning Unconsumed Material

When you return a picked up material, you need to record the transaction details in the RMW. You can later edit the inventory details.

Note RMW ensures that the returned material is material that was staged and picked up. When you return a material, the Quantity on Hand for the returned material is added to the Returned Quantity in the material's inventory.

To return the unconsumed material:

1. Search **Materials > Consume** and select a consume record.
2. Click **Return**.
3. In **Returned By**, search and select the ID of the user returning the unconsumed material.
4. In the **Quantities** table, search and select the **Return to Location** and specify **Returned Date**.
5. Click **Finish**.

Managing Analytical Activities

This chapter includes the following:

▪ Working with Assays.....	35
▪ Working with Parameter Templates.....	37
▪ Working with Specification Plans.....	39
▪ Working with Samples	42
▪ Working with Lot Release Process	44

RMW helps you analyze various material activities for effective utilization of available material. This is required to ascertain the quality of material.

The Analytical component in RMW helps you to define and record various tests, i.e., Assays, which you can carry out on a material sample. You can define the test parameters and material specification plans. On the basis of the test results, you can either reject the entire Lot of the material or create a Lot Release process for its consumption.

Working with Assays

Assays are tests performed on materials.

Creating a New Assay

To create a new assay:

1. In the **Create New** menu, select **Analytical > Assay**.
2. In the **General** tab, enter the required information.
Significant inputs:
 - **Assay ID** - A meaningful, unique ID, used to track assays.
 - **Estimated Execution Time (in days)** - Number of days typically needed to run this assay.
 - **External Reference** - The identification tag, if this assay is used in any lab data software.
 - **Objective** - The reason for running this assay.
3. Click **Next**.
4. In the **Validation** sub-tab under **Details** tab, click **Add Row(s)** to specify the **Validation Type** that are required for this Assay.
You can add as many validations as required.
5. Select the **Validation Required** box if you require a particular validation to be verified.
6. Click **Finish**.

Creating a New Assay Group

To create a new assay group:

1. In the **Create New** menu, select **Analytical > Assay Group**.
2. In the **General** tab, enter the required information.
Significant inputs:
 - **Assay ID** - A meaningful, unique ID, used to track assays.
 - **Estimated Execution Time (in days)** - Number of days typically needed to run this assay.
 - **External Reference** - The identification tag, if this assay was used in any management software for lab data.
 - **Objective** - The reason for running this assay.
3. Click **Next**.
4. In the **Assays in Group** sub-tab under **Details** tab, click **Add** to search and select the Assays that you wish to allocate in this Assay Group.
5. Click **Next**.
6. In the **Validation** sub-tab under **Details** tab, click **Add Row(s)** to specify the **Validation Type** that are required for this Assay.
You can add as many validations as required.
7. Select the **Validation Required** box if you require a particular validation to be verified.
8. Click **Finish**.

Changing the Lifecycle Phase of an Assay or Assay Group

To change the lifecycle phase of an assay:

1. Search **Analytical > Assay** and select an Assay.
Assay Groups are searched from Assays only. There is no differentiator for Assay Groups.
2. Click **Change > Lifecycle Phase** and select appropriate state:
 - **Draft** - A newly created Assay is in draft state.
 - **Approved** - When an Assay is valid for use.
 - **Obsolete** - When an Assay is no longer in use. You cannot create a new Assay from an Obsolete Assay using the Save As function.

Activating or Deactivating an Assay

You can activate an Assay, which was deactivated or whose **Effective End Date** is over. When you activate an Assay, the system purges out the Effective End Date, i.e., this field becomes available for assigning a new date.

To activate an assay:

1. Search **Analytical > Assay** and select an Assay.

2. Click **More > Activate**.

When you deactivate an Assay, the system assigns the current date as its **Effective End Date**.

To deactivate an assay:

1. Search **Analytical > Assay** and select an Assay.
2. Click **More > Deactivate**.

Working with Parameter Templates

A Parameter Template prescribes the measurements that are carried out on a material. These measurements are defined in the Specification Plans and Recipe Actions. Generic parameters are modeled as parameter templates so that they can be reused in different Recipe Actions.

A Parameter is fairly generic; the generic parameters are modeled as parameter template. You can reuse this parameter template in different Recipe Actions to apply a uniform calculation. The Parameters are variables associated with the recipe entities. These variables are used in campaign, equipment procedural elements and can be referenced by other parts of recipe variables.

Purpose

Each parameter template is associated with one purpose. You can select the purpose based on your requirement:

- Quality
- Process
- Safety
- Efficacy

Result Source

Result Source indicates the results that are associated for this parameter and is captured from a specific equipment and material.

- Manually Entered
- From Formula
- From Service

Note If the **Parameter Has Constraints** field is set to No, the **Constraints** tab will not appear.

Data Type

Parameter value attributes can be organized by defining parameter value types. Parameter value types include simple values, expressions, or references to parameters that are defined at the same level or higher levels in the procedural hierarchy. The values that are expressions may include references to other parameters.

RMW provides the following data types to capture results:

- Integer

- Float
- Text
- EVV
- Boolean
- Date

Parameters can be related in a number of ways, including the following:

- Algebraic or Boolean equations
- Product specific entry forms that work on one or more parameters
- Standard operating procedures (SOPs) that display or otherwise utilize parameters (e.g., dynamic values, recipe values)
- Deferral of parameters to different recipe entities (at the same or another level)
- External applications that use parameters

The formula is represented in the data model as recipe parameters. A recipe's formula is a collection of selected parameters to the recipe procedure and includes parameters that are defined at lower levels of the procedural hierarchy.

Parameters are often scaled, based on batch size or other key attributes. Scaling may be more complex than a simple linear relationship. More complex scaling methods can be accommodated with user-defined algorithms and relationships.

Creating a Parameter Template

To create a parameter template:

1. In the **Create New** menu, select **Analytical > Parameter Template**.
2. In the **General** tab, enter the required information.

Significant inputs:

- **Purpose** of the parameter
- **Parameter Has Constraints** - If the parameter does not have any constraints, the **Constraints** sub-tab will not appear in the **Details** tab.
- **Assay Reference** - The Assay ID that you associate with this parameter for measuring the results.

3. Click **Next**.
4. In the **Data Definition** sub-tab under **Details** tab, enter the required information.

Significant inputs:

- **Data Type** - Based on your selection, the results for the parameter will get captured.
- **Float Precision** - Enter the number of digits allowed after the decimal place. This field is active only when you select Float as the Data Type.
- **UOM Group** - This captures the UOM group that is associated with the Parameter data and results.
- **Compound Tested For** - Indicates if the parameter is used for measurements on experiments done for compounds. For example, the parameters could be % contaminant, % of salt, %

- of water. This parameter would be testing for the presence or absence of certain materials.
- **Entry Field Size** - The size of the results field visible on the measurements tab for a recipe action during execution.
5. Click **Next**.
If you selected **Yes** for **Parameter has Constraints** in the **General** tab, the **Constraints** sub-tab appears. Skip this step if you selected **No**.
 6. In the **Constraints** sub-tab under **Details** tab, select the **Value UOM**, the Unit of Measurement.
 7. For each constraint, select the **Defined By** value and its **Operand**.
 8. Enter the value of the **Constant** if you selected **Constant** as the **Defined By** value.
If you selected **N/A**, the Constant field becomes inactive.
 9. Click **Next**.
 10. In the **Results** sub-tab under **Details** tab, enter the required information.
Significant inputs:
 - **Minimum Number of Results** - The least amount of results expected to be recorded.
 - **Maximum Number of Results** - The highest amount of results expected to be recorded.
 - **Allow Range Results** - Option to record results in a given range of upper and lower limits.
 - **Measurement Frequency** - If you select **At Set Interval**, specify the following values:
 - **Take Measurement Every** - the interval at which the measurements will be recorded.
 - **Start Measurement Timer** - The phase of measurement action.
 - **Reset Timer After Each Measurement**.
 - **Take Measurements In Time Window (plus or minus %)** - The tolerance in measurement time intervals.
 11. Click **Finish**.

Working with Specification Plans

A Specification Plan is a template that defines the test procedure for a material. It consists of a set of tests to identify and confirm certain characteristics about the material.

A Specification Plan is valid only for a certain period of time after which you can re-evaluate the material. Re-evaluation period is defined in each Specification Plan to determine the re-evaluation date of a Lot.

As an engineer, you define a series of Specification Plans for a material and include some sample material through a series of assays or tests. These assays and tests are defined in the Specification Plan. You can choose the qualified material lot that meet the specifications so that they can be consumed in your project.

A Specification Plan defines the following:

- Name and usage type
- Re-evaluation Period
- List of tests

A Specification Plan definition has the following characteristics:

- Specification Plan need not be associated with a specific material item. It can be a generic test.
- Specification Plan can be applied to more than one material, and one material can have more than one Specification Plan.
- Each Specification Plan has re-evaluation duration to determine a lot's re-evaluation date.
- Each Specification Plan comprises one or more parameters or tests.
- Each Specification Plan can have only one approved version active.

Based on their area of usage, specification plans can be of the following types:

- General
- Process Specific
- Peroxide Forming

Creating Specification Plans

Once you create a specification plan, it has to be approved so that you can use it to test a sample material.

To create a specification plan:

1. In the **Create New** menu, select **Analytical > Specification Plan**.
2. In the **General** tab, enter the required information.

Significant inputs:

- **Usage Type:**
 - **General Use** - When there are no specific processes associated with the plan.
 - **Peroxide Forming** - When plan is used for testing peroxide formation.
 - **Process Specific** - When plan is used for a specific process. You must associate a Control Recipe with this plan and provide information in **Initiated By Process**.
 - **Stability Study** - For studying the stability of the material.
- **Operating Mode:**
 - **Clinical Supply** - if the Specification Plan is for clinical trials.
 - **Development** - if the Specification Plan is for experimental development.
 - **Not Applicable** - if you do not wish to associate an operating mode with the Specification Plan.
- **Initiated By Process** - If you select **Usage Type** as *Process Specific*, you are required to select a Control Recipe associated with the plan.

If you leave this field blank and do not specify a Contact Person in **Contacts**, you get a warning.

Once you select a Control Recipe, the Campaign ID and the version No. fields are automatically filled by the application.

- **Owner Site** - By default, the ID of site you logged-in with appears in this field.
1. Click **Next**.
 2. In the **Parameters** tab, click **Parameter > New**.
 3. In the *New Parameter* window, choose one of the following:
 - **User Parameter Template** - to base the parameter on an existing template.
 - **Copy Specification Plan Parameter** - to copy a parameter from another specification plan.
 - **Copy Recipe Parameter** to copy a parameter from a Recipe.
 Also choose one of the following:
 - **Parameter Name** - if you wish to assign a new parameter name.
 - **Use Original Name** - if you wish to use the name obtained by the system from the parameter template or recipe parameter.
 4. Click **Enter More Info**. Refer [Working with Specification Plan](#) on page 39 for complete details.
 5. Click **Next**.
 6. If you wish to add material later, click **Finish**.
 7. In **Material** tab, click **Add Material**. Search and select a material.
 8. Click **OK**.
 9. Click **Finish**.

Constraints

- If a Spec Plan is of *Process Specific* type then it must have a Process Step associated with it.
- If a Spec Plan is of *Peroxide Forming* type then it must be associated with a Material with the *Peroxide Forming* flag enabled.

Changing Lifecycle Phase of Specification Plans

The specification plan has the following lifecycle phases:

- **Draft** - When you create a Specification Plan or when a new version of Specification Plan is generated, it is in Draft state. You cannot use a Specification Plan that is in the Draft state to evaluate a lot or a container.
- **Submitted** - When the Specification Plan is submitted for approval, it is in Submitted state. You cannot use the Specification Plan that is in this status to evaluate a lot or container. If the Specification Plan has a workflow that is in progress, then you cannot edit the Specification Plan.
- **Approved** - When a Specification Plan is approved, it is in Approved state and it can be used on the sample material. You can edit, duplicate, inactivate, activate and change the status for the approved Specification Plan.
- **Rejected** - When the Specification Plan is rejected, it is in Rejected state and cannot be used.
- **Obsolete** - You cannot request the Specification Plan to evaluate a lot or container in this status.

To change the lifecycle phase of a specification plan:

1. Search **Analytical > Specification Plan** and select a specification plan.
2. Click **Change > Lifecycle Phase** and select the applicable state.

Purging Revision of Specification Plans

To purge revisions of a specification plan:

1. Search **Analytical > Specification Plan** and select a plan.
2. Click **More > Purge Revisions**.

Specification Plan Alerts

An alert is initiated when you submit a Specification Plan for review. This alert message is sent to all authorized persons associated with the workflow and allows them to take the next step.

The types of alerts are:

- **Create Request Alert** — This alert is initiated when you create and submit your Specification Plan for review and approval. The message has the subject line as "New Spec Plan Request Created."
- **Cancel Request Alert** — This alert message is sent when you cancel a Specification Plan request.
- **Approved Request Alert** — This non-mandatory alert is sent when a Specification Plan is approved.

Working with Samples

Before a material can be put to use, for development or clinical objectives, its specifications have to be ascertained as per the specifications plan. For this purpose, samples of material from each container are subjected to applicable tests and verifications. These material samples are stored in separate containers, called Target Containers.

Creating a New Sample

To create a new sample:

1. In the **Create New** menu, select **Analytical > Sample**.
2. In the **Sample From Container** field, search and select the name of the container from which you are collecting the sample material.
3. In **Choose One**, select the purpose of this sampling - Campaign, Control Recipe, Process Step, Project or Work Request.
4. Corresponding to the selected purpose, search and select the data:
 - for Campaign, the Campaign ID.
 - for Control Recipe, the control recipe ID.
 - for Process Step, the process step Name.

- for Project, the project ID.
 - for Work Request, the work request ID.
5. Click **Next**.
 6. In the **General** tab, select the **Sample Type** and fill the **Sample Taken on** date.
 7. In the **Containers** tab, click **Add Rows** to fill the essential details, such as Container Type, Container Status, etc., of the *Target Containers* in which the sample material will be stored. The system will generate and assign a unique **Target Container ID** and **Sample ID**.
 8. Click **Next**.
 9. In the **Specification Plans** tab, click **Add Specification Plan** to select the Specification Plans to which this sample material will be associated.
 10. Click **Finish**.

Changing Lifecycle Phase of a Sample

A sample has the following Lifecycle Phases:

- **To be Evaluated** - The state of a newly created sample.
- **Passed** - Approved for use.
- **Failed** - The sample did not meet the requirements.
- **Canceled** - Withdrawn from use.

To change the lifecycle phase of a sample:

1. Search **Analytical > Sample** and select a sample.
2. Click **Change > Lifecycle Phase** and select the applicable state.

Entering Results for a Sample

You can enter results for a sample, when the samples are associated with a Specifications Plan. You can enter more than one result for a sample.

To enter results for a sample:

1. Search **Analytical > Sample** and select a Sample.
2. Click **More > Enter Results**.
3. Select a **Specification Plan Parameter** in the Sample.
4. Click **New Result**.
5. In the *Result* window, enter the data and click **OK**.
6. Click **OK** to finish.

Splitting a Sample

See *Working with Material Inventory* on page 15.

Working with Lot Release Process

A Lot Release Process is a way for an engineer to put together a collection of Samples to the Quality Assurance for review and approval. Once approved, the system updates the status of specified Inventory (Lot /Container).

Creating a New Lot Release Process

To create a new lot release process:

1. In the **Create New** menu, select **Analytical > Lot Release Process**.
2. In the General tab, enter the required information.
Significant inputs:
 - **Source** - The ID of the container from which the Lot is taken.
 - **Auto-update Inventory Status** - The option to update the inventory status automatically after subtracting the amount of inventory released.
 - **Evaluation Type**
 - **Blanket** - Applicable to the entire lot
 - **Process Specific** - When the lot is released for a specific process.
 - **Evaluation Start Date** - This field appears only when you select No option in **Start Evaluation on Date of Approval**.
3. In the **Samples** tab, select the samples.
4. If you wish to add more samples, click **Add**. See *Working with Samples* for complete details.
5. In the **Effect On Inventory** tab, enter the required information.
6. In the **Do not change if status is** box,
7. Click **Finish**.

Constraints:

- If no value is specified then the Start Evaluation Date for the Spec Plan would be assumed to be the Submission Approval Date.
- Results Expiration Date = Proposed Evaluation Date + Spec Plan Re-evaluation duration.
- If the Results against a Spec Plan expire then the submission is automatically considered to be "Out of Evaluation".

Changing the Lifecycle Phase of a Lot Release Process

A Lot Release Process goes through the following Phases:

- **Draft** - The state of the newly created Lot Release Process.
- **Submitted** - Sent for approval.
- **Canceled** - Withdrawn from use.
- **Approved** - Ready for use.
- **Rejected** - Discarded from use.

To change the lifecycle phase of a lot release process:

1. Search **Analytical > Lot Release Process** and select a process.
2. Click **Change > Lifecycle Phase** and select the applicable state.

