**Oracle® Manufacturing Execution System**

for Process Manufacturing User's Guide

Release 12

**Part No. B28826-01**

November 2006

ORACLE®

Oracle Manufacturing Execution System for Process Manufacturing User's Guide, Release 12

Part No. B28826-01

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**Oracle Manufacturing Execution System for Process Manufacturing User's Guide, Release 12**

**Part No. B28826-01**

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# Preface

## Intended Audience

Welcome to Release 12 of the *Oracle Manufacturing Execution System for Process Manufacturing User's Guide.*

This guide assumes that you have working knowledge of your business area's processes, tools, principles, and customary practices. It also assumes that you are familiar with Oracle Process Manufacturing. If you have never used Oracle Process Manufacturing, we suggest you attend one or more of the Oracle Process Manufacturing training classes available through Oracle University.

See Related Information Sources on page xii for more Oracle Applications product information.

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# Structure

### 1  Understanding MES for Process Manufacturing

Oracle Manufacturing Execution System (MES) for Process Manufacturing is part of the Oracle Process Manufacturing (OPM) product family. The application provides a seamless integration to OPM products for rapid deployment and tracking of procedures, work instructions, and batch records. Its features include the setup and management of work instructions and instruction sets, material dispensing, electronic record keeping with electronic signature control, nonconformance management, label printing, master batch record management, and control batch record management. These features are intended to virtually eliminate paper from the shop floor.

### 2  Setting Up

This topic discusses the setup tasks required for Oracle Manufacturing Execution System (MES) for Process Manufacturing.

### 3  Instruction Sets and Instructions

Instruction sets are a convenient method to group or categorize instructions. Instruction sets are reusable. Instructions are the text that becomes part of the batch record. Standard Operating Procedures (SOPs) are documents, images, or other files containing information that give detailed instructions on a specific step such as setting up a blender or other plant equipment, and cleaning of equipment. You access a link to an SOP from an individual instruction. An SOP link can be a URL, a document, or another file stored in the Oracle Applications attachments repository. Individual instructions can reference one or more SOPs.

### 4  Operator Workbench

The Operator Workbench guides you through a set of predefined instructions created to complete operations required for a production batch.

### 5  Dispensing

Dispensing the right materials to the right batches prior to the manufacturing process is a key activity in life sciences and other process industries. The process is critical when working with potent active pharmaceutical ingredients (APIs) in drug manufacturing. Decimal errors in API calculation can be life threatening. Companies preweigh

materials to avoid these errors and to assure rapid delivery at the critical stages of the drug formulation process.

OPM MES Dispensing lets you deliver material in several modes of operation with full label printing capabilities. Functionality supported includes:

- Dispensing modes

- Tolerances

- Label printing

- Scale reading

- Reverse dispensing

### 6  Device Integration

Oracle Manufacturing Execution System (MES) for Process Manufacturing uses the device integration capability of Oracle Warehouse Management System (WMS) to read weighing scales. Read data from the scale with a single click. Full mobile device support provides a query for dispensable items directly from a handheld device, and selection of dispensing jobs. Device support extends to printout of the barcode labels. Once a dispensing job is retrieved, weigh scale device integration captures the actual container weights during the processing and enables operators to enter process parameters such as temperature and appearance characteristics associated to material quality.

### 7  Nonconformance Tracking

Unexpected events that adversely affect the manufacturing process and quality of the finished product can occur in any controlled production environment. These nonconformances must be tracked in the Control Batch Record (CBR). Quality departments analyze nonconformances as part of for their Corrective Action and Preventive Action initiatives (CAPA). To document the complete manufacturing batch record, evidence of nonconformances must be included in the CBR. Oracle Manufacturing Execution System (MES) for Process Manufacturing helps you manage nonconformance in the batch manufacturing process.

### 8  Label Printing

Labels are used to mark contents of containers. They are used to mark raw materials, products, and samples, namely material labels, product labels, and sample labels, respectively. Retain copies of labels affixed to containers and archive them as a part of the batch record.

### 9  Batch Records

Oracle Manufacturing Execution System (MES) for Process Manufacturing provides comprehensive electronic Master Batch Record (MBR) and Control Batch Record (CBR) documents that contain critical batch information from the product recipe and each production batch respectively.

### 10  Batch Validation

The batch validator functionality lets you validate the correctness of data during a batch progression. You can close the batch only if there are no pending instructions.

**A Oracle MES for Process Manufacturing Navigation Paths**

This appendix provides information on the paths to navigate to the various Oracle Manufacturing Execution System (MES) for Process Manufacturing application windows.

**B Oracle E-Record Events in Oracle MES for Process Manufacturing**

Oracle Manufacturing Execution System (MES) for Process Manufacturing supports the acquisition of electronic signatures on electronic records. Electronic documentation replaces paper with a seamless interface of business activities that improves manufacturing throughput and enhances the overall quality of operations in the supply chain. The following provides information for events that are e-record and e-signature enabled in the Oracle Manufacturing Execution System (MES) for Process Manufacturing application. A brief discussion of each event is provided.

**Glossary**

# Related Information Sources

**Related Guides**

Oracle Process Manufacturing shares business and setup information with other Oracle Applications products. Therefore, you may want to refer to other guides when you set up and use Oracle Process Manufacturing. You can read the guides online from the Oracle Applications Document Library CD included in your media pack, or by using a Web browser with a URL that your system administrator provides. If you require printed guides, then you can purchase them from the Oracle Store at http://oraclestore.oracle.com

**Guides Related to All Products**

*Oracle Alert User's Guide*

This guide explains how to define periodic and event alerts to monitor the status of your Oracle Applications data.

*Oracle Applications Concepts*

This book is intended for all those planning to deploy Oracle E-Business Suite Release 12, or contemplating significant changes to a configuration. After describing the Oracle Applications architecture and technology stack, it focuses on strategic topics, giving a broad outline of the actions needed to achieve a particular goal, plus the installation and configuration choices that may be available.

*Oracle Applications Flexfields Guide*

This guide provides flexfields planning, setup, and reference information for the Oracle Applications implementation team, as well as for users responsible for the ongoing maintenance of Oracle Applications product data. This guide also provides information on creating custom reports on flexfields data.

*Oracle Application Framework Personalization Guide*

This guide covers the design-time and run-time aspects of personalizing applications

built with Oracle Application Framework.

*Oracle Applications Installation Guide: Using Rapid Install*

This book is intended for use by anyone who is responsible for installing or upgrading Oracle Applications. It provides instructions for running Rapid Install either to carry out a fresh installation of Oracle Applications Release 12, or as part of an upgrade from Release 11*i* to Release 12. The book also describes the steps needed to install the technology stack components only, for the special situations where this is applicable.

*Oracle Application Server Adapter for Oracle Applications User's Guide*

This guide covers the use of OracleAS Adapter in developing integrations between Oracle applications and trading partners.

Please note that this guide is in the Oracle Application Server 10*g* (10.1.3.1) Documentation Library.

*Oracle Applications System Administrator's Guide Documentation Set*

This documentation set provides planning and reference information for the Oracle Applications System Administrator. *Oracle Applications System Administrator's Guide - Configuration* contains information on system configuration steps, including defining concurrent programs and managers, enabling Oracle Applications Manager features, and setting up printers and online help. *Oracle Applications System Administrator's Guide - Maintenance* provides information for frequent tasks such as monitoring your system with Oracle Applications Manager, managing concurrent managers and reports, using diagnostic utilities, managing profile options, and using alerts. *Oracle Applications System Administrator's Guide - Security* describes User Management, data security, function security, auditing, and security configurations.

*Oracle Applications User's Guide*

This guide explains how to navigate, enter data, query, and run reports using the user interface (UI) of Oracle Applications. This guide also includes information on setting user profiles, as well as running and reviewing concurrent requests.

*Oracle e-Commerce Gateway User's Guide*

This guide describes the functionality of Oracle e-Commerce Gateway and the necessary setup steps in order for Oracle Applications to conduct business with trading partners through Electronic Data Interchange (EDI). It also contains how to run extract programs for outbound transactions, import programs for inbound transactions, and the relevant reports.

*Oracle e-Commerce Gateway Implementation Guide*

This guide describes implementation details, highlights additional setups for trading partner, code conversion, and Oracle Applications as well as provides the architecture guidelines for transaction interface files. This guide also contains troubleshooting information and how to customize EDI transactions.

*Oracle Report Manager User's Guide*

Oracle Report Manager is an online report distribution system that provides a secure

and centralized location to produce and manage point-in-time reports. Oracle Report Manager users can be either report producers or report consumers. Use this guide for information on setting up and using Oracle Report Manager.

*Oracle iSetup User Guide*

This guide describes how to use Oracle iSetup to migrate data between different instances of the Oracle E-Business Suite and generate reports. It also includes configuration information, instance mapping, and seeded templates used for data migration.

*Oracle Workflow Administrator's Guide*

This guide explains how to complete the setup steps necessary for any product that includes workflow-enabled processes. It also describes how to manage workflow processes and business events using Oracle Applications Manager, how to monitor the progress of runtime workflow processes, and how to administer notifications sent to workflow users.

*Oracle Workflow Developer's Guide*

This guide explains how to define new workflow business processes and customize existing Oracle Applications-embedded workflow processes. It also describes how to define and customize business events and event subscriptions.

*Oracle Workflow User's Guide*

This guide describes how users can view and respond to workflow notifications and monitor the progress of their workflow processes.

*Oracle Workflow API Reference*

This guide describes the APIs provided for developers and administrators to access Oracle Workflow.

*Oracle XML Gateway User's Guide*

This guide describes Oracle XML Gateway functionality and each component of the Oracle XML Gateway architecture, including Message Designer, Oracle XML Gateway Setup, Execution Engine, Message Queues, and Oracle Transport Agent. The integrations with Oracle Workflow Business Event System and the Business-to-Business transactions are also addressed in this guide.

*Oracle XML Publisher Report Designer's Guide*

Oracle XML Publisher is a template-based reporting solution that merges XML data with templates in RTF or PDF format to produce a variety of outputs to meet a variety of business needs. Using Microsoft Word or Adobe Acrobat as the design tool, you can create pixel-perfect reports from the Oracle E-Business Suite. Use this guide to design your report layouts.

*Oracle XML Publisher Administration and Developer's Guide*

Oracle XML Publisher is a template-based reporting solution that merges XML data with templates in RTF or PDF format to produce a variety of outputs to meet a variety

of business needs. Outputs include: PDF, HTML, Excel, RTF, and eText (for EDI and EFT transactions). Oracle XML Publisher can be used to generate reports based on existing E-Business Suite report data, or you can use Oracle XML Publisher's data extraction engine to build your own queries. Oracle XML Publisher also provides a robust set of APIs to manage delivery of your reports via e-mail, fax, secure FTP, printer, WebDav, and more. This guide describes how to set up and administer Oracle XML Publisher as well as how to use the Application Programming Interface to build custom solutions.

**Guides Related to This Product**

*Oracle Process Manufacturing Cost Management User's Guide*

The Oracle Process Manufacturing Cost Management application is used by cost accountants to capture and review the manufacturing costs incurred in their process manufacturing businesses. The guide describes how to set up and use this application.

*Oracle Process Manufacturing Process Execution User's Guide*

The Oracle Process Manufacturing Process Execution application lets you track firm planned orders and production batches from incoming materials through finished goods. Seamlessly integrated to the Product Development application, Process Execution lets you convert firm planned orders to single or multiple production batches, allocate ingredients, record actual ingredient usage, and then complete and close production batches. Production inquiries and preformatted reports help you optimize inventory costs while maintaining a high level of customer satisfaction with on-time delivery of high quality products. The *Oracle Process Manufacturing Process Execution User's Guide* presents overviews of the tasks and responsibilities for the Production Supervisor and the Production Operator. It provides prerequisite setup in other applications, and details the windows, features, and functionality of the application.

*Oracle Process Manufacturing Product Development User's Guide*

The Oracle Process Manufacturing Product Development application provides features to manage formula, routing, recipe, and validity rule development within process manufacturing operations. Use it to manage multiple laboratory organizations and support varying product lines throughout the enterprise. Characterize and simulate the technical properties of ingredients and their effects on formula performance and cost. Simulate and optimize formulations before beginning expensive laboratory test batches. Product Development coordinates each development function to provide a rapid, enterprise-wide implementation of new products in your plants. The guide describes how to set up and use this application.

*Oracle Process Manufacturing Quality Management User's Guide*

The Oracle Process Manufacturing Quality Management application provides features to test material sampled from inventory, production, or receipts from external suppliers. The application lets you enter specifications and control their use throughout the enterprise. Customized workflows and electronic recordkeeping automate plans for sampling, testing, and result processing. Compare specifications to assist in regrading

items, and match customer specifications. Aggregate test results and print statistical assessments on quality certificates. Run stability testing with unrivaled ease. Several preformatted reports and inquiries help manage quality testing and reporting. The guide describes how to set up and use this application.

*System Administration User's Guide*

Much of the System Administration duties are performed at the Oracle Applications level, and are therefore described in the Oracle Applications System Administrator's Guide. The *Oracle Process Manufacturing System Administration User's Guide* provides information on the few tasks that are specific to Oracle Process Manufacturing. It offers information on performing Oracle Process Manufacturing file purge and archive, and maintaining such things as responsibilities, units of measure, and organizations.

*Regulatory Management User's Guide*

Oracle Process Manufacturing Regulatory Management provides solutions for document management that help meet the FDA 21 CFR Part 11 and other international regulatory compliance requirements. Regulatory information management is facilitated by use of electronic signatures. Manage hazard communications by collaborating with Oracle partners to dispatch safety documents, attached printed documentation sets such as the MSDS to shipments, and set up workflows to manage documentation revisions, approvals, and transmittals. The *Oracle Process Manufacturing Regulatory Management User's Guide* provides the information to set up and use the application.

*Oracle Manufacturing Execution System for Process Manufacturing*

Oracle Manufacturing Execution System (MES) for Process Manufacturing provides a seamless integration to product development and process execution applications for rapid deployment and tracking of procedures, work instruction tasks, and batch records. Set up and manage material dispensing operations and produce electronic batch records interactively with full electronic signature control, nonconformance management, and label printing routines. The *Oracle Manufacturing Execution System for Process Manufacturing User's Guide* delivers the information to set up and use the application.

*API User's Guides*

Public Application Programming Interfaces (APIs) are available for use with different Oracle Process Manufacturing applications. APIs pass information into and out of the application tables, thereby bypassing the user interface. Use of these APIs is documented in separately available documentation.

*Oracle Engineering User's Guide*

This guide enables your engineers to utilize the features of Oracle Engineering to quickly introduce and manage new designs into production. Specifically, this guide details how to quickly and accurately define the resources, materials and processes necessary to implement changes in product design.

*Oracle Inventory User's Guide*

This guide describes how to define items and item information, perform receiving and

inventory transactions, maintain cost control, plan items, perform cycle counting and physical inventories, and set up Oracle Inventory.

*Oracle Bills of Material User's Guide*

This guide describes how to create various bills of material to maximize efficiency, improve quality and lower cost for the most sophisticated manufacturing environments. By detailing integrated product structures and processes, flexible product and process definition, and configuration management, this guide enables you to manage product details within and across multiple manufacturing sites.

*Oracle Work in Process User's Guide*

This guide describes how Oracle Work in Process provides a complete production management system. Specifically this guide describes how discrete, repetitive, assemble –to–order, project, flow, and mixed manufacturing environments are supported.

*Oracle Quality User's Guide*

This guide describes how Oracle Quality can be used to meet your quality data collection and analysis needs. This guide also explains how Oracle Quality interfaces with other Oracle Manufacturing applications to provide a closed loop quality control system.

*Oracle Shipping Execution User's Guide*

This guide describes how to set up Oracle Shipping to process and plan your trips, stops and deliveries, ship confirmation, query shipments, determine freight cost and charges to meet your business needs.

*Oracle Purchasing User's Guide*

This guide describes how to create and approve purchasing documents, including requisitions, different types of purchase orders, quotations, RFQs, and receipts. This guide also describes how to manage your supply base through agreements, sourcing rules and approved supplier lists. In addition, this guide explains how you can automatically create purchasing documents based on business rules through integration with Oracle Workflow technology, which automates many of the key procurement processes.

*Oracle interMedia User's Guide and Reference*

This user guide and reference provides information about Oracle interMedia. This product enables Oracle9i to store, manage, and retrieve geographic location information, images, audio, video, or other heterogeneous media data in an integrated fashion with other enterprise information. Oracle Trading Community Architecture Data Quality Management uses interMedia indexes to facilitate search and matching.

*Oracle Self–Service Web Applications Implementation Guide*

This manual contains detailed information about the overview and architecture and setup of Oracle Self–Service Web Applications. It also contains an overview of and procedures for using the Web Applications Dictionary.

**Installation and System Administration**

*Oracle Applications Concepts*

This guide provides an introduction to the concepts, features, technology stack, architecture, and terminology for Oracle Applications Release 11i. It provides a useful first book to read before an installation of Oracle Applications. This guide also introduces the concepts behind Applications-wide features such as Business Intelligence (BIS), languages and character sets, and Self-Service Web Applications.

*Installing Oracle Applications*

This guide provides instructions for managing the installation of Oracle Applications products. In Release 11i, much of the installation process is handled using Oracle Rapid Install, which minimizes the time to install Oracle Applications and the Oracle technology stack by automating many of the required steps. This guide contains instructions for using Oracle Rapid Install and lists the tasks you need to perform to finish your installation. You should use this guide in conjunction with individual product user guides and implementation guides.

*Upgrading Oracle Applications*

Refer to this guide if you are upgrading your Oracle Applications Release 10.7 or Release 11.0 products to Release 11*i*. This guide describes the upgrade process and lists database and product-specific upgrade tasks. You must be either at Release 10.7 (NCA, SmartClient, or character mode) or Release 11.0, to upgrade to Release 11*i*. You cannot upgrade to Release 11*i* directly from releases prior to 10.7.

*"About" Document*

For information about implementation and user documentation, instructions for applying patches, new and changed setup steps, and descriptions of software updates, refer to the "About" document for your product. "About" documents are available on OracleMetaLink for most products beginning with Release 11.5.8.

*Maintaining Oracle Applications*

Use this guide to help you run the various AD utilities, such as AutoUpgrade, AutoPatch, AD Administration, AD Controller, AD Relink, License Manager, and others. It contains how-to steps, screenshots, and other information that you need to run the AD utilities. This guide also provides information on maintaining the Oracle applications file system and database.

*Oracle Applications System Administrator's Guide*

This guide provides planning and reference information for the Oracle Applications System Administrator. It contains information on how to define security, customize menus and online help, and manage concurrent processing.

*Oracle Alert User's Guide*

This guide explains how to define periodic and event alerts to monitor the status of your Oracle Applications data.

*Oracle Applications Developer's Guide*

This guide contains the coding standards followed by the Oracle Applications

development staff and describes the Oracle Application Object Library components that are needed to implement the Oracle Applications user interface described in the Oracle Applications User Interface Standards for Forms-Based Products. This manual also provides information to help you build your custom Oracle Forms Developer forms so that the forms integrate with Oracle Applications.

*Oracle Applications User Interface Standards for Forms-Based Products*

This guide contains the user interface (UI) standards followed by the Oracle Applications development staff. It describes the UI for the Oracle Applications products and how to apply this UI to the design of an application built by using Oracle Forms.

**Other Implementation Documentation**

*Oracle Applications Product Update Notes*

Use this guide as a reference for upgrading an installation of Oracle Applications. It provides a history of the changes to individual Oracle Applications products between Release 11.0 and Release 11*i*. It includes new features, enhancements, and changes made to database objects, profile options, and seed data for this interval.

*Oracle Workflow Administrator's Guide*

This guide explains how to complete the setup steps necessary for any Oracle Applications product that includes workflow-enabled processes, as well as how to monitor the progress of runtime workflow processes.

*Oracle Workflow Developer's Guide*

This guide explains how to define new workflow business processes and customize existing Oracle Applications-embedded workflow processes. It also describes how to define and customize business events and event subscriptions.

*Oracle Workflow User's Guide*

This guide describes how Oracle Applications users can view and respond to workflow notifications and monitor the progress of their workflow processes. Oracle Workflow API Reference This guide describes the APIs provided for developers and administrators to access Oracle Workflow.

*Oracle Applications Flexfields Guide*

This guide provides flexfields planning, setup and reference information for the Oracle E-Records implementation team, as well as for users responsible for the ongoing maintenance of Oracle Applications product data. This guide also provides information on creating custom reports on flexfields data.

*Oracle eTechnical Reference Manuals*

Each eTechnical Reference Manual (eTRM) contains database diagrams and a detailed description of database tables, forms, reports, and programs for a specific Oracle Applications product. This information helps you convert data from your existing applications, integrate Oracle Applications data with non-Oracle applications, and write custom reports for Oracle Applications products. Oracle eTRM is available on Oracle *Metalink*.

*Oracle Applications Message Manual*

This manual describes all Oracle Applications messages. This manual is available in HTML format on the documentation CD-ROM for Release 11*i*.

## Integration Repository

The Oracle Integration Repository is a compilation of information about the service endpoints exposed by the Oracle E-Business Suite of applications. It provides a complete catalog of Oracle E-Business Suite's business service interfaces. The tool lets users easily discover and deploy the appropriate business service interface for integration with any system, application, or business partner.

The Oracle Integration Repository is shipped as part of the E-Business Suite. As your instance is patched, the repository is automatically updated with content appropriate for the precise revisions of interfaces in your environment.

# Do Not Use Database Tools to Modify Oracle Applications Data

Oracle STRONGLY RECOMMENDS that you never use SQL*Plus, Oracle Data Browser, database triggers, or any other tool to modify Oracle Applications data unless otherwise instructed.

Oracle provides powerful tools you can use to create, store, change, retrieve, and maintain information in an Oracle database. But if you use Oracle tools such as SQL*Plus to modify Oracle Applications data, you risk destroying the integrity of your data and you lose the ability to audit changes to your data.

Because Oracle Applications tables are interrelated, any change you make using an Oracle Applications form can update many tables at once. But when you modify Oracle Applications data using anything other than Oracle Applications, you may change a row in one table without making corresponding changes in related tables. If your tables get out of synchronization with each other, you risk retrieving erroneous information and you risk unpredictable results throughout Oracle Applications.

When you use Oracle Applications to modify your data, Oracle Applications automatically checks that your changes are valid. Oracle Applications also keeps track of who changes information. If you enter information into database tables using database tools, you may store invalid information. You also lose the ability to track who has changed your information because SQL*Plus and other database tools do not keep a record of changes.

# 1

# Understanding MES for Process Manufacturing

Oracle Manufacturing Execution System (MES) for Process Manufacturing is part of the Oracle Process Manufacturing (OPM) product family. The application provides a seamless integration to OPM products for rapid deployment and tracking of procedures, work instructions, and batch records. Its features include the setup and management of work instructions and instruction sets, material dispensing, electronic record keeping with electronic signature control, nonconformance management, label printing, master batch record management, and control batch record management. These features are intended to virtually eliminate paper from the shop floor.

This chapter covers the following topics:

* About This Guide
* About Oracle MES for Process Manufacturing
* Tasks and Responsibilities
* Process Flow
* Interface to Other Applications

## About This Guide

This guide provides reference information to users of the Oracle Manufacturing Execution System (MES) for Process Manufacturing application. It presents:

* Component overviews

* Setup and administrative tasks

* Recipe design and instruction setup, including:

    * Resource-to-device mapping instructions

- Standard Operating Procedure (SOP) integrations

- Batch action, instruction, and task integrations

- Streamlined electronic signatures

- Browser-based user interfaces

- Querying batch records, scheduling batches, and batch workflow

- E-record events-enabled dispensing user interface, dispense types, dispensing setup, reverse dispense, dispense material activity record, dispensing labels, dispense dispatch, and dispense history reports

- Device integration setup and scale reader integration using the Oracle Warehouse Management Systems (WMS) application to interface to devices

- Integration with quality nonconformance, using E-record events for nonconformance tracking, closing nonconformance or nonconformance lifecycle, and completing the corrective actions, preventive actions (CAPA) workflow

- WMS label print technology, label types, label setup, and label content modification

- Master Batch Record (MBR), Control Batch Record (CBR), batch progression reports, and a list of new E-record events

- Navigation paths and profile options

Depending on your system security profile, it is possible that you do not have access to all of the windows and functions described in this guide. If you do not see a menu option that is described in this documentation, and you need to access it, then contact your system administrator.

## About Oracle MES for Process Manufacturing

Oracle Process Manufacturing closes the gap between conventional Enterprise Resource Planning (ERP) and Manufacturing Execution Systems (MES) for process manufacturers with Oracle Manufacturing Execution System (MES) for Process Manufacturing. Batch execution is simplified by paperless record keeping and support for dispensing and pre-weigh operations. Devices are integrated to the manufacturing process. Nonconformances are captured during process execution.

Traditionally, manufacturers invested in building and maintaining costly interfaces between ERP, which held financial, human resources, inventory, sales, purchasing, and master recipe data and MES, which manages the actual execution activities of the production batches on the shop floor.

Oracle Manufacturing Execution System (MES) for Process Manufacturing adds

additional MES capabilities to other Oracle E-Business Suite applications so that costs, data replication, and risk of error are reduced. Data accuracy, process repeatability, and information visibility are improved by managing all information in a single, real-time database.

Oracle Manufacturing Execution System (MES) for Process Manufacturing enhances the production batch execution functionality and increases the usability for manufacturing operators, enabling paperless batch record keeping and adding support for dispensing operations.

Oracle Manufacturing Execution System (MES) for Process Manufacturing is designed for use in many process industry plants, especially those looking to move to electronic batch record keeping and those that previously opted to purchase a third-party MES. Oracle Manufacturing Execution System (MES) for Process Manufacturing offers the advantage of providing true, enterprise-wide information from the shop floor to the boardroom.

Following is an overview of the components of the Oracle Manufacturing Execution System (MES) for Process Manufacturing application.

## Standard Operating Procedures

Managing Standard Operating Procedures (SOPs) ensures access to the current versions of procedures, thereby reducing the risk of nonstandard manufacturing and quality practices.

The instruction setup lets you:

- Associate SOPs to a group of instructions, or use them at the unit instruction level

- Specify operator acknowledgement for an instruction

- Specify signatures for an instruction

- Associate a batch action to an instruction

- Navigate actions using instructions

- Copy instructions from an existing group

- Define various instruction types for an entity such as process, dispensing, reverse dispensing

## Operator Workbench

The Operator Workbench lets you:

- Identify tasks based on a specified set of search criteria

- Identify batch status at the instruction level

- Lock a task to complete instructions and associated tasks at the operation, activity, and resource level

- View instructions interactively

- Acknowledge instructions

- Navigate to tasks and related actions that use the instructions

## Dispensing

Dispensing the proper materials to batches prior to the manufacturing process is a key activity in pharmaceutical, chemical, and food and beverage process industries. The Production process during the manufacture of products in these process industries requires allocation of the right materials with specific quality parameters and precise quantities. Accuracy of these quantities is critical. To enable this, the dispensing functionality is integrated with weigh scale devices.

Dispensing is usually performed in dedicated locations such as environmentally controlled clean rooms that must be maintained in strict accordance with documented procedures.

Proper labeling of containers that hold dispensed material is also a critical requirement for the positive identification of material and all its related production components.

## Device Integration

Device readings are captured directly from the manufacturing equipment during the dispensing process from weighing devices such as scales and balances and as process parameters during batch production.

Device reading capabilities include:

- Synchronous device responses

- Resource-to-device mapping

- Device selection capabilities

- Multiple device interface support using RS232C, USB, RS485 and other common protocols

## Nonconformance Tracking

Nonconformance is defined as the difference between the observed conditions and acceptance criteria as stated within an approved protocol such as a master batch record,

or if the testing performed deviates from the approved procedure.

Features provided for nonconformance tracking are:

- Nonconformance capture

- Unique identifier for nonconformance

- Classification and disposition of nonconformance

- Corrective actions and preventive actions (CAPA)

- Availability of nonconformance records in the Control Batch Record (CBR)

## Label Printing

Oracle Manufacturing Execution System (MES) for Process Manufacturing offers the following label printing features:

- Automatic label printing with reprint capabilities

- Configurable label content using XML

- E-signature control

- Label printing history

## Master Batch Record

The Master Batch Record (MBR) is the approved and documented set of instructions for manufacturing a specific product, in a specific plant, using specific resources, during a specified date range, to produce a specific batch size. The required elements of MBR are described in the United States Food and Drug Administration (FDA) Code of Federal Regulations (CFR) Title 21 Part 211.186. The recipe created in Oracle Process Manufacturing Product Development application includes material requirements, equipment and resource requirements, instructions, sampling requirements, and notes related to batch manufacturing processing. This recipe is the template that is used repeatedly to manufacture a consistent product.

The three recipe types that can be built in the Oracle Process Manufacturing Product Development application are:

- Master recipes to define how a product is made in a specific process manufacturing cell.

- Site recipes to define how a specific site makes the product, or some portion of the product. A site recipe has the same structure as a general recipe, but may be modified for the local language and unit of measure. It may also be modified to take

into account local material availability, or it may only define a part of the general recipe that is actually performed on the site.

- General recipes to define in an equipment-independent manner, the material and process dependencies required to make a product. The general recipe is usually created during or after the pilot plant scaleup of a research and development recipe.

## Control Batch Record

The Control Batch Record (CBR) document records all events in the life cycle of a production batch order.

Oracle Manufacturing Execution System (MES) for Process Manufacturing offers the abilities to:

- Control the printing of the MBR and CBR with e-signature control

- Monitor production status

- Modify the format and content of the MBR and CBR

- Monitor external events

## Streamlined Electronic Signatures

During the production process, completed tasks are verified on the shop floor using electronic signatures. Oracle E-Records offers a paperless signing process for capturing the requisite electronic signatures on specific events, such as dispensing, reverse dispensing, controlling the progression of business processes and a specific quality result, or creation and modification of key setup data.

Transactions under consideration for approval are listed on the e-signature window. Event signoff status displays on the CBR, and includes the individual who signed, date, time (and time zone), and the reason for signing. Initialing is used to confirm signer identity by entry of an approved user name and password.

The initialing process does not replace the requirement for full signatures on more complex events that require review of information spanning several application windows. Examples of events that require the full signature process include recipe approval, production, batch record closing, and sample results disposition.

Streamlined electronic signatures provide:

- Streamlined navigation flow to complete signatures

- Support for custom approvers and flexible signature rules

- Optionally, use the Oracle Approval Management Engine (AME) to specify users, responsibilities, and the number and hierarchy of signers.

# Tasks and Responsibilities

Following is a representative work breakdown structure for managing a manufacturing execution system for process manufacturing within the enterprise. It lists many of the key tasks and the job titles usually responsible for these tasks:

| Tasks | Responsibilities |
| --- | --- |
| Setting Up Oracle Manufacturing Execution System (MES) for Process Manufacturing | • MES for Process Manufacturing Administrator<br><br>• Dispensing Supervisor |
| Creation and Maintenance of Instructions | • Process Engineer<br><br>• Formulator<br><br>• Production Supervisor<br><br>• MES for Process Manufacturing Administrator |
| Using the Operator Workbench | • Production Operator (OPM Process Execution)<br><br>• Production Supervisor<br><br>• Process Shop Floor Operator<br><br>• MES for Process Manufacturing Administrator |
| Dispensing | • Dispensing Operator<br><br>• MES for Process Manufacturing Administrator |

| Tasks | Responsibilities |
|-------|------------------|
| Viewing the Master Batch Record | • Production Operator<br>• Production Supervisor<br>• MES for Process Manufacturing Administrator<br>• Formulator<br>• Process Engineer<br>• Production Auditor or Regulatory Manager |
| Viewing the Control Batch Record | • Dispensing Operator<br>• Production Supervisor<br>• MES for Process Manufacturing Administrator<br>• Production Auditor or Regulatory Manager |

# Process Flow

The Oracle Manufacturing Execution System (MES) for Process Manufacturing process flow documents the batch life cycle. The business process permits a product designer to define processing instructions and associate them to an operation, routing, or recipe. By defining individual attributes of these entities and associating them to tasks, the operator can use processing instructions at runtime to act on the instruction and enter data against it based on its definition. The overall process is controlled by e-signatures that are captured and become part of a permanent record in the Evidence Store.

1. Define formula, routing, operations, activities and select resources in the Oracle Process Manufacturing (OPM) Product Development application.

   Define the instruction sets and instructions.

2. Design a recipe.

   Create recipe and define process instructions.

3. Create recipe validity rules and review the master batch record.

4. Set up dispensing.

   Define dispensable items, dispensing rules, and instructions for the dispensable items.

5. Schedule and release batches.

   Reserve the material.

   Schedule the shop floor.

   Release the batch.

6. Dispense material.

   Preweigh designated ingredients.

   Dispense material and print labels.

7. Execute batch steps.

   Lock steps using the Operator Workbench.

   Follow instructions and perform tasks to manage batch operations.

8. Manage quality.

   Take samples for testing.

   Print quality sample labels.

   Log nonconformances.

9. Monitor the batch progress.

   Use the interactive batch progression inquiry and report.

   Print product labels.

10. Complete the batch.

    Complete the tasks.

    Resolve and sign off on nonconformances.

11. Validate the control batch record.

    Optionally, print the batch record for reference.

12. Close the batch.

Oracle Process Manufacturing (OPM) Product Development is the design source for assembling recipes, formulas, routings, operations, and activities. OPM Process Execution is the production application used to process recipes into batches. Oracle

Quality provides the structure for nonconformance tracking. Oracle Warehouse Management System (WMS) provides label printing and device integration infrastructure. Oracle MES for Process Manufacturing uses Oracle XML Publisher to generate its reports and formatted electronic records.

# Interface to Other Applications

Oracle Manufacturing Execution System (MES) for Process Manufacturing interfaces with other product applications in the Oracle E-Business Suite to accomplish proper and complete functioning of some of its features.

Following are examples of application interfaces:

Oracle Process Manufacturing Process Execution for:

- Defining e-record events to generate the Control Batch Record (CBR)

- Triggering nonconformance tracking

- Acknowledging the instructions

- Material consumption using dispensing

Oracle Process Manufacturing Product Development for:

- Viewing Master Batch Record (MBR)

- Defining instructions

Oracle E-Records for:

- Retrieving XML with e-signature from the E-Records Evidence Store for batch records

- Accepting signers at run time for instructions

- Accepting signers for dispensing setup

- Accepting signers for CBR

- Dispensing and reverse dispensing material

- Printing labels

- Setting the signing rules

Oracle Quality for tracking nonconformances

Oracle Warehouse Management System for:

- Integrating devices

- Printing labels

Oracle XML Publisher for printing reports and electronic records in a human-readable format

# 2

# Setting Up

This topic discusses the setup tasks required for Oracle Manufacturing Execution System (MES) for Process Manufacturing.

This chapter covers the following topics:

- Setting Up Profile Options
- Enabling Oracle MES for Process Manufacturing
- Enabling Control Batch Record
- Setting Up Document Numbering
- Creating and Deleting a Document Numbering Rule
- Updating a Document Numbering Rule
- Searching for a Document Numbering Rule
- Setting Up Dispensing
- Creating a Dispensing Setup Rule
- Updating a Dispensing Setup Rule
- Searching for a Dispensing Setup Rule
- Setting Up a Device and Label Printing
- Setting Up Nonconformance Tracking

## Setting Up Profile Options

During implementation, set a value for selected profile options to specify how your Oracle Manufacturing Execution System (MES) for Process Manufacturing application controls access to and processes the data.

Your System Administrator sets user profile options at one or more of the following levels: Site, Application, Responsibility, and User. Use the Personal Profile Options window to view or set your profile options at the user level. Refer to *Oracle Applications*

*System Administrator's Guide - Configuration* for a list of profile options common to all Oracle Applications.

Following are profile options set up with concurrent programs at implementation.

## GMO: MES for Process Manufacturing is Enabled

Enables the Oracle Manufacturing Execution System (MES) for Process Manufacturing application.

**Default**

No

**Options**

Yes: Oracle Manufacturing Execution System (MES) for Process Manufacturing is enabled

No: Oracle Manufacturing Execution System (MES) for Process Manufacturing is disabled.

**Recommended Change Level**

Can only be set to Yes once by the concurrent program.

## GMO: Control Batch Recording

Enables generation of the Control Batch Record (CBR) in the Oracle Manufacturing Execution System (MES) for Process Manufacturing application.

**Default**

Null

**Options**

Yes: Control Batch Record is enabled

Null: Control Batch Record is disabled.

**Recommended Change Level**

Can only be set to Yes once by the concurrent program. Refer to the "Enabling Control Batch Record" for instructions.

Following are profile options set up after enabling the application:

## GMO: Device Integration Mode

Set device read as enabled or mandated.

**Default**

Both

**Options**

Auto: Device Read is enabled; manual entry is disabled.

Manual: Device Read is disabled; only manual entry is enabled.

Both: Device Read is enabled; you can also enter data manually.

**Recommended Change Levels**

Site, Organization

## GMO: Device Measure Response Component for Dispense

Identifies the dispensing scale device message component that corresponds to the measurement data element.

**Default**

Null

**Options**

Provided manually as part of device response setup.

**Recommended Change Levels**

Site, Organization

## GMO: Device UOM Response Component for Dispense

Identifies the dispensing scale device message component that corresponds to the unit of measure (UOM) data element.

**Default**

Null

**Options**

Provided manually as part of device response setup.

**Recommended Change Level**

Site, Organization

## GMO: Device Read Timeout (Seconds)

Represents the time that the application waits for data from an integrated device before giving window control back to the user.

**Default**

10

**Options**

Provided manually

**Recommended Change Level**

Site

## GMO: Label Print Mode

Set the mode of label printing.

**Default**

Null

**Options**

AUTO: Automatic Label printing. User intervention is not required.

MANUAL: Manual label printing. User intervention is required.

**Recommended Change Level**

Site

# Enabling Oracle MES for Process Manufacturing

Enable Oracle MES for Process Manufacturing by running the Enable MES Functionality concurrent program. This setup is done during application implementation.

## Prerequisites

❑ Determine that the GMO: MES for Process Manufacturing is Enabled profile option is set to No.

> **Warning:** You cannot disable the Oracle Manufacturing Execution System (MES) for Process Manufacturing application after you enable it at implementation.

### To enable the Oracle MES for Process Manufacturing application:

1. Navigate to the **MES for Process Manufacturing Administrator** responsibility.

2. Choose **Run** from **Request**.

3. Click **Single Request**.

4. Click **OK**.

5. Select **Enable MES Operations Functionality** for the request **Name**.

6. Click **OK**.

7.  Submit the request to run the concurrent program.

8.  Verify success by determining that the GMO: MES for Process Manufacturing is Enabled profile option is set to Yes.

# Enabling Control Batch Record

Enable Control Batch Record (CBR) by running the Enable Control Batch Record concurrent program. The concurrent program is run before creating batches.

### To run the Enable Control Batch Record concurrent program:

1.  Navigate to the **MES for Process Manufacturing Administrator** responsibility.

2.  Choose **Run** from **Request**.

3.  Click **Single Request**.

4.  Click **OK**.

5.  Select **Enable Control Batch Record** for the request **Name**.

6.  Click **OK**.

7.  Submit the request to run the concurrent program.

8.  Verify success by determining that the GMO: Control Batch Recording profile option is set to Yes.

# Setting Up Document Numbering

Document numbers are unique identifiers (IDs) for transactions. Dispensing and the reverse dispensing functions use the document numbering feature to assign a unique material dispense number and material reverse dispense number.

Assign numbers to the documents manually or automatically. If you use automatic number assignment, then the documents are numbered sequentially. Manual number assignment is useful when you are using preprinted forms or when document numbers are generated by another system.

> **Important:** You cannot set up document numbering at the organization level. Document numbering is global.

The document numbering procedure includes:

1.  Creating a document numbering rule

2. Updating a document numbering rule

3. Searching for a document numbering rule

# Creating and Deleting a Document Numbering Rule

Creating a document numbering rule includes selecting a context organization, transaction type, and assignment type.

### To create a document numbering rule:

1. Navigate to the **Create Document Numbering** window.

2. Search and select **Dispense** or **Dispense Reversal** as **Transaction**. Required.

3. Enter the context **Organization**.

4. Select **Assignment Type** as:

   - **Automatic** - Proceed to the next step.

   - **Manual** - No additional entries are required.

5. Enter **Start With** as the starting document number. Required.

   For example, enter 10.

6. Enter the desired **Increment** between document numbers. Required.

   For example, if you enter 1, then the numbering sequence is 1, 2, 3, and so forth. If you enter 10 then the numbering sequence is 10, 20, 30, and so forth.

7. Enter the **Length** of digits for the document number. Use positive numbers ranging between 1 and 10. For example, enter 10.

8. Select **Zero Padding** as:

   - **No** to display document numbers as 1, 12, and so on.

   - **Yes** to display document numbers as 01, 0012, and so on.

9. Enter a **Prefix**. For example, enter PRE

10. Enter a **Suffix**. For example, enter SUF

11. Enter a **Separator** to display after the prefix and before the suffix. For example, enter #

    The **Format Example** displays as you enter the values in the different fields. For

example, PRE#0000000010#SUF

**To delete an existing document numbering rule :**

1. Navigate to the **Document Numbering** window.

2. Select a document numbering rule.

3. Click **Delete**.

# Updating a Document Numbering Rule

Modify the assignment type, length, zero padding setting, and other values of the document numbering rule.

**To update a document numbering rule:**

1. Navigate to the **Document Numbering** window.

2. Search and select a document number.

3. Click **Update**.

4. Modify the **Assignment Type**, **Zero Padding**, **Start With**, **Increment**, **Length**, **Prefix**, **Suffix**, and **Separator**.

> **Note:** Refer to "Creating and Deleting a Document Numbering Rule" for information on these fields.

5. Click **Apply**.

# Searching for a Document Numbering Rule

Search for existing document numbering rules from the Document Numbering window. Update or delete an existing document numbering rule.

**To search for document numbers:**

1. Navigate to the **Document Numbering** window.

2. Enter any of the following to narrow your search:

   • Search and select an organization by **Organization** code or **Organization Name** .

- Search and select a recipe by the **Transaction** type such as Dispense or Dispense Reversal.

3. Click **Go**. The results of the search display.

   Refer to "Updating a Document Numbering Rule" to change an existing document numbering rule.

# Setting Up Dispensing

Define the dispensing setup to dispense material. Dispensable items in a formula are required to be dispensed prior to consumption when a batch that uses the formula is created. Dispense items that are reservable, recipe-enabled, active, and inactive.

The dispensing setup procedure for an item, item and its associated organization, or for a combination of item, organization, and recipe includes:

- Creating a dispensing setup rule

- Updating a dispensing setup rule

- Searching for dispensing setup rule

# Creating a Dispensing Setup Rule

Creating a dispensing setup rule includes indicating a unit of measure (UOM), tolerance type and limits, and adding instructions for the item dispensing operation.

### To create a dispensing setup rule:

1. Navigate to the **Create Dispensing Setup** window.

2. Search and select an **Organization** by code or **Organization Name**.

3. Search and select a **Recipe** by name or **Recipe Description**. If there are several recipe versions, then select the version when it is requested.

4. Search and select a recipe-enabled **Item** by name. Required.

   > **Note:** Define the dispensing setup for item, item-organization, or a combination of item, organization, and recipe. The combination of item, organization and recipe is the most restrictive option.

5. Search and select **Dispense UOM** by **Dispense UOM Class**. Required.

> **Note:** The Dispense quantity UOM must be convertible to the item's primary UOM. It is independent of other item-assigned UOMs such as those assigned to the secondary quantity, reservation quantity, batch quantity, and formula quantity.

6. Select **Tolerance Type**:

   • Percentage

   • Quantity

     The tolerance limit is applied to the planned quantity and not the reserved quantity. If the dispense quantity is lower than the lower tolerance value, then it is treated as partial dispense.

7. Enter **Upper Tolerance**. Depending on the tolerance type selected, this is either a percentage of the desired dispense quantity or an actual quantity not to exceed.

8. Enter **Lower Tolerance**. Leave this field blank for zero tolerance.

9. Select **Yes** for **Dispense Required** to enforce dispensing. The batch enforces dispensing at the batch material line level.

10. Enter **Start Date**. Required.

11. Enter **End Date**.

12. Click **Apply**.

13. Click **Create Instructions** to add an instruction set to the dispensing setup.

    Refer to "Creating an Instruction Set" for detailed information.

14. Obtain electronic signatures for the dispensing setup, if e-record events are enabled.

    > **Note:** Enable the oracle.apps.gmo.dispense.setup.create business event to obtain electronic signatures for a dispensing setup rule.

    > **Important:** You cannot manually transact material that requires dispensing.

# Updating a Dispensing Setup Rule

Update a dispensing setup rule from the Dispensing Setup window. Modify the

tolerance type and tolerance limits and also add instruction sets to the dispensing setup.

**To update a dispensing setup rule:**

1. Navigate to the **Dispensing Setup** window.

2. Select a dispensing setup from the list of setups available in the search results.

3. Click **Update**.

4. Modify **Dispense Required**, **Tolerance Type**, **Upper Tolerance**, **Lower Tolerance**, and **UOM**.

5. Click **Update Instructions** to update the instruction sets. Refer to "Updating Instructions" for detailed information.

# Searching for a Dispensing Setup Rule

Search for existing dispensing setup rules from the Dispensing Setup window. Update or delete an existing setup rule.

**To search for dispensing setup rules:**

1. Navigate to the **Dispensing Setup** window.

2. Enter any of the following to narrow your search:

   - Search and select an organization by **Organization** code or **Organization Name**.

   - Search and select a recipe by the **Recipe** name or **Recipe Description**.

   - Search and select an item by the **Item** name or **Item Description**. The list displays all recipe-enabled items.

3. Click **Go**.

4. Click **Show Details** to view the dispensing setup details with the associated instructions.

   Update an existing setup or manage the dispense instructions. Refer to "Updating a Dispensing Setup Rule" for detailed information.

# Setting Up a Device and Label Printing

Following are the steps performed in Oracle Manufacturing Execution System (MES) for Process Manufacturing to use the device integration capability of Oracle Warehouse

Management System (WMS):

## To integrate a device:

1. Define a device:

    1. Log in to the **MES for Process Manufacturing Administrator** responsibility.

    2. Choose **Define Devices** from **Setup**.

    3. Define a new device, or select from the available devices.

    4. Select **Enabled** to configure device reading.

    5. Set the default **Output Method** for this device to WMS API.

    6. Set **Device Type** to Scale for dispensing or to Manufacturing Equipment for process parameters.

        > **Note:** Specify the subinventory for each device. For Scales, select the subinventory where dispensing is performed. This is the same selection as made for the batch material consumption subinventory. Enter Level as the Subinventory.

    7. Assign a message template to the device.

2. Assign the device to the new OPM business event. For example, Process Parameter Event or Process Dispensing Event:

    1. Choose **Assign Devices** from **Setup**.

    2. Click **Save**.

        > **Note:** The organization must be Warehouse Control System-enabled. Device integration is only supported in OPM for the Process Parameter and Process Dispensing business events.

3. Define request and response directives in the WMS:

    1. Create a device directive for the OPM business event.

    2. Request a directive. Directives specify the data field sequences for the communication messages between Oracle Applications and the device.

    3. Define message templates. Message templates specify the data field sequences for the communication messages between the device and Oracle Applications.

4. Map device response to the message component codes. For example, Weight UOM Code, Quality, or Batch.

5. Navigate to the **Define Devices** window and assign the message template defined for the device.

> **Caution:** Automatic Storage and Retrieval System (ASRS) device types can result in an error. Valid options include Scales and Manufacturing Equipment.

### To set up label printing:

1. Navigate to **Label Printing** through **Inventory Set Up**.

2. Define a printer.

3. Associate a label type to the business flow at the site level. Label types are:
   - Process Dispensing associates to:
     - Dispense Palette
     - Process Dispense Material
     - Process Material
   - Process Production associates to Process Product
   - Process Quality associates to Process Sample

4. Assign a printer to each label type.

5. Create a label format or use the default format shipped.

   An XML file is generated with instructions to print a label of specified format to the printer label when you perform a transaction. The XML file is deposited in the specified directory. The third party label printing software retrieves this XML file and prints the label.

   Refer to "Defining Devices," "Assigning Devices to Business Events," and "Label Printing Integration Kit" in the *Oracle Warehouse Management Implementation Guide* for additional information on setting up label types, devices, and device integration.

# Setting Up Nonconformance Tracking

Unexpected events can occur that have direct impact on the manufacturing process and

the quality of finished goods. Nonconformances must be tracked and recorded in the batch record and used for analysis by the quality departments for Corrective Action and Preventive Action (CAPA). To document a complete record of a manufacturing batch, evidence of nonconformance must be included in the control batch record, along with appropriate details of when the nonconformance occurred, the phase of the batch in which it occurred, details of the incident or observation, level of criticality, and the required follow up and signatures by the operators and supervisors. Oracle Manufacturing Execution System (MES) for Process Manufacturing tracks all the manufacturing nonconformances caused by item substitutions, resource substitutions, and dynamic operator observations such as a power interruption or machine failure. Notification of nonconformance may be routed electronically to the reviewers and approvers with the nonconformance details such as electronic signature information logged in the control batch record electronic document.

Copy the seeded nonconformance collection plan to the inventory organizations to log nonconformance events for the production batches.

**To set up nonconformance tracking in Oracle Quality:**

1.  Navigate to the **Copy Collection Plan** window in Oracle Quality.

2.  Search for the **Template Nonconformance Master Plan (Nonconformance only)** collection plan.

3.  Initialize a copy process by selecting the target organizations.

4.  Make all necessary additions or deletions to customize the collection plan.

    > **Note:** Go to the Collection Plan window to add or delete collection elements from the collection plan.

5.  Enable the **Process Manufacturing Transaction**.

6.  Click **Enable Deferred E-Signature** to enable the inclusion of the nonconformance in the Control Batch Record.

7.  Repeat the process for all organizations under which the nonconformance must be tracked.

## Restrictions

The following process-specific collection elements must be part of the copied collection plan:

| Collection Element | Description |
| --- | --- |
| Organization | Process Plant |
| Batch No | Batch Number |
| Material | Material |
| Lot | Lot |
| UOM | Unit of Measure |
| Qty | Quantity |
| Step No | Batch Step Number |
| Operation | Operation Number with the description associated to it |
| Activity | Activity Number with the description associated to it |
| Resource | Resource with the description associated to it |
| Process Parameter | Resource Process Parameter |

Refer to the *Oracle Quality Implementation Guide* for additional information.

# 3

## Instruction Sets and Instructions

Instruction sets are a convenient method to group or categorize instructions. Instruction sets are reusable. Instructions are the text that becomes part of the batch record. Standard Operating Procedures (SOPs) are documents, images, or other files containing information that give detailed instructions on a specific step such as setting up a blender or other plant equipment, and cleaning of equipment. You access a link to an SOP from an individual instruction. An SOP link can be a URL, a document, or another file stored in the Oracle Applications attachments repository. Individual instructions can reference one or more SOPs.

This chapter covers the following topics:

- Requirement
- Understanding Instruction Sets and Instructions
- Creating an Instruction Set
- Creating Instructions
- Adding Instructions to an Instruction Set
- Reordering Instructions in an Instruction Set
- Searching for Existing Instructions
- Updating Instructions
- Viewing the Instructions List
- Updating an Instruction Set
- Viewing the Instruction Set List
- Adding Instructions to an Operation

## Requirement

Following is a requirement that customers have for instructions and instruction sets:

## Can we use the application to manage standard operating procedures (SOPs)?

Yes. SOPs play an important role in assuring quality and adherence to established procedures. It is essential that they are understood and followed by all roles in a manufacturing facility. Create instruction sets and attach SOPs to them to meet your compliance standards.

**Simplify SOP Management**

You can use instructions and instruction sets to attach SOPs to line items of a recipe or for dispensing operations. You can also attach SOPs to a batch during batch release. Display the SOP during reporting, and provide links to an individual SOP from both the batch and its process instructions. Individual process instructions can refer to one or more SOPs.

# Understanding Instruction Sets and Instructions

The instruction set is an electronic folder of common instructions. Use instruction sets to group or organize a series of instructions. For example, set up individual instruction sets for pulverizing, blending, mixing, washing, and cooking. These sets serve as containers to help organize groups of instructions with common themes, maintenance requirements, or associations to responsibilities in the work breakdown structure.

## Setting Up Instruction Sets

Instruction sets are the containers for instructions. Use instruction sets to organize, classify, or maintain a series of instructions.

Define an instruction set for any of the following:

- Item in a formula

- Operation, activity in an operation, or resource in an operation

- Operation, activity, or resource in a routing

- Operation, activity, resource, or item in a recipe

> **Note:** Override instructions are defined at the lowest level in the hierarchy. The progression from lowest to highest is: item, operation, routing, and recipe. It is recommended that you define instructions at the Operation or Step Quantity level in the recipe. Instructions defined at these levels are automatically presented to the production operator in the Operator Workbench. Instructions defined at other levels, such as Activity, Resource, or Material are available in the Operator Workbench, but the production operator

must search for them by selecting a specific entity.

## Setting Up Instructions

Instructions are important components of the manufacturing process that provide details on specific steps. Instructions make processing steps easier to follow. They assure a documented, repeatable process to improve productivity, quality, and consistency throughout the manufacturing process.

Instruction setup streamlines the batch execution process by letting the manufacturing engineers associate viewable characteristics to an instruction. During batch execution, production operators can navigate to the tasks using a single keystroke.

Set up instructions to:

- Drive process execution at the instruction level

- Acknowledge and comment on instructions interactively at the operator level

- Secure e-signature approvals for instructions

- Support different types of instructions

- Associate tasks and Standard Operating Procedures (SOPs) to instructions

- Support instruction at the process operation, activity, resource, and material level

- Copy instructions from other entities

- Group instructions into reusable instruction sets

# Creating an Instruction Set

Create instruction sets and add standard operating procedures (SOPs) to them. Instruction sets are used to associate several instructions into a logical grouping that can be reused.

Add instructions to the newly created instruction set. Create new instructions or search for and add existing instructions.

Define an instruction set for any of the following:

> **Important:** You create or access an instruction set from the reference entity. For example, from an operation or dispense setup. Other reference entities are routing, recipe, formula, activity, and resource.

## Prerequisites

- Create SOPs.

- Create reference entities such as operations, dispense setup, routings, recipes, formulas, activities, or resources.

### To create an instruction set:

1. Navigate to the **Instruction Set** window.

2. Click **Create**.

3. Enter a name for the **Instruction Set**. Required.

4. Select an **Instruction Type**.

   - Dispense

   - Reverse Dispense

   - Process

5. Enter a **Description** for the instruction set.

6. Click **More** for **SOP** to add the related SOPs, or click **AddAttachments** to add other attachment types.

7. Search for attachments by Title, Description, Category, Last Updated By, Last Update Date, Type, and Usage.

8. Click **Go**.

9. Enter a **Description** for the instruction set.

10. Click **Apply** to save.

11. Click **Add Attachments** to attach an electronic document to the instruction set. The **Add Attachment** window displays.

# Creating Instructions

Create instructions, identify the tasks, and add standard operating procedures (SOPs) to the instructions using the Instructions window.

Create instructions for:

- Operation, Activity, and Resource

- Routing

- Recipe

- Item

> **Tip:** Create instructions at the operation level for the most flexibility in using them.

## Prerequisites

- Create reference entities such as operations, dispense setup, routings, recipes, formulas, activities, or resources.

- Create Instructions on the Instruction Create window.

- Determine the structure for the instruction.

### To create instructions:

1. Navigate to the **Create Instruction** window.

2. Enter the **Instruction Number**. Required.

3. Enter the **Instruction Text**. Required.

4. Select a value for the **Acknowledgement**:

   - **Optional** indicates the acknowledgement is optional for this instruction.

   - **Mandatory - Able to Proceed**- to indicate the acknowledgement is mandatory for this instruction. You can proceed to the next instruction and acknowledge it. However, you must return to this instruction to complete it prior to closing the batch or batch step.

   - **Mandatory** to indicate the acknowledgement is mandatory for this instruction. You cannot proceed to the next instruction without acknowledging the current instruction.

     > **Note:** Approver setup and configuration is supported only for mandatory instructions.

5. Enter a **Task**. For example, Dispense.

6. Enter a **Task Attribute**.

7. Enter a **Task Label**. For example, Dispense.

8. Click **More** to add the related **SOP**.

9. Click **Add another row** to specify the number of signatures.

10. Specify the **Number of Signatures** required for validating this instruction and the **Role** of the signer.

    A role can be a user name or a responsibility. When a responsibility is used, then specify the number of signers who must sign the transaction. When a user name is used, then the number of signers is not valid.

11. Click **Apply** or click **Apply and Create Another** to save the changes and proceed to create another instruction.

# Adding Instructions to an Instruction Set

Use the Add Instructions window to add instructions to an instruction set.

## Prerequisites

- Create instruction sets.

- Create instructions.

### To add existing instructions:

1. Navigate to the **Add Instructions** window.

2. Search for and select an instruction set that has instructions of the same instruction type.

3. Click **Next**.

4. Select instructions.

5. Click **Next**.

6. Enter instruction numbers.

7. Click **Next**.

8. Review selected instructions.

9. Click **Finish**.

10. Create new instructions or add existing instructions to the set.

11. Move selected instruction up or down the displayed order.

> **Note:** When you copy instructions from an existing instruction set, there is no linkage back to the source instructions. Subsequent changes you make to the source instruction set do not impact instructions copied from this set.

Refer to "Reordering Instructions in an Instruction Set" for details.

# Reordering Instructions in an Instruction Set

Use the Reorder function to reorganize instructions.

## Prerequisites

- Create instructions sets.

- Create instructions

### To reorder instructions in the instruction set:

1. Navigate to the **Instructions** window.

2. View the newly added instructions.

3. Click **Reorder**.

4. Move selected instruction up or down the list.

# Searching for Existing Instructions

Use the search capability in the Add Existing function to search for an existing instruction in an instruction set.

## Prerequisites

- Create instruction sets

- Create instructions.

**To search for existing instructions:**

1.  Navigate to the **Instruction Set** window.

2.  Select an instruction set.

3.  Click **Add Existing**.

4.  Search for an existing instruction set.

# Updating Instructions

If you change an instruction or its characteristics for an approved entity or its nodes, then it results in a version change.

## Prerequisites

*   Create instruction sets.

*   Create instructions.

**To update instructions:**

1.  Navigate to the **Update Instructions** window.

2.  Modify the instruction text,acknowledge, task, task attribute, and the task label information.

3.  Click **SOP** to add more SOPs to the instructions.

4.  Update the number of signers and the role for validating this instruction.

5.  Click **Apply**.

# Viewing the Instructions List

View the list of instructions from the Instructions window.

## Prerequisites

*   Create instruction sets.

*   Create instructions

**To view the list of instructions:**

1. Navigate to the **Instructions** window.

2. Click **Instructions**.

# Updating an Instruction Set

Use the Update function in the Instruction Set window to modify instruction text, descriptions, and attachments to instructions.

# Prerequisites

- Create instruction sets.

- Create instructions.

**To update the instruction set:**

1. Navigate to the **Instructions Set** window.

2. Click **Update** for the instruction set to update.

3. Modify the instruction text and description.

4. Modify Standard Operating Procedure (SOP) attachments.

5. Click **Apply**.

# Viewing the Instruction Set List

Navigate to the **Instruction Set** window to view the list of instruction sets.

# Adding Instructions to an Operation

Following is an example of how to add instructions to an operation used in a production batch.

# Prerequisites:

- Set up the Process Engineer responsibility in the Oracle Process Manufacturing Process Execution application.

- Set up GMO profile options.

- Grant GMO access to the Process Engineer.

- Grant e-signature batch e-signature permission to the Process Engineer.

- Enter Standard Operating Procedures (SOPs) that you search for and add as attachments.

**To add an instruction to an operation:**

1. Navigate to the **Process Operation Details:Activities** window in the Process Engineer responsibility.

2. Query the desired **Operation**.

3. Choose **Process Instructions** from the **Actions** menu. The **Instruction Set** window displays for the selected operation.

4. If the desired instruction set is displayed, then click it and proceed to step 5. Otherwise, create the instruction set as follows:

    1. Click **Create**.

    2. Enter the **Instruction Set** name.

    3. Select **Process** as Instruction Type. Default.

    4. Click **More** next to SOP to search for and add an existing SOP.

    5. Click **Add New** to add the SOP as an attachment.

    6. Enter a **Description** for the instruction set.

5. Click **Apply**. The instruction set is added to the list, and the SOP is attached to the set.

6. Navigate to the **Instructions** window for the desired instruction set.

7. If the desired instruction is displayed, then click it and proceed to step 8. Otherwise, create the instruction as follows:

    1. Click **Create**.

    2. Enter **Instruction Num** as the instruction number. This number is entered automatically when you set up the application for automatic numbering.

    3. Enter the **Instruction Text**

    4. Select one of the following as **Acknowledgement**:

- **Optional** for an instruction that is informational. Perform this instruction in any order, or skip it. If you do not acknowledge the instruction, then batch processing proceeds without interruption.

- **Mandatory** for an instruction that must be acknowledged and signed electronically if it is configured to require an e-signature. If you do not acknowledge the instruction, then you cannot proceed to the next instruction. The application requires that all mandatory instructions are acknowledged before the batch step and the batch can be closed.

- **Mandatory: Able to Proceed** for an instruction that must be acknowledged and signed electronically if it is configured to require an e-signature. You can temporarily bypass this instruction and proceed to other instructions, however, the application requires that these instructions are acknowledged before the batch step and the batch can be closed.

5. Search and select a **Task**.

6. Search and select a **Task Attribut**e.

7. Enter a task **Label**.

8. Configure signers for approval:

   1. Select **Add Another Row** in the **Signers** region.

   2. Add signers using only one of these methods:

      - **Number of Signatures** as 1 and **Role** as user name.

      - **Number of Signatures** as 1 and **Role** as responsibility.

      - **Number of Signatures** as the total number of signers required and leave **Role** blank.

      - **Number of Signatures** as 1 and **Role** as either user name or responsibility. Enter the lowest ranking role first, followed by any additional roles in increasing rank within the organization.

   3. Repeat from step 1 until all signers are added.

9. Click **Apply**.

10. Click **Reorder** to reposition instructions in the list:

    1. Select the instruction.

2. Click the arrow in the **Move Up** column to move the instruction up the list.

3. Click the arrow in the **Move Down** column to move the instruction down the list.

4. Click **Apply**.

11. Return to the "Note: Navigate to HTML Applications..." message.

12. Click **OK**. The process instruction is added to the operation.

# 4

# Operator Workbench

The Operator Workbench guides you through a set of predefined instructions created to complete operations required for a production batch.

This chapter covers the following topics:

- Requirement
- Understanding the Operator Workbench
- Locking Batch Steps
- Acting on Instructions

## Requirement

Following is a requirement that customers have for a simple graphical navigation tool to manage their production processes:

### Is there a way to navigate through production steps with an easy to use graphical tool?

Yes. Use the Operator Workbench to navigate and manage the whole production process. This simple tool provides rapid access to every part of your production process.

**Operator Workbench Simplifies Navigation**

Use the Operator Workbench to identify incomplete tasks. Simple queries help find batches on a wide variety of search criteria such as product, resource, date range, and entity. Simplified, single-click navigation lets you act on an instruction and enter data against it based on the requirement.

## Understanding the Operator Workbench

Batch records are work orders that provide a detailed step-by-step course of action to steer production operators through the batch manufacturing process. Depending on

individual work instructions, some batch steps can be done at any time, while other steps must be completed before batch production can proceed. Steps can require one or more signatures to indicate the formal approval to proceed. Entry of production data such as the actual quantity of material added, temperature and pressure observed at various batch steps, or collection of quality samples for in-process testing all add to the complexity of completing the tasks that complete the batch, and must also be archived in the batch record. Oracle Manufacturing Execution System (MES) for Process Manufacturing simplifies this work by putting all the information that the production schedulers, supervisors, and operators need to manage a batch into a single application that virtually eliminates the complexity of paper recordkeeping. As part of the recipe development process, you can create instructions individually, or in unitized sets that can be organized into reusable procedures. Instructions can be enhanced with images, data files, and paperless attachments that assist in completing batch processing. Associate procedures to major components of the recipe, including its materials, resources, operations, and activities. Processing instructions can have associated tasks that require specific actions. Actionable tasks and each instruction can require one or more electronic signatures for completion. For example, in the runtime activity for a blending operation, one instruction can require the operator to take the temperature of the blender before material addition. A task is designed to access the process parameter for blender temperature, and another task consumes material into the blender hopper. If either task requires a signoff before the runtime activity can proceed, then an electronic e-signature is mandated. When e-signature permission is granted, the runtime activity can proceed. Both supervisors and production schedulers have top-to-bottom access to real-time production batch status. They can determine batch status immediately using a flexible search engine that displays instruction-level batch details. This provides the agility to take rapid corrective action that is fully documented in the batch audit trail.

The Operator Workbench offers capabilities to:

- Identify tasks to complete. The search window lets you search the batches on a wide variety of search criteria such as product, resource, date range, and entity.

- Lock operations. Take ownership of an operation step by locking it while completing the task. Unlock the step after the task is completed.

- View instructions interactively. View the instructions at material level that are associated to the task such as a recipe, operation, activity, or resource.

- Acknowledge instructions. Acknowledge the instructions and enter comments during the process and indicate to the application that the instruction is completed.

- Navigate to transactional tasks in one click. During batch execution, a single click lets you act on an instruction and enter data against it based on the requirement.

    For example, in an instruction to measure the temperature of a liquid and enter it as a resource process parameter, you create the resource process parameter entry as a task that can be accessed directly from its related instruction.

- View the batch summary and navigate to related actions. Navigate to different related actions in an operation, activity, or resource such as quality, resource transaction, and so on.

## Operator Workbench Process

Following summarizes the process to use the Operator Workbench:

1. Create the batch.

2. Release the batch

3. Release batch steps.

4. Retrieve the worklist of released steps.

5. Lock each step as it will be processed.

6. Complete process instructions and related tasks.

> **Note:** Log nonconformances through the OPM Process Execution window interfaces. Refer to the *Oracle Process Manufacturing Process Execution User's Guide* for additional information.

# Locking Batch Steps

Use the Operator Workbench to search for and lock a batch step to claim ownership of it.

## Prerequisites

- Determine that the desired batch operation or step has a status of WIP.

- Verify your permission to access and lock the batch and its batch steps.

### To lock a batch step:

1. Navigate to the **Operator Workbench** window.

2. Select an **Organization** code. Required.

3. Click **Go**.

4. Enter any of the following to narrow your search:

- Search and select the **Batch**.

- Search and select the code for the primary **Product** used in the batch by **Product** or **Description**.

- Search and select the **Resource** associated with the batch steps by the **Resource** name or **Description**.

- Search and select the **Lock Owner** by **User Display Name** or **User Name**.

5. Select the **Status** of the batch. Enter any of the following to narrow your search in the context organization entered:

   - Select **All** to find all the available batches listed.

   - Select **Closed** to find the batches that are closed.

   - Select **Complete** to find the batches that are completed.

   - Select **New** to find the new batches.

   - Select **Pending** to find the batches that are scheduled.

   - Select **WIP** to find batches that are in process. Oracle Manufacturing Execution System (MES) for Process Manufacturing acts on batches with this status.

   - Select **Canceled** to find the canceled batches.

     > **Important:** The following batch and batch step statuses cannot be processed in the Operator Workbench: New, Pending, Complete, Closed, and Canceled.

6. Select a **Planned Start Date** from the calendar. It is the planned start date and time of the batch.

7. Select a **Planned Completion Date** from the calendar. It is the planned completion date and time of the batch.

8. To refine the search, click **Show More Search Options**, then search and select by name or description the:

   - **Formula**

   - **Recipe**

   - **Routing**

- **Operation**

- **Activity**

- **Ingredient**

- **Actual Start Date** and time of the batch.

- **Actual Completion Date** and time of the batch.

9. Click **Go**.

10. Select one or multiple batch steps to lock or unlock. The batch steps display in a tabular format. **Status** displays the current batch step statuses as:

    - **Locked** indicates the batch steps that are locked. You cannot lock the batch steps already locked by others. **Lock Owner** displays the locked by information.

    - **Lock Disabled** indicates the batch steps that cannot be locked because the step is not in WIP status.

    - **Lock Enabled** indicates the batch steps that are available to lock.

        **Note:** You can only lock batch steps that are lock enabled.

11. Click **Lock** to lock each batch step.

12. Take appropriate action on each locked step.

13. Click **Unlock** to release batch step ownership.

## Acting on Instructions

Use the Operator Workbench to:

- View the instructions.

- Perform actions associated each instruction.

- Complete instructions and their associated tasks.

Following is an example of how to act on instructions associated to a batch. It is possible, however, to act on instructions associated to other entities.

## Prerequisites

- Create instruction sets.

- Create instructions

- Optionally, associate tasks to instructions

- Determine that the desired batch has a status of WIP.

- Verify your permission to access and lock the batch and its batch steps.

### To act on instructions:

1. Navigate to the **Operator Workbench**.

2. Click **Execute Instructions**.

   > **Note:** You can only execute instructions for steps that you locked. If you have not locked a step, then instructions are read-only.

3. Click **Batch Details**.

4. Review the batch information details such as batch number, batch material, operations, and activities; and the dispense details such as dispense required, dispensed quantity, and WIP plan quantity.

   > **Important:** Refer to the *Oracle Process Manufacturing Process Execution User's Guide* for definitions of all fields displayed.

5. Perform actions such as batch update, material update, reservation, nonconformance tracking, and material dispensing.

6. Click **Operation Execution**.

7. Click **Lock**.

8. Display the instruction **Label**.

9. Click **Task** to open the relevant application window.

10. Perform the transaction.

11. Click **Save**.

12. If an electronic signature is required, then complete it, and click **Close**.

13. Click **Apply** to proceed.

14. Perform and mark all pending mandatory instructions as **Complete**.

15. Optionally, perform and mark all pending optional instructions as **Complete**.

16. Click **Apply**.

# 5

# Dispensing

Dispensing the right materials to the right batches prior to the manufacturing process is a key activity in life sciences and other process industries. The process is critical when working with potent active pharmaceutical ingredients (APIs) in drug manufacturing. Decimal errors in API calculation can be life threatening. Companies preweigh materials to avoid these errors and to assure rapid delivery at the critical stages of the drug formulation process.

OPM MES Dispensing lets you deliver material in several modes of operation with full label printing capabilities. Functionality supported includes:

- Dispensing modes

- Tolerances

- Label printing

- Scale reading

- Reverse dispensing

This chapter covers the following topics:

- Requirement
- Understanding Dispensing
- Reserving Material
- Searching for Reserved Material to Dispense
- Executing Dispense Instructions
- Dispensing Reserved Material
- Searching for Dispensed Material
- Viewing the Dispensed Material Activity Details
- Viewing Reverse Dispense Instructions

- Performing Reverse Dispensing

- Viewing the Reverse Dispensed Material Activity Details

- Running Reports for Dispensing Operations

# Requirement

Following is a requirement that customers have for supporting dispensing room operations:

## Does the application support dispensing room operations?

Yes. Dispensing functionality is a key requirement in the life sciences industry. Dispensing appropriate materials to the right batches prior to the manufacturing process is a key activity in the pharmaceutical and life sciences Industries.

**Full Dispensing Room Support**

Oracle Manufacturing Execution System (MES) for Process Manufacturing assists the dispensing operator with the in the formulation process by tracking quantities of critical materials used in the manufacturing process. For example, drugs require critical quantities of materials to be added in the manufacturing process. Each material has specific quality parameters and ingredient addition quantities. Oracle Manufacturing Execution System (MES) for Process Manufacturing provides full dispensing room support that is integrated with weigh scale operations to avoid costly manufacturing errors. Drug formulation requires sterile cleanroom environments that must which must be maintained and cleaned according to documented standard operating procedures (SOPs). Weighing equipment must be calibrated and verified. Therefore full dispensing room support for both the environmental conditions and equipment used is essential to accurate drug manufacture.

# Understanding Dispensing

Oracle Manufacturing Execution System (MES) for Process Manufacturing manages dispensing and pre-weigh processes to control the labeling, containerization, and delivery of precise quantities of specific materials to their appropriate batch steps. All delivery stages are tracked, including material identification from the point of issue in inventory to point of delivery in the batch manufacturing process. Tracking is critical when working with active pharmaceutical ingredients in drug formulation. Dispensing must meet the guidelines set forth by the U.S. Food and Drug Administration (FDA) regulations (Title 21 Part 211.101). Dispensing is also critical when using ingredients that have hazardous properties such as the volatile organic compounds (VOCs) used in paint and plastics manufacturing. Control over the precise delivery of material is essential to ensure a safe manufacturing process and consistent quality product. Standard weighing scale integration into the dispensing process provides a precise, safe, effective delivery of material. Oracle Manufacturing Execution System (MES) for

Process Manufacturing minimizes the risk of data entry errors by removing error prone manual steps from the batch manufacturing process. Dispense material automatically or manually to labeled pallets in the holding cage. The application generates labels for full traceability throughout the manufacturing process. Oracle Manufacturing Execution System (MES) for Process Manufacturing provides online access to standard operating procedures (SOPs), detailed acknowledgeable work instructions, and simplified e-signature processing. This seamless integration streamlines signoff processes for even the most complex batch operations. Operator and supervisor approvals are orchestrated with a complete audit trail that follows current guidelines for good manufacturing practices.

The dispensing functionality:

- Displays dispense pending detail reservations based on the parameters used for query.

- Lets you acknowledge all instructions defined for dispensing.

The functionality supports partial dispenses. Partial dispense is when the full quantity required is not achieved in one dispense, possibly because of the size of the containers into which you are dispensing. For example, the amount required is 112.5 kg, but the minimum number of dispenses to achieve is three: two of 50 kg and one of 12.5 kg. When there is an partial dispense, another dispense is required to complete the allocation for the raw material used in the partial dispense. A check is performed on the reserved material before selecting the raw material so that the actual quantity required displays on the window.

The dispensing functionality is comprised of the following components:

- Dispensing Process

- Label Printing

- Reverse Dispensing

- Scale Integration

- Integration to instructions and e-records

- Dispense Dispatch and Dispense History reports

Redispense the dispensed material after a reverse dispense.

Approve dispense operations individually using e-records and e-signatures.

## Dispensing Process Flow

Following summarizes the process to dispense material:

1. Create a batch.

2. Create detailed reservation for material that must be dispensed.

3. Acknowledge the defined instructions.

4. Weigh materials.

5. Perform dispensing.

6. Obtain electronic signatures.

7. Print labels.

# Dispensing Features

Following presents the dispensing features provided:

## Material Identification

You can identify the material or lots to dispense to the target batch and requisitioned from the warehouse or dispensing store. You can also identify the material or lots required to support dispensing for a specified batch by determining the material or lots reserved for dispensing.

## Multiple Dispensing Modes

Following are dispensing modes offered:

- Full Container Dispense mode is used to deliver the total quantity of material present in the source container. The source container is released to the production batch for consumption.

- Source Container Dispense mode is used to deliver material from a source container. The whole source container is released to the production batch. Required material is dispensed and consumed by the batch. Any remaining material is physically transferred to a new target container, and returned to the warehouse.

  For example, a formula requires 45 kilograms (kg) of material. The source container quantity is 50 kg, and 5 kg is removed to a new container in the dispensing process for return to stock. The remaining 45 kg in the source container is dispensed to the batch.

- Target Container Dispense mode is used to deliver material from a target container. Required material is dispensed from a source container to a target container in the dispensing process. The target container material is consumed by the batch. Material remaining in the source container is returned to the warehouse.

### Tare Weights

Tare weight is the weight of the actual container when it is empty. The tare weight function lets you:

- Capture tare weight data

- Store the average tare weight for a container in the Item Master

- Use tare weight to calculate the quantity to dispense

The tare weight of the target container defaults from the entry made in the Oracle Inventory Item Master. You can enter this value manually.

> **Note:** To set up the container item, navigate to the Item Master Physical Attributes tab. Select Container Item. The UOM must be the dispense UOM for items dispensed into a container. The weight = TARE Wt.

### Tolerance

Tolerance is the permitted variation between requested or planned dispense quantity and the actual dispensed quantity.

- The dispensing tolerance is stored in the dispensing setup.

- The dispensing tolerance is applied both during dispensing and after confirmation that the dispense is complete. If a batch is only partially dispensed, then the lower tolerance is applicable only to the total quantity and not to the partial quantity dispensed.

- It is possible to maintain the tolerance either as a percentage or as a quantity.

### Label Printing

The label printer automatically prints bar code labels at a specified dispensing location. You can reprint labels. If a label is reprinted, then the print count indicator clearly marks it as a reprint by showing the number of times the label was printed. Printable label types are:

- Dispense Pallet label to identify a pallet of dispensed materia for a single production batch.

- Process Dispense Material to identify the material dispensed.

- Process Material label to identify material left over from a dispensing operation. This label assists in returning the excess material to stores.

You can specify the label to print in the manual mode of operation. Labels are

preselected for printing in the automatic mode of operation.

### Reverse Dispensing

A dispensed container can be reverse dispensed in the event of batch cancellation, or when you need to adjust the dispensed material quantity. Reverse dispense either the individual raw material or all the materials for a production batch.

### Integration to Instructions

Dispensing and reverse dispensing windows are integrated with instructions. You can acknowledge instructions associated with dispensed material through the Recipe Details window in the Oracle Process Manufacturing Product Development application.

### Device or Scale Integration

Dispensing and reverse dispensing windows are integrated with external devices to read weights directly from scales.

### E-Record and E-Signature

Dispensing and reverse dispensing windows are integrated with Oracle E-Records to capture e-signatures for dispensing, reverse dispensing, and label printing operations.

### Reporting

Generate XML Publisher-based reports to list all the pending dispense operations. These reports are:

- Pending Dispense Activity List

- Dispense Dispatch

Generate a new XML-Publisher based report to list all completed dispense operations. The reports are:

- Completed Dispense

- Dispense History

## Reserving Material

You must detail reserve material before dispensing it. Refer to the *Oracle Process Manufacturing Process Execution User's Guide* for details on reserving the material.

Refer to "Dispensing Reserved Material" in this guide for detailed information on dispensing the reserved material.

# Searching for Reserved Material to Dispense

Following is the procedure to search for reserved material to dispense.

**To search for reserved material to dispense:**

1. Navigate to the **Dispensable Material** window.

2. Enter any of the following to narrow your search for reserved material.

   - Select an **Organization**. Required. The list displays only the process-enabled organizations.

   - Search and select a **Dispense Area** by the **Description**.

   - Search and select a **Batch**. The list displays only the pending and work in process (WIP) batches in the selected organization.

   - Select a **Batch Step** number.

   - Search and select an **Ingredient** by **Name** or **Description**.

   - Search and select a **Product** by **Name** or **Description**.

   - Select a **From Date** and **To Date** from the calendar to refine the search to the batch material requirement date.

3. Deselect the **Show Partially Dispensed** indicator to display all dispenses where the total dispensed quantity is below the lower tolerance. This is the default. Select this indicator to display all dispenses less than target quantity.

4. Click **Go**.

# Executing Dispense Instructions

Following is the procedure to view dispense instructions for the material.

**To view dispense instructions for the material:**

1. Search for a reserved material from the **Dispensable Material** window. Refer to "Searching for Reserved Material" for detailed information.

2. Select an item to dispense.

3. Click **Dispense**.

4. Perform tasks as defined in the instructions.

5. Click **Finish** to navigate to the **Dispense Material** window.

# Dispensing Reserved Material

Following is the procedure to dispense reserved material for each of the listed modes of operation.

### To dispense reserved material using the Full Container mode:

1. Navigate to the **Dispense Material** window.

2. Enter the **Dispense Number**. This is the dispense document number. It is valid only if you have configured manual document number entry. Required.

3. Select dispensing **Mode** as **Full Container**.

4. Search and select the **Source Container** by **Container Name** or **Description**.

   > **Note:** Container information is set up in the Oracle Inventory Item Master.

5. Click **Read Measure** to measure the container weight. The application calculates the full container quantity.

6. Enter a **Security Tag** number.

7. Select **Dispense Label** and **Material Label** to indicate label formats for printing.

8. View the dispense instructions.

9. View the **Partial Dispense History** report.

10. Obtain e-signatures.

11. Print the labels.

### To dispense reserved material using the Source Container mode:

1. Navigate to the **Dispense Material** window.

2. Enter the **Dispense Number**. This is the dispense document number. It is valid only if you have configured manual document number entry. Required.

3. Select dispensing **Mode** as **Source Container**.

4. Search and select the **Source Container** by **Container Name** or **Description**.

5. Search and select the **Target Container** by **Container Name** or **Description**.

> **Note:** Click **Read Measure** to capture readings directly from an integrated device.

6. The empty target container weight defaults. Modify this weight if required.

7. Measure or enter the source container weight.

8. Transfer the excess material into target container.

9. Measure the target container weight with the material transferred. The dispensed quantity is calculated and displayed. This quantity is the tare adjusted source container weight minus the tare adjusted target container weight.

10. Remeasure the source container weight to verify the dispensed quantity.

11. Enter a **Security Tag** number.

12. Select **Dispense Label** and **Material Label** to print labels.

13. View the dispense instructions.

14. View the **Partial Dispense History** report.

15. Obtain e-signatures.

16. Print the labels.

## To dispense reserved material using the Target Container mode:

1. Navigate to the **Dispense Material** window.

2. Enter the **Dispense Number**. This is the dispense document number. It is valid only if you have configured manual document number entry. Required.

3. Select dispensing **Mode** as **Target Container**.

4. Search and select the **Source Container** by **Container Name** or **Description**.

5. Search and select the **Target Container** by **Container Name** or **Description**.

> **Note:** Click **Read Measure** to capture readings directly from an integrated device.

6. The empty target container weight defaults. Modify this weight if required.

7. Measure or enter the source container weight.

8. Transfer the required material into target container.

9. Measure the target container weight with the material transferred. The dispensed quantity is calculated and displayed as the tare adjusted target container weight.

10. Remeasure the source container weight to verify the dispensed quantity.

11. Enter a **Security Tag** number.

12. Select **Dispense Label** and **Material Label** to print labels.

13. View the dispense instructions.

14. View the **Partial Dispense History** report.

15. Obtain e-signatures.

16. Print the labels.

# Searching for Dispensed Material

Use the Dispensed Material Activity window to find dispensed materials and print labels for them. You can reverse dispense from this window. Following is the procedure to search for dispensed material.

## Prerequisites:

- Dispense material.

- Optionally, identify the requirement to print labels for dispensed material.

### To search for dispensed material:

1. Navigate to the **Dispensed Material Activity** window.

2. Enter as many parameters as needed to complete the search:

    - Select an **Organization** from the list. Required.

    - Search and select a **Dispense Area** from the list by **Dispense Area** name or **Description**.

- Search and select a **Batch** from the list. The list displays only the pending and work in process (WIP) batches in the selected organization.

- Select a **Batch Step** number.

- Search and select an Ingredient by **Name** or **Description**.

- Search and select a Product from the list by **Name** or **Description**.

- Narrow your search by selecting the material dispense date as, **From Date**, **To Date**.

3. Select the reservation **Status**. The available options include **All**, **Deleted Reservations**, and **Reverse Dispense Only**.

4. Select **Show Zero Net Dispensed Quantity Rows** to display all items not yet dispensed.

    **Note:** Deselect this option for reverse dispensing operations.

5. Click **Go**.

# Viewing the Dispensed Material Activity Details

Run any pending instructions, print labels, and reverse dispense from the Dispensed Material Activity Details window. Following is the procedure to view the dispensed material activity details. Use this window to:

- Determine if all instructions were performed.

- View the Reverse Dispense History.

- Associate scanned labels to their corresponding label history record. This record becomes part of the Control Batch Record (CBR) when you select the GMO Label category before you upload the scanned label images.

## Prerequisites:

- Create dispensable material.

- Optionally, run pending instructions, print labels, or scan labels for upload to the dispensed material record.

**To view the dispensed material activity details:**

1. Search for dispensed material from the **Dispensed Material Activity** window.

   Refer to "Searching for Dispensed Material" for detailed information.

2. Click **Details**. The **Dispensed Material Activity Details** window displays for the selected material:

   - **Organization** is the abbreviated name of the context organization.

   - **Organization Name** is a brief description of the organization.

   - **Dispense Area** is the code that identifies the subinventory where the batch consumes the dispensed material.

   - **Ingredient Description** is a brief description of the material dispensed.

   - **Dispense UOM** is the unit of measure for the dispensing equipment.

   - **Lot** is the code used to identify the

   - **Hazardous Material** (Yes or No)

   - **Hazard Class** is the classification for a hazardous material.

   - **Material Status** is Dispensed or Reverse Dispensed.

   - **Batch** is the batch document number.

   - **Batch Step** is the batch step identified with this dispense operation.

   - **Operation** is the code used to identify the dispense operation.

   - **Line Num** is the batch sequence line number for the operation.

   - **Product** is the code used to identify the product.

   - **Description** is a brief description of the product.

   - **Source Device** is code assigned to the source dispensing device.

   - **Description** is a brief description of the source device.

   - **Dispense**

     - **Dispense Number** is the document number assigned to the dispense operation.

- **Mode** is the dispense mode used. Options are Full Container, Source Container, or Target Container.

- **Source Device** or **Target Device** is the name of the device used for the dispensing operation.

- **Description** is a brief description of the source or target device.

- **Requested Quantity** is the total quantity needed for the dispensing operation in the selected dispense mode.

- **Material Loss** is the quantity of material lost due to a problem other than the actual dispensing operations, such as spillage or equipment failure.

- **Reverse Dispensed Quantity** is the quantity of material removed from the container holding the dispensed material for adjustment purposes.

- **Net Dispensed Quantity** is the actual quantity of material dispensed in the selected mode.

- **E-record** is the e-record associated to the dispensing operation.

- **Containers**

  - **Source Container** or **Target Container** is the item code associated to the container.

  - **Description** is a description of the container.

  - **Source Container Tare** or **Target Container Tare** is the tare weight of the source container or target container.

- **Measures**

  - **Measure of Source Container** is the number of times the source container was measured.

  - **Quantity Dispensed** is total quantity dispensed from the source container.

  - **Measure of Target Container** is total quantity dispensed from the source container.

  - **Quantity Dispensed** is total quantity dispensed from the source container.

- **Labels**

  - **Security Tag** is the alphanumeric tag used to label the dispensed material.

- **Dispense Label** indicator is used to select the dispense label for printing.

- **Material Label** indicator is used to select the material label for printing.

- **Pallet Label** indicator is used to select the pallet label for printing.

> **Note:** Select the labels to print and click **Print Labels**.

- **Dispense Instructions**
  - **Instruction Set** is the name of the instruction set for the dispensed material activity.

  - **Description** is a brief description of the instruction set.

  - **SOP** is the standard operating procedure associated to this dispensed material activity.

- **Instruction**
  - Click **Details** to display complete instruction information.

  - **Status** is the instruction status. xxx

  - **Instruction Num** is the instruction number. This number is assigned when you set up the application numbering.

  - **Instruction Type** is the instruction type.

  - **Instruction Text** is the instruction text entered.

- **Label Printing History**
  - **Label Type** is the type of label printed. Seeded label types include: Material Label for Raw Materials, Product Label Sample Label, Dispensed Ingredient Label, and Pallet Label.

  - **Print Count** is the total number of labels printed for the label type associated to this dispensing operation.

  - **Print Date** is date this label type was printed.

  - **Printed By** is the name of the resource that printed the labels.

  - **Status** is the print status for this label type.

- **E-record** is the e-record associated to printing this label type.

- **Attachments** are the graphical representations of this label.

- **Reverse Dispense History**
  - **Item** is the material dispensed as it appears on the inventory Item Master.

  - **Description** is a brief description of the material.

  - **Reverse Dispense Number** is the reverse dispense document number. It is valid only if you have configured manual document number entry.

  - **Lot** is the item lot associated to this reverse dispense action.

  - **Batch** is batch associated to this reverse dispense action.

  - **Batch Step** is the batch step associated to this reverse dispense action.

  - **Operation** is the operation in the listed batch step that is associated to the performance of this reverse dispense action.

  - **Quantity** is the quantity of material reverse dispensed.

  - **UOM** is unit of measure of the quantity.

  - **Reverse Dispensed Date** is date and time stamp of the reverse dispense action.

  - Click **Details** for detailed information on this reverse dispense number.

# Viewing Reverse Dispense Instructions

Following is the procedure to view reverse dispensing instructions.

## Prerequisites:

- Enter reverse dispense instructions.

- Dispense material.

### To view reverse dispense instructions for the dispensed material:

1. Search for a dispensed material from the **Dispensed Material Activity** window.

   Refer to "Searching for Dispensed Material" for detailed information.

2. Select an item for reverse dispensing.

3. Click **Reverse Dispense**.

4. Perform tasks as defined in the instructions.

5. Click **Finish**.

# Performing Reverse Dispensing

There are several reasons to perform reverse dispensing in production operations. Some typical reasons are:

- A parent batch is cancelled or scaled down after material is dispensed.

- To perform quality testing on material subjected to adverse conditions during transit to the shop floor.

Following is the reverse dispensing procedure.

## Prerequisites:

- Dispense material.

- Optionally, run pending instructions, print labels, or scan labels for upload to the dispensed material record.

### To reverse dispense reserved material using the Full Container mode:

1. Navigate to the **Reverse Dispense Material** window

2. Enter the **Dispense Number**. This is the dispense document number. It is valid only if you have configured manual document number entry. Required.

3. Select dispensing **Mode** as **Full Container**.

4. Search and select the **Source Container** by **Container Name** or **Description**.

   > **Note:** Container information is set up in the Oracle Inventory Item Master.

5. Click **Read Measure** to measure the source container weight. The reverse dispense weight is calculated.

6. Enter a **Security Tag** number.

7. Select **Dispense Label** and **Material Label** to indicate label formats for printing.

8. View the reverse dispense instructions.

9. Obtain e-signatures.

10. Print the labels.

**To reverse dispense reserved material using the Source Container mode:**

1. Navigate to the **Reverse Dispense Material** window.

2. Enter the **Dispense Number**. It is valid only if you have configured manual document number entry. Required.

3. Select dispensing **Mode** as **Source Container**.

4. Search and select the **Source Container** by **Container Name** or **Description**.

5. Search and select the **Target Container** by **Container Name** or **Description**.

> **Note:** Click **Read Measure** to capture readings directly from an integrated device.

6. Measure or enter the source container weight.

7. Click **Reverse Dispense** to remove the excess material.

8. Measure the target container weight with the material transferred. The reverse dispensed quantity is calculated and displayed.

9. Remeasure the source container weight to verify the reverse dispensed quantity.

10. Enter a **Security Tag** number.

11. Select **Dispense Label** and **Material Label** to print labels.

12. View the dispense instructions.

13. View the **Partial Dispense History** report.

14. Obtain e-signatures.

15. Print the labels.

# Viewing the Reverse Dispensed Material Activity Details

Run any pending instructions, or reprint the reverse dispense labels. Following is the procedure to view the reverse dispensed material activity details.

## Prerequisites:

- Reverse dispense material.

### To view the reverse dispensed material activity details:

1. Navigate to the **Dispensed Material Activity Details** window.

2. View the Reverse Dispense History of an item.

3. Click **Details** to display the material activity details.

    > **Note:** Refer to "Viewing the Dispensed Material Activity Details" for explanations of the fields displayed on the Reverse Dispensed Material Activity Details window.

# Running Reports for Dispensing Operations

The Dispense Dispatch report lists all the pending dispenses. The Dispense History report lists all the completed dispense operations.

### To run and print the Dispense Dispatch report:

1. Navigate to the **Submit a New Request** window:

    Select **MES for Process Manufacturing Administrator: Request : Run**.

2. Select the request type as **Single Request**.

3. Click **OK**.

4. Enter **Dispense Dispatch Report** as the request **Name**.

    If you are submitting a request set, then enter the **Request Set** name in the **Submit Request Set** window.

5. Complete the other fields on the window. Refer to "Request Submission" in *Oracle Applications User's Guide* for detailed information.

6. Select the various parameters such as Plant, Dispense Area, Batch, From and To

dates.

7. Click **Submit Request**.

8. Following is the output of the Dispense Dispatch report

    • **Organization** is the abbreviated name of the context organization.

    • **Search Criteria**

        • **Batch** is the batch document number.

        • **Plant** is the name of the production facility where the material is dispensed.

        • **Dispense Area** is the inventory source for the dispensed material.

        • **From Date** is the start date for this report.

        • **To Date** is the end date for this report.

    • **Dispensable Material**

        • **Item** is the material dispensed as it appears on the inventory Item Master.

        • **Description** is a brief description of the material.

        • **Lot** is the item lot associated to this dispense action.

        • **Batch No** is the batch document number.

        • **Batch Step** is the batch step associated to this dispense action.

        • **Operation** is the operation in the listed batch step that is associated to the performance of this dispense action.

        • **Required Quantity** is the prescribed quantity for the dispense operation.

        • **UOM** is the unit of measure for the dispensing equipment.

        • **Required Date** is the date and time the dispense operation is required.

**To run and print the Dispense History report:**

1. Navigate to the **Submit a New Request** window:

    Select **MES for Process Manufacturing Administrator: Request : Run**.

2. Select the request type as **Single Request**.

3. Click **OK**.

4. Enter **Dispense History Report** as the request **Name**.

5. Complete the other fields on the window. Refer to "Request Submission" in *Oracle Applications User's Guide* for detailed information.

6. Select the appropriate parameters for the report such as Plant, Dispense Area, Batch, From and To dates.

7. Click **Submit Request**.

   To submit another request, select **Yes**.

8. Following is the output of the Dispense History report:

   - **Organization** is the abbreviated name of the context organization.

   - **Dispense Area** is the code that identifies the subinventory where the batch consumes the dispensed material.

   - **Search Criteria**

     - **Batch** is the batch document number.

     - **Plant** is the name of the production facility where the material is dispensed.

     - **Dispense Area** is the inventory source for the dispensed material.

     - **From Date** is the start date for this report.

     - **To Date** is the end date for this report.

     - **Operator** is the name of the person who performed the dispensing operation.

   - **Dispensed Material**

     - **Item** is the material dispensed as it appears on the inventory Item Master.

     - **Description** is a brief description of the material.

     - **Dispense Number** is the dispense document number. It is valid only if you have configured manual document number entry.

     - **Lot** is the item lot associated to this dispense action.

     - **Batch** is the batch document number.

- **Batch Step** is the batch step associated to this dispense action.

- **Operation** is the operation in the listed batch step that is associated to the performance of this dispense action.

- **Line Number** is the batch sequence line number for the operation.

- **Net Dispensed Quantity** is the actual quantity of material dispensed in the selected mode.

- **Dispensed Date** is the date and time stamp of the dispense action.

- **Required Quantity** is the prescribed quantity for the dispense operation.

- **Dispense Mode** is the dispense mode used. Options are Full Container, Source Container, or Target Container.

- **Dispense UOM** is the unit of measure for the dispensing equipment.

- **E-record ID** is the e-record associated to this dispense operation.

- **Quantity Reverse Dispensed** is the quantity of material reverse dispensed using the dispense mode indicated.

- **Material Loss** is the quantity of material lost due to a problem other than the actual dispensing operations, such as spillage or equipment failure.

- **Operator** is the name of the person who performed the dispensing operation.

# 6

# Device Integration

Oracle Manufacturing Execution System (MES) for Process Manufacturing uses the device integration capability of Oracle Warehouse Management System (WMS) to read weighing scales. Read data from the scale with a single click. Full mobile device support provides a query for dispensable items directly from a handheld device, and selection of dispensing jobs. Device support extends to printout of the barcode labels. Once a dispensing job is retrieved, weigh scale device integration captures the actual container weights during the processing and enables operators to enter process parameters such as temperature and appearance characteristics associated to material quality.

This chapter covers the following topics:

- Requirement
- Understanding Device Integration
- Mapping a Device to a Resource
- Using Integrated Devices to Enter Process Parameters

## Requirement

Following is a requirement that customers have for supporting device integration:

### Does the application support mobile device integration?

Yes. Most data entry required for dispensing and preweigh is related to specifying material details, such as item number, lot and quantity information. Barcode readers provide faster data entry and virtually eliminate data entry errors.

**Full Barcode and Weighing Scale Integration**

Use bar code readers to scan in item and lot information for the source and target containers. Standard weighing scale integration is provided to read the quantities data directly from production scales or balances.

# Understanding Device Integration

Oracle Manufacturing Execution System (MES) for Process Manufacturing integrates shop floor equipment such as weighing scales into preweigh and dispensing processes so that these critical operations are controlled by the manufacturing execution system. Devices can also be integrated as resources in the production batch to capture the actual process parameter readings directly from shop floor equipment such as mixing vessel temperature and pressure. Devices are integrated using the standard RS232C protocol to communicate with printers, programmable logic controllers and computers. Devices that have USB remote software integration provide connectivity for multiple devices. RS485 protocol connectivity provides a long distance networking protocol to connect devices over a wide area. Oracle E-Records delivers the event approval framework for fully electronic record keeping with electronic signatures to govern proper use of integrated devices.

You can sign onto one or multiple devices prior to accepting tasks. When you sign on to a device you unlock it for use in the manufacturing process. Your system administrator configures the device to require sign-on prior to task dispatch.

You can flag devices that require exportation of lot-specific information, and include this information in the data transmission.

# Mapping a Device to a Resource

The warehouse management material handing device integration toolkit lets you manage data through several different methods. After mapping a dispenser to a resource, you can export a measurement command to a dispenser and import measurement data from that device for processing in the Oracle Manufacturing Execution System (MES) for Process Manufacturing application.

## Prerequisites:

- Define material handling devices. Refer to "Defining Devices" in the *Oracle Warehouse Management Implementation Guide*.

- Assign each material handling device to a business event, and configure the device directives:

    - Associate devices at the subinventory level.

    - Associate the message template to the device definition.

    - Specify the PL/SQL API specification interface for the device. The export method uses a PL/SQL package procedure called from warehouse management in the context of processing the business event.

> **Note:** A carousel bridge implementation is available for device communications. Contact your System Administrator for details.

Refer to "Assigning Devices to Business Events" and "PL/SQL API Specification" in the *Oracle Warehouse Management Implementation Guide*.

- Initiate the business event:

  - Process Parameters Event for mapping the device to acquire process parameters such as temperature, pressure, humidity, and other critical environmental variables.

  - Process Dispensing Event for mapping the device to a dispenser.

    > **Note:** You can map a single device for both the Process Parameter Event and the Process Dispensing Event.

- Export task information to the material handling device. Bidirectional communications run the device task. For example, take a scale measurement.

- Device indicates the task is complete and exports XML-formatted data to the application using the API-based interface defined.

- 

Refer to "Material Handling Device Integration Toolkit" in the *Oracle Warehouse Management Implementation Guide* for a complete discussion on how to map a device to a resource.

### To map a device to a resource:

1. Navigate to the **Plant Resources** window in the Process Engineer responsibility.

2. Enter the context **Organization**.

3. Query the desired **Resource**.

4. Click **Devices**. The **Resource Devices** window displays.

5. Enter device information as described in the planning application documentation.

6. Enter the **Device Response** to the process **Parameter** to map the device to the resource.

7. Save your work.

8. Verify the device mapping by performing an appropriate task that requires entry of a process parameter or performance of a dispensing-related operation.

   Refer to "Using Integrated Devices" for information on device verification.

# Using Integrated Devices to Enter Process Parameters

A process parameter is entered to record information such as temperature, humidity, relative barometric pressure, or elapsed time that is pertinent to product manufacture. Use process parameters as set points, comparison values, or in conditional logic to document environmental conditions or the measured duration of an operation.

Refer to "Mapping a Device to a Resource" for information on device mapping.

Following is the procedure to use integrated devices for making measurements that enter process parameters.

### To measure process parameters using an integrated device:

1. Navigate to the **Production Supervisor** responsibility.

2. Create a batch from a recipe that requires entry of process parameters.

3. Navigate to the **Batches** window to release the batch.

4. Navigate to the **Batch Steps** window to release the batch step that has the requirement for process parameter entry.

5. Click **Activities** to display the **Step Activities** window.

6. Select the desired activity.

7. Click **Resources** to display the **Step Resources** window.

8. Select the desired resource.

9. Click **Process Parameters** to display the **Resource Process Parameters** window.

10. Select the desired process parameter.

11. Click **Read Selected Process Parameter** to trigger the measurement and data entry sequence. The application reads the parameter from the integrated device and communicates the reading to the application. The **Actual** process parameter displays.

# 7

# Nonconformance Tracking

Unexpected events that adversely affect the manufacturing process and quality of the finished product can occur in any controlled production environment. These nonconformances must be tracked in the Control Batch Record (CBR). Quality departments analyze nonconformances as part of for their Corrective Action and Preventive Action initiatives (CAPA). To document the complete manufacturing batch record, evidence of nonconformances must be included in the CBR. Oracle Manufacturing Execution System (MES) for Process Manufacturing helps you manage nonconformance in the batch manufacturing process.

This chapter covers the following topics:

- Requirement
- Understanding Nonconformance Tracking
- Capturing Material Nonconformances
- Capturing Resource Nonconformances
- Disposing Nonconformances
- Logging Nonconformances

## Requirement

Following is a requirement that customers have for tracking nonconformances:

### Does the application support nonconformance tracking?

Yes. Upon identifying a nonconformance, suppliers should document, evaluate, segregate (where practical) and disposition the nonconformance in accordance with the defined nonconforming material control process. Oracle Manufacturing Execution System (MES) for Process Manufacturing provides the toolset for rapid identification and tracking of manufacturing nonconformances.

**Capture and Process Material and Resource Nonconformances**

Written procedures for production and process control are designed to assure that critical materials such as drug products have the identity, strength, quality, and purity they claim to have or are represented to possess. Oracle Manufacturing Execution System (MES) for Process Manufacturing helps ensure that written nonconformance procedures, including any changes, are drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit. Electronic records are maintained with electronic signatures so that these process control procedures are followed in the execution of the various production and process control functions. Tasks are documented at the time of their performance. Any deviation from the written procedures is then captured, recorded, and an appropriate disposition is assigned.

## Understanding Nonconformance Tracking

Nonconformances observed during the following events are tracked and recorded in the Control Batch Record (CBR) and are used for analysis by Quality Control for Corrective Action, Preventive Action (CAPA). When there is nonconformance from the Master Batch Record (MBR), a window displays the following details:

- Time the event occurred

- Batch number, product produced

- Phase of the batch where the event occurred

- Specific details of the incident or observation, including:

    - Date of the nonconformance

    - Level of criticality

    - Individual who logged the issue

    - Type of nonconformance

    - Target value (not required)

    - Actual value

    - Preliminary cause

    - Reason code or severity code

    - Remarks

    - Links to standard operating procedures for managing nonconformance

- Required follow-up steps with signatures of responsible operators and supervisors

Classify nonconformances as either critical or noncritical. Specify the actions to take after a nonconformance is recorded. For example, critical nonconformance is signed off by a quality control manager, while the production supervisor signs off noncritical nonconformance.

If additional follow-up and analysis documentation is created, then it is associated with the batch and incorporated into the CBR. Display the SOPs that link to a specific type of nonconformance.

Each nonconformance is identified by a nonconformance number and is available for viewing from the CBR.

Log a dynamic nonconformances during the batch execution process by assigning nonconformance severity, priority, and nonconformance ownership.

Oracle Manufacturing Execution System (MES) for Process Manufacturing tracks manufacturing nonconformances caused by such things as batch material quantity changes, item substitutions, resource substitutions, as well as any ad-hoc operator observations, such as power interruptions. Notifications of any nonconformances are automatically routed electronically to those who need to review and approve or disapprove continued processing. This includes all appropriate nonconformance details and electronic signature information so that batch status can be determined and appropriate actions can be taken. Batches with unapproved critical nonconformance events are now allowed to proceed to a closed status until all critical nonconformance events have received an approval disposition.

# Capturing Material Nonconformances

If batch material quantities are changed or substituted in the manufacturing process, then a nonconformance is recorded manually in the Oracle Process Manufacturing Process Execution application by choosing Log Nonconformance from the Actions menu. This can occur when the dispense material workorder is modified to change dispense quantities prior to staging material for addition on the shop floor. It can also occur when batch scaling is required to correct for material discrepancies.

This is a critical nonconformance. It must be authorized by the quality manager. Notifications of this nonconformance are sent to individuals who need to review and approve or disapprove the continuance of batch processing.

# Capturing Resource Nonconformances

If resources are changed during batch production, then a nonconformance is recorded. By definition, a resource is anything of value, except material and cash, required to manufacture, cost, and schedule products. Resources include people, tools, machines, labor purchased from a supplier, and physical space used in the manufacturing process.

Resource nonconformances are defined as:

- Resource substitutions in the batch manufacturing process that were not previously defined as acceptable alternates.

- Resource failures and performance issues

This is a critical nonconformance and must be authorized by the quality manager.

## Disposing Nonconformances

A workflow approval process is available to make disposition on nonconformance. The post disposition actions such as putting a batch on hold, changing grade, and so on are manual.

Refer to the *Oracle Quality User's Guide* for details.

## Logging Nonconformances

A collection plan and rules are seeded for Oracle Manufacturing Execution System (MES) for Process Manufacturing. Nonconformance e-records and associated e-signatures are part of the Oracle E-Records store for each event tracked. Following is an example of logging a nonconformance from the Batch Steps window in the Production Supervisor responsibility of the Oracle Process Manufacturing Process Execution application.

## Prerequisites:

- Set up nonconformance tracking in the Oracle Quality application.

  Refer to "Setting Up Nonconformance Tracking" for additional information.

- Identify the batch step where the nonconformance occurred.

### To log a nonconformance:

1. Navigate to the **Batch Steps** window.

2. Select the **Step** and **Operation** where the nonconformance was observed.

3. Choose **Log Nonconformance** from the **Tools** menu. The **Enter Quality Results** window displays.

4. Verify the **Collection Plan**, **Owner** and **Enter By User** fields. You can only select a collection plan that has a current effective date. If a default collection plan has been specified, it is automatically selected.

5. Click **Enter**. The **Update Quality Results** window displays.

6. Enter the **Nonconformance Number**.

7. Enter **Nonconformance Source** as INPROCESS. Required.

8. Enter a brief **Description** of the nonconformance. Required.

9. Enter a **Detailed Description** of the nonconformance. Required.

10. Click **Update**.

# 8

# Label Printing

Labels are used to mark contents of containers. They are used to mark raw materials, products, and samples, namely material labels, product labels, and sample labels, respectively. Retain copies of labels affixed to containers and archive them as a part of the batch record.

This chapter covers the following topics:

- Requirement
- Understanding Label Management
- Printing Dispense Labels

## Requirement

Following is a requirement that customers have for a printing and tracking labels:

### Is label printing and tracking supported?

Yes. Labels mark the contents of containers in organizations that produce controlled materials such as pharmaceuticals and fine chemicals. Oracle Manufacturing Execution System (MES) for Process Manufacturing prints and tracks labels for raw materials products, intermediates, and quality samples that are part of the production process. Track label reprinting with a reprint number that appears on the actual label.

**Produce Accurate Labels for Every Part of the Production Process**

Oracle Manufacturing Execution System (MES) for Process Manufacturing prints labels, and determines whether a label was previously printed for a defined set of key values such as a raw or intermediate material, batch number, product number, or sample number. If the label was previously printed, then a reprint number is created to track the label printing operation. The reprint number is printed on the label itself to indicate that more than one copy exists. A variety of data elements are available for customized label design.

# Understanding Label Management

The flow of raw materials, components, and finished goods must be tracked and managed throughout the supply chain. Tracking raw materials, ingredients, intermediates and finished goods throughout production requires timely information capture and transfer to improve production speed and efficiency. Production tracking to the unit or material level helps improve efficiencies at every level within the production process. Barcode printers and readers are used in the context of many business events including dispensing, in-process quality sampling, and batch output. Oracle Manufacturing Execution System (MES) for Process Manufacturing provides label support that integrates third-party label printing software packages with components from the Oracle Warehouse Management System (WMS). The application extracts data from tables, and manages it with Extensible Markup Language (XML) formats to print custom labels. Configure individual application business events to enable user-initiated or automatic label printing. Label count and reprint options are available. XML provides fully configurable label output. Embedded barcode images in the Control Batch Record assist operators on the plant floor to retrieve batch information quickly and reliably using mobile barcode readers.

Oracle Manufacturing Execution System (MES) for Process Manufacturing uses the label-printing solution available in Oracle Warehouse Management System (WMS) to print customized labels.

Refer to "Compliance Labeling Setup" and related topics in the *Oracle Warehouse Management Implementation Guide* for additional information.

Labels available include:

- Material Label for Raw Materials

- Product Label

- Sample Label

- Dispensed Ingredient Label

- Pallet Label

# Major Features

Configure the application to print selected labels automatically. Copies of the labels affixed to containers are retained and archived in image or PDF formats. Print or reprint labels at various points in a business scenario. When you reprint, the labels display the print count to indicate the total number of times the label was printed. Authorized approvers must approve the label printing or reprinting Configure the label content as described the *Oracle Warehouse Management Implementation Guide*.

## Material Label

The material label is used primarily for identifying raw materials in the manufacturing process. The label is printed for raw materials moved to an inventory organization during purchase receipt. It is also printed to label materials dispensed into containers, or to identify materials that are reverse dispensed and returned to stores.

Data presented on a material label includes:

- Item Number and Description

- Lot

- Date Received

- Expiration Date

- Hazardous Material Classification

**Triggering Events**

Material label printing is triggered by the following business events:

- Raw Material Receipt

    As part of the receiving process, labels are placed on the pallets before they are sent to the warehouse. Label printing is triggered by a variety of configurable business events, including the reading of a Radio Frequency Identification (RFID) tag, scanning a barcode, or manual entry of a standard receipt or a direct receipt against a purchase order.

- Full Container Dispense

    Label printing is triggered by dispensing the full container.

- Source Container Dispense

    Excess material is removed from the source container and placed in an empty target container. The source container is used in the production batch. The target container is returned to inventory and so must be labeled with this label. Label printing is triggered by saving the source container dispense record.

- Target Container Dispense

    Material is removed from the source container and placed in a target container. The target container is used in the production batch. The source container is returned to inventory, if it has material remaining in it. This container must be relabeled to indicate the new quantity. Label printing is triggered by saving the target container dispense record.

## Product Label

Print product labels manually for lots reserved to a batch. This is useful when you preallocate product lots for a batch and print the labels in advance. The product label is generated for all products produced as part of the batch. Data elements in a product label are:

- Product Number

- Product Description

- Plant Code

- Batch Number

- Lot

- Quantity Produced

- Date of Manufacture as the Lot Creation Date

- Expiration Date

- Hazardous Material Class

- Notes

## Sample Label

Print sample labels manually. The sample label is generated when the intermediates or products are yielded and marked for clearance by quality control. The data elements that are present in a product label are:

- Intermediate or Product Number

- Intermediate or Product Description

- Sample Number

- Lot

- Quantity

- Date Sampled

- Date of Manufacture, that is, Lot Creation Date

- Expiration Date

- Hazardous Material Class

- Notes

**Triggering Event**

Quality sample labels are printed automatically when a sample record is saved.

## Pallet Label

Dispensed raw materials for each individual batch are stored in individual cages. These cages are identified using the Batch Collation Label. This is generated when the first dispense of the material in a batch occurs.

## Label Storage

All labels of ingredients, intermediates, products, and samples are stored against each batch record. In addition to storing the labels generated by the application, you can attach labels scanned from hard copies produced for a specific batch.

## Security Code on Labels

A security code is used for controlling raw material for drugs. When controlled drugs are dispensed, the bags are sealed with a security tag. This number is recorded against the dispense in dispensing window that prints out on the label. The same number is also recorded in batch records, enabling a three-way match of the security code for the seal code, label, and batch record. This ensures that the container seal is not

## Handling Code

The handling code is the hazard code attached to a raw material that indicates the precautions to take when dispensing or handling it.

# Printing Dispense Labels

Following is the procedure to print dispense labels.

### To print dispense labels:

1. Navigate to **Dispensing**.

2. Select the **Label Type** to print and dispense the material.

> **Note:** Selecting the label type is not necessary if autoprint configuration is enabled

3. Click **Apply** and obtain the e-signature.

Scan and attach the label to the dispense record from the Dispensed Material Activity Details window, if you want to retain the copy of the label in Oracle Applications. The Label Details window displays the history of labels printed earlier for a business flow or for a given label type.

## Related Topics

Refer to the *Oracle Process Manufacturing Process Execution User's Guide* for details on printing the product and sample labels.

# 9

# Batch Records

Oracle Manufacturing Execution System (MES) for Process Manufacturing provides comprehensive electronic Master Batch Record (MBR) and Control Batch Record (CBR) documents that contain critical batch information from the product recipe and each production batch respectively.

This chapter covers the following topics:

- Requirement

- Understanding Batch Records

- Viewing and Printing the Master Batch Record

- Viewing the Production Status

- Viewing the Batch Progression

- Viewing and Printing the Control Batch Record

## Requirement

Following is a requirement that customers have for supporting electronic batch records:

### Does the application support electronic batch records?

Paper batch records are replaced by an electronic procedure management and recordkeeping system. The application provides a complete solution with electronic signatures and audit trails. The Electronic Batch Record (EBR) that defined by the US FDA, includes text, graphics, data, audio, pictorial or other information represented in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system. The Oracle Manufacturing Execution System (MES) for Process Manufacturing application lets you store all batch-relevant data in the database for rapid retrieval and processing.

**Use the Master Batch Record and Control Batch Record for Paperless Recordkeeping**

The master production record is often referred to as the master batch record. This is the

documented and approved set of instructions used to describe how to manufacture a specific product. The required elements of the master batch record are outlined in CFR Title 21 Part 211.186.

The OPM master batch record consists of the recipe, which includes the material requirements, equipment, resource requirements, processing instructions, sampling requirements and various notes regarding batch processing. It is the template that is used repeatedly to manufacture a consistent product.

The OPM control batch record is a journal that documents all events in the batch lifecycle. The control batch record aligns to the specifications of CFR Title 21 Part 211.188.

# Understanding Batch Records

The U.S. Food and Drug Administration (FDA) provides guidelines for master production and control recordkeeping that meet current good manufacturing practice for finished pharmaceuticals:

- Master Batch Record (MBR) Section 211.186, Code of Federal Regulations (CFR) of the US Food and Drug Administration (FDA)

- Control Batch Record Section 211.188, Code of Federal Regulations (CFR) of the US Food and Drug Administration (FDA)

The intent of these records is to assure product uniformity from batch to batch. The master production and control records for each product include written procedures for batch formulation that must be followed on the shop floor, and a complete batch control record to document that each significant step in the manufacture, processing, packing, or holding of the batch is done. These records must be signed and dated by at least one individual, and independently checked, dated, and signed by a second person. Oracle Manufacturing Execution System (MES) for Process Manufacturing uses Oracle E-Records to provide a comprehensive, paperless method to comply with Title 21 Code of Federal Regulations (21 CFR Part 11) Electronic Records; Electronic Signatures.

## Master Batch Record

The Master Batch Record (MBR) provides detailed recipe-specific information. It is a complete specification for manufacturing a specific batch size in a specific plant at a specific time. The MBR must provide:

- Name and strength of the product with its description

- Name and weight or measure of each active ingredient

- Complete list of components designated by names or codes sufficiently specific to indicate any special quality characteristics

- Accurate statements of the weight or measure of each component, using the same weight system

- Statement concerning any calculated component excesses

- Statement of theoretical weight or measure at appropriate phases of production processing

- Statement of theoretical yield, including the maximum and minimum percentages of theoretical yield beyond which an investigation is required

- Description of product containers, closures, and packaging materials, including a specimen or copy of each label and all other labeling signed and dated by the individuals responsible for label approval

- Complete manufacturing and control instructions, sampling and testing procedures, specifications, special notations, and precautions to be followed

The MBR contains all the key information in the product recipe, including a complete specification to manufacture the product in a given plant, batch size, and date range. The MBR contains the recipe header information, validity rule data, formula details, routing details, instructions, and material dispensing setup information with the corresponding instructions. It is available for viewing and printing after the recipe validity rule is approved for general use.

## Control Batch Record

Batch control records provide a complete information set related to the production and control of each individual batch. The Control Batch Record (CBR) is updated with actual data as the batch proceeds through its lifecycle. Material usage, dispensing activities, and component weights and measure records provide batch traceability. Product output quantities, lot details, manufacturing nonconformances, and quality sampling and test results all add to this batch history. The CBR must provide:

- An accurate reproduction of the appropriate MBR checked for accuracy, dated, and signed

- Documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including:
  - Start date, stop date, and time stamps for each step

  - Identity of specific major equipment and production lines used

  - Identification of each batch of component or in-process material used

  - Weights and measures of components used in processing

- In-process and laboratory control results

- Inspection of the packaging and labeling area before and after use

- Statement of the actual product yield

- Statement of the percentage of theoretical yield appropriate phases of batch processing

- Complete labeling control records, including specimens or copies of all labeling used

- Description of product containers and closure systems

- Quality sampling performed

- Identification of the individuals who performed each task

- Identification of individuals who supervised or checked each significant step in the operation

- Documentation of any investigations for nonconformance

- Results of examinations made for compliance

The electronic CBR is created when the production batch is created. It is updated with actual data as the batch progresses though its life cycle. The CBR contains information such as actual material usages, product output quantities and lot details, manufacturing nonconformance, quality samples and results, label images, instructions, material dispensing setup information with the corresponding instructions, changes in batch and batch step status, operator comments, and all electronic signatures captured during the processing of the batch. Configure the system to obtain e-signature approvals before closing a batch.

The final stage of the production batch lifecycle is to close the batch. Oracle Manufacturing Execution System (MES) for Process Manufacturing documents this transaction with e-signature approvals. The final CBR is secured in the e-records repository, where authorized responsibilities can view or print it.

## Title III of the US Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Title III of the US Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (also known as the "Bioterrorism Act") is "Protecting Safety and Security of Food and Drug Supplies." Title III requirements include "... the need to establish and maintain records by those who manufacture, process, pack, transport, distribute, receive, hold, or import food, as may be necessary to trace the source and the chain of

distribution of food, its components and ingredients, and its packing in order to address threats of serious adverse health consequences or death to humans or animals." Oracle Manufacturing Execution System (MES) for Process Manufacturing provides fully traceable recordkeeping that can be used to meet the requirements of this act. Coupled with other Oracle Process Manufacturing (OPM) applications such as Quality Management and Process Execution, build Hazard Analysis Critical Control Points (HACCPs) throughout the manufacturing supply chain. Oracle Manufacturing Execution System (MES) for Process Manufacturing helps meet the requirements for this important requirement for food and drug safety.

## E-Record Events

The CBR captures the major events of the batch including dates of the event and name of the person who made the transaction for:

- New Material Added

- Material Removed

- Step Added

- Step Removed

- Additional Resource Requirements

- Deletion of Resource

- Activity Added

- Activity Update

- Resource Details Updated

- Batch Update (Header)

- Batch Step Update

- Process Parameter

Oracle Manufacturing Execution System (MES) for Process Manufacturing modifies the output of several events, including:

- Batch Release

- Material Allocation

- Step Release

- Step Reopen

- Batch Reopen

- Step Complete

- Step Close

- Batch Complete

- Batch Close

- Batch Termination

- Revert to Work in Process

# Viewing and Printing the Master Batch Record

View and print the Master Batch Record (MBR) from Recipe and Recipe Validity Rules windows. The Master Batch Record (MBR) consists the recipe hierarchy:

- Recipe Summary Information such as Recipe and Recipe Validity Rule

- Material Requirements such as Formula
  - Sample

  - Instructions with Standard Operating Procedure (SOP) Reference

  - Dispensing Setup

- Detailed Routing Information, that is, Routing Steps
  - Instructions with SOP Reference

  - Activities

  - Resource Requirements and Instructions with SOP Reference

  Refer to "Recipes" in the *Oracle Process Manufacturing Product Development User's Guide* for detailed information on recipes and recipe validity rules.:

### To view and print the MBR from a recipe:

1. Navigate to the **Recipe Details** window.

2. Create or query a recipe. Enter as many parameters as needed to complete the search:

Select **Recipe**, **Description**, **Formula**, **Routing,** or **Product** with appropriate **Version** for Recipe, Formula, or Routing. Select **Organization**, **Customer**, **From Date**, **To Date**, **Status**, and **Recipe Use**.

3. Select **View Master Batch Record** from **Actions**.

4. Print the draft version of Master Batch Record.

**To view and print the MBR from the recipe validity rule:**

1. Navigate to the **Recipe Validity Rules** window.

2. Create or query a recipe. Enter as many parameters as needed to complete the search.

3. Select **View Master Batch Record** from **Actions**.

4. Print the Master Batch Record.

# Viewing the Production Status

View current production status for multiple batches at a time. Navigate to the **Production Status** window from the **MES for Process Manufacturing Administrator** responsibility.

# Viewing the Batch Progression

View detail batch progression details for a specific production batch.

**To view the batch progression:**

1. Navigate to the **Production Status** window.

2. Create or query batches. Enter as many parameters as needed to complete the search.

   Select **Organization**, **Batch**, **Product**, **Status**, **From Date**, and **To Date**.

3. Click a batch number.

# Viewing and Printing the Control Batch Record

View current production status for multiple batches at a time and also view detail batch progression details for a specific production batch.

**To view and print the Control Batch Record:**

1.  Navigate to the **Batch Progression** window.

2.  Click **View Control Batch Record**.

    View or print the CBR from the **Batch Details** window using the Operator Workbench.

Control Batch Record (CBR) consists of:

*   Material Details
    *   Instructions

    *   Samples

    *   Nonconformance

    *   Dispensing

    *   Material Transactions

*   Routing Steps with Overrides
    *   Instructions

    *   Nonconformance

    *   Operations
        *   Nonconformance

        *   Instructions

        *   Activities
            *   Nonconformance

            *   Instructions

            *   Resource Requirements
                *   Instructions

                *   Process Parameters

                *   Resource Transactions

# 10

# Batch Validation

The batch validator functionality lets you validate the correctness of data during a batch progression. You can close the batch only if there are no pending instructions.

This chapter covers the following topics:

- Requirement
- Understanding the Batch Validator
- Validating Batch Information

## Requirement

Following is a requirement that customers have for validating the progress of their batches:

### Can batch progress be validated?

Yes. Use the batch validator to verify the completeness of defined instructions and proper information entry.

**Use the Batch Validator to Report Batch Progress**

The batch validator verifies task completion and highlights exceptions or mismatched information. Use the batch validator to identify the completeness of information entry and proper authority to perform various tasks in the batch. Identify exceptions rapidly for appropriate corrective action or nonconformance reporting.

## Understanding the Batch Validator

The batch validator highlights any exceptions, incomplete tasks, mismatch in data, and missing information. The key features of the batch validator include:

- Runtime Validation

- Reporting

## Runtime Validation

Complete instructions for a batch after proper verification and identify any pending instructions at all levels of a batch. Verify and mark any pending or non-disposed nonconformance against a batch. The batch validator lets you make a secured disposition on the instructions. For example, only a supervisor can dispose instructions that are pending for a batch containing hazardous materials.

## Reporting

The batch validator provides a paper-based reporting solution to help print the valuation output.

# Validating Batch Information

Run the batch validator at batch close to ensure that all the tasks are performed as stipulated in the master batch record. Trigger the batch validator automatically or manually.

- Automatic mode is triggered when you try to close a batch step or the batch itself from the Oracle Process Manufacturing Process Execution application.

- Manual mode is used to request batch validation from a user interface at any stage of a batch to determine whether the batch has any exceptions. This mode lets you take proactive steps to resolve exceptions and helps avoid future exceptions.

### To validate batch automatically from batch step close or batch close:

1. Navigate to the **Batch** window.

2. Enter as many parameters as needed to complete the search. Select **Recipe**, **Formula**, **Routing**, or **Product** with appropriate **Version** for Recipe, Formula, or Routing. Select **Organization**, **From Date**, **To Date**, and **Status**.

3. Select a batch step or batch.

4. Click **Close**. The batch validator performs validations. A message displays if there are any exceptions that require corrective action.

5. Click **Cancel** to stop the closure of batch step or batch or click **Skip** to close the batch step or the batch.

**To validate batch manually from batch step close or batch close:**

1. Navigate to the **Batch** window.

2. Enter as many parameters as needed to complete the search. Select **Recipe**, **Formula**, **Routing**, or **Product** with appropriate **Version** for Recipe, Formula, or Routing. Select **Organization**, **From Date**, **To Date**, and **Status**.

3. Select a batch step or batch.

4. Navigate to either the **Batch Header** window or the **Batch Details** window.

5. Select **Validate** from **Actions**.

6. Generate a validation results report using the XML publisher. A PDF report displays on Reporting user interface.

# A

# Oracle MES for Process Manufacturing Navigation Paths

This appendix provides information on the paths to navigate to the various Oracle Manufacturing Execution System (MES) for Process Manufacturing application windows.

This appendix covers the following topics:

- Oracle Manufacturing Execution System (MES) for Process Manufacturing Navigation Paths

## Oracle Manufacturing Execution System (MES) for Process Manufacturing Navigation Paths

Although your System Administrator may have customized your navigator, typical navigation paths are described in the following tables. In some cases, there is more than one way to navigate to a window. These tables provide the most typical default path.

| Window | Path |
| --- | --- |
| Add Instructions | Instructions:Add Existing |
| Batch Progression | Production Status:Search:Batch Details |
| Control Batch Record | Batch Progression:View Control Batch Record |
| Create Dispensing Setup | Dispensing Setup:Create |
| Create Document Number | Document Numbering:Create |

| | |
|---|---|
| Create Instruction | Instructions:Instructions:Create |
| Create Instruction Set | Instruction Set:Create |
| Dispensable Material | MES for Process Manufacturing Administrator:Dispensing:Dispensable Material |
| Dispense Material | Dispense Material Instructions:Apply |
| Dispensed Material Activity Details | Dispensed Material Activity:Search:Details |
| Dispense Material Instructions | Dispensable Material:Search:Dispense |
| Dispensed Material Activity | MES for Process Manufacturing Administrator:Dispensing:Dispensed Activity |
| Dispensing Setup | MES for Process Manufacturing Administrator:Setup:Dispensing Setup |
| Document Numbering | MES for Process Manufacturing Administrator:Setup:Document Numbering |
| Instruction Set | Create Dispensing Setup:Create Instructions |
| | Process Engineer:Recipes:Recipe Details:Actions:Process Instructions |
| | Process Engineer:Process Routings:Process Routing Details:Actions:Process Instructions |
| | Process Engineer:MES Operations:Process Operation Details:Actions:Process Instructions |
| | Process Engineer:MES Operations:Process Operation Details:Activities:Actions:Process Instructions |
| | Process Engineer:MES Operations:Process Operation Details:Resources:Actions:Process Instructions |
| Instructions | Create Instruction Set:Apply:Instruction Set Name |
| Master Batch Record | Process Engineer:Engineering Workbench:Recipe Details |

| | |
|---|---|
| Operator Workbench | MES for Process Manufacturing Administrator:Workbench |
| Production Status | MES for Process Manufacturing Administrator:Inquiry |
| Print Label | MES for Process Manufacturing Administrator:Dispensing:Dispensable Material:Dispense:Search:Dispense:Apply:Dispense Material:Print Label |
| Reverse Dispense Material | Reverse Dispense Material Instructions:Apply |
| Reverse Dispense Material Instructions | Dispensed Material Activity:Search:Reverse Dispense |
| Update Dispensing Setup | Dispensing Setup:Search:Update |
| Update Document Number | Document Numbering:Search:Update |
| Update Instruction Set | Instruction Set:Update |
| Update Instructions | Instructions:Update |

# B

# Oracle E-Record Events in Oracle MES for Process Manufacturing

Oracle Manufacturing Execution System (MES) for Process Manufacturing supports the acquisition of electronic signatures on electronic records. Electronic documentation replaces paper with a seamless interface of business activities that improves manufacturing throughput and enhances the overall quality of operations in the supply chain. The following provides information for events that are e-record and e-signature enabled in the Oracle Manufacturing Execution System (MES) for Process Manufacturing application. A brief discussion of each event is provided.

This appendix covers the following topics:

- Oracle E-Record Events in MES for Process Manufacturing
- Events
- Subscriptions

## Oracle E-Record Events in MES for Process Manufacturing

Following are the Oracle E-Record events in the Manufacturing Execution System for Process Manufacturing:

## Events

The following tables list the events that are e-record and e-signature enabled and used by Oracle Manufacturing Execution System (MES) for Process Manufacturing. Refer to documentation of specific event details in other applications where indicated.

| Event | Online or Deferred |
| --- | --- |
| GMD ERES Sample Creation Event | Refer to OPM Quality Management |

| Event | Online or Deferred |
| --- | --- |
| GMD ERES Results Entry | Refer to OPM Quality Management |
| Batch Close | Refer to OPM Process Execution |
| Batch Complete | Refer to OPM Process Execution |
| Batch Release | Refer to OPM Process Execution |
| Batch Reopen | Refer to OPM Process Execution |
| Batch Scale | Refer to OPM Process Execution |
| Batch Termination | Refer to OPM Process Execution |
| Batch Revert to WIP | Refer to OPM Process Execution |
| Batch Unrelease | Refer to OPM Process Execution |
| Batch Step Addition | Refer to OPM Process Execution |
| Batch Step Close | Refer to OPM Process Execution |
| Batch Step Complete | Refer to OPM Process Execution |
| Batch Step Release | Refer to OPM Process Execution |
| Batch Step Removal | Refer to OPM Process Execution |
| Batch Step Reopen | Refer to OPM Process Execution |
| Batch Step Revert to WIP | Refer to OPM Process Execution |
| Batch Step Unrelease | Refer to OPM Process Execution |
| Batch Step Update | Refer to OPM Process Execution |
| Resource Transaction | Refer to OPM Process Execution |
| Batch Update | Refer to OPM Process Execution |

| Event | Online or Deferred |
| --- | --- |
| Batch Material Addition | Refer to OPM Process Execution |
| Batch Material Removal | Refer to OPM Process Execution |
| Batch Material Update | Refer to OPM Process Execution |
| Batch Step Activity Resource Addition | Refer to OPM Process Execution |
| Batch Step Activity Resource Removal | Refer to OPM Process Execution |
| Batch Step Activity Resource Update | Refer to OPM Process Execution |
| Batch Transaction | Refer to OPM Process Execution |
| Batch Cancellation | Refer to OPM Process Execution |
| Batch Reschedule | Refer to OPM Process Execution |
| Batch Reroute | Refer to OPM Process Execution |
| Batch Creation | Refer to OPM Process Execution |
| Batch Step Activity Resource Process Parameters | Refer to OPM Process Execution |
| Batch Step Activity Update | Refer to OPM Process Execution |
| Batch Step Activity Removal | Refer to OPM Process Execution |
| Batch Step Activity Addition | Refer to OPM Process Execution |
| GMO ERES Material Reverse Dispense Event | Online |
| GMO Instruction Set Update | Online |
| GMO ERES Material Dispense Event | Online |
| GMO ERES Label Printing | Online |
| QA ERES Nonconformance Detail Approval | Refer to Oracle Quality |

| Event | Online or Deferred |
|---|---|
| QA ERES Nonconformance Update | Refer to Oracle Quality |
| QA ERES Nonconformance Creation | Refer to Oracle Quality |
| QA ERES Nonconformance Master Approval | Refer to Oracle Quality |
| QA ERES Disposition Creation | Refer to Oracle Quality |
| QA ERES Disposition Update | Refer to Oracle Quality |
| QA ERES Disposition Header Approval | Refer to Oracle Quality |
| QA ERES Disposition Detail Approval | Refer to Oracle Quality |

**Note:** The GMO Instruction Set Update event (oracle.apps.gmo.instrset.update) is not an e-record or e-signature event. The event is raised at Instruction Set Level to include the instructions in Control Batch Record.

## Oracle MES for Process Manufacturing Event Information

| Name | Display Name | Description | Status | Owner Name | Owner Tag |
|---|---|---|---|---|---|
| oracle.apps.gmo.instruction.complete | GMO ERES Instruction Complete | GMO ERES Instruction Complete | ENABLED | MES for Process Manufacturing | GMO |
| oracle.apps.gmo.mtl.revdisp | GMO ERES Material Reverse Dispense Event | GMO ERES Material Reverse Dispensing Business Event | ENABLED | MES for Process Manufacturing | GMO |

| Name | Display Name | Description | Status | Owner Name | Owner Tag |
|------|--------------|-------------|--------|------------|-----------|
| oracle.apps.gmo.labelprint | GMO ERES Label Printing | GMO ERES Label Printing Event | ENABLED | MES for Process Manufacturing | GMO |
| oracle.apps.gmo.dispense.setup.create | GMO ERES Dispense Setup Creation Event | This event is raised for each dispense setup that is created. | ENABLED | MES for Process Manufacturing | GMO |
| oracle.apps.gmo.dispense.setup.update | GMO ERES Dispense Setup Update Event | This event is raised each time a dispense setup is updated. | ENABLED | MES for Process Manufacturing | GMO |
| oracle.apps.gmo.mtl.dispense | GMO ERES Material Dispense Event | MES for Process Manufacturing - ERES Material Dispense | ENABLED | MES for Process Manufacturing | GMO |
| oracle.apps.gmo.mbr.approve | GMO ERES Master Batch Record Approval | Master Batch Record Approval | ENABLED | MES for Process Manufacturing | GMO |
| oracle.apps.gmo.cbr.approve | GMO ERES Control Batch Record Approval | Control Batch Record Approval | ENABLED | MES for Process Manufacturing | GMO |

## Event Keys

| Name | Event Key | User Event Key |
|------|-----------|----------------|
| GMO ERES Instruction Complete | INSTRUCTION_ID | INSTR_NUMBER |
| GMO ERES Material Reverse Dispense Event | UNDISPENSE_ID | UNDISPENSE_NUMBER |
| GMO ERES Label Printing | LABEL_ID | Business Flow Name Label |
| GMO ERES Dispense Setup Creation Event | CONFIG_ID | ITEM |
| GMO ERES Dispense Setup Update Event | CONFIG_ID | ITEM |
| GMO ERES Material Dispense Event | DISPENSE_ID | DISPENSE_NUMBER |
| GMO ERES Master Batch Record Approval | RECIPE_ID-ORG_ID-RECIPE_VALIDITY_RULE_ID | RECIPE_NO-VERSION(Org_Code) |
| GMO ERES Control Batch Record Approval | Batch_ID | BATCH_NO(Org_Code) |

## Subscriptions

| Source Type | Event Filter | Phase | Rule Data | Rule Function | Parameters |
|-------------|-------------|-------|-----------|---------------|------------|
| Local | oracle.apps.gmo.cbr.approve | 0 | KEY | EDR_PSIG_RULE.PSIG_RULE | EDR_AME_TRANSACTION_TYPE=oracle.apps.gmo.cbr.approve |
| Local | oracle.apps.gmo.mbr.approve | 0 | KEY | EDR_PSIG_RULE.PSIG_RULE | EDR_AME_TRANSACTION_TYPE=oracle.apps.gmo.mbr.approve |

| Source Type | Event Filter | Phase | Rule Data | Rule Function | Parameters |
|---|---|---|---|---|---|
| Local | oracle.apps.gmo.instruction.complete | 0 | MESSAGE | EDR_PSIG_RULE.PSIG_RULE | EDR_AME_TRANSACTION_TYPE=oracle.apps.gmo.instruction.complete EDR_XML_MAP_CODE=gmoinsmp |
| Local | oracle.apps.gmo.labelprint | 0 | KEY | EDR_PSIG_RULE.PSIG_RULE | EDR_AME_TRANSACTION_TYPE=oracle.apps.gmo.labelprint EDR_XML_MAP_CODE=oracle.apps.gmo.labelprint FORCE_ERECORD=Y |
| Local | oracle.apps.gmo.dispense.setup.create | 0 | KEY | EDR_PSIG_RULE.PSIG_RULE | EDR_AME_TRANSACTION_TYPE=oracle.apps.gmo.dispense.setup.create |
| Local | oracle.apps.gmo.dispense.setup.update | 0 | KEY | EDR_PSIG_RULE.PSIG_RULE | EDR_AME_TRANSACTION_TYPE=oracle.apps.gmo.dispense.setup.update |
| Local | oracle.apps.gmo.mtl.dispense | 0 | KEY | EDR_PSIG_RULE.PSIG_RULE | EDR_XML_MAP_CODE=gmodisp FORCE_ERECORD=Y |

| Source Type | Event Filter | Phase | Rule Data | Rule Function | Parameters |
|---|---|---|---|---|---|
| Local | oracle.apps.gmo.mtl.revdisp | 0 | KEY | EDR_PSIG_RULE.PSIG_RULE | EDR_XML_MAP_CODE=gmoundisp FORCE_ERECORD=Y |
| Local | oracle.apps.gmo.labelprint | 2 | MESSAGE | GMO_CBR_GRP.PROCESS_EVENT | N/A |
| Local | oracle.apps.gmo.mtl.dispense | 2 | KEY | GMO_CBR_GRP.PROCESS_EVENT | N/A |
| Local | oracle.apps.gmo.mtl.revdisp | 2 | KEY | GMO_CBR_GRP.PROCESS_EVENT | N/A |
| Local | oracle.apps.gmo.instrset.update | 0 | KEY | GMO_CBR_GRP.PROCESS_INSTANCE_INSTR_SET | GMO_XML_MAP_CODE=gmoinsup |

**Note:** Priotities are all NORMAL.

## AME Events

| TRANSACTION_TYPE_ID | TRANSACTION_TYPE_DESCRIPTION | LINE_ITEM_ID_QUERY |
|---|---|---|
| oracle.apps.gmo.dispense.setup.update | GMO ERES Dispense Setup Update | N/A |
| oracle.apps.gmo.mtl.revdisp | GMO ERES Material Reverse Dispense | N/A |
| oracle.apps.gmo.labelprint | GMO ERES Label Printing | N/A |

| TRANSACTION_TYPE_ID | TRANSACTION_TYPE_DESCRIPTION | LINE_ITEM_ID_QUERY |
|---|---|---|
| oracle.apps.gmo.mbr.approve | GMO ERES Master Batch Record Approval | N/A |
| oracle.apps.gmo.instruction.complete | GMO ERES Instruction Complete | N/A |
| oracle.apps.gmo.dispense.setup.create | GMO ERES Dispense Setup Creation | N/A |
| oracle.apps.gmo.mtl.dispense | GMO ERES Material Dispense | N/A |
| oracle.apps.gmo.cbr.approve | GMO ERES Control Batch Record Approval | N/A |

# Glossary

**21 CFR Part 11**

FDA regulations that set forth the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

**Electronic Batch Record (EBR)**

Electronic Batch Record (EBR) replaces manual procedures and paper batch records with an electronic procedure management and record-keeping system. This system is complete with electronic signatures and audit trails. An EBR, as defined by the FDA, includes text, graphics, data, audio, pictorial, or other information represented in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system. With an EBR, all batch-relevant data are stored in the computer system.

**Electronic Record (e-record)**

Any combination of text, graphics, data, audio, pictorial, or other information in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

**Electronic Signature (e-signature)**

A computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be legally binding equivalent of the individual's handwritten signature.

**GMO**

Oracle Manufacturing Execution System (MES) for Process Manufacturing.

**Gross Weight**

The total weight of material, without deduction for tare, tret, or waste, as distinguished from neat, or net weight.

### Label Format

A single design of a label that may include fixed data such as field prompts and variable data such as a part number. A label format is associated to a label type; it includes a subset of the available data elements from a particular label type. Multiple label formats can be associated to one label type.

### Label Print Business Flow

An identifiable business process that occurs as part of material handling within Oracle Warehouse Management System. Oracle recognizes a predetermined list of business flows that can be set up to include label printing as part of the transaction processing.

### Label Type

A broad category of labels that specifies the super-set of available data elements that can be included on a single label. Currently, there are eleven label types, such as Material, Serial, License Plate Number (LPN), LPN Contents, LPN Summary, Location, Shipping, Shipping Contents, and WIP Contents.

All label types are available to a WMS user. Most label types are available to an MSCA user. For instance, MSCA has no association to a license plate, so the LPN, LPN Contents, and LPN Summary label types are not applicable and therefore not available in MSCA. Multiple label formats can be defined per label type.

For example, the Material label type includes information such as Part Number, Description, Unit of Measure, Quantity, Hazard Code, Lot Number, Lot Expiration Date, Lot Attributes, and so on.

### Instruction

Instructions are used to amplify the manufacturing process flow by providing details on how to execute certain steps. They also assure a documented, repeatable process; provide for ease of assembly; and improve productivity, quality, and consistency.

### Net Weight

The weight of actual goods, excluding packing materials; also called actual net weight.

### Tare

The weight of a container or wrapper deducted from the gross weight to obtain net weight.

### WMS

Warehouse Management System product in Oracle Applications E-Business Suite.

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