

# ORACLE MANUFACTURING EXECUTION SYSTEM FOR PROCESS MANUFACTURING

## KEY FEATURES

ORACLE MES FOR PROCESS INCLUDES:

- Instruction-driven, operator-friendly user interface
- Electronic Batch Records for 21 CFR Part 11 Compliance
- Dispensing
- Nonconformance Management
- Labeling
- Device Integration

*Oracle® Manufacturing Execution System (MES) for Process Manufacturing is an add-on application to Oracle Process Manufacturing that provides intensive, multifaceted shop floor execution capabilities. The application allows process manufacturers to deploy Oracle Process Manufacturing directly on their shop floors as the manufacturing execution system (MES). For most process manufacturers, this removes the requirement to invest in a third party or a homegrown MES system, and helps reduce costs while eliminating integration and support headaches. MES for Process Manufacturing eliminates many unnecessary and non-value-added activities by providing a structured and standards-based shop floor execution toolset.*

*MES for Process Manufacturing is designed for use in process industry plants that are looking to move to electronic batch recordkeeping or for those that previously may have opted to purchase a third-party MES. It offers the advantage of providing true enterprise-wide information from the shop floor to the boardroom.*

## Major Features

### Process-Driven Operator Workbench

The *process* in process manufacturing is as important as the material inputs and outputs. The work orders or batch records are detailed, step-by-step guides, which lead production operators through the process of making a product. Some steps may be done at any time, while others must be completed before proceeding. Some require one or more signatures, while others may not require any formal approval, but simply an indication that they were completed. Others may require entry of specific production data, such as quantities, temperature, or pressure and some may point the operator to perform tasks such as taking quality samples for in-process testing.

Oracle MES for Process Manufacturing puts all of the information that production schedulers, supervisors and operators need at their fingertips, and where possible, no more than one click away. As part of the recipe development, you can create individual or unit instructions, which can be ordered into reusable procedures.

Instructions and procedures can have standard operating procedure documents, images, or any other files associated to them readily accessible to the production operator during batch processing.

Processing instructions may also have predefined actionable tasks that require electronic signoff for completion. For example, you may have defined a series of instructions associated with the runtime activity for a blending operation. One instruction may tell the operator to take a temperature reading. You can define a task for that instruction to allow the operator to access the process parameter window with a single click, and then manually enter or accept the reading directly from the piece of equipment. You can also require any number electronic signatures before the process can continue.

Supervisors and schedulers have access to real-time production batch status, down to the level of instruction completion status so they know precisely what has been done and what remains to be done for any production batches for which they have responsibility. A flexible search engine allows the user to quickly bring up the precise batch or batches in question.

### **Dispensing**

The management of the ingredient dispensing (also known as preweigh) process to control the measurement, containerization and labeling of precise quantities of specific materials to the right batch steps prior to, or during the manufacturing process is a key requirement in many process industries, including pharmaceutical, biotechnology, food and beverage and chemical manufacturing. This process is especially critical when working with the active pharmaceutical ingredients (APIs) in a drug product formulation (*per FDA Code of Federal Regulations Title 21 Part 211.101*), with pigments when formulating paints and when working with materials that may become explosive or otherwise hazardous when not blended in precise ratios in chemical processing.

The production batch process requires the right materials to be dispensed to production batch steps with specific quality parameters and in right quantities. Since the formulation quantities may run into decimals, the accuracy of the quantities is critical, so standard weigh-scale integration has been provided to minimize the risk of data entry error. Oracle MES for Process Manufacturing also provides configurable container and dispensed material holding cage label printing, which may be automatic or user-initiated.

Dispensing and preweigh must often be done in accordance with documented standard operating procedures (SOPs) and indication of the satisfactory completion of the processes may require signoff by one or more individuals, such as the operator and supervisor. Oracle MES for Process Manufacturing Dispensing provides dispensing operators with on-line access to up-to-date SOPs, detailed, acknowledgeable work instructions and electronic signatures, which provides a configurable level of control and auditability of the completion of the dispensing process in accordance with current good manufacturing practices.

### **Nonconformance Management**

Even in the most controlled production environments, unexpected events can happen that may have direct impact on the manufacturing process and the quality of final product. Nonconformances that arise need to be tracked and recorded for recording in the batch record and to be used for analysis by the Quality Department for CAPA (Corrective Action, Preventive Action) analysis. In order to document a complete record of a manufacturing batch, evidence of nonconformances must be included in the control batch record, along with appropriate details of when the event occurred, the phase of the batch in which it occurred, details of the incident or observation, level of criticality and required follow-up and signatures by the operator(s) and/or supervisors.

Oracle MES for Process Manufacturing tracks all 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 a power interruption. Notification of nonconformances are automatically routed electronically to those who need to review and approve the continued processing or hold of the batch and all nonconformance details, including electronic signature information, are logged in the control batch record electronic document.

### **Electronic Master and Control Batch Record**

Most manufacturing industries keep detailed paper records of their manufacturing records and some industries such as pharmaceutical and food and beverage manufacturers are mandated to do so by federal regulations (*per FDA Code of Federal Regulations Title 21 Part 211.186 / 211.188*). Oracle MES for Process Manufacturing provides comprehensive electronic Master Batch Record (MBR) and Control Batch Record (CBR) documents, which contain all of the critical batch information from the product recipe (compiled in the MBR) and each product batch (compiled in the CBR). You can even have the batch records automatically translated into other languages.

### **Labeling and Device Integration**

**Labeling** - Labels are used extensively to mark contents of containers in process industries. They are created and read, often via barcode readers, in the context of many business events, including dispensing, in-process sampling and when intermediate and finished products are output from production batches.

The application can be configured to print labels automatically based on a trigger from a business event, or label printing can be manually initiated. Reprint labels with full traceability. The reprint event and print count indicate the number of times each label was printed. Label content is also configurable. You may configure electronic signatures to control who has authority to print labels.

**Device Integration** - Integrate shop floor equipment such as manufacturing equipment and weigh scales in the preweigh and dispensing process with the manufacturing execution system. This improves the speed and efficiency with which actual data is captured during the manufacturing process, increases the amount of data that you can capture, and removes the risk of operator data entry errors.

Oracle MES for Process Manufacturing provides the capability to capture data directly from shop floor devices in the dispensing business flow and during batch processing for in-process equipment data capture.

### Oracle MES for Process Manufacturing Key Benefits

- *Board Room to Shop Floor Visibility* – Why use disparate MES systems and integrate each one to your ERP backbone? With Oracle, you have one source of truth, data model, technology and system to validate.
- *Process Repeatability* – This is key in validated systems. Consider the potential for error involved in assembling a paper batch record for every production order or batch. A fully electronic system that is validated assembles the correct components 100 percent of the time.
- *Enforce Best Practice SOPs* – Build controls into the system. For example, make sure you have collected samples and test results were acceptable, before completing a production batch. Make sure you have collected the appropriate signoffs before moving on. Oracle enforces these controls systematically, rather than having to rely on procedural controls.
- *Reduce Labor* – Consider dispensing: in a paper system, you need double signoff. The weighing operator signs for their manual weight entries, and another person signs that they checked the entries. With a validated electronic system, the manual entry signature is just not needed. It's a new paradigm in the electronic world.
- *Eliminate Massive Amounts of Paper* – Benefits are obvious when you consider that a batch record may be 200 or more pages, and has to be saved for seven years after product obsolescence in most pharmaceutical industries.
- *Advanced Search* - Information on paper is static and standalone. Analysis to find trends across a multitude of paper records is tedious, time consuming and complex. Analysis across a large set of records may be impossible. Enterprise systems that run on advanced relational database management systems excel at searching data records for the purpose of finding trends and patterns across large numbers of records.
- *Eliminate Errors* – Eliminate duplicate entry of production data. Put the data entry in the hands of the product operators with easy to use interfaces. Achieve a single point of data entry.
- *Lower Training Costs* – The application drives the behavior of the operator, eliminating the need to rely on manual procedures.

**KEY BENEFITS**

- Board room to shop floor visibility
- Process repeatability
- Enforce best practice SOPs
- Reduce labor - remove a level of approvals
- Eliminate massive amounts of paper
- Advanced search capability
- Eliminate errors
- Lower training costs
- Lower cost of compliance

**RELATED PRODUCTS**

Oracle Manufacturing Execution System for Process Manufacturing is designed to work together with the following products:

- Oracle Advanced Planning and Scheduling
- Oracle E-Records
- Oracle Inventory
- Oracle Process Manufacturing Process Execution
- Oracle Process Manufacturing Product Development
- Oracle Process Manufacturing Quality
- Oracle MSCA

**RELATED SERVICES**

The following services are available from Oracle Support Services:

- Oracle E-Business Suite Accelerators
- Oracle Application Solution Centers
- Oracle University
- Oracle Consulting

**Oracle E-Business Suite—The Complete Solution**

Oracle E-Business Suite enables companies to efficiently manage customer processes, manufacture products, ship orders, collect payments, and more—all from applications that are built on unified information architecture. This information architecture provides a single definition of your customers, suppliers, employees, and products—all important aspects of your business. Whether you implement one module or the entire Suite, Oracle E-Business Suite enables you to share unified information across the enterprise so you can make smarter decisions with better information.

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