

# ORACLE E-BUSINESS SUITE PROCESS MANUFACTURING REGULATORY MANAGEMENT

## KEY FEATURES

- Hazardous Material Data Repository
- File Storage, Approval, and Versioning of Safety Documents, Instructions, and Labels
- Access to Safety Documents from Production Batches and Other Processes
- Safety Document Rebuild Workflow Notification Based on Product or Formulation Changes
- Automatic Attachment of Safety Documents with Sales Orders and Shipments
- Document Dispatch History of Customer Distributions
- Open Interface for Partner Authoring, Management, and Distribution of Safety Documents

*Oracle® Regulatory Management is a regulatory information management tool providing hazardous material information to critical components of Oracle's E-Business Suite. This application enables any industry that stores or ships hazardous materials to comply with industry and government regulations for safety documentation.*

### **Maintain a Repository of Hazardous Material Data**

As part of Product Information Management, Oracle's Regulatory Management application holds information that most manufacturers and distributors cannot be without. Any company that uses industrial machines or instruments stores materials used for the maintenance of those resources, and these materials generally have important storage and handling requirements. Manufacturers and distributors in the chemical industry – paints, adhesives, specialty chemicals, etc. – legally must document any hazardous components in their products at shipping time. Plant workers, health and safety administrators, and other employees must have access to the safety documentation associated with the materials being used on-site.

The solution for all of these scenarios is to make the data available throughout Oracle's E-Business Suite by managing the information with Oracle Process Manufacturing Regulatory Management. Regulatory items and their properties are easily accessed and displayed through an expandable tree navigator and its associated forms. Physical properties, heavy metals, risk and safety phrases, and other valuable information can all be stored within the application.

Oracle helps companies meet safety compliance with "employee right to know" legislation about toxic chemicals in the workplace by ensuring that chemical hazards are properly evaluated, and that information concerning these hazards is transmitted to appropriate employees. Safety documents can be included with production batches or any other processes where hazardous material storage and handling documentation is required.

### **Storage, Approval and Access to Safety Documents**

Material Safety Data Sheets (MSDS), Technical Data sheets, Hazard Labels, and Internal Plant Instructions are an integral part of any material handling processes including storage, production, and shipping. Oracle Regulatory Management uses Oracle E-Records, a 21 CFR Part 11 compliant file approval process, which enables you to upload any type of file to the database, and route it for approval to a configurable list of reviewers and approvers. You can capture electronic signatures, enforce file version control, track an audit trail of the version history of the file,

secure the file based on its status, and associate the document with entities throughout the Oracle E-Business Suite. Additionally, if modifications are made to a product or formula, a workflow notification can be sent to request a document rebuild that incorporates the changes.

### **Distribute Safety Documents**

Automatically attach Material Safety Data Sheets and other critical safety documents to Sales Orders and Shipments. Print and distribute any safety documents as a standard part of your shipping and transportation documentation. Oracle's built-in "Attachments" feature will automatically associate the safety document with the appropriate sales order line and shipments, and as part of the Ship Confirm process your document set will include all related safety documents.

### **Hazard Communications Open Interface**

To provide full compliance with international safety standards, Oracle offers a hazard communications open interface that lets companies use their existing hazard communication solution with the Oracle E-Business Suite. Several Oracle partners specialize in safety document authoring, management, and distribution to provide the tools, configurable business rules, and expertise on the most recent hazardous materials regulations.

Oracle provides the content for items and formulas. Oracle partners re-create the formula, evaluate its contents using sophisticated rules engines, and produce the Material Safety Data Sheet (MSDS) documentation that can be:

- Distributed directly from a partner application
- Uploaded for distribution with Oracle shipping and transportation documents

Oracle offers the following business solutions to help manage chemical hazard safety documentation:

- Author safety documents in an Oracle partner application using data from the Oracle E-Business Suite.
- Attach safety documents or labels that were authored in an Oracle partner application to objects within the Oracle E-Business Suite.
- Synchronize hazard communication data between Oracle partners and the Oracle E-Business Suite.
- Keep a history of safety hazard communication documents dispatched within the Oracle E-Business Suite, regardless of where, or from which system the dispatch originated.

**KEY BENEFITS**

- Lower Risk of Compliance Issues
- Accurate Reporting and Safety Documentation of Hazardous or Regulated Materials

**RELATED PRODUCTS:**

- Oracle Approvals Management
- Oracle E-Records
- Oracle Inventory
- Oracle Order Management
- Oracle Process Manufacturing Product Development
- Oracle Workflow

**RELATED SERVICES:**

The following services are available from Oracle Support Services:

- Update Subscription Services
- Product Support Services
- OnlineDBA
- OnlineDBA for Applications

**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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