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ORACLE DATA SHEET

# Oracle Process Manufacturing Quality Management

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KEY BENEFITS

**Process Manufacturing Quality provides:**

- Reduced Quality Lead Times
- Improved Material Usage
- Improved Lab Management
- Better Customer Responsiveness
- Reduced manufacturing nonconformances
- Enforced quality standards and compliance

Oracle® Process Manufacturing Quality Management empowers Process companies to achieve product consistency, enforce proactive quality assurance, streamline quality lab productivity, and assure customer and regulatory compliance.

## Achieve Product Consistency

### Stability Studies Management

OPM Quality Management streamlines research and development activities for product expiration dating by delivering the tools and methodology to manage the lifecycle of stability studies. Typically performed in Life Science, Chemical, and Food & Beverage industries, these studies characterize the effects of environmental aging on the quality and shelf life of a material, as it is subjected to normal and stressed environmental conditions and various packaging configurations. OPM supports the planning and implementation of stability testing across pre-defined time intervals, including the management of sample storage, retrieval, testing, and disposition. The project-oriented interface, workflow-driven stage gating, and reusable templates enable stability study management under an auditable, guided methodology. Based on the study data, recommendations for the product shelf life and storage condition can be recorded.

### Quality View of Inventory

OPM Quality Management helps Process companies validate the quality of expired or expiring materials, taking a proactive approach to optimizing date-sensitive goods. OPM Quality Management reflects the inherent variability of lot attributes in material availability and on-hand inventory adjustments by assigning and updating the lot status, grade, and release date. As a result, inventory is viewed from a quality perspective, which is critical to the containment of materials from inappropriate use in purchasing, planning, production, and shipping operations.

### Inspection Hold at Receiving

Streamlining the communications between the receiving dock and quality laboratory, Oracle can hold a receipt until material analysis results are acceptable before allowing inventory delivery or supplier return of the material. Suppliers can be paid based on the quality of the incoming material, improving your control of product costs. Receiving inspection also reduces the risk of nonconformance further downstream in the supply chain by ensuring proper material classification which presents rejected items from reaching production or shipping.

### Quality-Controlled Batch Processing

OPM Quality Management gives you a quality-based view of your materials on-hand before you begin production, improving your ability in making formula-to-formula or

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batch-to-batch changes to satisfy customer specifications and quality control tests. OPM Quality Management works together with Process Execution to hold batch processing based on the acceptability of sampling results. Manufacturing deviations can also be recorded as critical nonconformances that become part of the Control Batch Record and require resolution before the completion of the batch.

## Enforce Proactive Quality Assurance

### Standardized Inspection Methodologies

To ensure consistent development and application of quality standards across the enterprise, OPM Quality Management supports the definition of quality tests, test methods, test classes, and sampling plans. These inspection methodologies aid quality laboratory activities and test execution.

### Flexible Specifications Management

OPM Quality Management improves the process of creating and managing specifications through base and overlay templates, version and status control, and workflow approval. Specifications are critical to drive sample analysis, certify quality compliance, and designate the actions to be taken with nonconforming results. Several specifications can be established for an item and optionally grade to capture the variations in acceptance criteria with the tests required, their targets, and limits. Specification Validity Rules distinguish which specification is approved and active for an inspection point (e.g. receiving, production, inventory, shipment). These validity rules ensure that the appropriate specification is used for matching available inventory, committing orders, and reporting quality documentation.

### Detailed Sample Tracking and Analysis

Through acceptance sampling techniques, OPM Quality Management makes it easy to verify quality levels from inventories, vendors, or production runs or highlight inventory requiring quality control attention. Depending on the sampling scenario, samples can be created spontaneously or automatically for immediate testing or retained in storage for future testing needs. When one sample is inconclusive in determining the quality characteristics of a material, multiple samples may be taken from the same source and grouped together to determine an overall material disposition. When a specification validity rule applies to an inspection point, a specification may be assigned to the sample to schedule and guide lab testing. OPM Quality Management accurately tracks the lifecycle of sample and maintains the history of testers, test kit materials, and external test providers—which are critical for regulatory audits and traceability in the event of contamination or investigation.

### Decisive Results Evaluation

OPM Quality Management ensures accurate results entry by adding lab security, tester identification, and a review point for results interpretation. Results can be recorded iteratively for one or more tests in order to determine the acceptability of the sample and lot inspected. OPM Quality Management provides the tools to evaluate test results for conformance to specification, copy results across items and lots for easier finished goods reporting, and calculate result statistics for further analysis. Quality measurements obtained through OPM Quality Management can play an essential role in helping you provide necessary documentation for a Certificate of Analysis, or determine actions to be taken in formulation, production, or other areas of the enterprise.

**KEY FEATURES**

**Process Manufacturing Quality supports:**

- Automated Stability Study Management
- Lot Expiration Handling and Retesting
- Potency or Variability Management
- Quality Holds During Receiving and Production
- Material and Grade Classifications
- Specifications-Driven and Ad-Hoc Sampling and Analysis
- Environmental Monitoring
- Composite Results
- Workflow-Driven Quality Processes
- Electronic Records and Electronic Signatures of Quality Events
- Quality Workbench
- Lot Selection Based on Customer Specification Matching
- Certificates of Conformance and Analysis
- Lot Genealogy with Sampling History
- Efficiently manage process quality sampling process and lab workload using Quality Command Center
- Insight into root cause analysis of product quality issues across sample sources using quality command center

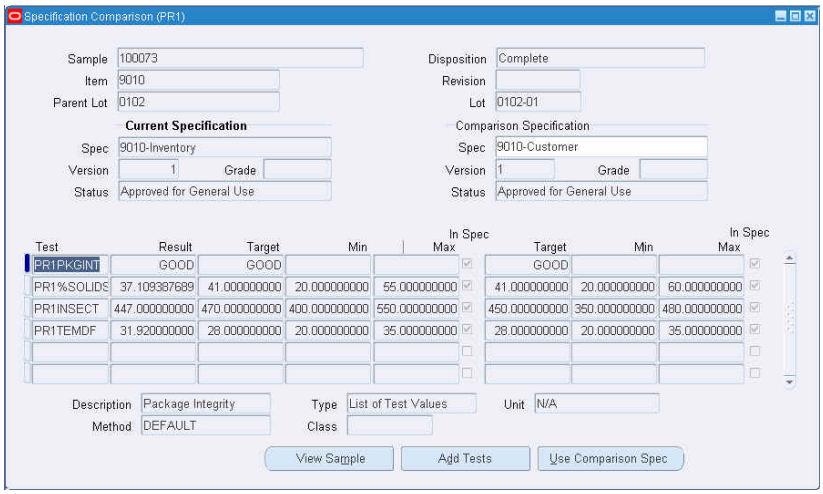



**Figure 1: Evaluate Lot Conformance to Other Specifications for Regrading and Repurpose**

### Environmental Monitoring

OPM Quality Management supports the monitoring of environmental factors at the time of inspection, manufacture, and storage—which can affect the quality characteristics of a material. Through sampling, test measurement, and exception-based notification, environmental monitoring compliance helps maximize material and resource utilization under optimal conditions.

### Workflow-Driven Quality Processes

To help reduce your quality lead-times and account for quality testing in supply chain activities, the pre-built workflows in OPM Quality Management provide automatic notification to the key personnel who must complete tasks pertaining to specifications management, quality sampling, testing, and disposition. Information for the entire lifecycle of the sample—beginning with the need to create a sample, through notification to testers of what tests are required, to rejection or re-testing, to final approval—is circulated to the proper individuals or teams automatically.

### 21 CFR Part 11 Compliant Electronic Recordkeeping

Oracle looks to the United States Food and Drug Administration (FDA) Part 11 of Title 21 of the Code of Federal Regulations (21 CFR Part 11) and related regulations as the basis for designing the compliance solutions offered to customers. Electronic recordkeeping is available on critical business events in Oracle Process Manufacturing Quality Management, including the approval of specifications and specification validity rules, creation and approval of samples, entry and evaluation of results, and the approval of stability study stages.

## Streamline Quality Lab Productivity

### Secure, Personalized Data Management

OPM Quality Management provides the tools to secure access levels to real-time quality data as well as the presentation of the information. Quality managers and technicians with the proper authority can access the appropriate information to perform their responsibilities of specifications management, sample drawing and analysis, and results communication. Using Oracle Folder technology, you can tailor and save the display of quality screens according to your business needs.

Quality Management is part of the Oracle Process Manufacturing (OPM) product family, designed to work together with the following products:

- Oracle Advanced Planning and Scheduling
- Oracle Approvals Management
- Oracle E-Records
- Oracle Inventory
- Oracle MES for Process Manufacturing
- Oracle Order Management
- Oracle Purchasing
- Oracle Quality
- Oracle Workflow

The Quality Workbench also enables easier accessibility and maintenance of quality data, organized into intuitive views of specifications and samples with built-in drill-downs to tests and results. Personalized views of the data can also be saved as personal and public shortcuts for quick inquiry. You can easily identify active specifications and samples and distinguish which have completed testing, providing better visibility into the quality laboratory workload.

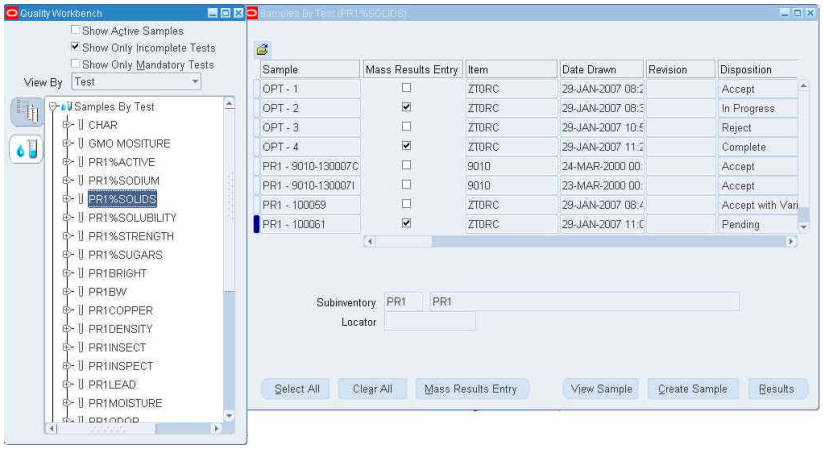



**Figure 2: Organize Quality Laboratory Workload to Identify Incomplete Testing**

## Access from Anywhere

Process manufacturing quality managers can monitor the quality inspection of the laboratory samples and take quick actions on the go using the Oracle Mobile Process Quality Manager for Oracle E-Business Suite. They can view the progress of samples or tests and perform quick actions to expedite the inspection, like change disposition of the sample, evaluate test results and assign tester or resource to tests. The mobile app benefits the quality Managers to collaborate with the testers using device features like email, phone and text.

## LIMS Integration

When integration with other application software such as a Laboratory Information Management System (LIMS) is utilized to extend and complement Oracle Process Manufacturing's capabilities, Application Programming Interfaces (APIs) are available for the import and export of OPM Quality Management data. APIs are written for key business objects—including tests, specifications, samples, and results—and facilitate data exchange for easier integration to legacy systems, in-house developed applications, and third party software. OPM manages a single, centralized repository that maintains quality data and transactional traceability.

## Assure Customer and Regulatory Compliance

### Customer Specification Matching

OPM Quality Management in conjunction with Oracle Order Management delivers the solution to better match the quality of your finished products to your customers' requirements, reducing returns and improving your bottom line. This inquiry finds available lots that match customer-specific quality specifications when allocating inventory during order entry and picking processes. In addition, OPM Quality Management provides a side-by-side comparison of lot results against the tested specification and an alternate specification in order to repurpose the material for a particular customer, lot status, or grade.

### Generating Quality Certificates

While managing all the data to produce quality compliance documentation, OPM Quality Management offers Certificate of Conformance (CoC) and Certificate of Analysis (CoA) reporting capabilities with flexibility in defining, finalizing, and formatting results. You can report the average of composite results and configure the displayed name and decimal precision of reported results based on customer-specific needs. The CoA can also be included automatically with a sales order/shipment from Oracle Order Management.

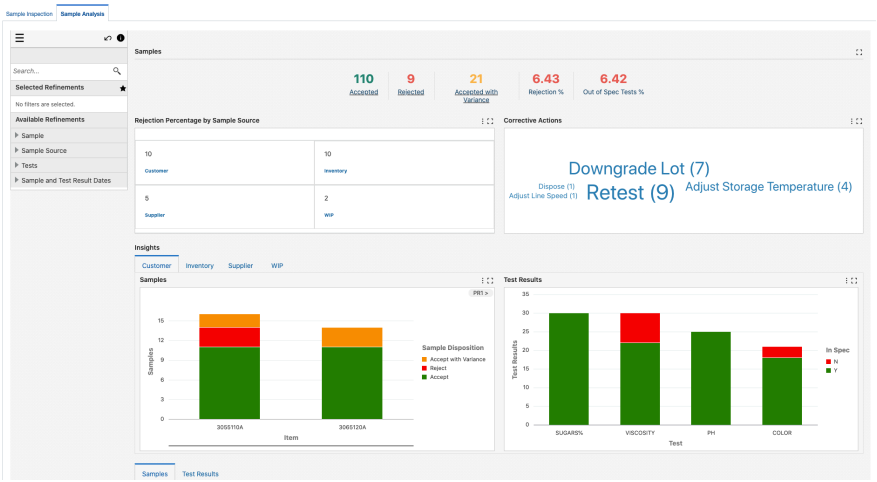
### Lot Traceability

OPM Quality Management offers comprehensive lot genealogy capabilities to trace materials from receipt through customer shipment. It provides an easily accessible, online record that indicates when lots were sampled for quality inspection and were used in production, moved, or shipped as end products—the information needed to prove compliance with government regulations, ISO 9000 requirements, or your own internal quality standards.

## Oracle Quality Command Center

The Oracle Quality Command Center for process manufacturing provides Sample Inspection and Sample Analysis dashboards empowering quality manager, lab manager, quality inspector and quality analysts to quickly explore and analyze product and process quality data within E-Business Suite Process Manufacturing, prioritize sample inspections, manager lab workload of testers or test equipment, identify sample delays and expedite tests that are due, identify out-of-spec tests and quality rejections and take corrective actions to control quality deviations across sample sources like customer, inventory, wip and supplier.

The Oracle Quality Command Center feature is available at no additional cost to licensed users of Oracle Quality. It can be applied to Release 12.2.4 and above.




## Conclusion

Quality management apart from enterprise-wide visibility and integration into supply chain operations becomes the sole responsibility of quality personnel. To implement quality assurance throughout the Process enterprise, quality information must be accessible and integral to all responsibilities including inventory, receiving, planning, product development, production, and shipping. The OPM Quality Management solution delivers the following benefits:

*Reduced Quality Lead Times* – The automation of quality notifications and updates throughout the Process enterprise speeds the communication of quality results and streamlines quality assurance practices. Without these automated business rules, quality

testing lengthens the overall processing time of receiving, developing, manufacturing, and shipping materials.

*Improved Material Usage* – Since material quality can vary from lot to lot, knowing the exact quality characteristics facilitates decisions on how to use a material for product development, production, and shipping activities. By updating the lot status and grade, quality management enables efficient use and movement of materials.

*Better Customer Responsiveness* – Process companies consistently have to meet their customer requirements despite variable quality characteristics of materials received and produced. Visibility to inventory that conforms to customer specifications and the comparison to changing specifications enhances their ability to meet customer demands and responsiveness to any changes in customer requirements.

## 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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