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ORACLE DATA SHEET

Oracle Quality

ORACLE 12
E-BUSINESS SUITE

ORACLE QUALITY

KEY BENEFITS

Oracle Quality is designed to be a flexible enterprise-wide Quality Management system that enforces quality data collection at the source and delivers better visibility, analysis, and responsiveness to your supply chain quality.

- Alignment to business goals through integrated quality management
- Adaptation to changing business environment
- Support of quality management best practices
- Enforcement of regulatory compliance

Oracle® Quality is a flexible enterprise-wide quality management system that lets you collect, distribute, and analyze critical quality data throughout your supply chain. Oracle Quality is part of Oracle E-Business Suite. Its tight integration with the rest of the supply chain modules, enables you to collect quality data at the source and achieve better visibility, analysis, and responsiveness to your quality and compliance business challenges.

Secure, Integrated Supply Chain Quality Management

Oracle Quality collects and manages quality information throughout your supply chain and enables you to measure product and process quality to ensure adherence to quality standards. Quality data can be shared across the supply chain to measure yield, track defects, conformance to specifications, and monitor supplier performance. Strong security allows only authorized users access to input or update quality data. Electronic signatures can be used as an additional level of security to ensure that the person signing the record is fully authorized to perform the transaction. Automatic actions, such as electronic-mail notifications or placing a job on hold, can be taken based on actual quality results. Using techniques such as skip lot and sampling for receiving inspection, Oracle Quality helps you reduce inspection costs. Oracle Quality is tightly integrated with Oracle E-Business Suite Applications and serves as the enterprise-wide repository for supply chain quality.

Flexible Quality Data Collection

Oracle Quality is highly configurable and can be tailored to collect quality information pertinent to your company's specific business needs. Oracle Quality lets you create user-defined, easily maintainable quality collection plans, and also control where, when, who, and how you collect data throughout your supply chain. Parent and child collection plans allow you to store information in a hierarchical and multi-leveled structure to obtain the flexibility needed to collect quality data for detailed collection of quality information. Parent and child collection plans can also be used to maintain an audit trail of all the updates to the quality data through history collection plans.

With the deployment of Oracle Manufacturing Execution System (MES) for Discrete Manufacturing, quality data can also be read automatically from shop floor devices and test equipment via Oracle Connectivity Suite for KepServerEX OPC drivers into Oracle Quality collection plans. Real-time quality data collection using device connectivity reduces manual data entry errors and the need to import quality and test data solely through open interfaces. This ensures quality test data to be captured in real-time and provides flexibility for user override if necessary.

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KEY FEATURES

Oracle Quality supports:

- Enterprise-wide quality data repository
- Built-in quality checks integrated with manufacturing, logistics, maintenance and service modules in the Oracle E-Business Suite
- Flexible online and background actions Processing based on data validation and specification violations
- Supplier quality management with Skip Lot and Sampling Inspection
- Nonconformance and disposition management
- Closed-loop corrective and preventative actions
- Electronic records and electronic signatures of quality events for 21 CFR Part 11/820 compliance
- Quality management system audits
- Mobile data collection
- Lot / serial genealogy with collection plan history
- Results reporting and charting
- Forms and Quality Workbench personalization of user interface
- Multimedia attachments
- Actionable Insights into product and process quality data within e-business suite with quality command center
- Manage process quality sampling process and lab workload

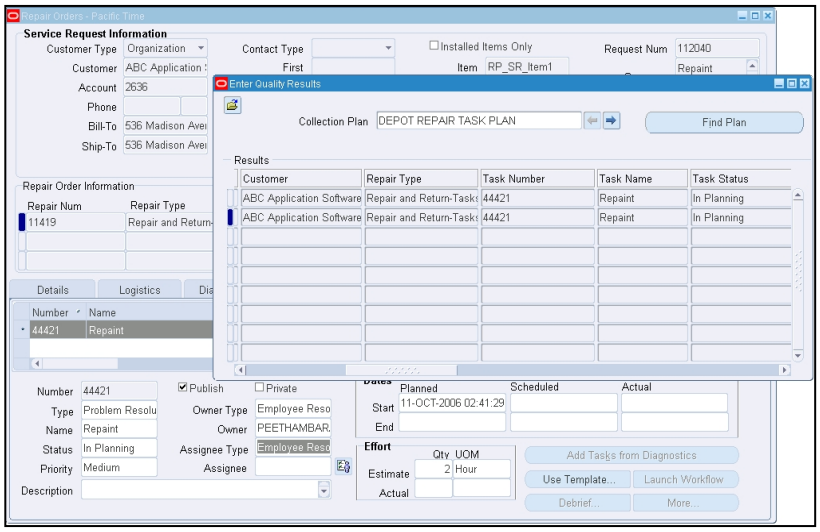

Figure 1: Quality Data Collection Within a Service Request

Electronic Records and Electronic Signatures

If required by your business processes — such as FDA regulated medical device manufacturers, or some government contractors — you can implement Electronic Records and Signatures (ERES). You can require an electronic signature in 60 separate business events and then store an electronic record in XML format for future recall and to ensure to outside auditors the validity of your electronic records. It is also possible to have approval levels and approval hierarchies that allow records to be processed only after going through a signature chain you configure to meet your internal organization approval hierarchy.

Quality at the Source

Delays and errors in reporting quality results and detecting quality problems can lead to defective products, downstream failures, and delayed product shipments. By making quality data collection a part of your standard workflow, you can distribute quality assurance responsibilities throughout the enterprise.

You can record quality results as you are transacting material to ensure early detection of problems. You can have your suppliers and subcontractors collect quality data and have them enter it into your system. You can log nonconformances, initiate corrective actions and dispose of suspect material by initiating a rework order, adding rework operations, scrapping material, or moving material to a Material Review Board inventory area. Similarly, during receiving inspection you can collect data to ascertain the quality of incoming materials. If and when an issue is detected, you may take action such as sending an email notification, putting a job on hold, or placing a supplier on hold.

Nonconformance and Corrective Action

Oracle Quality's Nonconformance and Disposition solution can easily help your business deploy an electronic nonconformance and disposition system. The solution's design is based on a set of pre-defined related collection plans and actions that store nonconformance and disposition-related information, combined with an organized best practices methodology. The appropriate and meaningful status for each recorded nonconformance is maintained and each nonconformance can handle multiple defects and /or multiple dispositions. There are several automated disposition actions that can be taken. The Nonconformance and Disposition solution can be easily set up and customized to your organization's policies and procedures.

In support of continuous improvement programs, Oracle Quality also delivers an integrated, closed-loop Corrective and Preventive Action (CAPA) solution that manages the lifecycle of corrective and preventive actions and their effectiveness. It enables analysis and collaboration by streamlining communication and tracking problems through to resolution.

Quality Audits

An important aspect of any Quality Management System (QMS) is the assessment of its effectiveness in meeting its objectives and continuous improvement. One of the tools to identify areas of improvement is a quality audit. An audit is performed to establish the level of compliance to published standards and document any corrective actions needed.

Oracle Quality supports the complete end-to-end audit process, including audit planning, audit execution, audit reporting and audit follow-up. Seeded audit solution templates and a reusable question bank allow you to quickly implement and conduct quality audits and assess compliance to established procedures.

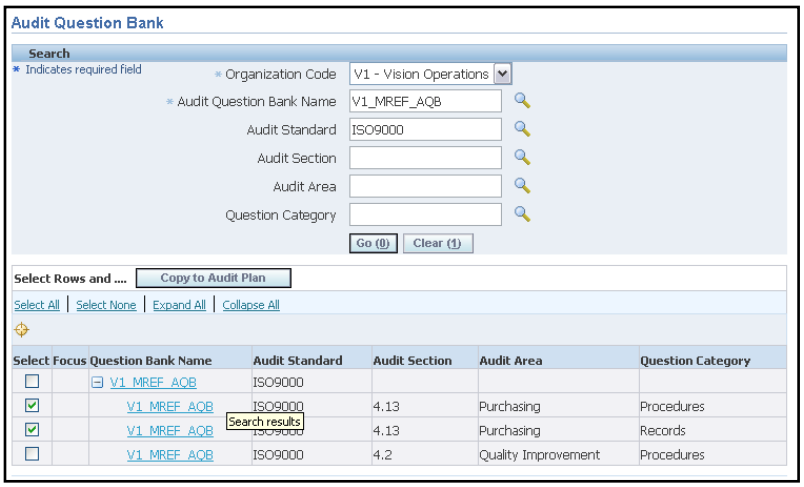

Figure 2: Audit Question Bank

Intuitive Quality Analysis and Reporting

After quality data are captured, it is vital to your business that you are able to extract, analyze, and react to it quickly and easily. Oracle Quality lets you react to quality problems immediately through user-defined action rules. For example, you can automatically send an electronic-mail alert to notify proper personnel or put a job on hold when a particular quality problem is found. In addition, powerful reports, flexible inquiries, and intuitive Pareto, histogram, control charts, or trend charts let you analyze your quality data efficiently for improved responsiveness. The lot and serial genealogy inquiry available in the Material Workbench in Oracle Inventory also provides greater visibility into the traceability of collection plan results for a particular lot and serial. These analysis tools give you comprehensive views of the information that you gather throughout your business process and store in your quality repository. You can also export quality data to your choice of statistical analysis packages through spreadsheets and preserve your investment in analysis tools, techniques, and training.

ORACLE QUALITY

RELATED PRODUCTS

Oracle Quality is part of the Oracle Manufacturing product family, designed to work together with the following products:

- Oracle Work in Process
- Oracle Manufacturing Execution System for Discrete Manufacturing
- Oracle Flow Manufacturing
- Oracle Shop Floor Management
- Oracle Inventory
- Oracle Warehouse Management System
- Oracle Enterprise Asset Management
- Oracle Purchasing
- Oracle iSupplier Portal
- Oracle Service
- Oracle Depot Repair
- Oracle Complex Maintenance, Repair, and Overhaul
- Oracle Mobile Supply Chain Applications

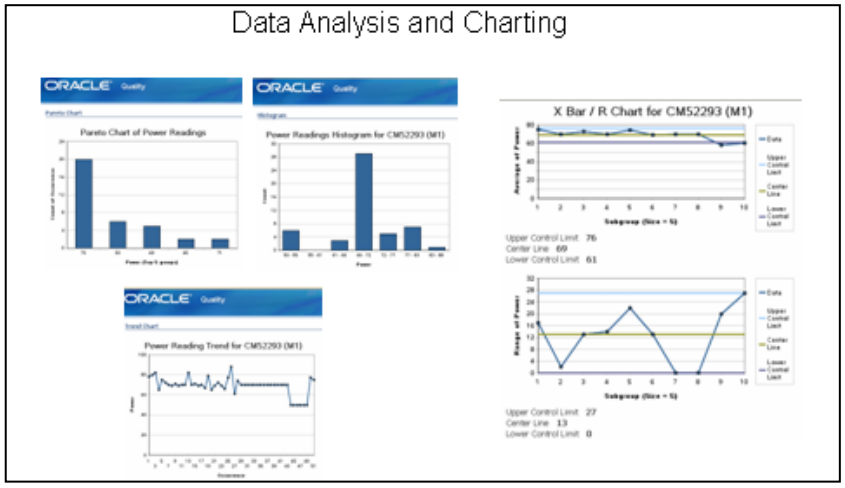

Figure 3: Quality Data Analysis and Charting Capabilities

Oracle Quality Command Center

The Oracle Quality Command Center provides dashboards empowering quality inspector, quality analyst and quality managers to quickly explore and analyze product and process quality data within E-Business Suite, manage process quality sampling process, manage lab workload, identify nonconformance sources, investigate the root cause and take corrective action, near real time. With tools and visualizations such as actionable indicators, tag clouds, interactive charts, and consumer-like search and filters, users can browse and drill on whatever captures their attention, revealing new information on which to base next discovery steps. Through this "information-driven navigation", users can quickly narrow in on priority transactions and take immediate, informed action.

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

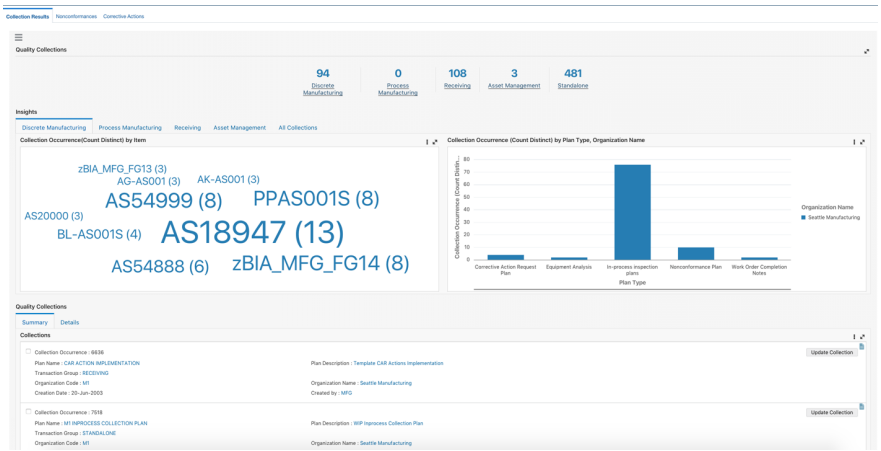

Figure 3: Collection Results Dashboard in Oracle Quality Command Center

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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For more information about Oracle Quality, visit oracle.com or call +1.800.ORACLE1 to speak to an Oracle representative.

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Hardware and Software, Engineered to Work Together

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