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Oracle Fusion Cloud Quality Management

As organizations strive for excellence in an increasingly competitive landscape, maintaining high product quality has become more crucial than ever. Companies face the ongoing challenge of integrating and synchronizing their quality management system (QMS) to keep up with rapidly evolving customer expectations, stringent regulatory requirements, and the growing complexity of global supply chains. By enabling zero-defect operations with a closed loop, connected, intelligent, and automated enterprise QMS, Oracle Cloud Quality Management drives organizations toward unparalleled product excellence, operational efficiency, and customer trust.

Key business benefits:

- Increase enterprise visibility to quality information through digital thread.
- Enable quality-based design decisions.
- Enforce execution compliance to quality plans across supply chain.
- Ensure a closed-loop quality process from issue detection to resolution.
- Drive proactive quality-based improvements.

Connected quality management in the cloud

Organizations that rely on quality systems disconnected from other operational systems often face significant inefficiencies. These isolated systems can lead to delays in communication, inconsistent data, and errors in decision-making. Without integration with production, supply chain, or product development maintaining real-time visibility on quality metrics becomes challenging.

This can result in increased costs, slower response to defects, and difficulty in meeting regulatory requirements or customer expectations. Ultimately, this hinders the organization's ability to deliver consistent, high-quality products, making system integration key to streamlined operations and continuous improvement.

Oracle Quality Management is a set of modern enterprise quality management capabilities built into the Oracle Fusion Cloud Supply Chain and Manufacturing suite of applications, with embedded best practice processes and built-in GenAI and analytics. Built for the cloud, Oracle Quality Management connects research and development, manufacturing, inventory, maintenance, and quality assurance and control to achieve greater quality visibility, insights, and collaboration.

Oracle Quality Management helps organizations:

- **Design for quality**: Specifications defined at the time of product design naturally flow to inspection plans. This approach helps to make sure that current and accurate data drives the inspection process without the cost of custom integration between traditional systems such as product lifecycle management, enterprise resource planning, and quality management.
- **Perform inspections**: Manufacturing, inventory, and maintenance personnel perform inspections at critical points in supply chain execution, identify non-conforming materials, and alert stakeholders of potentially harmful and costly problems.
- **Manage issues**: Quality teams manage identified quality events in a controlled, consistent, and auditable manner from containment, to root cause analysis, to implementing corrective actions.

Effectively identify non-conformances through inspections

With Oracle Quality Management, quality engineers can define inspection plans (optionally using GenAI and AI Agents) across supply chain management. Inspection characteristics with quality specifications or tolerances can be integrated with product specs to identify when and where inspections should occur (receiving, work in process, inventory).

Receiving inspection levels are based on sampling percentages and skip lot frequencies, customized to supplier performance, rather than defaulting on 100% inspections.

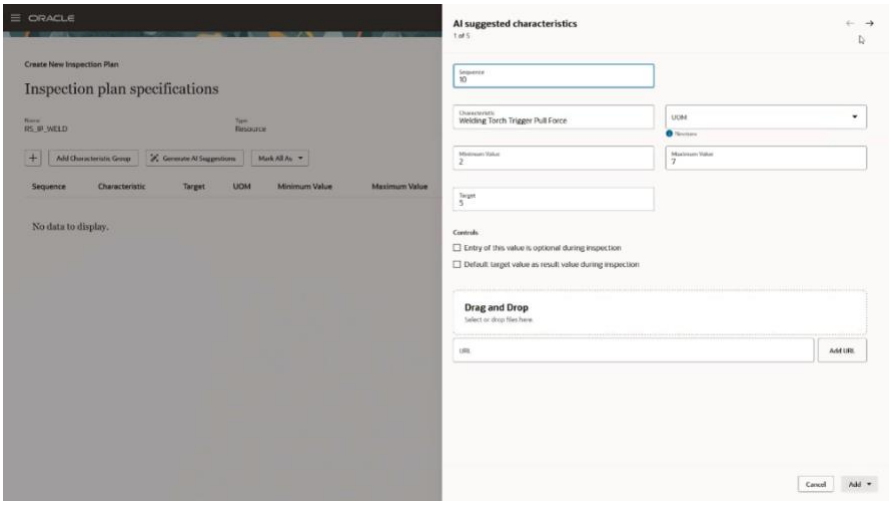

Figure 2. Define quality requirements in an inspection plan with AI Assist

Inspection processes also adhere to ANSI/ASQC Z1.4 standards to ensure accurate sampling and quality reflection. Automatic sample numbering, barcode scanning, and tablet-optimized interfaces streamline data collection, with results determining acceptance or rejection.

Non-conformances are triggered by inspection failures, allowing subsequent root cause analysis and corrective actions to prevent costly defects from being discovered by a customer or in the field.

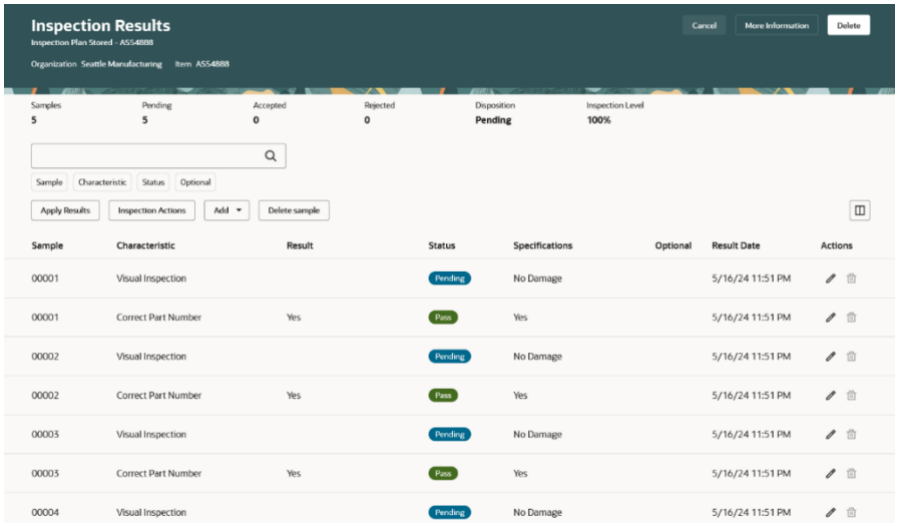

Figure 3. Enter inspection results to determine quality conformance.

Cloud Quality use cases and key features

- **Drive closed-loop quality**: unified quality across Cloud SCM eliminate data chase to make high-speed 360-degree decisions with near real time transparent and traceable information starting at innovation funnel.
- **Integrated inspection plan**: Quality engineers work on SCM quality plan authoring with characteristics, tolerances, sampling, and gauge tracking. Leverage GenAI, AI Agents to fast track their work.
- **Better risk mitigation**: quality team can review risk planning tool to see if the risk was predicted and aligned with operational requirements to determine if a possible resolution can be identified.
- **Quality digital thread**: Cloud Quality Management is an integrated feature embedded in Cloud SCM that creates a single digital thread to drive product data through the closed loop and accelerate end-to-end quality.
- **Settle supplier issue**: for all problem reports related to any suppliers, organizations can initiate an audit and investigate. The supplier corrects the overall quality of the product and improves the production process.
- **Integrated non-conformance management:** Quality team work on Non-Conformance from failed inspection and Quality actions to fast-track issue resolution by leveraging e.g., CAPA, Root Cause Analysis, 8D, 5Whys. SCARs are assigned to suppliers on Supplier Portal.
- **Interoperability in the cloud**: Connects R&D, manufacturing, inventory, maintenance, quality assurance and control to achieve greater visibility, insights, and collaboration.
- **Genealogy**: Capture genealogy for lot track and trace and serialize products to maintain compliance with local

To enhance workforce productivity, receiving agents can perform quality inspections of received goods directly at the point of receipt using an industrial handheld device.

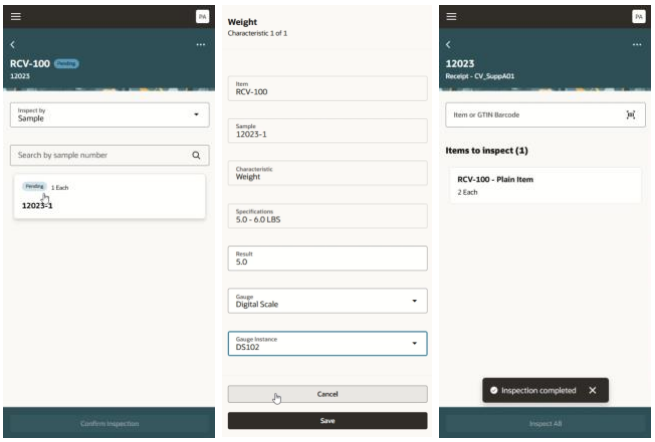

Figure 4. Receiving inspection from industrial handheld device

Manage problem reports and corrective actions

A company's strategic direction can be at risk due to problem reports of real or potential impact. Unfortunately, the potential impact posed by a given issue is not always clear at the time of discovery. Therefore, organizations require effective quality tools to guide team members through quality processes and controls to implement safe and effective solutions.

Oracle Quality Management reduces cost of quality with a built-in enterprise closed loop QMS to define, identify, analyze, and correct quality events and improve the overall effectiveness, safety, and profitability of your products and services.

Problem report and/or CAPA resolution are directly linked into the engineering change order (ECO) process to ensure that quality problems are resolved. In addition, quality data is visible during product development to prevent future problems.

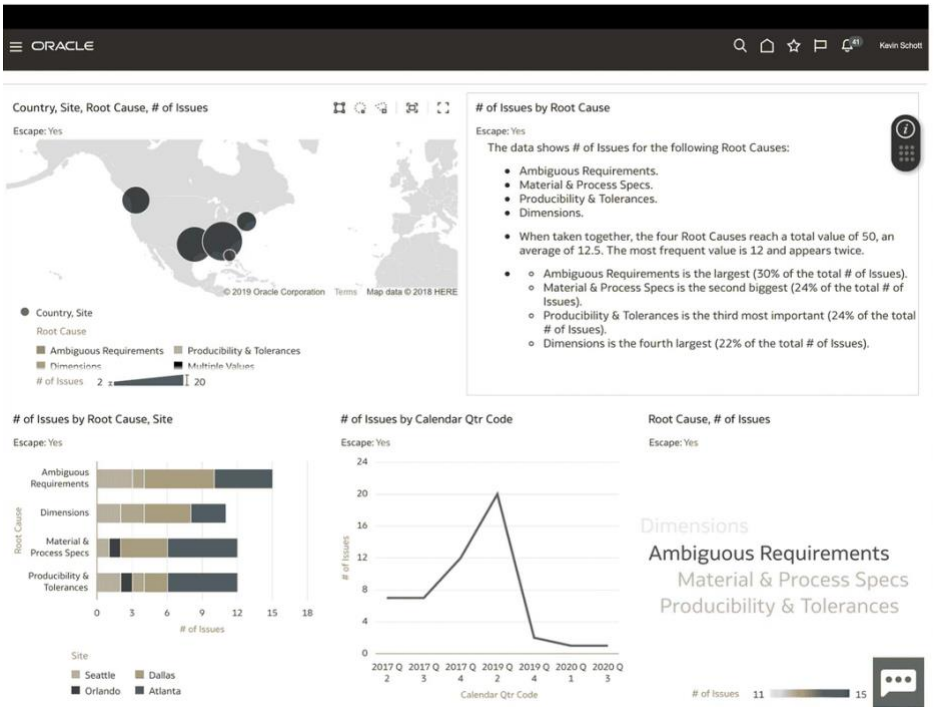

Figure 5. Custom dashboard for root cause, defect, issues visibility

regulations.

- **Industry-specific features**:
  - FDA 21 CFR Part 11 electronic records and electronic signatures
  - Unique device identifiers (UDI) for medical device manufacturers
  - Electronic production record for a product

Graphically track and trace materials through its lifecycle

In many industries, there is an ever-increasing need to provide inclusive lot and serial tracking from supplier through production and shipment to support quality containment and recall events.

If you have a product failure, the Oracle Product Genealogy solution enables you trace the entire history of any serial or lot to determine possible sources of the failure, understand where the problem product is at this moment, where the other potentially impacted items are, and then investigate if the failure has been corrected or if it is ongoing.

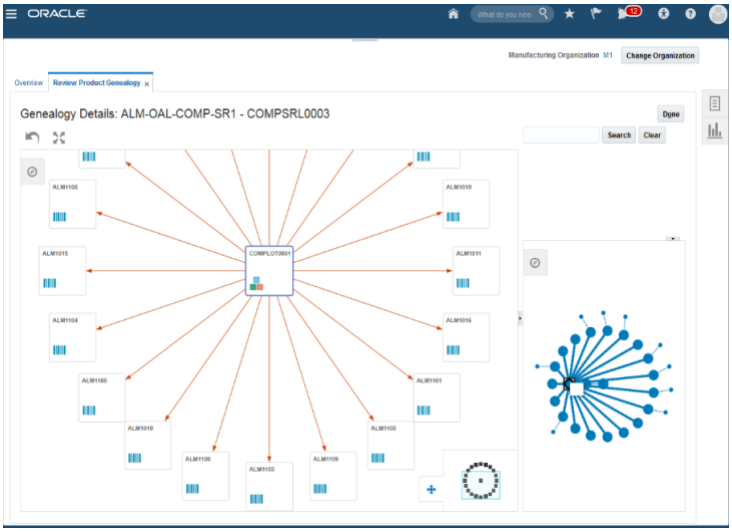

Figure 6. Product Genealogy Visual Representation

Seamlessly integrate between external systems

You can integrate Oracle Quality Management with other enterprise systems and extensions running on Oracle using REST services. From any external application (for example, third-party QMS, LIMS or MES), you can use REST services to make requests to, for example, create inspection plans, inspection results or problem reports.

Learn more about Oracle Quality Management

Oracle Fusion Cloud Quality Management is designed to streamline quality processes across the supply chain. By connecting various operational areas such as R&D, manufacturing, inventory, and quality control, it ensures greater visibility, insights, and collaboration. Leveraging modern technologies like GenAI, AI Agents, and built-in analytics, it helps organizations maintain compliance, reduce costs, and drive continuous improvement in product quality.

Take a product tour

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