

AGILE PRODUCT GOVERNANCE AND COMPLIANCE

KEY FEATURES & BENEFITS

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- Environmental compliance functionality supports RoHS, WEEE, JEDEC, China RoHS, and Japanese Green Initiative
- Due diligence functionality supports FDA (QSR), DoD, ISO 9000/14000/13485, and SEC guidelines
- Compliance data linked to product record
- Hazardous materials compliance risk analysis and reports
- Automated compliance validation and out-of-compliance detection whenever the product's definition or supply chain changes
- Policy and procedure documentation support and links
- Support for industry data collection formats such as JGPSSI and IPC 1752

KEY BENEFITS

- Track and maintain full compliance
- Access regulatory information faster
- Provide auditors with accurate and transparent data
- Reduce business interruption risk
- Decrease product and operations cost
- Design more-compliant and lower-cost products
- Improve risk/return profile

Oracle's Agile Product Governance and Compliance enables organizations to manage the compliance of their products and programs with government and industry standards and regulations. The solution merges compliance activities with the enterprise product record, allowing companies to more-reliably comply with environmental standards, create policy documentation, and design compliant products from the start—reducing the risk of costly business interruption or shutdown.

The Challenges of Ensuring Compliance

Increasing regulation is a trend in the life sciences, automotive, and high-technology industries that can slow time to market or—when compliance is not achieved—derail the product lifecycle altogether. Companies and products must comply with a multitude of standards, regulations, and due diligence requirements, including

- Corporate standards such as those set by the International Organization for Standardization (ISO 9000, 14000, 13485)
- Environmental and safety regulations such as those set by the U.S. Food and Drug Administration (FDA)
- Industry-specific regulations such as those set by the U.S. Securities and Exchange Commission (SEC) or the U.S. Department of Defense (DoD)

Periodic audits by these regulatory bodies and customers mean product lifecycle processes must be transparent and audit ready.

Companies need a solution that links all product governance and compliance data and processes in a single database with enterprisewide visibility. Agile Product Governance and Compliance manages compliance within the enterprise product record—the complete, up-to-the-minute definition of the product. Its core functionalities track and maintain full compliance by linking critical steps in the product lifecycle with processes that ensure standards and regulations are met.

Agile Product Governance and Compliance Overview

Companies that cannot manage product compliance across the range of regulatory bodies suffer costly business interruptions such as product redesigns, delayed market launches, product returns, recalls, FDA citation, or even disastrous business shutdown. In conjunction with Oracle's Agile Product Collaboration, Agile Product Governance and Compliance enables companies to transform their reactive, manual compliance processes into a repeatable, audit-ready system that reduces the risk of

business interruption, and restores a favorable risk/return product profile.

By integrating the product record with government and industry regulations and standards, Agile Product Governance and Compliance allows companies to manage product policies and operations within a system that has built-in compliance support. Agile Product Governance and Compliance offers the following core functionalities.

Oversight of Compliance Processes

When users and managers conduct internal and external audits, management reviews, and closed-loop continuous improvement processes, the system prompts them to validate or correct critical governance and compliance processes. Proper procedures can be managed, measured, and communicated automatically to the appropriate personnel to maintain continuous compliance and address failure points.

Environmental Compliance

Manufacturing companies, particularly electronics producers, are challenged to comply with European Union and other global directives regarding hazardous materials—including the Restriction of Hazardous Substances Directive (RoHS) and the Waste Electrical and Electronic Equipment Directive (WEEE). The environmental compliance functionality allows manufacturers to collect information about resources, substances, materials, and components used in the production of a product, as well as the waste that was generated to manufacture the product, perform related risk analysis, and supply reports to customers or regulatory agencies. Material declarations and certificates of compliance are collected and stored in a central database. This database can be further enriched with content from reliable industry sources or third-party databases.

The information in this database is then used to validate compliance with legislation or customer specifications that enable product teams to detect when a product is out of compliance—such as when legislation changes, when the materials and components in a product change, or when the product’s supply chain changes. Detecting such critical issues early allows the team to bring the product back into compliance without costly delays and disastrous product recalls.

Design for Environment

The design for environment functionality improves the process of designing new products. It guides designers to build products that satisfy environmental regulations from the initial concept phase by integrating the product record with limits set by government standards and regulations. Design teams can analyze new product designs for environmental compliance, and conduct what-if analysis to ensure they meet environmental requirements at all levels—including environmental protections that regulate business, technical attributes, and operations in specific countries.

Government and Industry Compliance

Companies must comply with their own operating procedures as well as with the standards and regulations of such entities as ISO, DoD, and the FDA. Compliance managers create and maintain the documentation that specifies policies and

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procedures that enforce this compliance. Such documentation is the cornerstone of the governance and compliance programs within their organization. Agile Product Governance and Compliance tracks and logs all actions taken in the system to ensure compliance with these policies and procedures.

System Validation

Companies that manufacture medical devices must comply with FDA regulations concerning how these companies manage documents and control design. In particular, the FDA Quality System Regulation 21 Code of Federal Regulations Part 820 requires manufacturers to conduct “intended-use validation” of the automated systems that manage product-related processes as the first step in getting FDA approval of medical devices. Oracle’s Agile Food and Drug Administration Validation Pak is an off-the-shelf solution that quickly validates an implementation of Oracle’s Agile product lifecycle management to ensure that it is compliant with this regulation.

Contact Us

For more information about how your organization can leverage the power of Oracle’s Agile Product Governance and Compliance, please visit oracle.com or call +1.800.ORACLE1 to speak to an Oracle representative.

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