

AGILE FORMULATION AND COMPLIANCE FOR PROCESS

KEY FEATURES

Agile Formulation and Compliance for Process is a Web-based application with a zero-client footprint that is accessible anytime, anywhere over a security-based Web browser. It provides prebuilt integrations with all bundles and modules of Oracle's Agile product lifecycle management for process solution. Features of the modules are listed below.

Design Workbench Module

- Electronic lab book maintenance
- Multicriteria optimization
- Real-time analysis of product, nutrition, and compliance data
- Availability of experimental what-if scenarios
- Ingredient statement development
- Substitution and ingredient reuse
- Specification and formulation comparison

Computer Aided Compliance Screening Module

- User-defined compliance and regulatory screens and rules
- Nested screens for modeling compliance scenarios
- Screens applicable to any level in the product structure

Nutrition Surveillance Management Module

- Ability to capture, maintain, composite, and compare nutrition surveillance results to nutrition data

Product Quality Scorecard Module

- Sample and quality session management
- Quality scorecarding based on testing protocols
- Real-time quality tracking and reporting

To gain competitive advantage, consumer goods companies need to be able to quickly respond to evolving customer needs and adapt to changing standards and regulations. Oracle's Agile Formulation and Compliance for Process, an option that can be bundled with Oracle's Agile Product Data Management for Process, enables organizations to meet customer requirements, improve product quality, and ensure product compliance. Agile Formulation and Compliance for Process includes four key modules—Design Workbench, Computer Aided Compliance Screening, Nutrition Surveillance Management, and Product Quality Scorecard.

Design Workbench

The Design Workbench module of Agile Formulation and Compliance for Process is a collaborative design tool enabling virtual prototyping, evaluation, and optimization of formulations. It allows you to measure the real-time impact of process and bill of materials changes on user-defined attributes, such as product cost, compliance, nutrition, and ingredient labeling.

With Design Workbench, you can design and optimize new formulations to meet user-defined design criteria, thereby reducing costs and increasing profits. By offering instant feedback, best-in-class optimization algorithms, and online collaboration, Design Workbench helps you accelerate the new product development process, launch successful products, and minimize costs.

Optimize Formulations

Design Workbench provides a best-in-class linear optimization algorithm, which allows users to optimize formulations based on any number of constraints tied to product properties, compliance, cost, nutrition, and formulation composition. The optimization engine produces the best-available solution based on user-defined optimization parameters, helping you quickly iterate through optimization scenarios and determine which experiments should be further investigated.

Track Impact on Costs, Compliance, and Nutrition

Design Workbench provides you with instant feedback on the impact of process and formulation changes on user-defined product characteristics, formulation costs, compliance, and nutrition, allowing you to quickly iterate formulation changes and understand the impact on all product properties. For example, nutrient data stored within each ingredient is rolled up to the formulation level, taking into account the impact of both process and formulation changes. You can then examine nutrient data to determine the source of each nutrient recursively across the entire formulation tree.

Save Formulations in Electronic Lab Books

With Design Workbench, you can save your experiments at any time as separate “snapshots,” which capture the entire data set related to the experiment at that point in time. This lets you preserve all your experimental iterations into an electronic lab book. It also allows you to test certain assumptions and return to previous iterations if these assumptions are not leading you down the desired path. Maintaining snapshots greatly accelerates the process of rationalizing experimental design.

Review the Impact of Process and Formulation Changes

When evaluating the impact of formulating or reformulating a product, it is critical to integrate the changes with both the formulation and the manufacturing process. The resulting product characteristics, such as density, total solids, and nutrient composition, will be affected by the process parameters, such as the component-level yield factor at each manufacturing step, the batch-level processing gain/loss factor, the water gain/loss factor, and the component-level nutrient degradation. Combining both process and formulation changes lets you fully understand the impact of formulation and reformulation.

Produce Optimal Ingredient Statements

Defining the ingredient statement for a product has traditionally been a manual, resource-intensive process. Design Workbench enables you to develop the most-desirable ingredient statement, based on a flexible, user-defined set of options and rules, such as renaming, grouping, aliasing, and reconstituting.

Additionally, you can restrict the construction of ingredient statements to the rules issued by specific government agencies, such as the U.S. Food and Drug Administration, U.S. Department of Agriculture, and Canadian Food Inspection Agency. You can capture all changes into an audit trail for justification and express the resulting ingredient statement as a combined or multipart statement. Design Workbench allows you to improve the efficiency of the ingredient statement development process and deliver more complete and accurate ingredient statements.

Leverage Design Scenarios

Running experiments might demand that you make changes to existing specification data in order to create what-if scenarios related to ingredients, intermediates, and product formulations. Design Workbench allows you to create these what-if scenarios within the formulation process itself, or store them with the specification data in the Global Specification Management module of Oracle’s Agile Product Data Management for Process. With Design Workbench, you will be able to experiment with specification changes without altering the specification data itself.

Optimize Batch Tuning and Analyze Formulations

Design Workbench lets you tune batch sizes based on criteria such as yield, ingredient quantity, and batch quantity. It also provides rounding rules that help you streamline how the ingredient quantities will be represented in the target batch. With Design Workbench, you will also be able to analyze the results of your experimental formulations and export these results to Microsoft Excel for further analysis.

Review Compliance

It is critical for research and development technologists to be able to screen their experimental formulations for compliance at any time throughout the design and development process. In conjunction with the Computer Aided Compliance Screening module, Design Workbench enables you to interrogate your formulations against the relevant compliance screens, understand whether they are compliant, and investigate the reasons for noncompliance. With Design Workbench, you will be able to discover the noncompliance nature of a product earlier in the development process, thus achieving significant savings.

Additionally, Design Workbench helps you determine which label claims are applicable to your experimental formulations based on the associated nutrient data.

Integrate Formulation and Specification Development

Design Workbench functions as an authoring tool for experimental formulations. In conjunction with the Global Specification Management module, it allows users to author formulations in Design Workbench and “export” them to Global Specification Management as specifications for review and approval. This ensures a seamless process from authoring to review and approval.

Computer Aided Compliance Screening

The Computer Aided Compliance Screening module of Agile Formulation and Compliance for Process enables you to inspect products for compliance against any number of user-defined screens. The compliance screens can include regulatory, market-driven, or customer-driven constraints and can be applied at any level in the product structure, from raw materials to finished product. By screening for compliance during the product development cycle, you can detect compliance issues early, thus lowering development, rework, recall, and withdrawal costs.

Improve Product Compliance

Computer Aided Compliance Screening lets you build screening rules to interrogate raw materials, intermediates, and finished products for fitness against particular compliance constraints at multiple points in the product development process. With Computer Aided Compliance Screening, the ability to check for compliance is fully embedded into the new product development, formulation, and specification processes, allowing you to detect compliance issues early.

Configure Compliance Screens for Specific Needs

You can build rules and screens into Computer Aided Compliance Screening to check raw materials, intermediates, and finished products against a number of parameters, including

- Presence and concentration of allergens, additives, and intolerances
- General compliance such as kosher, organic, and nongenetically modified
- Nutrients
- Specification attributes

- Known usage restrictions, such as business unit and country
- Custom attributes

Computer Aided Compliance Screening allows you to nest the screens to enable complex compliance scenarios in a modular way.

Obtain Immediate Feedback on Compliance Status

With Computer Aided Compliance Screening, you can obtain immediate feedback on compliance issues through a red or green color code on a compliance screen. At any time during the product development process, you will be able to look deeper into the results to find the root causes of any compliance deviation and implement remedies.

Nutrition Surveillance Management

The Nutrition Surveillance Management module of Agile Formulation and Compliance for Process allows you to accurately track nutrition surveillance results and compare them to the existing nutrient values for finished products or ingredients. You can tie nutrient data from the Nutrition Surveillance Management module to individual samples, or composite it to reflect a weighted average of nutrient data from several samples. You can opt to either enter the data directly into the user interface or push it via Web services integration from external systems, such as laboratory information management systems (LIMS). Additionally, you can compare results with existing nutrient profiles, to which you can easily apply required changes to reflect the newer surveillance information.

Nutrition Surveillance Management serves as a clearinghouse and repository for all enterprise nutrient information, providing a single location for all historical nutrient data. Nutrition Surveillance Management, when integrated with Global Specification Management, provides you with a closed-loop nutrition management solution.

Implement a Closed-Loop Nutrition Management Process

Nutrition Surveillance Management allows you to capture, store, and manage nutrient data on ingredients and finished products. At any time, you can compare these observed nutrient values to the nutrient data in specifications stored in Global Specification Management, ensuring that valid and accurate nutrient information is maintained for each product and ingredient specification.

Capture Data Through a User Interface or Web Services Integration

Nutrition Surveillance Management lets users easily enter data via a user interface. Additionally, a Web services-based integration allows for seamless data transfer from LIMS, eliminating the need for manual data entry, reducing errors due to data re-entry, and increasing productivity.

Maintain and Integrate Nutrient Data

Nutrition Surveillance Management allows you to maintain and use nutrient data in a single tool. You can compare and leverage the data captured in Nutrition Surveillance Management and use it to update the specification data in Global Specification Management. This ensures that the specification data used for design and labeling reflects what is observed through the company nutrition surveillance program.

Composite Sample Values

Nutrition Surveillance Management lets you composite sample values to obtain representative nutrient values from a number of sample analyses. This is useful when analysis data is obtained from multiple suppliers or labs. You can use the composites for comparison to the specifications stored in Global Specification Management.

Compare Nutrient Data

Nutrition Surveillance Management is equipped with a reporting and comparison engine that allows for comparison between observed nutrient surveillance values and those currently on nutrient profiles stored at the ingredient or finished product level. Additionally, the comparison tool allows for comparison and analysis of historical nutrient data stored in Global Specification Management so that you can better understand long-term trends.

Product Quality Scorecard

The Product Quality Scorecard module of Agile Formulation and Compliance for Process enables the tracking and disposition of product nonconformance, root cause remediation, prevention, and continuous quality improvement. Leveraging a flexible, user-defined scorecard architecture, you will be able to specify criteria to be used in evaluating product quality and performance, weighting each criterion based on important factors such as criticality to brand or risk. You can use Product Quality Scorecard for a variety of purposes, including consumer testing, sensory evaluation, product cuttings, and competitive benchmarking.

Manage Conformance to Specifications

Product Quality Scorecard lets you measure conformance to the specifications stored in the Global Specification Management module—across ingredients and finished products. You can link specifications to testing protocols, which allows you to convert analytical properties into a scoring template, and in particular, define scoring based on qualitative criteria. Additionally, you can arrange analytical properties into sections, which can be associated with separate scoring methods. The testing protocols link the product quality targets embedded into the specifications and the conformance to those quality targets.

Manage Samples

Product Quality Scorecard allows you to manage and track quality samples for identification and traceability back to suppliers. You can also store any related documentation against the sample if necessary.

Track Product Conformance

Product Quality Scorecard lets you create evaluation sessions for one or more evaluators against any number of product samples. You can link specific testing protocols to these samples to determine how they will be tested. You can then perform the product evaluations based on scorecards that are automatically created using the testing protocol. The individual score and notes attached to each individual property, as well as the scoring by section and in total, are stored in the Product Quality Scorecard database.

RELATED PRODUCTS

Agile product lifecycle management for process is a fully integrated, comprehensive suite of software and services for collaborative product lifecycle management in the consumer goods industry. Agile product lifecycle management for process solutions provide visibility across product portfolios, projects, activities, and suppliers, allowing you to achieve optimal results from your innovation efforts.

AGILE PRODUCT
LIFECYCLE
MANAGEMENT FOR
PROCESS BUNDLES

- Agile Product Data Management for Process
 - Agile Formulation and Compliance for Process
 - Agile Product Supplier Collaboration for Process
- Agile New Product Development and Introduction for Process

Analyze Product Conformance

Product Quality Scorecard provides real-time visibility to quality nonconformance across ingredients and finished goods, enabling you to quickly access product conformance information across multiple sourcing or usage locations. You can also configure Product Quality Scorecard data into customized reports, such as evaluation session results, Pareto charts, sample comparisons, supplier benchmarks, and supplier trends. As a foundation for quality benchmarking, Product Quality Scorecard offers a valuable tool for you to identify trends and measure quality conformance throughout the product lifecycle.

Contact Us

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

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