PLM for Recipes & Formulas

CIMdata Commentary

Key takeaways:

- *Process industries have shifted their focus from ERP and MES to managing the complete product definition from concept through retirement.*
- *Accurate regulatory compliance, labeling, and claims management are key issues for companies developing and producing formulated products.*
- *Siemens' SIMATIC IT R&D Suite provides deep capabilities to support formulated products.*

PLM for Process Industries

While process industries including food and beverage, specialty chemicals, and cosmetics have had PLM solutions available to them for many years, those solutions have not received the same level of attention as have their counterparts for discrete industries. Focus has shifted however, and PLM for process industries is now receiving significant attention and investment. Over the past decade or so it had supported production with enterprise resource planning (ERP) and manufacturing execution system (MES) technology. Now, PLM for process industries is focused on managing the complete product definition from concept through retirement, as it is for discrete industries. The goal is to enable the faster, more efficient, and higher quality manufacture of formulated products.

The product definition of a formulated product is a structure of items including the package or container, the artwork, the label, and of course the formula and recipe for the product. The product can be made in batches or in a continuous manner. The recipe includes the equipment needed for production, the ingredients, instructions on how to configure the equipment (e.g., required mixing time and temperature), and the procedure to combine the ingredients. The formula definition is the process industry's bill of material, and the recipe is the equivalent of the manufacturing routing and related instructions.

A formulated product structure is directly analogous to a discrete product's BOM structure. A finished discrete product consists of an assembly containing sub-assemblies and individual parts. A formulated product contains intermediate products or groups of ingredients that correspond to sub-assemblies, and individual ingredients that correspond to parts. Packaging is required for both formulated and discrete products. Each also has integrations to authoring tools like Microsoft Office and enterprise software solutions like ERP and MES. Process and discrete PLM solutions both support regulatory and labeling requirements. Finally, both need to manage change to ensure that the product has the correct configuration and traceability.

PLM for the process and discrete industries differ in several ways as well. In a discrete environment, users and especially authors are typically engineers and designers. Within the process industries, the corresponding people are scientists and chemists. Discrete parts and assemblies are defined with 3D models and 2D drawings; formulated products in process industries are described by specifications. Units of measure differ: most items in a discrete product are measured in integer quantities; within formulated products the units of measure are typically weights and volumes, and items may have different units such as ounces, pounds, and gallons, or in the metric system grams and liters. Production of a formulated product usually causes a chemical reaction, which may create byproducts that are removed

from the finished product. Packaging for formulated products can be extremely complex; the packaging needs to be designed so as not to create a chemical reaction with the formulated product, which can cause product contamination or even an explosion. In the discrete world, regulatory issues primarily consist of security issues such as those imposed by ITAR and hazardous substance reporting, which affect only a subset of manufactured products. Formulated products actually contain more hazardous substances than discrete products, including some that are byproducts of reactions, and are subject to many country-specific restrictions. In cases such as pesticides, the product itself is hazardous.

For products such as food and beverages, ingredient lists must be included on the labels. Some items can be represented as a single ingredient, though sometimes an ingredient needs to show its constituent materials. For example, lemon juice may need to be shown as concentrate and water if it is reconstituted during production. Product optimization is commonly done within the PLM solution in the process industry, while in discrete industries PLM solution optimization is done in authoring tools such as finite element analysis or with CAD applications.

Issues

The process industry has the same high level issue that all other industrial companies have: to get the right information to the right people at the right time. Data and documents need to be captured, managed, and validated. Processes need to be repeatable and approvals need to be captured. Key areas that need to be addressed with process industry PLM solutions include: document management, regulatory compliance, labeling, claims management, MES integration, and combined products.

Document Management

The process industry is specification driven and historically much of the data has been stored as Microsoft Word or Excel documents or as PDFs. To ensure that these files are properly managed, basic document management is necessary to control check-in, check-out, and change management. This control also implies that documents must be logically centralized. When specifications are stored in documents, much of the information ends up being duplicated, especially when derivative products or product families are created.

Regulatory Compliance

Regulatory requirements have a major impact on the process industry. The data describing regulatory requirements is published by countries or in some cases states, in forms including databases, electronic documents, and paper. There is no single source for all the regulations. To be efficient, product developers need to validate that the products they are developing meet requirements early, and throughout the development process. In addition during production, products need to be validated regularly to ensure that the product or process are not impacted by new requirements.

Labeling

Labeling products within the process industry is tied closely with regulatory requirements. Incorrect labels are an expensive issue and may require a product to be scrapped or even recalled. Regulatory requirements typically define what must be included on a label; ingredient lists and hazardous substances are common data elements. International shipments can cause even more labeling complexity, as the label will need to conform to requirements from multiple governmental entities. Another concern with labeling is putting too

much information on it thus giving away proprietary information. Important ingredients may not need to be reported if they are below specified reporting thresholds.

Claims Management

Claims are especially important within the food and beverage industry; typical claims include "kosher," "low fat," and "heart healthy." Ensuring that the ingredients and processing all meet their claim is a critical task. For example, if a product makes a claim to be kosher, all the ingredients must adhere to a strict kosher specification. If a supplier modifies an ingredient so it no longer meets the kosher specification, then the product containing that ingredient is no longer kosher, the claim cannot legally be made, and the product cannot be sold with that label. A well-implemented change management process helps to ensure that ingredient changes don't violate product claims.

MES Integration

MES integration can be a critical capability when production is in-house. By transferring data including recipes and specifications from PLM to MES via electronic workflows, processes become more reliable and repeatable. Transferring equipment settings and parameters improves control that helps to ensure consistent quality. Production results reported from MES provide feedback so developers can improve formulas and recipes.

Combined Products

Combined products, products with both discrete and formulated items in the bill of materials, have always existed, but historically they have been managed in separate non-integrated solutions. Within some products there is a tight coupling between formulation and the discrete structure, e.g., a pharmaceutical product and its delivery system, or a beverage and its container. Enabling cross-disciplinary access to information, including the change process, can reduce the risk of a change impacting another domain.

SIMATIC IT R&D Suite

Information technology (IT) has become a key component across all aspects of business. While IT has been used strategically for business transactions for decades, the strategic application within product development and production is more recent. Siemens is investing in vertical and industrial IT with its SIMATIC IT portfolio, a complete solution for the process industry, in order to promote its growth.

SIMATIC IT R&D Suite provides support for product development; SIMATIC IT Production Suite provides MES capabilities; and the SIMATIC IT Intelligence Suite supports reporting and decision making. In addition to providing a standalone environment, the SIMATIC IT portfolio has an out-of-the-box integration to SAP ERP, and a tight integration is also available to Teamcenter, Siemens PLM Software's discrete PLM solution. The Teamcenter integration enables the management of combination products containing both discrete and formulated items, such as consumer-packaged goods, and provides enterprise-level capabilities like project and portfolio management. The SIMATIC IT R&D Suite is an integrated set of modules used to support the development of formulas and recipes, as illustrated in Figure 1.

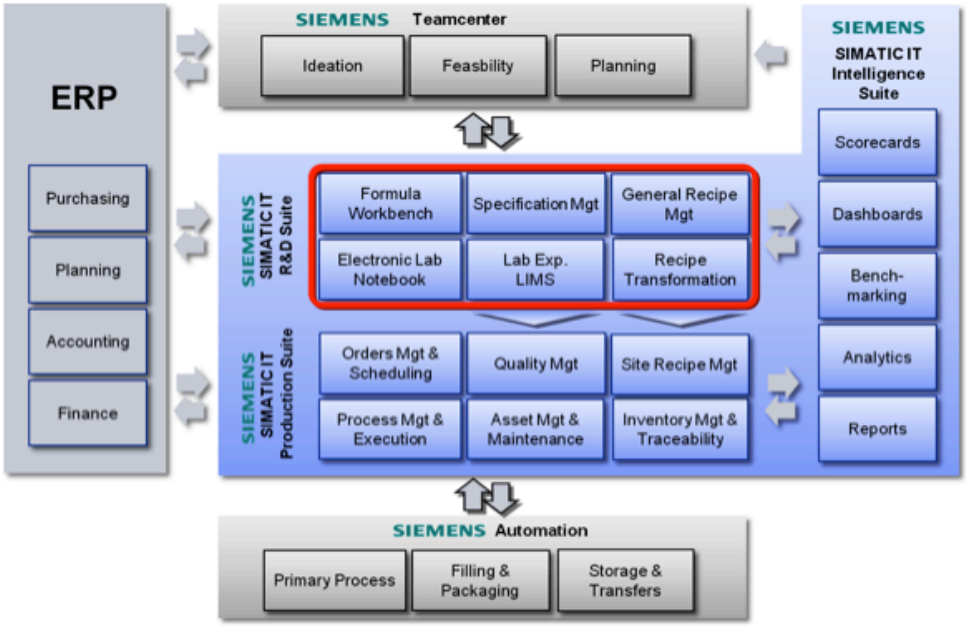

Figure 1—SIMATIC IT R&D Suite Modules
(Courtesy of Siemens)

SIMATIC IT Interspec, the specification management module, is the repository for specification documents describing raw materials, ingredients, formulas, recipes, and equipment. In addition to managing documents as files, it also can manage specifications as intelligent data records. This allows more granular management of the data, minimizing duplication. Documents can then be dynamically assembled from individual controlled data fields. A workflow engine supports business processes including change management, ensuring that specifications and recipes follow the appropriate approval process.

The Formula Workbench module allows scientists and R&D staff to develop and optimize new formulas. Existing ingredients, formulas, and recipes can be found by searching the specification repository across a variety of attributes. If an appropriate formula or recipe is found, it can be copied for use as a starting point. If necessary, new ingredients can be created, or a new formula started from scratch. Formula value roll-ups can be calculated including, e.g., nutritional content, cost, yields, and scrap. An optimization solver is available to adjust the formula based on rolled-up or individual targets. By leveraging data from the repository, the formula development-process timeline can be shortened and costs reduced because previously validated items can be used.

Regulatory and labeling functions are closely related within the SIMATIC IT R&D Suite. The regulatory database can support multiple regions for international distribution, and assessments can be done on rolled-up or calculated values. Hazardous substance and allergen assessments can be configured as rules. It is important to note that the regulatory assessment can be done repeatedly during development, and can also be run against released formulas to ensure that new regulations do not impact items already in production. The final piece of the regulatory functionality is assessing and validating claims.

Correct labeling is critical for formulated products. The label must be accurate and display legally required information, including hazardous substances, ingredient lists, and depending on the region, constituents. The labeling capability in SIMATIC IT R&D Suite supports region-dependent ingredient lists and multiple languages.

The Electronic Lab Notebook module provides access to the specification repository, Laboratory Information Management System (LIMS), and to MES. It provides a centralized, secure place to manage and share knowledge. Workflows are supported as well. Test plans can be defined and access to historical lab results are available, so duplicating experiments can be avoided. The LIMS module supports data collection from a wide variety of lab equipment.

The General Recipe module graphically assembles the formula, the equipment required for production, the production procedure including detailed parameter settings, and associated work instructions. The general recipe is a superset of the information required for all possible local options and simplifies the transformation to a site- or line-specific recipe.

Recipe transformation is a process where a general recipe is scaled and/or transformed, so the product can be manufactured in a particular plant or production line. Transformations can include mapping ingredient and process parameters to match the local requirements, through rearranging process steps to match equipment capacity or availability.

Closing Comments

Businesses face many pressures and risks in today's marketplace. Managing the product definition is critical to the process industry, and is a key element to business success. Complex spreadsheets, email, and file shares do not provide adequate control of product lifecycle data. PLM solutions like Siemens' SIMATIC IT R&D Suite help companies to manage their formulated product definition. Centralizing and controlling specifications and other product-related data makes information easier to find and improves the confidence that it is the right data. Applications like regulatory assessment and label creation take advantage of the centralization and improve the quality of the product.

Siemens' SIMATIC IT R&D Suite provides excellent, standalone support for a broad range of process-industry PLM issues. It also can be integrated with ERP, MES, and Teamcenter to provide end-to-end or "top floor to shop floor" control. Companies that need a PLM solution to support process industry issues should evaluate SIMATIC IT R&D Suite from Siemens.

About CIMdata

CIMdata, an independent worldwide firm, provides strategic management consulting to maximize an enterprise's ability to design and deliver innovative products and services through the application of Product Lifecycle Management (PLM). CIMdata provides world-class knowledge, expertise, and best-practice methods on PLM. CIMdata also offers research, subscription services, publications, and education through international conferences. To learn more about CIMdata's services, visit our website at http://www.CIMdata.com or contact CIMdata at: 3909 Research Park Drive, Ann Arbor, MI 48108, USA. Tel: +1 734.668.9922. Fax: +1 734.668.1957; or at Oogststraat 20, 6004 CV Weert, The Netherlands. Tel: +31 (0) 495.533.666.