104e From Discovery to Manufacturing: Recipe Life Cycle Management

Girish Joglekar, Chunhua Zhao, Venkat Venkatasubramanian, and Gintaras Victor Reklaitis

Recipe description constitutes the most important block of information in a batch process, and is the foundation for several software applications for process development and manufacturing, including simulation, safety analysis, recipe management, manufacturing execution systems. Over the past 10 years, two related standards have evolved to formally represent the recipe information: General Recipe and Master Recipe. A General Recipe expresses equipment independent process requirements for various processing steps, whereas a Master Recipe describes how to implement a specific batch of a given processing step on a specific piece of equipment. Master recipe has gained wider acceptance in the batch processing industry because it plays an important role in plant operation and in some of the business decisions. Even though it has the potential for providing a common framework that can be used by all stages in product lifecycle management, the development of general recipe standards is lacking. This in turn leads to difficulties in integrating different tools and effectively using functionalities provided by the tools.

A general recipe must capture for each processing step, information about operating conditions and material requirements, as well as logistics which is central to the execution of that step. In this paper, we provide a detailed discussion of the characteristics of batch processes which must be addressed in a general recipe representation. A review of the approaches which have been proposed so far, including Petri Nets or ad-hoc representations used in existing tools, has been provided. The current representation schemes have inherent limitations to accurately represent the wide range of recipe specifications that may arise in batch processes.

The proposed representation builds upon the concepts described in the general recipe standards. New concepts have been added to represent flow of material between two operations, to allow conditional execution of operations in a unit procedure, to identify the operation that coordinates the decisions in execution of material flows. We use ontology for defining the framework, and Web Ontology Language (OWL) for encoding the representation. A software tool has been developed for creating and managing the recipes. The methods for existing tools to adopt the representation, and developing new tools for batch processes based on the proposed representation are also discussed. We will demonstrate the proposed representation using a pharmaceutical process, and discuss how the proposed representation benefits batch process development and manufacturing.