SYNCADE™
Smart Operations Management Suite

Recipe Authoring (RA)

Simplify and speed the process for generating recipes.

- Ensures consistent content, best practices, and standardization of recipes
- Tracks and traces content changes—contemplated change can reviewed before use in all recipes
- Increases right-first-time manufacturing by reducing errors, omissions, and deviations
- Enforces workflow for operator-driven activities
- Provides context sensitive links to SOPs and reference documents
- Integrates training records and equipment status with the executing recipe
- Integrates bar code scanning for material and equipment verifications
- Automates operator calculations

Introduction

Recipe Authoring is an authoring environment for creating standardized recipes in FDA-regulated environments. RA simplifies and speeds the process of generating recipes using object-oriented recipe creation and offers multiple language capabilities for developing electronic work instructions that guide the operator through manual activities. The development environment includes an audit trail to track changes and is consistent with ISA88 and ISA95 standards. Batch record creation in RA is quick and easy, using objects and components of information. The RA simulation function enables quick, easy testing of recipes to ensure they work as intended.

Benefits

Increase right-first-time manufacturing. Recipes that address complex manual processing assure accurate and consistent process execution. RA can require forced sequencing, mandatory field completion, and electronic signatures, as well as providing the flexibility for deviation/exception handling and reporting. Each transaction is date/time stamped for inclusion in batch records. Forced phase and step sequencing coupled with parameter controls can prevent costly errors. For example, real-time verification that the correct materials are being charged by trained personnel can be performed at the point of action. Electronic controls can be authored into the batch record, as well as electronic signature approval by a supervisor if required for the work instruction.

Reduce plant floor deviations. Electronic work instructions within the recipe guide the operator to execute the right steps, in the right order. It assures the correct sequence of steps, correct equipment, and correct materials are used. Electronic guidance for manual activities reduces or eliminates deviations due to operator error. RA integrates with automation systems and PLCs to

enable one recipe that covers all aspects of the manufacturing process.

Standardized document objects. Standard work instructions, such as charging materials, line clearance, verification of equipment and other custom objects, are developed using RA - enabling the reuse of software modules.

Real-time work instructions. Using RA, you can provide real-time verification of operating instructions and parameters via the Electronic Batch Record module. The EBR module can collect manually entered data, as well as electronic data captured from control systems and other applications. This data is recorded as part of the electronic batch record.

Product Description

Recipe Authoring allows creation of any combination of sequential, parallel and branch work instructions. The recipe structure is consistent with ISA88 standard. The content can be authored to validate data based on a defined range, unit of measure, and limits or targets specifying the minimum and maximum value. In addition, content can be authored to collect, report, and maintain all required data for complete traceability, as well as operator activity associated with recipe execution. A sequential flow chart processing map of the production recipe is displayed and, with the EBR module, displays details about the executed work instructions. With proper authorization, operators can be allowed to re-execute a step, as well as, link additional orders to the recipe, such as equipment setup or weigh/dispense. Recipe Authoring allows referencing to SOPs for specific instructions associated with a process or phase to be linked electronically.

When RA is implemented, users quickly begin to realize value by creating sets of reusable and standardized work instructions from actual processes and current documentation. The resulting work instruction set serves as the basis for all recipes created in RA. In addition to fixed content, work instructions also contain variables called parameters, which are placeholders for data that is not fixed, but varies from recipe to recipe.

Work instructions are then combined to form operations, unit procedures, and process segments. Transitions control the flow from one work instruction to the next based on logical rules and responses to data from other parts of the recipe. Electronic work instructions can be connected to each other or an automation system. They can be connected in series or in parallel to support virtually any recipe requirement. Bills of materials, equipment, attachments, and labor are defined for each process segment to create a comprehensive recipe.

Electronic work instruction can be configured to include the following information:

- Text can be used to instruct operators regarding a manually processed recipe step.
- Data parameters can be either displayed to the operator as part of the instruction or manually entered by the operator as critical quality parameters to be part of the batch record.
- Formulas for automated calculations normally performed manually by the operator can be provided. Data input to formulas can be from an automation system (DCS, PLC), another application (LIMS, ERP), or entered by the operator.
- A variety of signature requirements for the work instructions are supported - from one operator sign-off to multiple role-based signatures.

In addition, RA can integrate with a recipe defined in an automation system, including phases, operations, unit procedures and procedures. This solution can provide a single recipe that spans the entire manufacturing floor, so the final batch record submitted for release includes the automated steps, as well as the manual steps performed by operators for complete documentation of the process.

RA provides a simulator to test recipes before they are approved and effective. This simulation provides flexibility to test specific components or the entire recipe. A comprehensive audit trail tracks recipe changes and compares recipe versions to identify modifications. Additionally, required attachments, such as a paper chart scan or lab analysis result, can be defined to ensure all information is gathered before the recipe order is closed.

When used with RA, Electronic Batch Record is the engine for electronic data collection, creation and management of the electronic batch record for

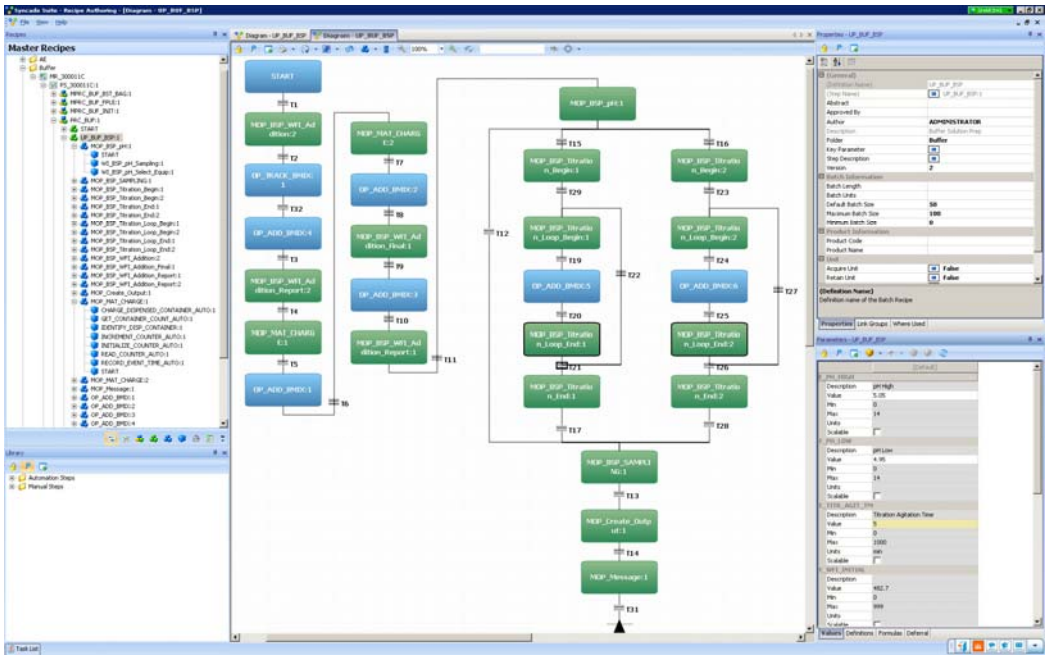
the entire production process. EBR displays instructions and collects data from any device that supports a web browser (PC or wireless hand-held devices). Real-time verification of operating parameters and FDA cGMP 21CFR Part 11-compliant user signature approvals significantly reduce errors and cycle time.

Other Syncade™ Smart Operations Management Modules

- Document Control & Archiving (DCA)
- Batch Production Records (BPR)
- Materials Management (MM)
- Weigh & Dispense (WD)
- Equipment Tracking (ET)
- Security & Audit (SA)
- Electronic Batch Record (EBR)
- Training & Development (TD)
- Management Information Portal (MIP)

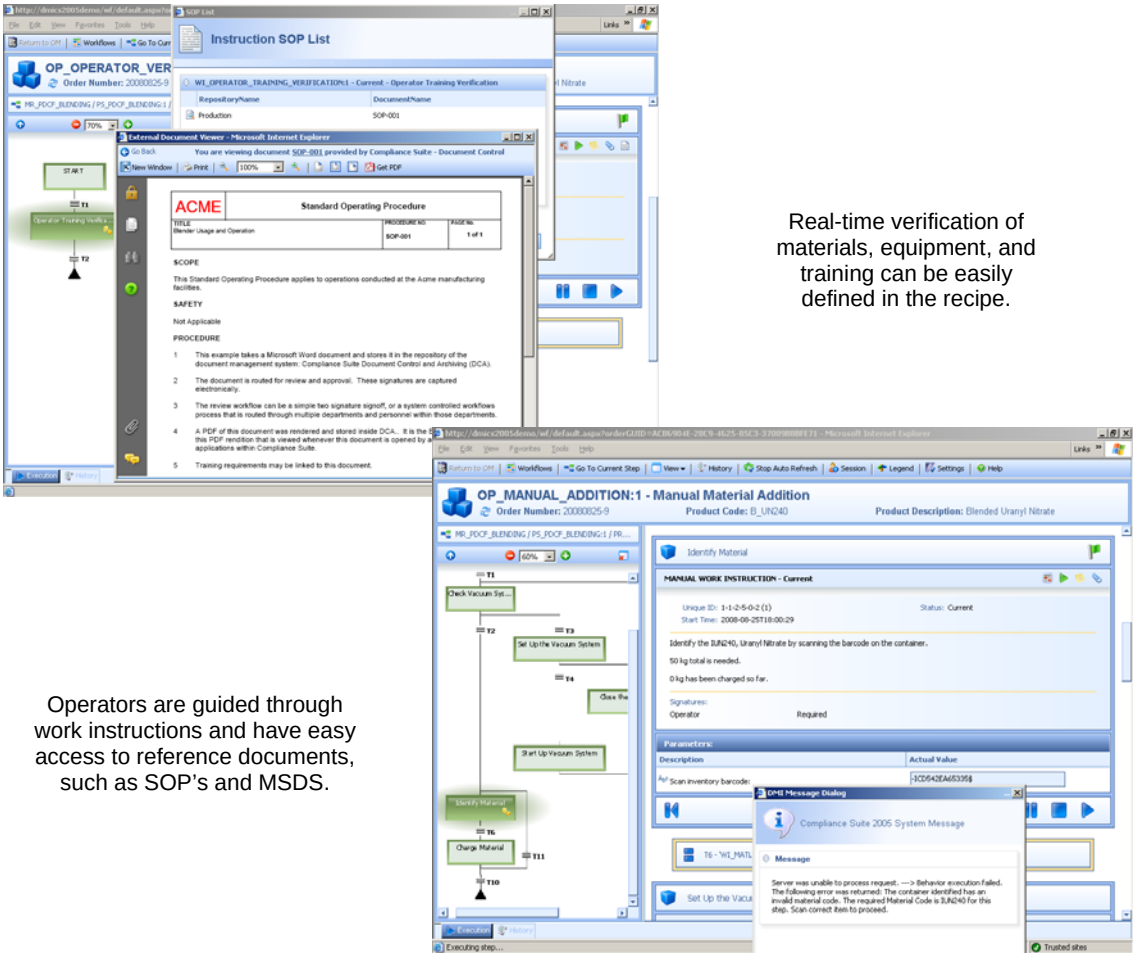
General System Requirements

A server-class PC with Internet Explorer is needed to support the Syncade solution. Microsoft SQL Server is the underlying database. For client access, a PC with Internet Explorer is needed. Please consult the factory for further details regarding hardware requirements and software versions.



RA provides a quick and easy interface to develop integrated recipes.

EMERSON. Process Management



Real-time verification of materials, equipment, and training can be easily defined in the recipe.

Operators are guided through work instructions and have easy access to reference documents, such as SOP's and MSDS.

To locate a sales office near you, visit our website at: www.EmersonProcess.com/Syncade

…or call us at: Asia Pacific: 65.777.8211
Europe, Middle East: 41.41.768.6111
North America, Latin America: +1 800.833.8314 or
+1 512.832.3774

...or email us at: Syncade@Emerson.com