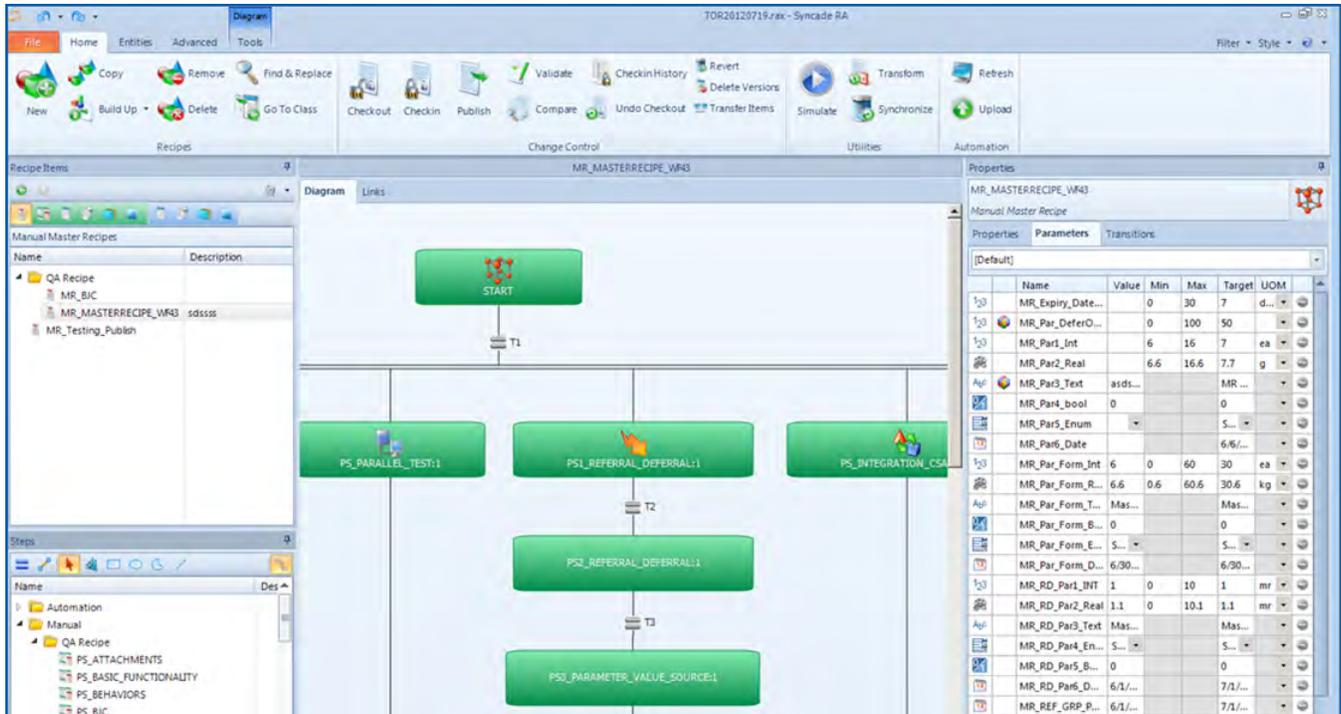


Recipe Authoring



Simplify and speed the process for generating recipes.

- Improve efficiency when creating electronic recipes
- Ensure consistent content, best practices, and standardization of recipes
- Track and trace content changes and allow approval before use
- Provide one engineering environment for the full ISA95™ recipe model
- Create automated and enforced workflow for operator-driven activities and calculations
- Integrate bar code scanning for material and equipment verification
- Provide context sensitive links to reference documents
- Integrate training records and equipment status with the executing recipe

Introduction

The Syncade™ Recipe Authoring module allows you to create standardized recipes per the ISA95 recipe model. Recipe Authoring simplifies and speeds the process of generating and approving recipes using object-oriented recipe building blocks. Recipe comparison and change management between sites is easily implemented and provides a full audit trail for highly-regulated FDA environments.

Recipe Authoring offers multiple language capabilities for developing electronic work instructions that guide operators through manual activity. You can easily integrate with material and equipment management and connect to other plant floor systems. The simulation function enables quick, easy testing of recipes to ensure quality.

Deliver Consistency

Increase right-first-time manufacturing. Recipes that require complex manual processing need accurate and consistent process execution. The Recipe Authoring module will create recipes that enable forced sequencing, mandatory field completion, and electronic signatures. All while, giving you the flexibility needed for deviation / exception handling and reporting. Easily expand automated recipe checks and status verification for equipment, materials, or personnel skills. For example, real-time verification that the correct materials are being charged by properly trained personnel can be performed at the point of action to avoid deviations. Ensure consistent production across all shifts.

Reduce plant floor deviations. Managing critical process parameters is key to successfully reducing deviations. Recipe Authoring provides a unique way to visualize where parameters are used and to configure how they are implemented across a recipe. Configure parameters in the process control system and easily integrate parameter exchanges with other systems like your ERP or LIMS. Through integration, one recipe will cover all critical parameters of the manufacturing process.

Standardize “Best Practices” document objects. Standard work instructions, such as charging materials, line clearance, verification of equipment and other configured objects, are developed in an class / object structure. Editing tools in Recipe Authoring make it easy to copy/paste/find/replace all or parts of the objects and classes - enabling easy reuse of software modules.

Create standard recipe documentation. Easily convert configured recipes into standard documentation. All Recipe Authoring recipes are stored as Extensible Markup Language (XML), with several different rendering formats so that you can easily convert into an updated design document or other standard format. Or you can also customize the output to your unique company standards.

Transfer technology enterprise-wide. In order to be competitive in a global environment, you need to author recipes at one site and transfer them globally. Recipe Authoring incorporates check-in/check-out system practices to facilitate comparisons and transfers. Recipe annotation enhances smart authoring and communication between team members between sites. You will gain “current” version indicators, object version comparisons, and permission management of configurations for small groups. Improving recipe review and approval, there is also a “read only” key to allow investigation without editing.

Achieve Standard and Efficient Work Processes

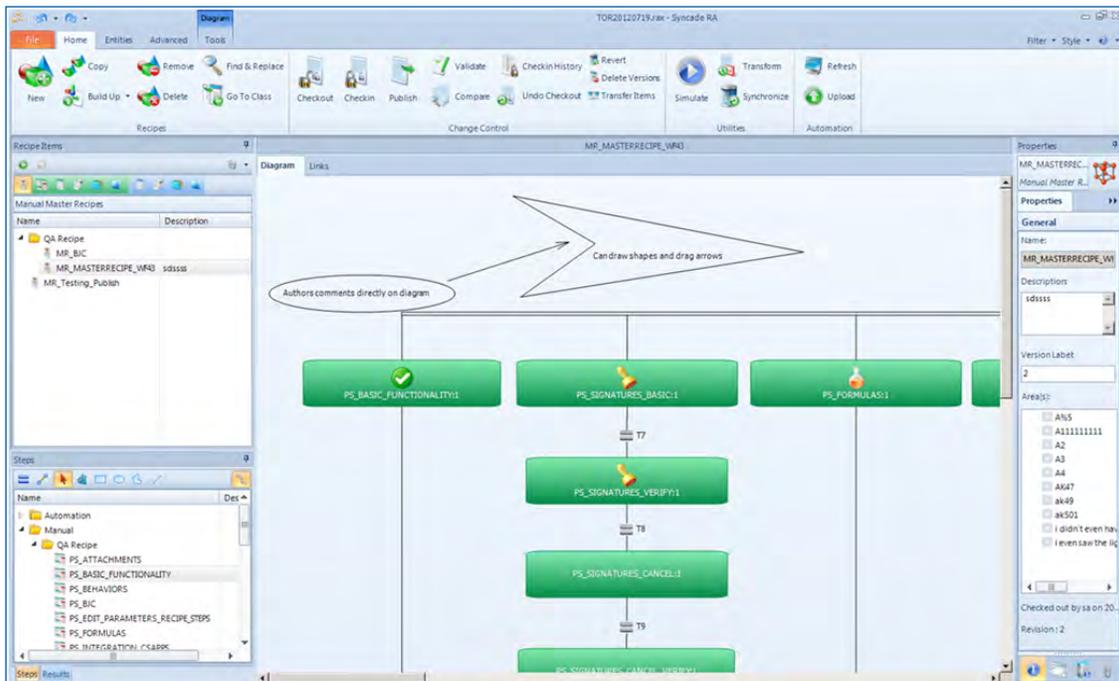
Recipe Authoring enables the creation of any combination of sequential, parallel and branch work instructions. The recipe structure is consistent with the ISA88™ and ISA95 standards. Author content to validate user input based on a defined range, unit of measure, and minimum and maximum value limits or targets. In addition, collect, report, and maintain required data for complete traceability, as well as operator activity associated with recipe execution. Electronically reference standard operating procedures for specific instructions associated with a process or phase. When combined with the Electronic Batch Record module, a sequential flow chart of the production recipe is displayed with details about executed work instructions.

Operators will quickly realize value by creating sets of reusable and standardized work instructions from actual processes and current documentation. The resulting work instruction becomes the basis for all recipes created in Recipe Authoring. In addition to fixed content, work instructions also contain placeholders for data that varies from recipe to recipe.

Work instructions are combined to form operations, unit procedures, and process segments. 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 to an automation system 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 to instruct operators regarding a manually processed recipe step.
- Data parameters displayed as part of the instruction or manually entered as critical quality parameters as part of the batch record.
- Formulas for automated calculations. 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 from one operator sign-off to multiple role-based signatures.



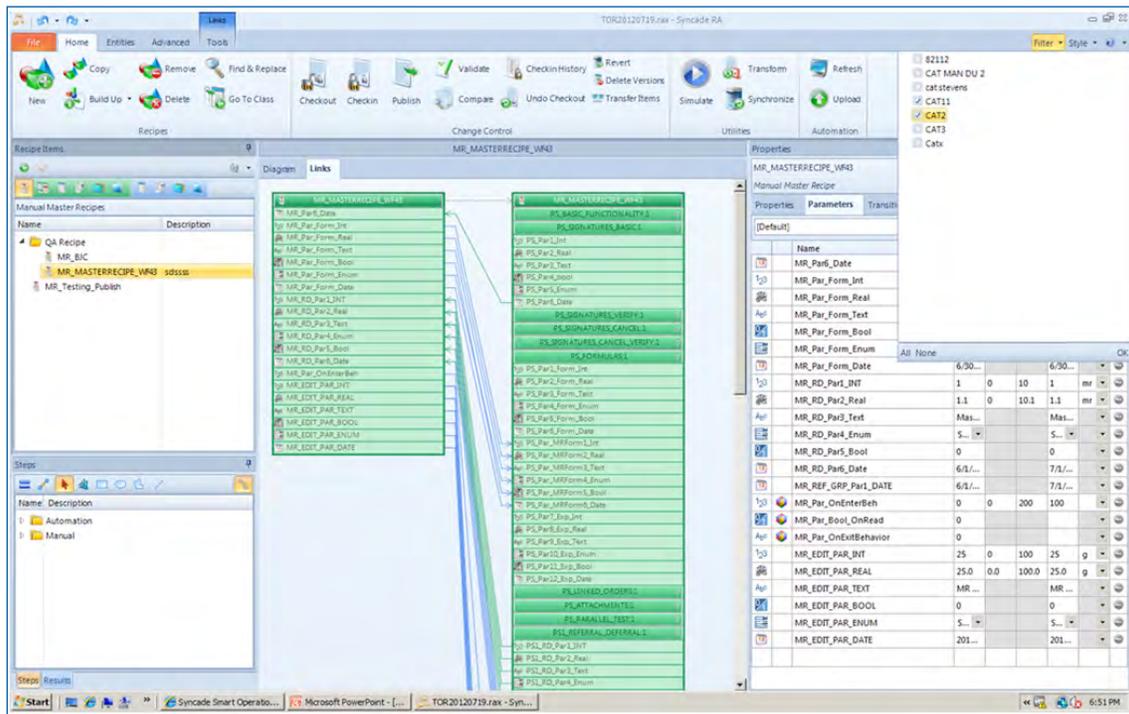
Provides an easy interface to develop integrated recipes

In addition, the Recipe Authoring module 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 and manual steps performed for complete documentation of the process.

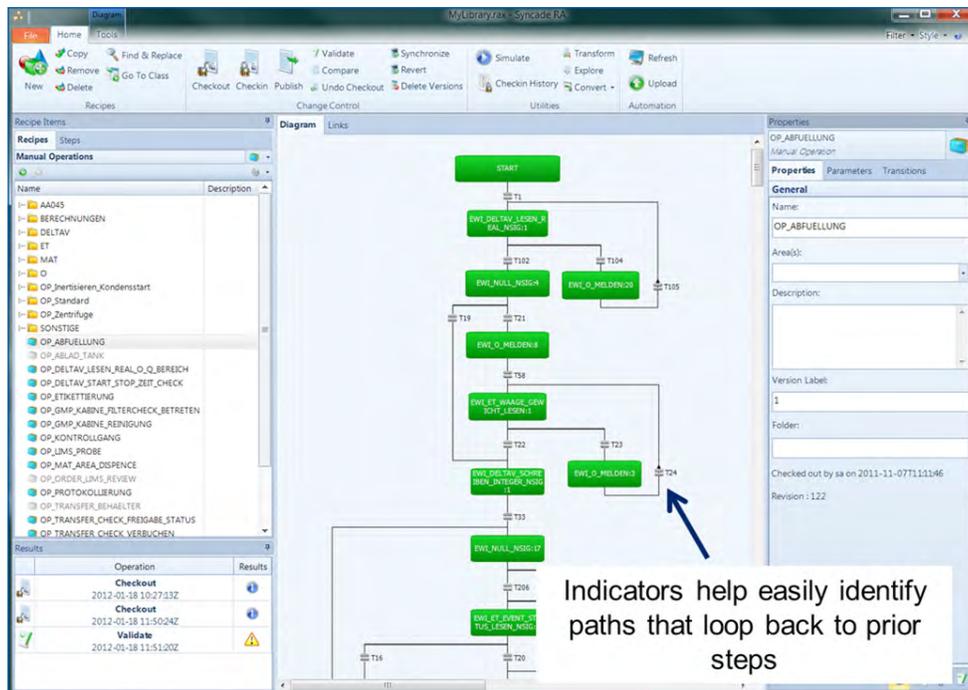
Test recipes using the simulator in Recipe Authoring before they are approved to ensure they are accurate and effective. You can test specific components or the entire recipe. A comprehensive audit trail tracks recipe changes and compares recipe versions to identify modifications.

Additionally, required attachments, such as a paper chart scan or lab analysis result, can ensure all information is gathered before the recipe order is closed.

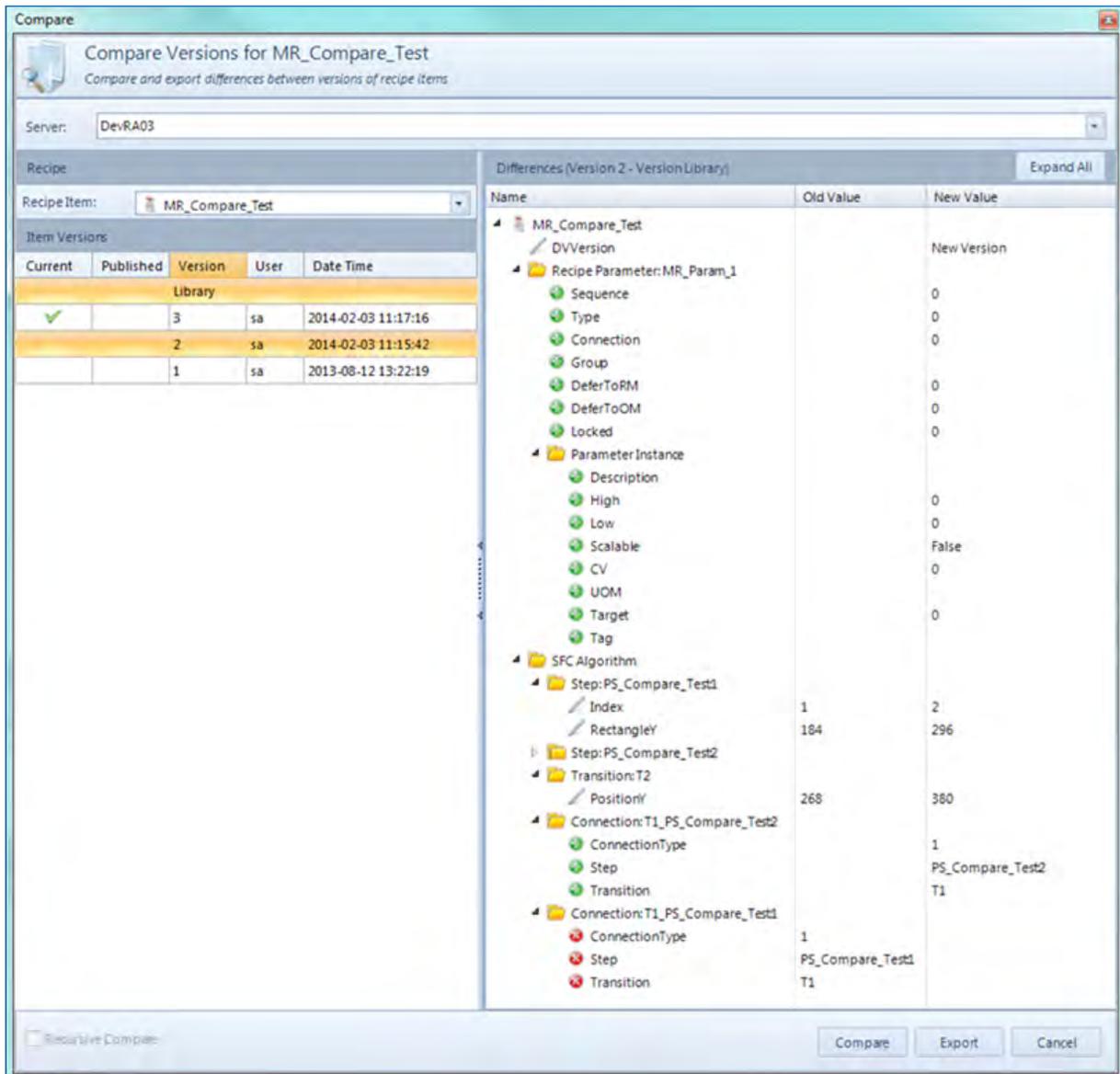
When used with Recipe Authoring, Syncade’s Electronic Batch Record module is the engine for electronic data collection, execution, and management of the electronic batch record for the entire production process. Electronic Batch Record displays instructions and collects data from any device that supports a web browser (PC or wireless handheld devices). Real-time verification of operating parameters and FDA cGMP 21CFR Part 11-compliant user signature approvals significantly reduce errors and cycle time.



Easily track and trace critical product parameters across all recipe levels.



Track and trace branches and logical loops within the recipe.



Compare and change manage recipe objects.

System Compatibility

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.

- Document Control & Archiving
- Batch Production Records
- Materials Management
- Weigh & Dispense
- Equipment Tracking
- Training & Development
- Security & Audit
- Electronic Batch Record
- Process Miner
- Handheld Mobile Operator

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