

Electronic Batch Records (EBR)



Achieve paperless batch records.

- Eliminates and streamlines manufacturing work practices
- Reduces complexity in the manufacturing process
- Embeds knowledge of the process to reduce future training costs
- Allows for release of batch by exception
- Provides a centralized, controlled repository for all executed batch records and related data for easy batch review
- Ensures that the correct manufacturing instructions are used for the intended batch process
- Guides the operator through each step with electronic work instructions
- Produces an unalterable batch record
- Provides a full audit trail history of production data collected
- Enables right-first-time manufacturing
- Significantly reduces errors, omissions and deviations
- Enables one comprehensive batch report with easy, secure data access
- Enables process optimization with playback functionality
- Microsoft .Net application built for the life sciences for secure batch record management, as well as simplified change management and validation
- Can be used standalone or bundled with other Syncade™ Smart Operations Management modules to maximize productivity

Introduction

Electronic Batch Record is designed for comprehensive data collection, operator work instruction execution, and electronic batch record reporting for cGMP operations. EBR displays batch records and manufacturing work instructions online, providing the advantage of paperless data recording. The system can be used on a desktop, laptop, or with wireless hand-held devices. EBR allows data to be entered manually, electronically, or by using a bar code scanner. As data is manually entered, the system helps to prevent common errors introduced by operator data entry. EBR is a web-based solution built on the Microsoft .NET framework and conforms to cGMP regulations.

Benefits

Generate Comprehensive Electronic Batch Records. EBR collects manually entered data, electronic data captured from plant-floor control systems such as DCS or PLCs, and data from enterprise planning systems. Using Electronic Work Instructions to enter data into the batch record document, assures all data is entered and eliminates problems with missing information. It can verify that data entered is within the expected range and detect an abnormal situation at the point it occurs - enabling corrective action during the batch processing, rather than after the batch is completed. Additionally, data is recorded automatically saving the operator time and avoiding transcription errors. Order specific attachments, such as a paper chart scan or lab analysis results, can be required to ensure all information is gathered before the recipe is complete.

Speed Batch Record Approval. A batch recipe that includes all manual activities assures that batch record information will be complete and accurate, including the correct data entries and signatures. Accurate information eliminates the need to send the batch record document back to manufacturing for remediation - reducing the batch record approval process by days and improving product release time.

Instruction Library. Standard work instruction objects, such as charging materials, line clearance, verification of equipment, and other work activity steps, can be quickly developed into guided operator instructions. The recipe structure and connectivity functions are consistent with ISA ISA88 and ISA95 standards.

Forced Sequencing. Work instructions can require forced sequencing, mandatory field completion, and electronic signatures. Each transaction is date/time stamped for batch record reports and auditing. With proper authorization, operators can re-execute a step, as well as, link additional orders to the recipe, such as equipment setup or weigh/dispense.

Real-Time Performance and Monitoring. Transactions are monitored in real time and can be viewed by work centers or lot; providing the ability for real-time performance monitoring. A sequential flow chart processing map of the executing recipe is displayed. The operator can drill into the recipe to the processing step and work instruction detail - enabling a top-down view of the executing process

sequence. With the Current Step feature, the operator can easily access the active step.

Material Integrity to Lot/Order. Material in the system is tracked by container through all operations. Unacceptable containers, such as expired, unallocated, and wrong material, are rejected. Work instruction execution enforces sequencing of the correct materials and quantities.

Verify Material Status. Material status is verified within EBR by scanning the component and checking the inventory or ERP/MRP system to ensure proper usage.

Verify Material ID. Material is identified by unique container identification tied to lots and orders. Material charged against an operation is verified as the correct material and correct quantity through bar code scanning.

Verify Operator Actions. Work instructions provide real-time verification of operating instructions and parameters.

Verify Training. Personnel qualifications and training records are verified for the current task and confirmed that they are up-to-date.

Verify Equipment. Manufacturing suites, instruments, equipment, and parts can all be verified prior to use, via operator instructions and sequence control.

Analyze Executed Recipes. Playback provides the functionality to review an order that has been executed. This capability can be used for process optimization, training and resolution of deviations.

Product Description

EBR manages the execution of standard operating procedures and production batch protocols while providing complete traceability, batch history, audit trails, and consistent reporting. EBR contains all of the functionality needed to implement an effective and comprehensive paperless solution that is "out-of-the-box" and configurable for a wide variety of needs.

EBR provides any combination of sequential, parallel and branch instruction processing. Features to address and handle deviations are included. EBR collects, reports and maintains all required data for complete traceability of materials, equipment and suite usage, as well as operator activities, such as cleaning, calibration, maintenance, repair, validation and use.



A comprehensive record is generated, including:

- Formulas, parameters, transitions, deferrals
- Signature expressions, behaviors, prompts
- Linked orders, branch selection, voiding
- Comments, attachments, SOP references

A processing map of the current state of the production process is displayed. Rules-based workflow control allows instructions for events and activities to be defined and followed. XML, OPC and Web Services support allows easy integration to control systems (BMS, PLCs, DCS) and other applications (CMMS, EDMS, ERP). EBR provides comprehensive support for bar code scanning, wireless hand-held devices, and biometric electronic signature authentication to make using EBR simple, auditable and controlled.

Batch playback allows executed recipes to be reviewed for optimization, training, and deviation resolution efforts. Autoplay moves through the execution history at timed intervals. Linear history can be viewed through the history dialog, or history for recipe steps can be viewed using the history tab. Using autoplay within the history tab, the recipe execution can be reviewed with the option to progress each step at a set interval, so path execution is displayed. Additionally, autoplay can be set to move through each step based on the length of execution time – enabling identification of bottlenecks or a step that took longer than typical.

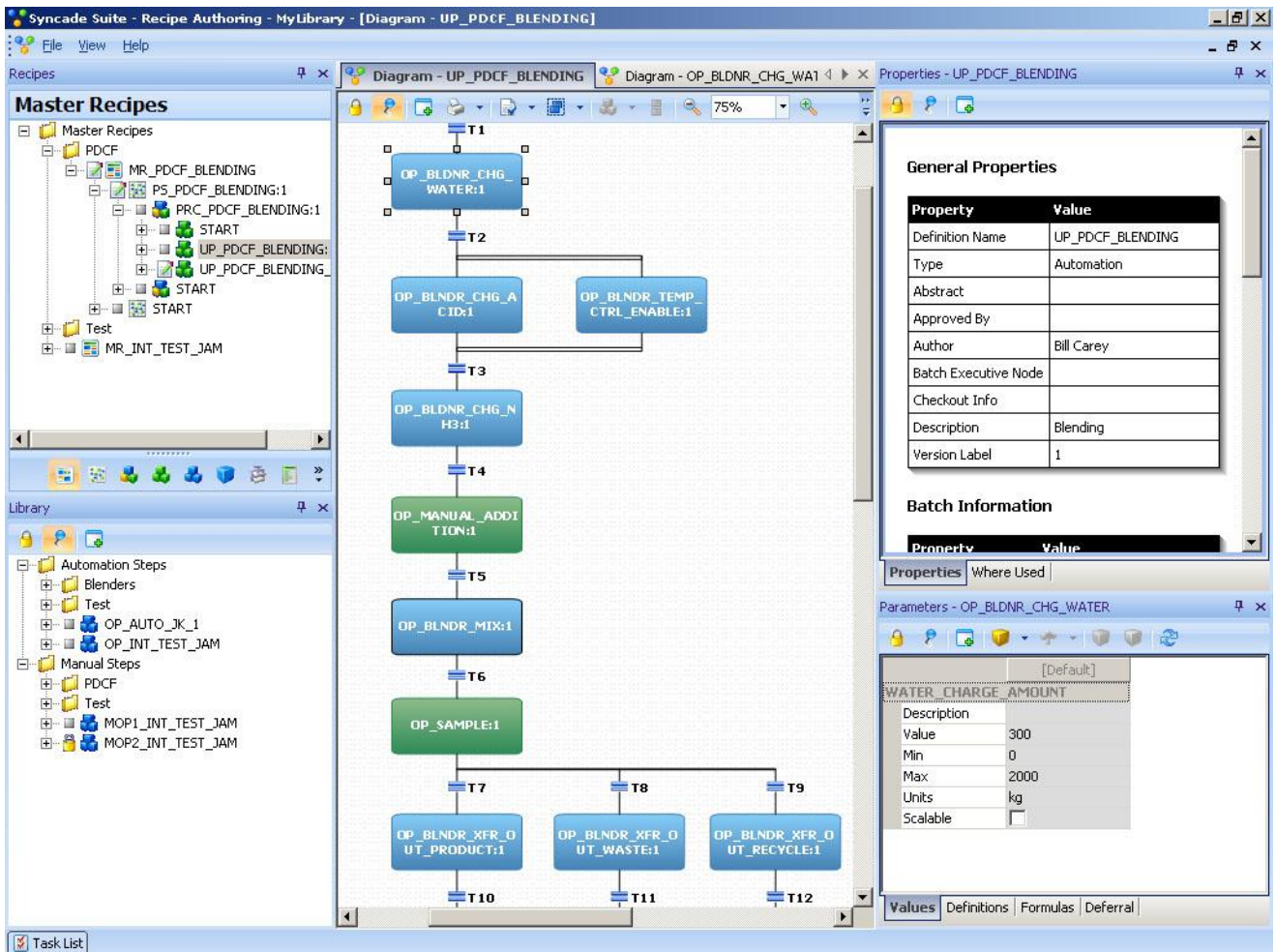
EBR can be used standalone or bundled with other Syncade software modules for maximum productivity.

Other Syncade Smart Operations Management Modules

- Equipment Tracking (ET)
- Document Control & Archiving (DCA)
- Materials Management (MM)
- Batch Production Records (BPR)
- Training & Development (TD)
- Recipe Authoring (RA)
- Security & Audit (SA)
- Weigh & Dispense (WD)
- Manufacturing 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.



The screenshot displays the Syncade Suite Recipe Authoring interface. The main window shows a process flow diagram for the recipe 'UP_PDCF_BLENDING'. The diagram consists of several steps connected by transition points (T1-T12). The steps include automated processes like 'OP_BLDNR_CHG_WATER:1', 'OP_BLDNR_CHG_A_CID:1', 'OP_BLDNR_TEMP_CTRL_ENABLE:1', 'OP_BLDNR_CHG_N_H3:1', 'OP_BLDNR_MIX:1', and 'OP_BLDNR_XFR_OT_PRODUCT:1', 'OP_BLDNR_XFR_OT_WASTE:1', 'OP_BLDNR_XFR_OT_RECYCLE:1'. It also includes manual steps: 'OP_MANUAL_ADDITION:1' and 'OP_SAMPLE:1'. The interface includes a 'Master Recipes' tree on the left, a 'Library' tree, and a 'Properties' panel on the right.

General Properties

| Property | Value |
|----------------------|------------------|
| Definition Name | UP_PDCF_BLENDING |
| Type | Automation |
| Abstract | |
| Approved By | |
| Author | Bill Carey |
| Batch Executive Node | |
| Checkout Info | |
| Description | Blending |
| Version Label | 1 |

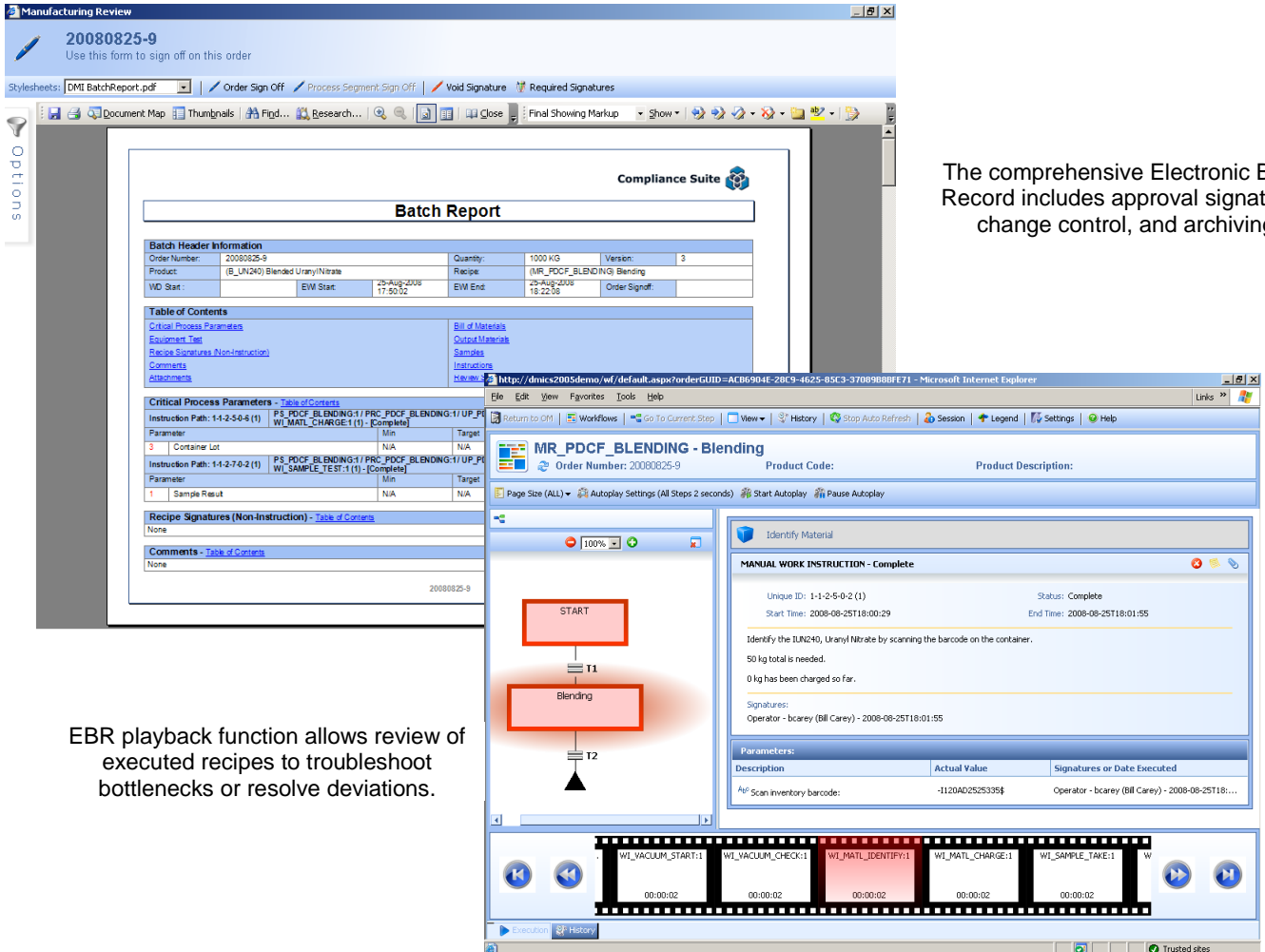
Batch Information

| Property | Value |
|------------|-------|
| Where Used | |

Parameters - OP_BLDNR_CHG_WATER

| [Default] | |
|---------------------|--------------------------|
| WATER_CHARGE_AMOUNT | |
| Description | |
| Value | 300 |
| Min | 0 |
| Max | 2000 |
| Units | kg |
| Scalable | <input type="checkbox"/> |

Manual instructions are easily integrated with automated processes enabling one comprehensive recipe and Electronic Batch Record.



The screenshot displays the 'Manufacturing Review' window for order 20080825-9. It features a 'Batch Report' section with 'Batch Header Information' and a 'Table of Contents' for various process parameters and materials. Below this is a 'Critical Process Parameters' table and a 'Recipe Signatures' section. The main area shows a process flow diagram with steps like 'START', 'T1', 'Blending', and 'T2'. A 'MANUAL WORK INSTRUCTION - Complete' panel is visible, detailing a task to identify material (UN240, Uranyl Nitrate) with start and end times and operator information. At the bottom, a filmstrip-style playback function allows reviewing executed steps.

The comprehensive Electronic Batch Record includes approval signatures, change control, and archiving.

EBR playback function allows review of executed recipes to troubleshoot bottlenecks or resolve deviations.

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