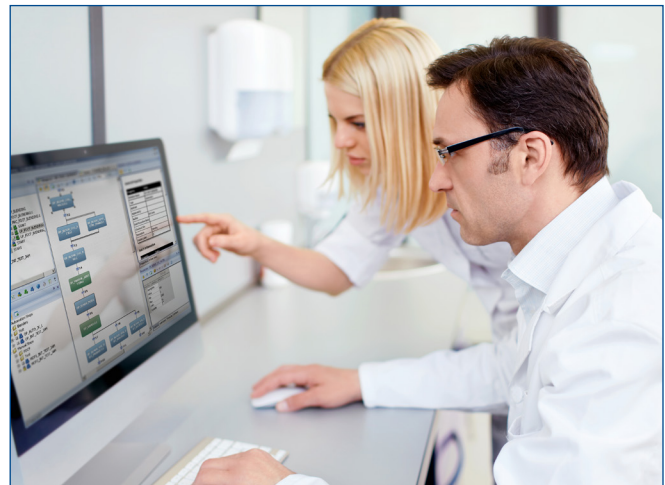# Electronic Batch Records

- Streamlines manufacturing work practices to increase productivity

- Reduces complexity in the manufacturing process to increase Right First Time

- Allows for release of batch by exception for expedited product release

- Allows real-time in-process changes with proper permissions to enable controlled flexibility

Overview

The Syncade Electronic Batch Records (EBR) module, designed for the Life Sciences industry, helps manufacturers ensure the identity, potency, purity, quality, and safety of product is right the first time. As a Life Sciences manufacturer, you will feel confident that product is manufactured in a consistent, reproducible manner every time.

Not only can the Electronic Batch Records module provide high quality product with reduced effort, but it also assures that your new hires have access to the same data and knowledge as your most experienced operators. You know that every operator has the tools to perform to the highest quality standards.

The Electronic Batch Records module aggregates data across silos of stored information and delivers one consolidated record for the lot produced. Data from ERP, LIMS, CAPA, CMMS, DCS, among others, is collected into a single comprehensive record of manufacturing – transforming distributed data into full scope knowledge.

The Electronic Batch Records module is fully compliant with 21 CFR Part 11 and EU Annex 11 regulations.

Consolidate Data for Better Decision-Making

Control Your Data Flow. Eliminate silos of information. The Electronic Batch Records module aggregates, contextualizes, and visualizes data required to ensure products adhere to critical process parameters and quality attributes. EBR utilizes workflows to guide operators through manual and automated steps to achieve production. Syncade's new workflow engine (WFX) provides higher performance and streamlined user interface.

By combining Electronic Batch Records with Syncade Quality Review Manager, aberrant results are automatically detected, an exception is created, and review personnel are notified in real time.

Make Every Operator Your Best Operator. Embed quality and process knowledge into your organization at all levels. The Electronic Batch Records module facilitates proper sequencing and data collection, enabling new operators to perform at the same high standards as your most experienced operators. Operator skill gaps can leave companies at risk, as they try to do more with less experienced operators.

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With Electronic Batch Records, operators can access decisions via linked Workflows, configured branching logics, configured exception Workflows, and configurable signature requirements. This ensures that all operators respond to events in a more reproducible (and compliant) manner.

Innovate Your Pre-Commercial Environments. The Electronic Batch Records module provides control to commercial manufacturing while also allowing flexibility for use in less rigid conditions. Complete in-process changes, including real-time parameter modifications, navigation adjustments, inserting new requirements / instructions, and requiring specific signing authority levels. This functionality is permission based to ensure only specified people can make alterations.

The module's authoring environment enables users to annotate changes as well as link to documentation for modification rationale. Associated documents provide more detail than an annotation and can include URS, design specifications, use cases, and validation reports.

Complete Record-Keeping Solution

Syncade's Electronic Batch Records module provides a simplistic "paper on glass" capability through full scale integration to the ERP and other level 4 systems, across the level 3 space (such as CAPA, CMMS, LIMS) and down to the level 0-2 instrument and control system space.

Electronic Batch Record integrates natively with Emerson's DeltaV™ digital control system or can easily communicate with other DCS, PLC or SCADA systems.

Generate Records with Increased Flexibility

The Electronic Batch Records module collects manually entered data, data from enterprise planning systems, and data captured from plant-floor control systems such as DCS or PLCs. The consolidated data is entered into the batch record document, ensuring that no data is missed. It also verifies that data is within the expected range and alerts operators to any abnormal situations.

This consolidated data enables operators to take corrective action during the batch process, rather than after the batch is completed. Data is saved automatically, avoiding transcription errors and allowing operators to focus on other tasks. You can require specific attachments, such as a paper chart scan or lab analysis results, to ensure all information is collected before an order is closed.

Speed Batch Record Approval

A batch recipe includes manual activities and assures that batch record information will be complete and correct. Accurate information eliminates the need to send the batch record document back to manufacturing for remediation. This reduces the batch record approval process and improves product release time. In addition, the Quality Review Manager add-on provides an embedded review by exception solution that expedites the batch release process.
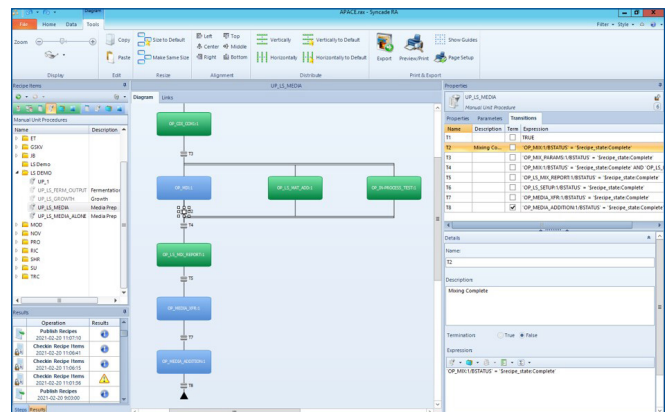
InfoBatch™ from Informetric is now integrated with Syncade for Order Manufacturing Review. InfoBatch is a flexible electronic batch reporting suite that generates comprehensive reports directly from underlying data sources. InfoBatch can aggregate information from DeltaV Batch Historian, process historians, and Syncade into comprehensive process reports that are suitable for batch release, manufacturing intelligence, equipment optimization, quality documentation, and regulatory compliance.

Manual instructions integrate easily with DeltaV to create one comprehensive record.

Recipe Library

Master recipe generation allows users to configure standard recipe objects quickly and validate to provide rapid development of future recipes. Class- and instance-based flexibility provides a mechanism for reusability, making recipe management easier. Recipe structure and connectivity functions are consistent with ISA ISA88 and ISA95 standards.

Native integration with DeltaV provides seamless and robust integration versus custom built solutions. The Electronic Batch Record module has a flexible structure supporting various combinations of MES and DCS activity orchestration.
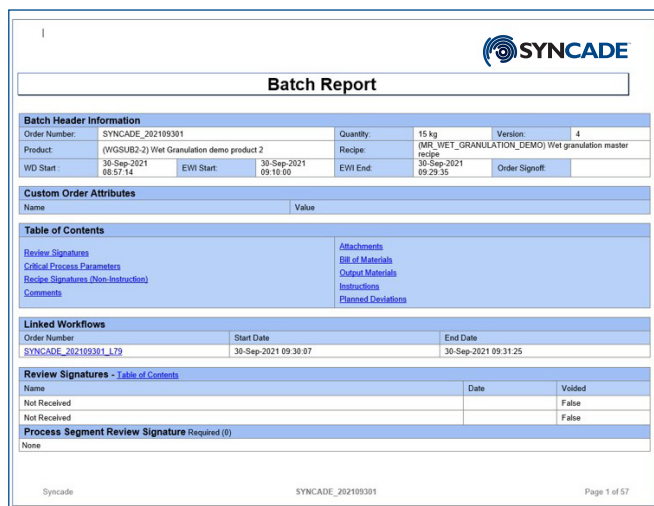

Manual instructions integrate easily with DeltaV to create one comprehensive record.

Controlled Flexibility

Work instructions can require electronic signatures, forced sequencing, and mandatory field completion. Each transaction has a date/time stamp for batch record reports and auditing. With proper authorization, operators can re-execute a step and link additional orders, such as equipment setup or cleaning to the electronic record.

With the proper permissions, users can override forced sequencing to provide flexibility for unforeseen scenarios or pre-commercial settings.

Electronic Batch Records include archiving, approval signatures, and change control.

Real-Time Performance and Monitoring

The Electronic Batch Records module allows you to monitor transactions in real-time. Display a sequential flow chart of the executing operation, view a complete start to finish tree view, or simply display the work instruction details. Personal preferences are stored in the user settings.

Additionally, the module includes a Manufacturing Portal that displays process metrics, allows users to select batch records to execute, performs manufacturing reviews, and more. The portal can be personalized to deliver the data and actions that meet each user's unique needs. Electronic Batch Records include archiving, approval signatures, and change control.

Material Integrity and Genealogy

Material can be tracked by container (or lot level) through all operations. The system will reject unacceptable containers when they are expired, unallocated, or the wrong material. Work instruction execution enforces sequencing of the correct materials and quantities. Additionally, users can automatically generate a material genealogy for quick and easy reporting.
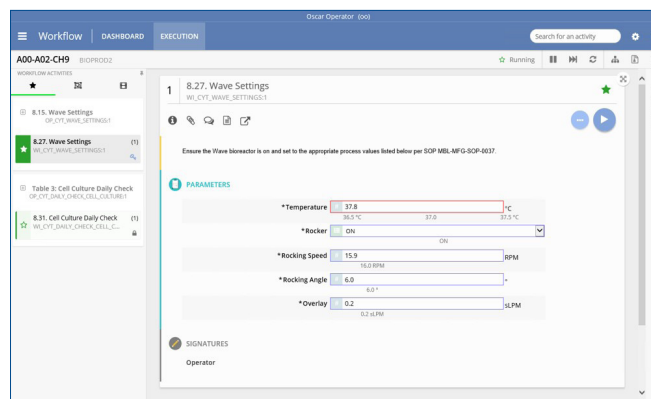
Verify Certifications

Verify personnel qualifications and training records for current tasks and confirm that all records are up-to-date.

Verify Equipment

Verify status of parts, equipment, instruments, and manufacturing suites prior to use and ensure correct equipment for the process.

Analyze Executed Recipes

Review previously executed orders to optimize processes, deliver training, or resolve deviations.

Various view options enable operators to troubleshoot bottlenecks and resolve deviations.

Ordering Information

Description	Part Number	Guardian Part Number
Electronic Batch Records (EBR) Solution	DF1001	DF1001-GS
Operations User - Tier 1 (1-150 users)	DF1209	DF1209-GS
Operations User - Tier 2 (151-325 users)	DF1210	DF1210-GS
Operations User - Tier 3 (326+ users)	DF1211	DF1211-GS
Recipe Authoring (RA) User License Key	DF1207	DF1207-GS
Additional License Key - NLB	DF1205	DF1205-GS
Additional Non-Production System License	DF1206	DF1206-GS
Same Site, Multi-Electronic Batch Records (EBR) Solution	DF1217	DF1217-GS
Quality Review Manager (QRM) Add-On License	DF1218	DF1218-GS
Event Monitor	DF1201	DF1201-GS
DeltaV Integration Package	DF1202	DF1202-GS
InfoBatch Server Runtime	DF1214	DF1214-GS
InfoBatch Connector for Emerson Syncade	DF1215	DF1215-GS
External Reporting Server	DF1204	DF1204-GS
Replacement License Key	DF1601	DF1601-GS
1-Year Electronic Batch Records (EBR) Extended Component Support - Comprehensive	DF1402	N/A
1-Year Syncade Extended Interface Support - Comprehensive	DF1502	N/A

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