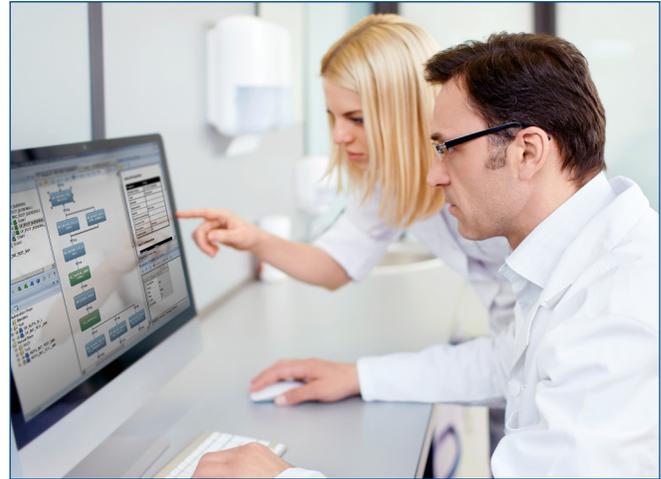# Electronic Batch Records

- 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 module, designed for the Life Sciences industry, helps manufacturers ensure the identity, potency, purity, quality and safety of product is right first time. 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, CTMS, 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. If aberrant results are detected, the module can associate with CAPAs, when desired, and provide an exception report for easy quality review.

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.

A recent ARC study reported that 2 million experienced operators retired between 1998 and 2000, while only 200,000 technical graduates advanced to fill their spaces[1]. This skill gap can leave companies at risk, as they try to do more with less experienced operators.

1 ARC, Human Reliability - A Major Component of the Process Industries Skill Gap Solution. ©2011

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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 the ability to N/A future steps, tracking a change number, inputting new requirements / instructions, and requiring specific signing authority levels. Make real-time parameter modifications and modifications to future steps. 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 Records integrates 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.
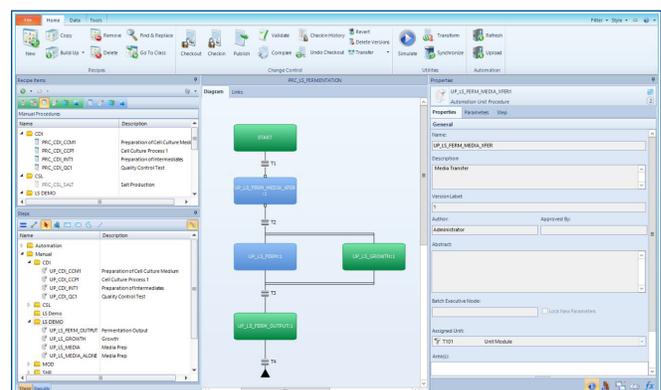
Speed Batch Record Approval

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, report by exception view expedites the quality review processes.

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.

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.
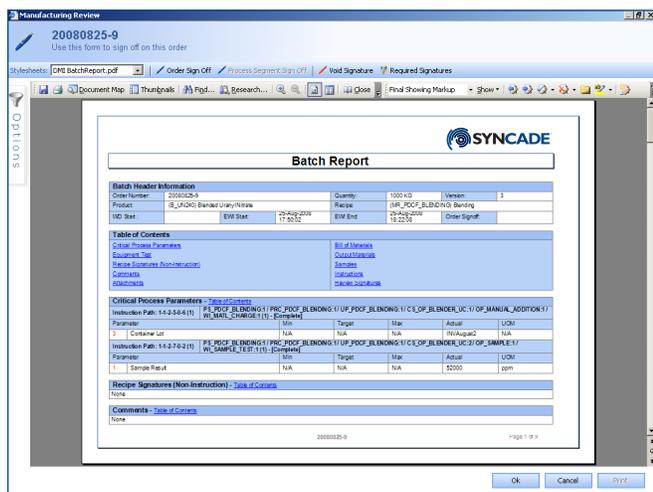

Manual instructions integrate easily with DeltaV to create one comprehensive record.

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.

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 deviation.
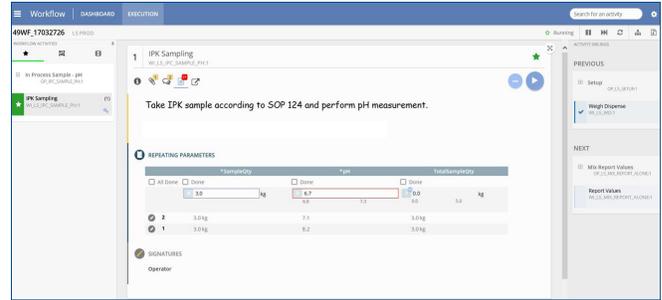
Bundled License Packages

There are four bundled license packages available for the Electronic Batch Records module:

Professional bundle contains two production site licenses and four non-production site licenses for each of the Syncade modules. This bundle supports up to 250 named users, five Recipe Author licenses, and two OPC to XML Web Service modules. It also includes an SAP Crystal Reports Runtime license and an ActivePDF Toolkit OEM license.

Experience bundle contains one production site license and two non-production site licenses for the Syncade modules. This bundle supports up to 50 named users, two Recipe Author licenses, and one OPC to XML Web Service module. It also includes an SAP Crystal Reports Runtime license and an ActivePDF Toolkit OEM license.

Professional bundle with DeltaV contains two production site license and four non-production site licenses for each of the Syncade modules. This bundle supports up to 250 named users, five Recipe Author licenses, and two OPC to XML Web Service modules. It also includes an SAP Crystal Reports Runtime license and an ActivePDF Toolkit OEM license.

Experience bundle with DeltaV contains one production site license and two non-production site licenses for the Syncade modules. This bundle supports up to 50 named users, 2 Recipe Author licenses, and one OPC to XML Web Service module. It also includes an SAP Crystal Reports Runtime license and an ActivePDF Toolkit OEM license.

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

Ordering Information

Description	Model Number
Electronic Batch Records Experience	SYOM1004EBRE
Electronic Batch Records Professional	SYOM1004EBRP
Electronic Batch Records Experience for DeltaV	SYOM1004EBREDV
Electronic Batch Records Professional for DeltaV	SYOM1004EBRPDV
Additional Non-Production Environment	SYOM11UPSNPE
Additional Recipe Authoring Client and Client HASP	SYOM11UPSRA
Network Load Balancing HASP	SYOM-HASP-NLB
Non-Production System HASP	SYOM-HASP-NON-PROD
Additional User Scale Ups	SYOMUPSUSxxxx
InfoBatch Server Runtime License	SYOM1004EBRIBS
InfoBatch Server Runtime License – Guardian Support	SYOM1004EBRIBS-FS
InfoBatch Connector for Emerson Syncade	SYOM1004EBRIBC
InfoBatch Connector for Emerson Syncade – Guardian Support	SYOM1004EBRIBC-FS
DCA Mobile Worker (DCAM)	SYOM1008DMMW
DCAM – Guardian Support	SYOM1008DMMW-FS

Note: Where xxxx represents the number of additional names users required. User additions can be ordered in quantities of 5, 25, 50, 100, 150, 200, 250, 300, 400, 500, 700, 1000, and 2000.

Emerson
North America, Latin America:
📞 +1 800 833 8314 or
📞 +1 512 832 3774

Asia Pacific:
📞 +65 6777 8211

Europe, Middle East:
📞 +41 41 768 6111

🌐 **www.emerson.com/syncade**

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