



SIEMENS DIGITAL INDUSTRIES SOFTWARE

What's new in **Opcenter Execution Pharma version 6.2.4**

Providing a paperless solution for the life sciences/pharma industries

Benefits

- Reduce paper usage until all processes can be handled electronically
- Reduce development effort and risk by integrating MES and DCS
- Standardize and harmonize processes
- Facilitate implementation across sites
- Increase safety and speed of batch-relevant information reviews

Summary

The Opcenter™ Execution Pharma software (Opcenter EX PH), formerly known as Simatic IT® electronic batch recording (eBR), offers native integration between the manufacturing execution system (MES) and distributed control system (DCS) layer. This expedites the design, execution and review steps that Opcenter EX PH must perform, which enables flexibility in the master batch record design process.

Opcenter EX PH, which is a part of the Xcelerator™ portfolio, the comprehensive and integrated portfolio of software and services from Siemens Digital Industries Software, enables all regulated processes to be managed without paper-based procedures or documents. The system offers easy configuration and an out-of-the-box (OOTB) functionality, which allows users to design any process without specific information technology (IT) skills.

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Features

- eBR report improvements and enhancements
- API framework enhancements and API ES improvements
- Archives enhancements
- Extended AD integration
- Native autolog off component
- Support of Simatic Batch 9.1 and BIL 6.1

Fully compliant with the United States Food and Drug Administration (FDA) and Good Manufacturing Practice (GMP) regulations, the system optimizes batch manufacturing processes and helps streamline resources such as user guidance, equipment allocation and standard operation procedures. It also systematically controls human or automated production execution at all stages.

Using Opcenter EX PH enables you to reliably acquire critical process data. It allows forward and backward searches using genealogy and audit trail tools, which significantly reduces manufacturing, review and release times and accelerates time-to-market.

Achieving operational excellence

Opcenter EX PH enables manufacturers in the life sciences industries to achieve operational excellence, reduce compliance costs and improve quality and productivity. It also helps companies maximize the efficiency of all resources, which provides users with guidance, equipment allocation and operation procedures. The system facilitates the product batch record review by exception, providing faster and more efficient product releases.

Opcenter EX PH is powered by an advanced workflow engine and easy-to-use electronic work instructions (EWIs). It can be used to direct manufacturing while recording and centralizing everything required for a completed batch record, which enables release by exception. Additionally, master batch record (MBR) management facilitates the key process parameters.

Opcenter EX PH 6.2.4 enhancements:

- The OOTB batch record includes new standard reports:
 - Production alerts
 - User involvement during production
 - Material and intermediate lot genealogy
 - Production equipment

Additional improvements include a print layout in landscape capability, select reports embedded in the batch record and more.

- The application programming interface (API) framework extends electronic signature (ES) capabilities. The framework now supports single and double checks, default and predefined comments, ES cancellation and more. The reconciliation API has been extended using these enhancements
- The API framework can support data exposition based on open data protocol (oData). Integrators can use this data exposition to retrieve a list of data based on the simple Oracle view by following naming convention. Advanced use cases are supported by creating a dedicated oData controller that follows our guidelines

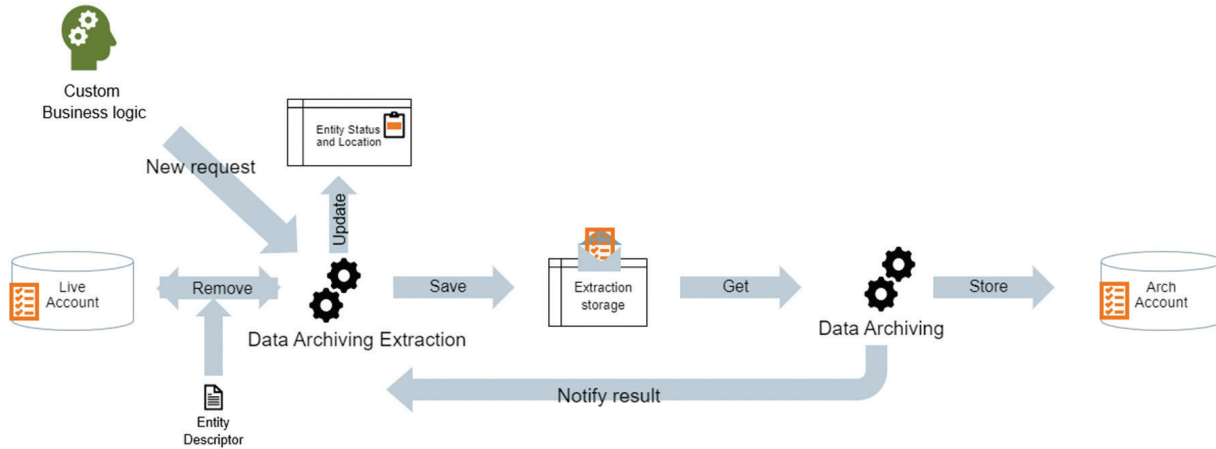
- The advanced archiving engine natively supports the archive and export process for item and work order entities without customization. Additionally, the advanced archiving engine has been extended to facilitate integrator life and trigger the archiving process for entities based on simple database views
- We deliver the next level of installation support via scripting, which provides the user with configuration files and log file information during installation. The configuration files are available to support:
 - Runtime deployment
 - Configuration of the *.ini file
 - Prerequisite checking for database installation
 - Binary module shortcut creation
- Active directory (AD) integration supports security account manager (SAM) and user principal name (UPN) authentication, nested AD groups, optimized password management and more. The AD integration now uses the latest Windows native APIs for up-to-date performance and seamless integration
- Simatic Batch 9.1 support and batch integration layer (BIL) version 6.1. deployment. Simatic Batch 9.1 supports Simatic IT eBR to 6.1 SP2 without needing MES installation updates, due to BIL middleware

- The autolock feature provides native autolog off if the operator leaves the workstation and forgets to stop the ongoing production activity in the process instruction (PI)
- Audit trail print report layouts have been added to enhance user experience (UX). This enables a compact mode to condense all the information in one row to increase readability

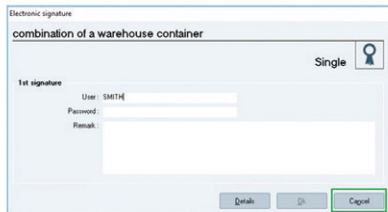
Amend mode supports complex use cases. It is now possible to interact with condition tags during the correction, allowing reevaluation of the conditions. Amend mode menus have been redesigned for better UX and include new features

- Noticeable other changes
 - eBR review notes are now controlled by access right, depending on the status of the review
 - Citrix supports are stated in prerequisite manuals
 - User proprietary authentication is deprecated from version 6.2.3 on. The feature will be removed in version 7.0. It is recommended to use AD authentication
 - Our product will not provide a structured query language (SQL) server application via our International Organization for Standardization (ISO) file from version 6.2.3 on. We advise the customer to look for the recommended SQL version

- New archiving concept:



- ES cancellation:



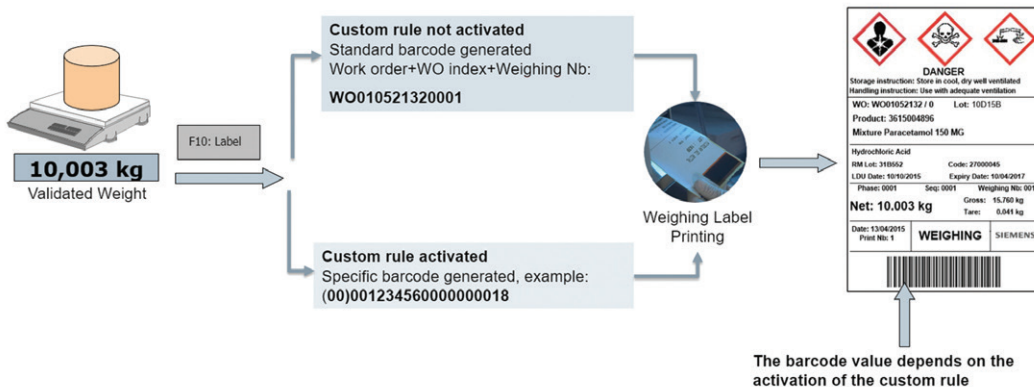
The trace is associated to the same function as the electronic signature and to the connected operator.

For example, the function for the “combination of a warehouse container” electronic signature is “COMBINATION”

There is no information saved about the electronic signatory (first signatory, remark of first signatory etc.)

Function	Remark
COMBINATION FORCE END OF COMBINATION	Electronic signature cancelled. Remarks: Cancellation of the action "Force combination"
COMBINATION	Electronic signature cancelled. Remarks: Cancellation of combination request for a warehouse container 0117110016 0004
LOT IDENTIFICATION	Phase: 0003 Seq: 0001 Dose: 1 RM: WC_ITEM_CODE_MA Lot 0117110016 in insufficient quantity in location START_ID: 0117110016 0004
FORCE COMB IMPOSED ORDER	The imposed phase order has not been respected (expected phase: 0001/0001/1, identified phase: 0003/0001/1) Combination forced Remarks: Combination forced
COMBINATION PER DOSE	Electronic signature cancelled. Remarks: Cancellation of the forcing of phase/sequence/dose change: 0002/0001/1 => 0003/0001/1. Combination cancelled
FORCE COMB IMPOSED ORDER	The imposed phase order has not been respected (expected phase: 0001/0001/1, identified phase: 0003/0001/1) Combination forced Remarks: Combination forced
LOT IDENTIFICATION	Phase: 0003 Seq: 0001 Dose: 1 RM: WC_ITEM_CODE_MA Lot 0117110016 in insufficient quantity in location START_ID: 0117110016 0004
COMBINATION	Electronic signature cancelled. Remarks: Cancellation of combination request for label OF00001047-0-TOUT-150067-7
FORCE COMB IMPOSED ORDER	The imposed phase order has not been respected (expected phase: 0001/0001/1, identified phase: 0002/0001/1) Combination forced Remarks: Combination forced
BARCODE KEYBOARD INPUT DURING COMBINATION	Electronic signature cancelled. Remarks: Cancellation of the barcode manual input: OF00001047-0-TOUT-150067-7
COMB TERMINATE MATERIAL LINE	Electronic signature cancelled. Remarks: Cancellation of the action "Terminate line" on phase 0003, sequence 0001, dose 1
CANCEL LABEL COMBINATION REQUEST	Electronic signature cancelled. Remarks: Cancellation of the action "Cancel ticket" OF00001047-0-TOUT-0117110006-4

- Barcode generation:



The barcode value depends on the activation of the custom rule

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001 800 03061910

For additional numbers, click [here](#).