

# What's new in Opcenter Execution Pharma version 6.2.2

## 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 to simplify the architecture, decrease configuration efforts and lower ownership cost
- Standardize process operations libraries by re-using functional blocks and parametric master batch records
- Standardize and harmonize processes and facilitate implementation across sites
- Make batch-relevant information reviews faster, safer and enable release by exception

### Summary

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

Opcenter EX PH enables all regulated processes to be managed without paper-based procedures or documents. The system offers easy configuration and out-of-the-box functionality and allows users to design any process without specific information technology (IT) skills.

Fully compliant with the U.S. Food and Drug Administration (FDA) and Good Manufacturing Practice (GMP) regulations, Opcenter EX PH optimizes batch manufacturing processes and helps streamline resources, such as user guidance, equipment allocation and standard operation procedures. It also systematically controls execution at all stages,

whether human operations or operations controlled by the automation layer.

Opcenter EX PH enables you to reliably acquire critical process data. It also allows forward and backward searches using genealogy and audit trail tools, significantly reducing manufacturing, review and release times and enabling faster time-to-market. Opcenter is a part of Xcelerator, a comprehensive and integrated portfolio of software and services from Siemens Digital Industries Software.

### Achieving operational excellence

Opcenter EX PH enables manufacturers in the life sciences industries to achieve operational excellence, accelerate time-to-market, reduce compliance costs and improve quality and productivity. Opcenter EX PH helps companies maximize the efficiency of all resources – user guidance, equipment allocation and operating procedures – and control and track every operation within production execution, whether human or automated. The system allows you to review the product batch record by exception, providing a faster and more efficient release of products.

Powered by an advanced workflow engine and an easy-to-use electronic work instructions (EWI) concept, Opcenter EX PH can be used to direct manufacturing while also recording and centralizing all required information for completed batch record, enabling release by exception. Management of master batch records (MBRs) facilitates the key process parameters.

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## Features

- New archiving engine
- New API framework and APIs
- Electronic signature trace enhancements
- Weighing enhancements
- Execution report enhancement
- Support of Simatic batch 9.0 Sp1 update 3 and delivered with last BIL version (BIL 5.0.3)

## Capabilities

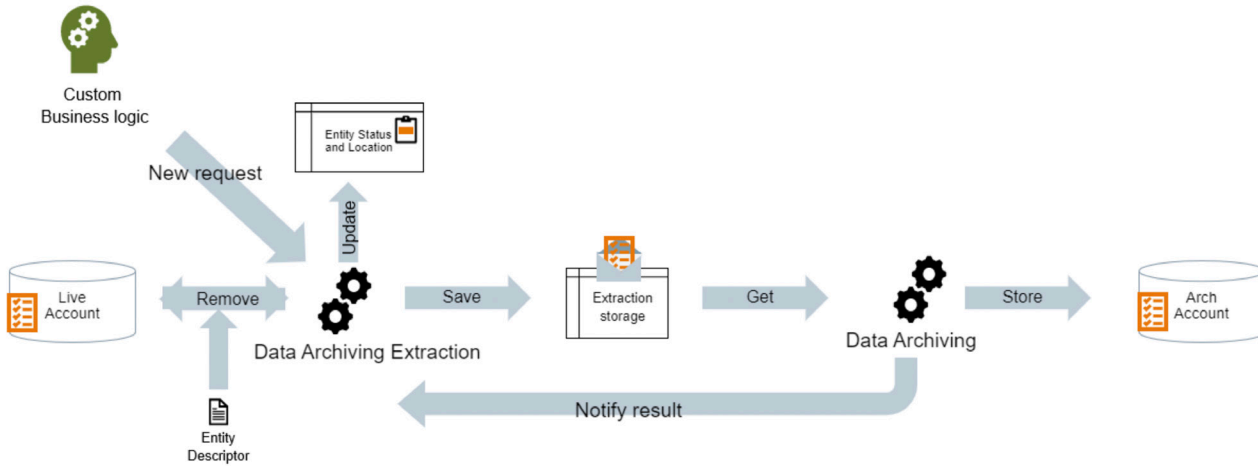
Opcenter EX PH version 6.2.2 is a functional enhancement of Opcenter EX PH version 6.2 and Simatic IT eBR version 6.0 (based on the former XFP solution) and provides the following new features:

- *New archiving engine:*  
The new archiving engine provides more flexibility to the integrator to support specific use cases
  - The new engine supports out-of-the-box archiving processes for items and annexes files entities
  - The integrator can customize which entity and when it's needed to archive them based on production events
  - The archiving process is described in XML descriptor and can be easily extended by the integrators. The new engine even supports the archiving process for custom tables
  - The legacy archive module remains available until the new archiving engine cover the same functionalities
- *New API framework and API*  
A new Web end point is provided to expose Opcenter EX PH business logic for remote or thin client. This Web end point is based on the OAuth2 standard for the authentication, providing a generic execution engine. The application programming interface (API) business logic is performed on Opcenter EX PH services, supporting 32bit and 64bit business logic. Integrators can easily extend the API using the 32bit or 64bit business logic of Opcenter EX PH.

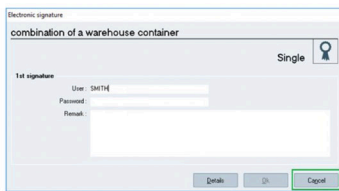
Here are the standard APIs delivered in this first release:

- Mission take
- Mission end
- Mission release
- Reconcile (before combination reconciliation)
- *Electronic signature trace enhancement:*  
The electronic signature cancellation traces have been extended for the following combinations actions:
  - Ticket combination
  - Warehouse container combination
  - Cancel ticket
  - Terminate line
  - Force combination
- *Weighing enhancements:*  
Control the usage of an already used container during the laser weighing mode. The system can now refuse the usage of a container that is part filled. This behavior is configurable.
  - New user exit at the end of weighing. This user exit may allow, for example, the generation of a specific barcode identifier that can be printed on the label.
- *Execution report order enhancement:*  
It's now possible to configure the order of the tasks in the execution report. By default, the tasks are ordered by ascending date of the last update of the tasks. It's now possible to order the tasks by ascending date of the creation of the tasks. This may better fit the reviewer's expectation of the execution report.
- *Support of Simatic batch 9.0 Sp1 update 3*  
In this new release, Opcenter EX PH is delivered with the last version of BIL 5.0.3. This version allows the filtering of the messages sent by Simatic batch to reduce unnecessary load between the systems.

## New archiving concepts



## ES cancellation



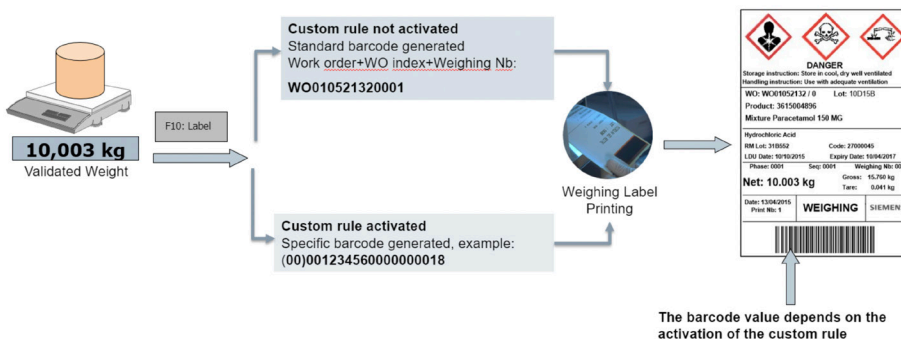
The trace is associated to the same function as the electronic signature and to the connected operator.

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

There are 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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