

Opcenter Execution Pharma version 6.2.3

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 and facilitate implementation across sites
- Make batch-relevant information reviews faster and safer

Features

- API framework enhancement and API electronic signatures
- Archives enhancements
- Scripted installation support
- New manual weighing signature
- Support of Simatic Batch 9.0 Sp1 update 4 and 5 and delivered with BIL6.0

Summary

The 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 that Opcenter EX PH must perform, and provides 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 out-of-the-box functionality, allowing 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, the system 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, either human operations or operations controlled by the automation layer.

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

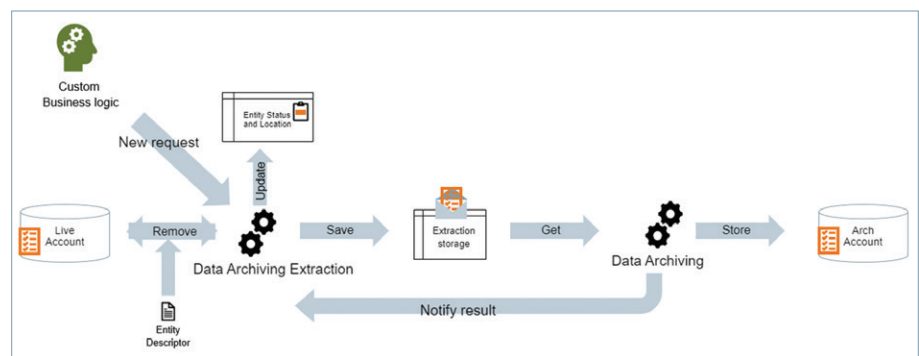


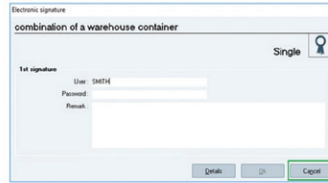
Figure 1. New archiving concept.

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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, providing user guidance, equipment allocation and operating procedures. It also allows companies to control and track every operation within production execution, whether human or automated. The system facilitates the review of the product batch record by exception, providing faster and more efficient product releases.

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



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: w/C_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: w/C_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 label" OF00001047-0-TOUT-0117110006-4

Figure 2. ES cancellation.

Enhancements to Opcenter EX PH 6.2.3 include:

- A new archiving engine that provides additional customization of processes with the capability to extract data before starting the archiving process. The engine transfers the information immediately before or after the process and manages dependency constraints between tables

The archiving engine can be used to reliably export the database (DB). It is possible to handle different DBs and store information about data and file location in a live account. The archiving architecture can manage work orders and provide support for custom entities archiving.

- Application programming interface (API) framework enhancement and API electronic signatures that support

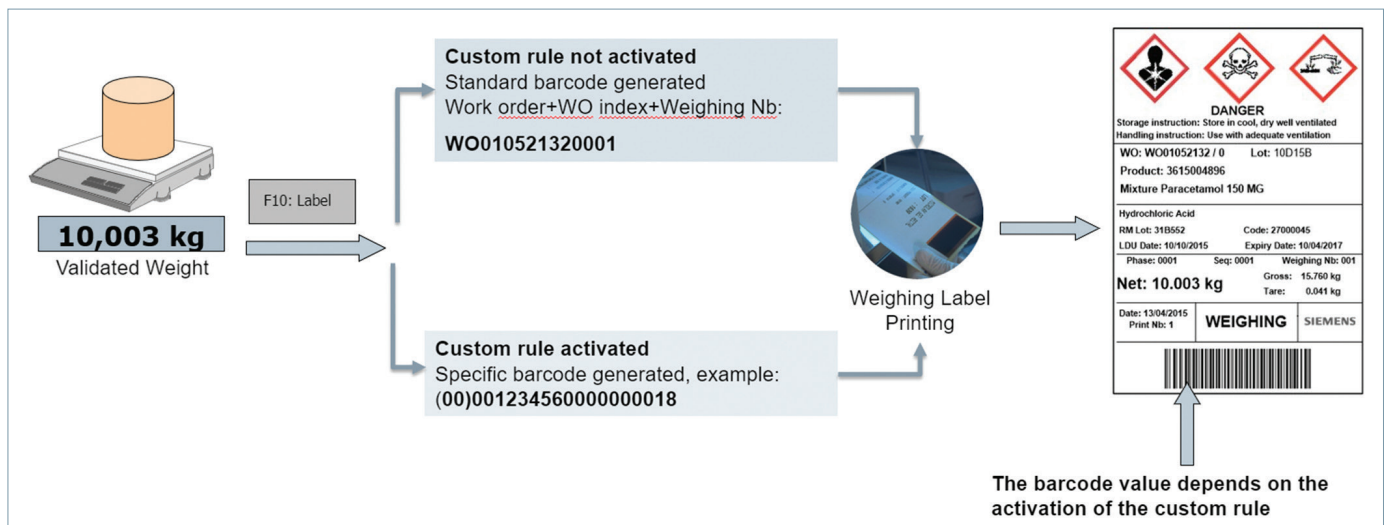


Figure 3. New archiving concept.

32-bit and 64-bit business logic integrators and easily extend the API to support the customers' specific needs. Translation API provides localized business logic messages to the end user and electronic signature API supports single electronic signature interaction with the client

Using Opcenter EX PH 6.2.3 improves the capabilities of the framework by supporting synchronous API calls. This approach drastically simplifies the interactions between the client and server.

- Installation support via scripting where the user will be supported via configuration files during installation and provided with log file information about the installation execution. The configuration files are available to support the installation of:
 - Workstations
 - Webservers
 - Opcenter EX PH server
- Electronic signatures for manual weighing are associated with the manual weighing mode and all container identification functions. The new manual weighing electronic signatures will keep the same configuration as the standard weighing recording
- Support of Simatic Batch 9.0 Sp1 update 4 and 5 removes business logic used to store and keep Simatic Batch engineering data updated. This version allows changes to the Simatic Batch Recipe and Formula if there are associated batches still not complete
- Maintenance updates:
 - Citrix support has been clarified
 - With version 6.2.3, the deprecated user proprietary authentication will be removed with next major version 7.0
 - From version 6.2.3 on, our product will not provide a structured query language (SQL) Server application via our International Organization for Standardization (ISO) file. We advise the customer to look for the recommended SQL version

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