

DIGITAL INDUSTRIES SOFTWARE

What's new in Opcenter Execution Pharma version 2211

Supporting the PostgreSQL database and introducing the new Equipment Logbook app

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

Summary

The Opcenter™ Execution Pharma software (Opcenter EX PH), formerly known as SIMATIC IT® suite electronic batch records (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 you perform using Opcenter EX PH to provide flexibility in the master batch record design process.

Opcenter EX PH, which is a part of the Siemens Xcelerator portfolio, the comprehensive and integrated portfolio of software, hardware and services, enables you to manage all regulated processes without paper-based procedures or documents. The system offers easy configuration and out-of-the-box (OOTB) 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 you streamline resources, such as user guidance, equipment allocation and standard operating procedures. It also systematically controls execution at all stages with either human operations or operations controlled by the automation layer.

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Features

- Use PostgreSQL as an alternative database
- Equipment Logbook App
- Generic process instruction improvements
- Authentication federation enhancements
- System monitoring KPIs
- Configurable operating text task in the HMI tasklist

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.

Achieving operational excellence

Using 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. Companies can also use Opcenter EX PH to control and track every operation within production execution, whether through human intervention or automatically. The system facilitates the review of the product batch record by exception, providing faster and more efficient product releases (PRs).

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

There are several new enhancements to Opcenter Execution Pharma 2211 that you can use including, delivering new out-of-the-box features, easing the engineering and drastically reducing the total cost of ownership (TCO) of the system.

Starting with the 2211 release, the PostgreSQL database is now supported as an alternative to Oracle DB. PostgreSQL reduces the cost of acquisition as an open-source database. Furthermore, its administration and maintenance processes are simpler than Oracle DB. An active community is easily accessible, reducing the TCO and allowing users to find companies that provide cost-effective services more easily.

It's easy for Siemens integrators and customers to adopt PostgreSQL, as it has equivalent functionalities to ORACLE DB including concepts, query syntax, etc.

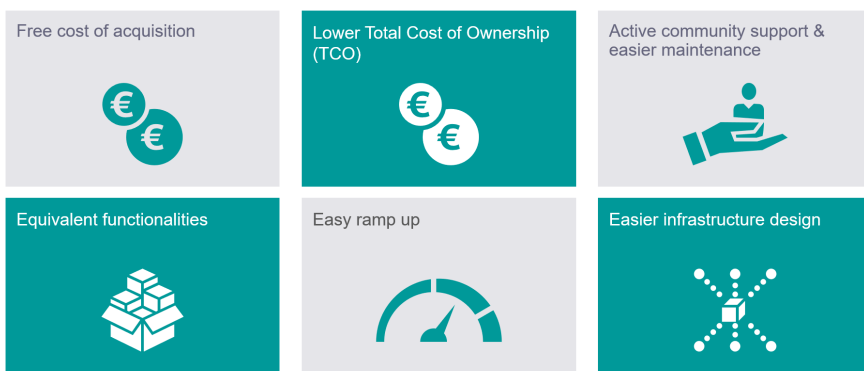


Figure 1. PostgreSQL support: key added value.

Due to its low TCO, using PostgreSQL enables you to explore new possibilities to define the infrastructure without DB cost constraints scaling vertically or horizontally.

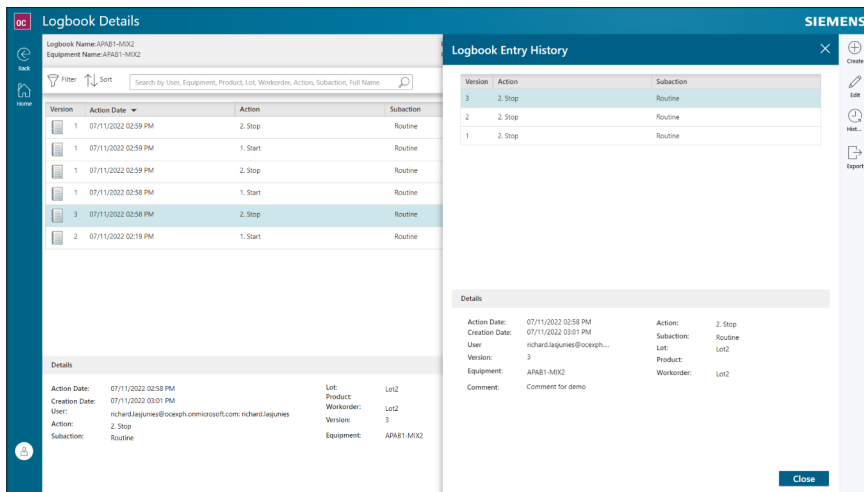
Feature benefits:

- No acquisition cost
- Lower TCO
- Easy ramp up
- Enable easier infrastructure design

The new Equipment Logbook App centralizes equipment events with an easy way to review, correct and export the logbook entries. The application was built to become more accessible via a web portal and designed to support desktop or mobile tablet devices.

This new OOTB feature is based on microservice software architecture design providing its user interface (UI) and database. You can use the Equipment Logbook App anywhere that Opcenter Execution Pharma is not yet deployed, quickly providing value for the end user at a lost cost.

Integrating the customer IT infrastructure is easy using open standards. Open ID and REST API standards are widely used to integrate the customer authentication system and other external systems like enterprise resource planning (ERP), MES and automation.



Feature benefits:

- Easy adoption for end users
- Easy deployment
- Quick return-on-investment (ROI)

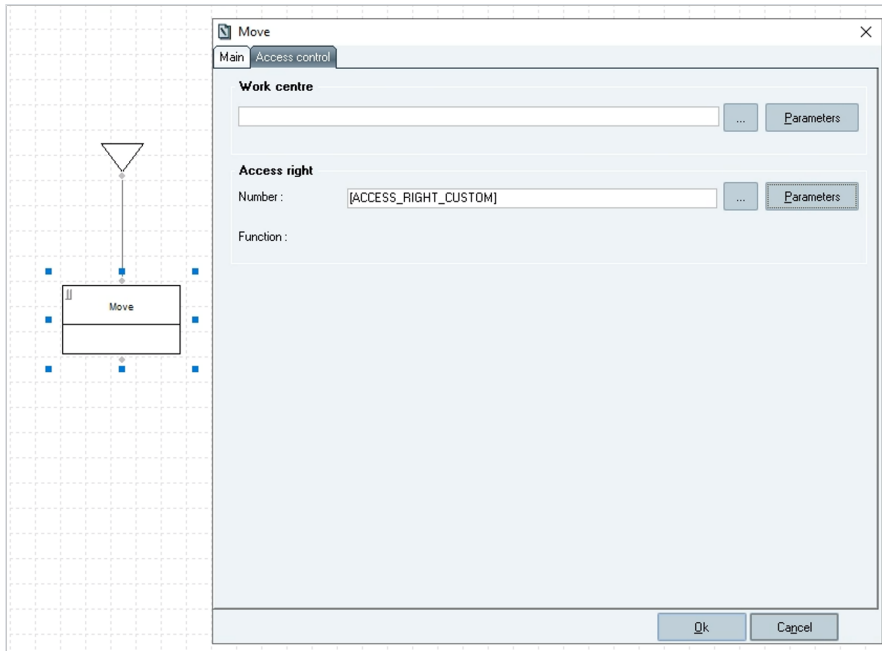
Process Instruction and Work Instruction features have been enhanced to facilitate the engineering of generic recipes. It's now possible to use parameters to configure the numeric tag and the access right for the tasks. With these enhancements, process design will be more generic among different end-user profiles, reducing the design and maintenance effort of process instruction.

Following the introduction of the multilanguage support in the previous release, it's now possible to upgrade preexisting process instructions by enabling the multilanguage feature. Furthermore, users can now export/import process instructions from different updates in the same release.

Work instruction numeric tag precision behavior has been improved to support additional scenarios and bring more flexibility.

It's now possible to configure the access right of a task in the workflow with a parameter.

It increases the genericity the process instruction and provides more flexibility for the design.



Feature benefits:

- Reduce process instruction (PI) engineering cost
- Reduce PI maintenance cost

WinCC® HMI system integration has been improved to help you control the operating text form with the human machine interface (HMI) tasklist. It's now possible to configure the position and the size of the operating text in the WinCC picture to show the best place for the operator without overlapping other widgets of the picture.

Feature benefits:

- Better user experience (UX) for operators

Each release offers improved serviceability and supportability (S&S) of the product. With Opcenter Execution Pharma 2211, the design architecture and infrastructure deployment (DAID) has been enhanced for users to manage the upgrades, reduce downtime during system upgrades and provide guidance for PostgreSQL database deployment.

In addition, new indicators have been added to monitor the usage and performance of the system to facilitate the administration and sizing.

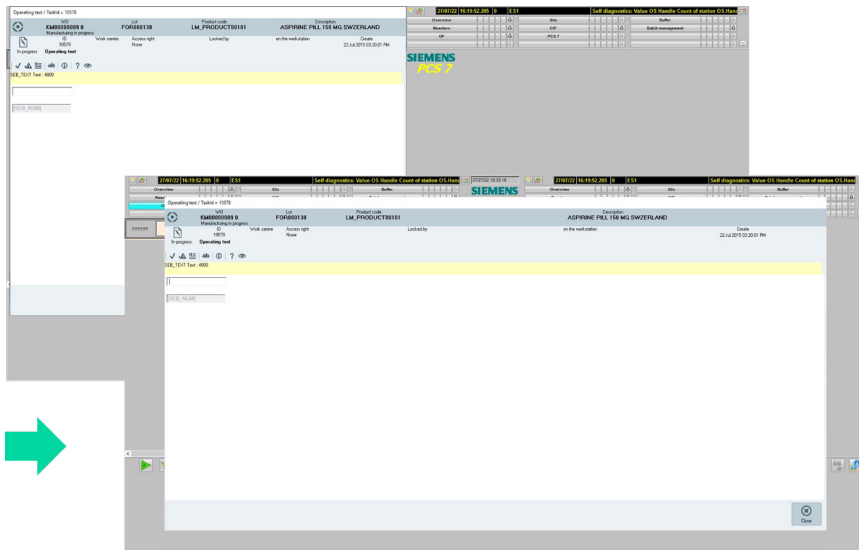


Figure 2. Move and resize of operating text task execution window.

Feature benefits:

- Easier administration
- Easier and better system definition

Enhancements to Opcenter EX PH 2211 include:

Support of PostgreSQL

- User management, audit trail, workstation management and genealogy
- Material and equipment management
- Flow/warehouse management
- Weighing & Dispensing
- Reconciliation and compounding
- PI Management
- PI Process
- Export/import
- Script management and execution
- XSI
- MBR

Equipment Logbook App

- Equipment logbook entry and correction
- Equipment logbook entry review and easy filtering
- Integration with external systems via an application programming interface (API)
- Plant layout and equipment definition
- Open ID support

Process instruction

- Enable translation support for preexisting PI
- Numeric tag decimal enhancements
- Parametrized task access right
- HMI tasklist enhancements
- Operating text windows positioning and sizing configurable in HMI tasklist

Serviceability and supportability

- OOTB key performance indicators (KPIs) for system monitoring
- Azure support
- Import PI export packages such as CAB from other updates
- Download expired lot/container

Other enhancements include:

- Azure deployment and SIMATIC Batch 9.1 SP1 and SP2
- Technical upgrades and security

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