DIGITAL INDUSTRIES SOFTWARE

What's new in Opcenter Execution Pharma version 2305

Using the Operator Cockpit app to execute manufacturing operations via a web client

Benefits

- Use the Operator Cockpit to execute manufacturing operations via a web client

- 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

- Create batch-relevant information reviews faster and safer

- Improve equipment logbook entry

Summary

Opcenter™ Execution Pharma (Opcenter EX PH) software – formerly known as SIMATIC IT® suite electric batch recording (eBR) – offers native integration between the manufacturing execution system (MES) and the distributed control system (DCS) layer. Using Opcenter EX PH, you can expedite the design, execution and review steps as well as provide flexibility in the master batch record design process.

Opcenter EX PH, which is a part of the Siemens Xcelerator business platform of software, hardware and services, enables you to manage all regulated processes without paper-based procedures or documents. With Opcenter EX PH, easily configure and leverage out-of-the-box (OOTB) functionality to facilitate design processes even if the user does not have specific information technology (IT) skills.

Since this system is fully compliant with the U.S. Food and Drug Administration (FDA) and Good Manufacturing Practice (GMP) regulations, you can optimize batch manufacturing processes and streamline resources such as user guidance, equipment allocation and standard operation procedures (SOPs).

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Features

- Introduce the Operator Cockpit web app

- Equipment logbook review enforcement

- Integrated generic Event PI for SIMATIC BATCH

- Extended features supported with PG database

- Advanced archiving capabilities

- Extended feature support using PostgreSQL database

You can also systematically control the execution at all stages, including human operations or operations controlled by the automation layer.

Using Opcenter EX PH enables you to reliably acquire critical process data. Additionally, you can forward and backward search using the genealogy and audit trail tools, which can significantly reduce manufacturing review and release times, and facilitate faster time-to-market.

For a harmonized offering across Siemens, Opcenter EX PH moves to a year-and-month-based version numbering. Therefore, version number 2205 follows version number 6.2.4.
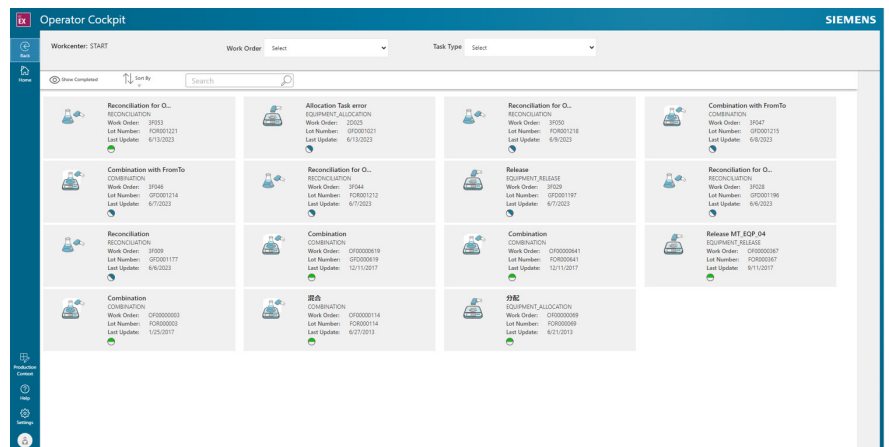
Opcenter EX PH manufacturing benefits

Manufacturers using Opcenter EX PH in the life sciences industries can accelerate time-to-market, reduce compliance costs and improve quality and productivity. Additionally, using Opcenter EX PH can help companies maximize the efficiency of all resources by providing user guidance for equipment allocation and operating procedures. Further, users can control and track all operations in every production execution stage, whether human or automated. Users can also review product batch records by exception to provide faster and more efficient product releases.

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 capability enables release by exception. Further, managing master batch records (MBRs) facilitates the key process parameters.

Opcenter EX PH 2305 includes several enhancements, delivers new OOTB features, eases the engineering requirements and reduces the total cost of operation (TCO) of the customer's system.

In Opcenter EX PH 2305, we improve our operator guidance capabilities by introducing Operator Cockpit.

Introducing the Operator Cockpit

Based on Siemens Xcelerator, this web-based and cloud-ready application helps users manage manufacturing task execution across the plant.
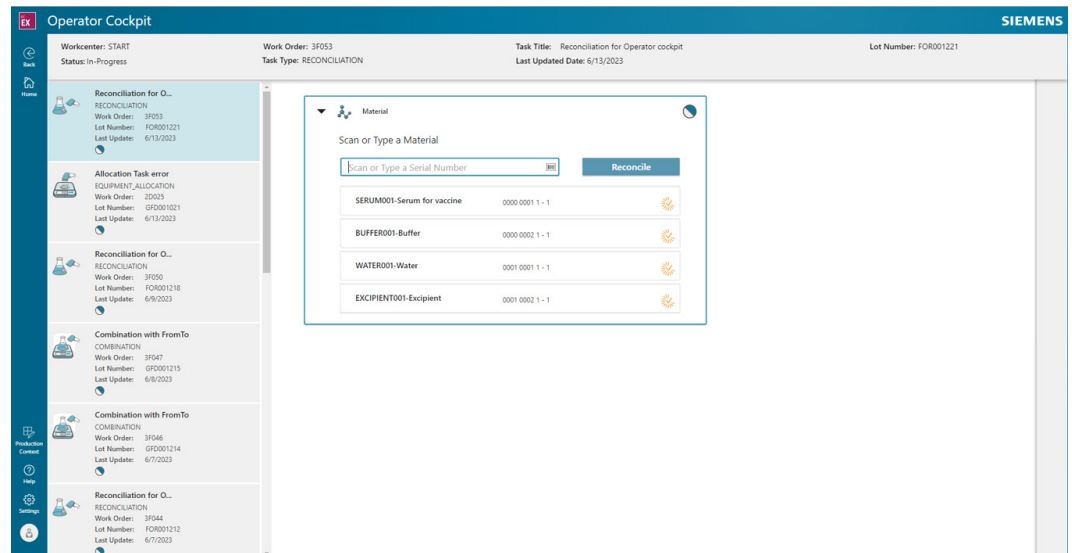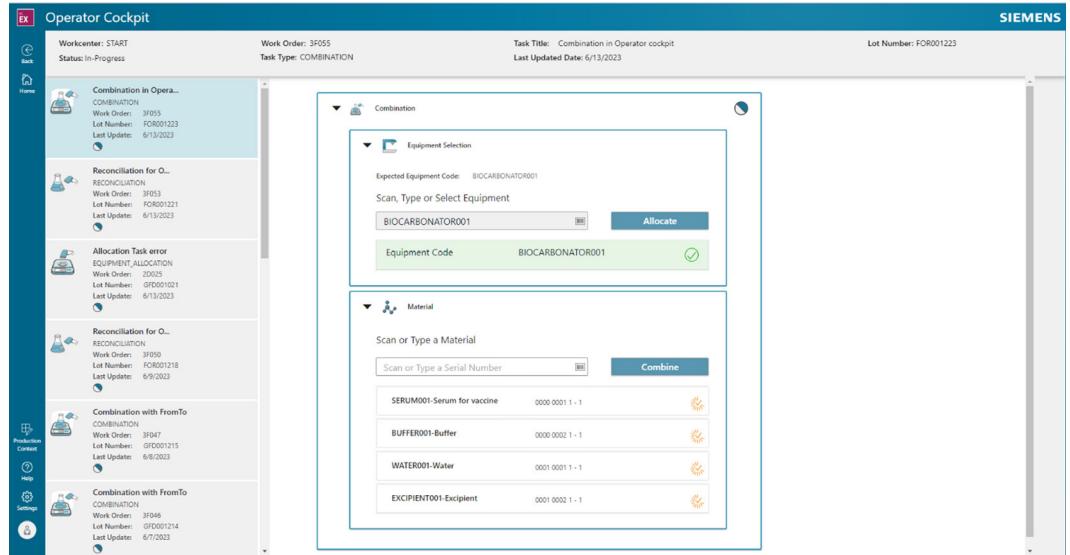
This tool's purpose is to:

• Display the list of tasks – also called packaged business capabilities (PBCs) – the connected operator can perform according to the task orchestration managed by the Opcenter EX PH workflow engine

• Guide the operator through task execution with a suitable user experience (UX)

In the future, it will also support the adaptive PBC concept: leveraging MENDIX™ platform low-code technology to enable users to customize and extend the task execution experience to customer-specific requirements.

In the Opcenter EX PH 2305 release, the Operator Cockpit comes with the following PBCs:

• Reconciliation

• Combination (scope not equivalent to the rich client application – see documentation for more details)

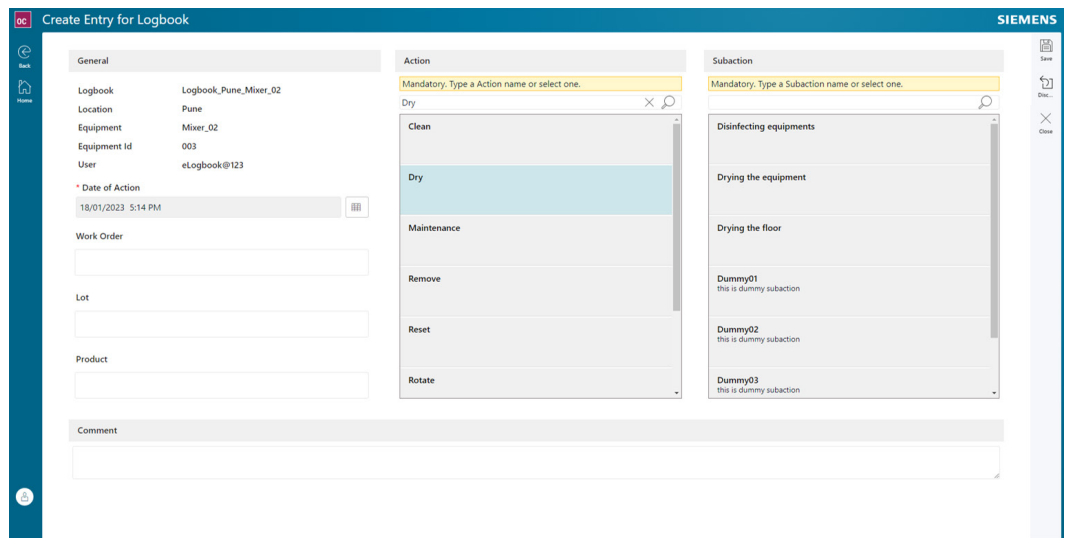• Equipment allocation and release

Benefits:

- Web task execution
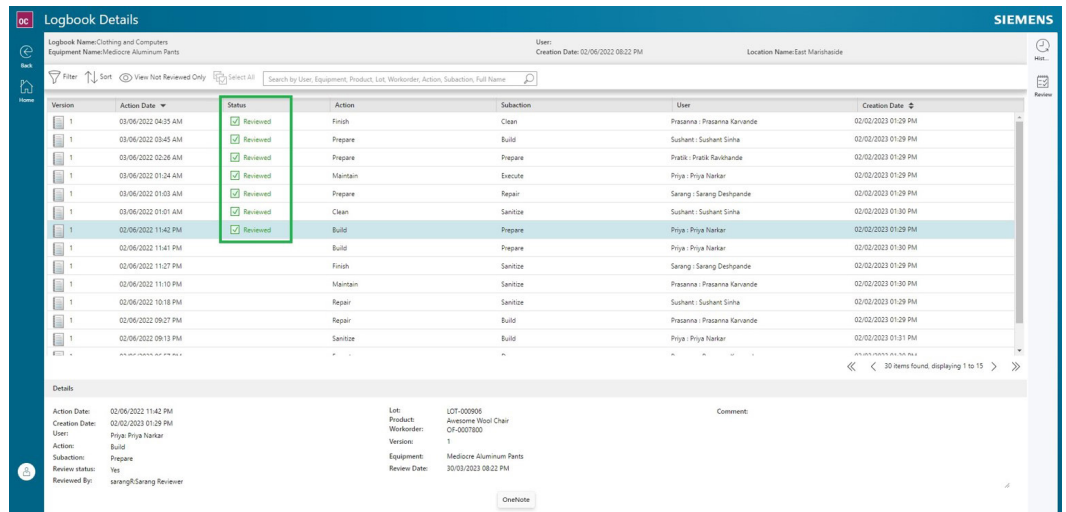- Harmonized UX

Equipment Logbook improvements

The Equipment Logbook app, introduced in release 2211, enables users to centralize equipment events in one place with easy to create, correct, review and export logbook entries.

With the Opcenter EX PH 2305 release comes several enhancements:

- An improved logbook entry page that can be a quick, systematic and error-proof way for a technician to efficiently log an entry. This includes environmental constraints, for example, wearing gloves

- A logbook entry review process, which allows a supervisor to quickly acknowledge a list of logbook entries not yet reviewed. Using the GMP audit feature can help capture each review action, plus you can configure an electronic signature for this review process

- The potential to configure a maximum time span between entry creation and action dates
- An enhanced interoperability feature, where all representational state transfer (REST) application programming interfaces (APIs) have tokenized access. Additionally, there is a new REST API for getting all entries related to a piece of equipment. With the equipment creation REST API, there is also an option to automatically create the related logbook

Benefits:
- More OOTB features
- Improved operator UX

Extended PostgreSQL support

With the release of Opcenter EX PH 2305, PostgreSQL supports:
- Automation integration via SIMATIC BATCH
- Automation integration via open platform communication (OPC)
- Reviewing by exception
- Archiving

With this release, most deployments will benefit from the PostgreSQL database, which can enable companies to reduce the cost of projects.

Using PostgreSQL can help reduce acquisition costs since it is an open-source database. Having access to a huge, active and accessible community allows users to reduce the TCO and make it easy to find companies that provide cost-effective services.

In this release, we enhanced PostgreSQL integration to support deployment on the Azure PostgreSQL managed service, which enlarged options for your IT administrator to deploy in the cloud with Opcenter EX PH.

Benefits:

- No acquisition cost
- Lower TCO

SIMATIC BATCH integration enhancements

With release of Opcenter EX PH 2305, we enhanced SIMATIC BATCH integration
in several domains:

- Support of recipe operation (ROP) libraries and alternative branches, enlarging the design capability of the master recipes
- Configuration of Event Process Instruction (PI) binding using wildcards, enabling the design of generic Event PI that can be triggered by different Pcells

Opcenter EX PH 2305 embedded BIL 7.1 brings additional configuration and performance capabilities and robustness.
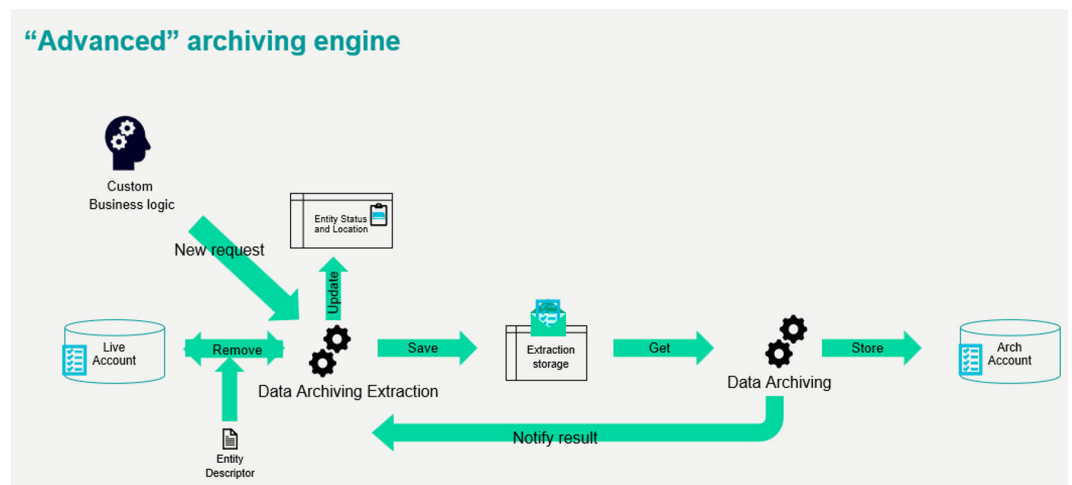
Benefits:

• Reduced integration engineering costs

• Improved performances

Advanced archiving engine

• Users of advanced archiving engine, which we introduced in a previous release, have benefited from its features and flexibility, it's now the default archive engine for Opcenter EX PH.

• With the Opcenter EX PH 2305 release, you can archive all manufacturing entities with this new engine, which offers several capabilities, such as:

• Archiving entities dependent on complex rules. For example, archive a work order (WO) depending on the type

• Archiving custom entities made easier using descriptor files without the need for heavy customs

• Archiving in different formats. By default, the system archives entities in the database; however, you can modify it to archive entities to files or other types of databases

• Integrating load balancing and high availability into the service architecture

Benefits:

• Enhanced support for complex use cases

• Increased flexibility to archive

• Improved performance

Improved serviceability, support and DAID

With each release, we improve the serviceability and supportability of our product. With Opcenter EX PH 2305, we are enhancing the design architecture and infrastructure deployment (DAID), providing guidance for better architecture and giving hints to make sure the system's performance. Further, we've extended DAID technical documentation to provide guidance for scripts implementation and customization.

Benefits:

• Easier administration

• Easier system definition

Summary of Opcenter EX PH 2305 enhancements

Operator cockpit app
- Includes reconciliation, combination and equipment allocation and release PBCs

Equipment logbook app
- Enhances logbook entry UX
- Improves time limit for logbook entry creation
- Simplifies logbook entry review process
- Includes an electronic signature
- Increases interoperability

SIMATIC BATCH integration enhancements
- Improves generic Event PI for different PCells
- Supports SIMATIC BATCH ROP libraries and alternative branches
- Upgrades BIL for performance enhancements

PostgreSQL support
- Includes features, such as: SIMATIC BATCH integration, PI review, archiving and OPC

Advanced archiving
- Supports complex archiving rules
- Archives custom entities
- Includes high availability and load balancing

Service and support
- Includes Azure Managed PostgreSQL service support
- Improves performance guidance
- Reduces upgrade downtime, client settings, scripts and guidance
- Enhances traceability for identification use cases
- Simplifies and modernizes the MBR module
- Adopts the Siemens advanced license tool

This version upgrades technical aspects, enhances security and fixes bugs