DIGITAL INDUSTRIES SOFTWARE

What's new in Opcenter Execution Pharma 2405

Evolving Mendix role-based modules and expanding a rich catalog of manufacturing capabilities

Benefits

- Use a web client via the operator cockpit and equipment logbook to execute manufacturing operations
- Configure native interoperability between the operator cockpit and the equipment logbook app
- Use ad-hoc processes triggered by external events for easy process design
- Reduce development effort and risk by using installation simplification and a new .NET SDK to implement tasks
- Integrate easily with an external system supporting the publish and subscribe mechanism using the NATS client
- Supports the latest Windows Server 2022

Summary

Opcenter™ Execution Pharma (EX PH) software serves as the foundation for leading pharmaceutical manufacturers and innovators that want to enable rapid change, lean paperless manufacturing, consistent quality output and higher profit margins. Offering native integration between the manufacturing execution system (MES) and the distributed control system (DCS) layer, Opcenter EX PH expedites the design, execution and review of the manufacturing process steps and provides flexibility in the master batch record (MBR) design process.

Opcenter EX PH 2405, which is a part of the Siemens Xcelerator business platform of software, hardware and services, enables users to regulate and manage processes without paper-based procedures or documents. With Opcenter EX PH, you can 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.

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Features

- Equipment logbook app and Opcenter EX PH OOTB interoperability
- Seamless navigation between the equipment logbook app and operator cockpit
- Support equipment's decommissioning in equipment logbook app
- Operator cockpit extension with new packaged business capabilities: equipment transfer and equipment move
- Operator cockpit task filtering and performance enhancements
- Ad-hoc process triggering

Powered by an advanced workflow engine and easy-to-use electronic work instructions (EWIs), manufacturers can use Opcenter EX PH to direct manufacturing while recording and centralizing everything required for a completed batch record. Further, leveraging MBRs facilitates managing key process parameters.

As the system is fully compliant with U.S. Food and Drug Administration (FDA) and Good Manufacturing Practice (GMP) regulations, manufacturers can optimize batch manufacturing processes and streamline resources such as user guidance, equipment allocation and standard operation procedures (SOPs). The software can also systematically control the manufacturing execution at all stages, including human operations or operations controlled by the automation layer.

Using Opcenter EX PH enables manufacturers to reliably acquire critical process data. Additionally, users can forward and backward search using the genealogy and audit trail tools and review product batch records by exception to provide faster and more efficient product releases. This significantly reduces the manufacturing review and release times and facilitates a faster time-to-market.

Opcenter EX PH 2405 includes several enhancements, delivers new OOTB features, eases the engineering requirements and reduces the total cost of operation (TCO) of a customer's system.

Capabilities

Operator cockpit with additional standard PBC

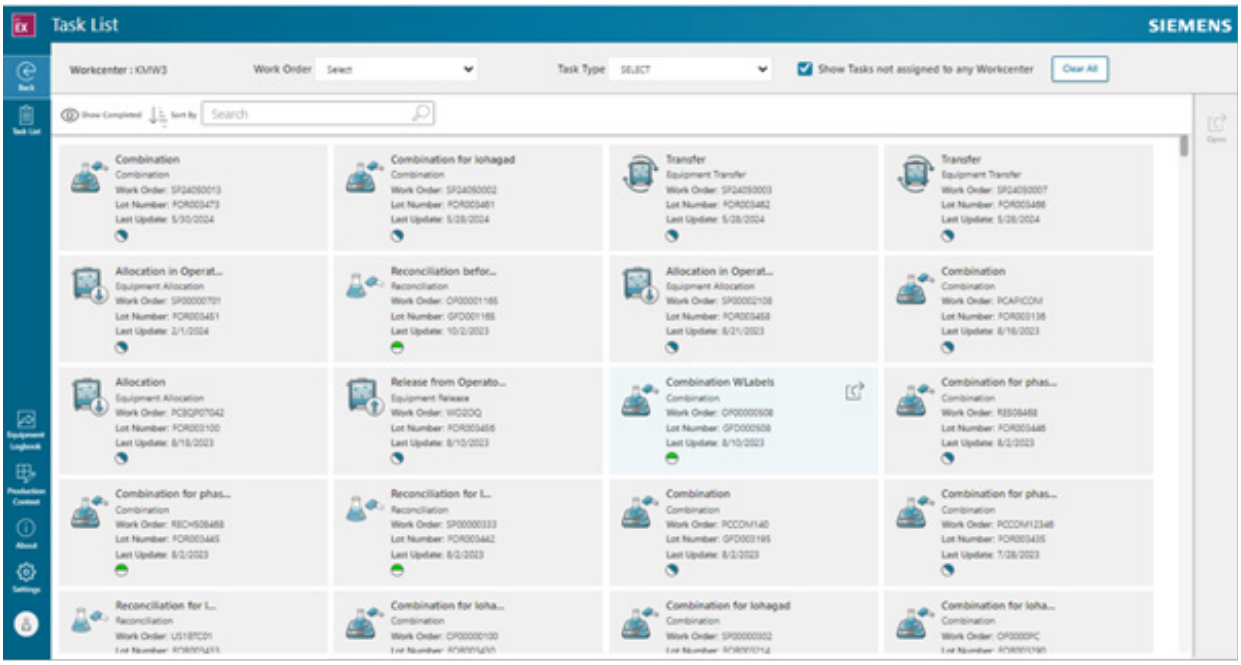
This web-based and cloud-ready application manages manufacturing task execution across the plant, based on the Siemens Xcelerator platform. Additionally, you can extend or adapt it using the Mendix™ Low-code platform, which is also part of the Siemens Xcelerator business platform.

Its purpose is to:

- Display the list of tasks the connected operator can perform according to the task orchestration mechanism managed by the Opcenter EX PH workflow engine
- Guide the operator through task execution based on a modern user experience (UX)

Tasks executable from the operator cockpit are defined in a packaged business capability (PBC).

In the next product versions, we will release more standard PBCs for the operator cockpit.


Task List
SIEMENS
Workcenter : KMW3
Work Order
Task Type
Show Tasks not assigned to any Workcenter
Clear All
Search
Combination
Combination for lohagad
Transfer
Transfer
Allocation in Operat...
Reconciliation befor...
Allocation in Operat...
Combination
Allocation
Release from Operato...
Combination WLabels
Combination for phas...
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Combination for phas...
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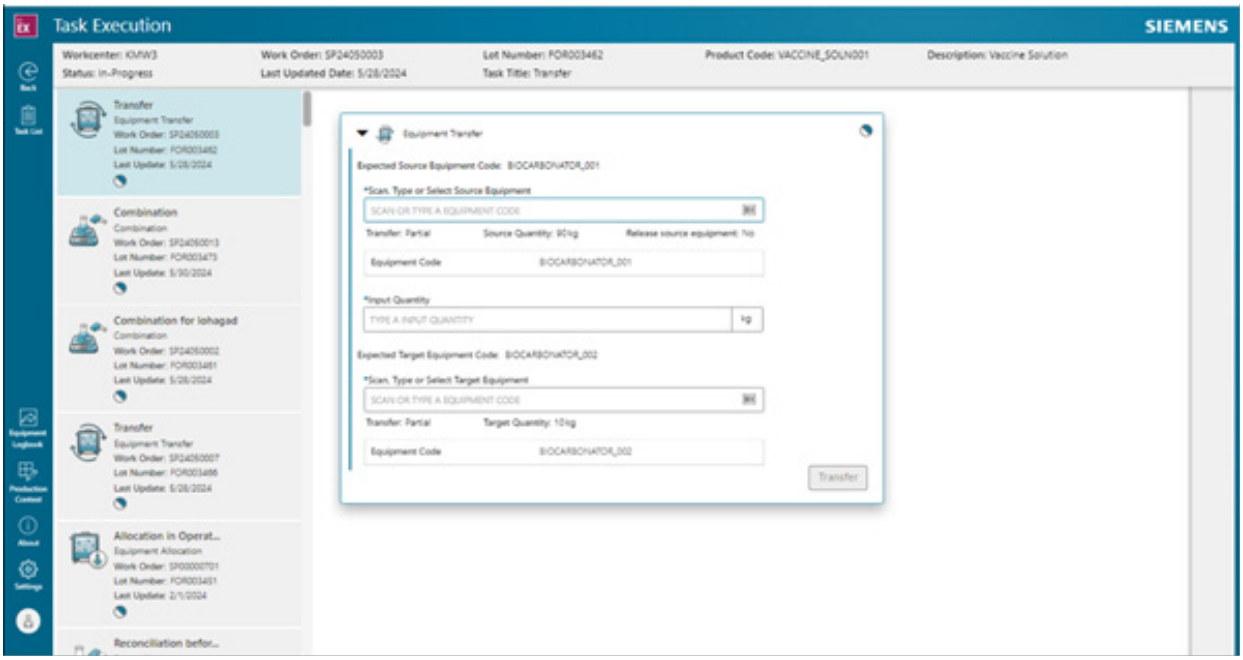

Task Execution
SIEMENS
Workcenter: KMW3
Work Order: SP24050003
Lot Number: FOR003462
Product Code: VACCINE_SOLN001
Description: Vaccine Solution
Status: In-Progress
Last Updated Date: 5/28/2024
Task Title: Transfer
Transfer
Combination
Combination for lohagad
Transfer
Allocation in Operat...
Reconciliation befor...
Equipment Transfer
Expected Source Equipment Code: BIOCARBONATOR_001
*Scan, Type or Select Source Equipment
SCAN OR TYPE A EQUIPMENT CODE
Transfer: Partial
Source Quantity: 90 kg
Release source equipment: No
Equipment Code
BIOCARBONATOR_001
*Input Quantity
TYPE A INPUT QUANTITY
kg
Expected Target Equipment Code: BIOCARBONATOR_002
*Scan, Type or Select Target Equipment
SCAN OR TYPE A EQUIPMENT CODE
Transfer: Partial
Target Quantity: 10 kg
Equipment Code
BIOCARBONATOR_002
Transfer

In this version, we addressed the following enhancements:

- Equipment transfer and move
- Electronic signature (single/single check) on deviation for combination PBC
- Cross-app navigation
- Performance and filtering improvements

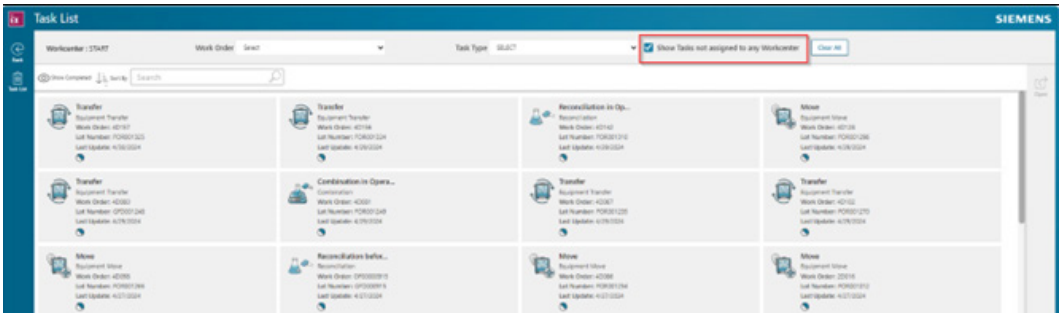
Standard PBCs

With each new product release, the focus is on delivering new standard PBCs to extend operator cockpit functional coverage. In version 2405, we introduce two new PBCs, equipment transfer and equipment move, which have a similar functional behavior to their related execution in the PIProcess application.

Performance and filtering improvements

It is now possible to link the device that runs the operator cockpit app with the workcenter. Consequently, you can filter the tasks displayed in the operator cockpit in the workcenter.

We also implement several nonfunctional requirements, for example, improving the task's display performance.



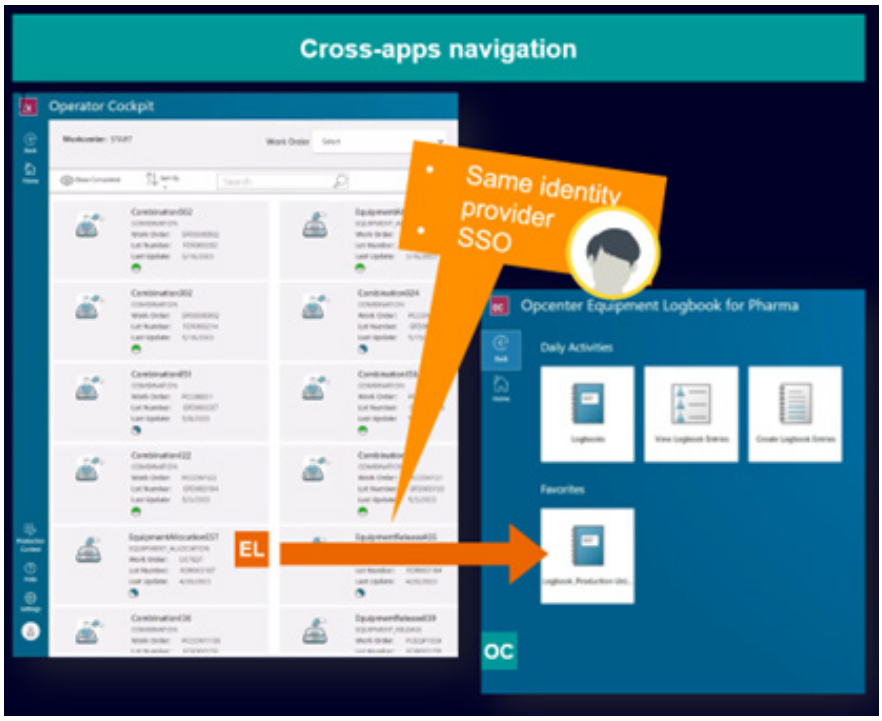
Example showing the workcenter filtering.

Benefits:

- More web capabilities
- Improved UX

Cross-app navigation

The operator cockpit now supports direct navigation to the equipment logbook app. This cross-app navigation improves the UX and makes it easier to address use cases involving both functionalities.



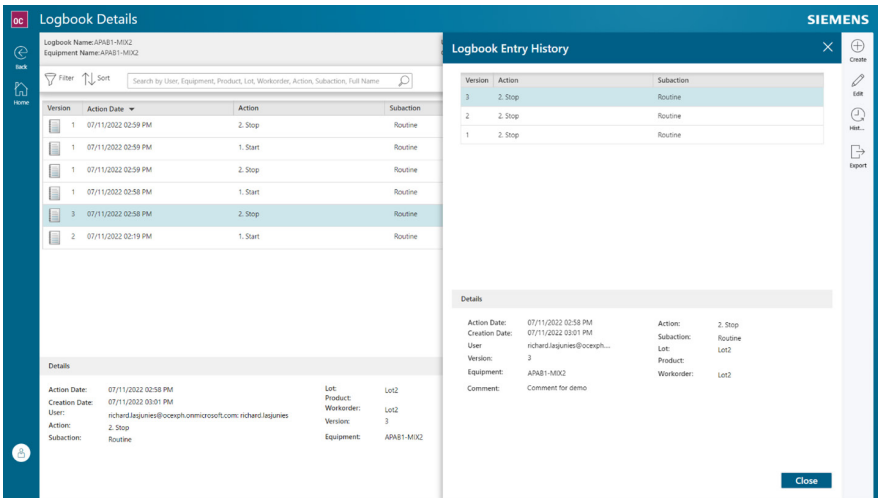
The operator cockpit to the equipment logbook navigation.

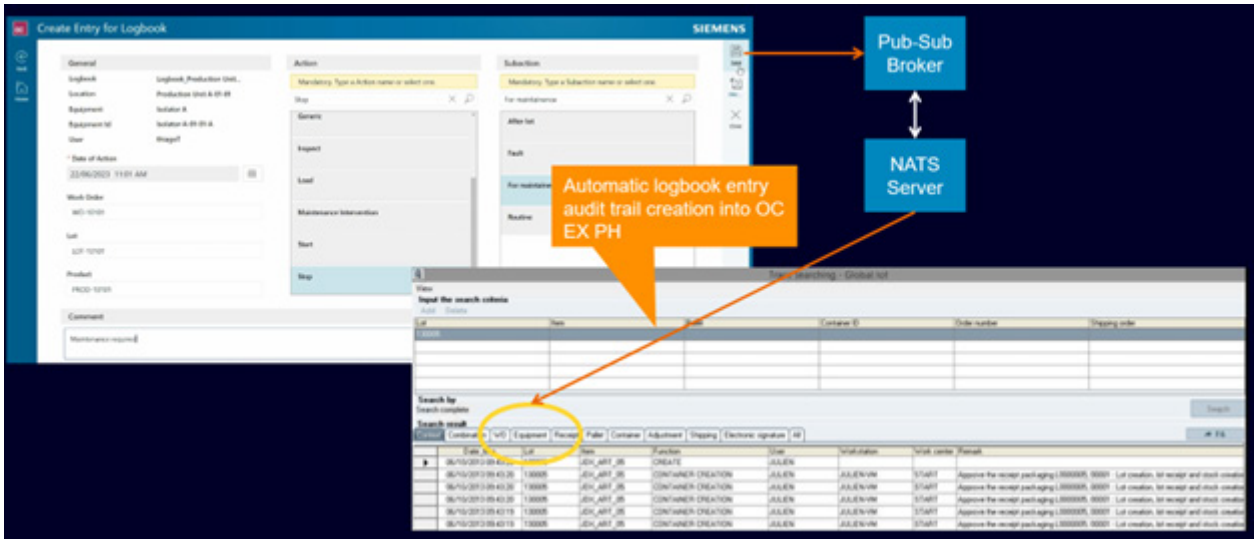
Equipment logbook and interoperability scenarios

The equipment logbook app centralizes equipment events in one place with an easy way to create, correct, review and export logbook entries. The application is accessible via a web portal designed to support desktop and tablet devices.

We built this new OOTB feature based on a microservice software architecture design pattern, encapsulating its own user interface (UI) and database. With this, the equipment logbook can also be used easily where Opcenter EX PH is not yet deployed, quickly providing value for the user community at a low cost.

Integration with the IT infrastructure is straightforward using open standards. Open ID Connect (OIDC) and API Rest standards are widely used to integrate the existing customer authentication system and other external systems, providing capabilities like enterprise resource planning (ERP), MES and automation.





Enhanced interoperability between the equipment logbook and MES.

With the 2405 release, the app comes with three major enhancements:

- Cross-app navigation
- Enhanced logbook management (locking)
- Enhanced interoperability with Opcenter EX PH

Enhanced interoperability with Opcenter EX PH

For an infrastructure setup where the equipment logbook app is used together with Opcenter EX PH, each new logbook entry you create in the equipment logbook leads to an automatic audit trail insertion in Opcenter EX PH.

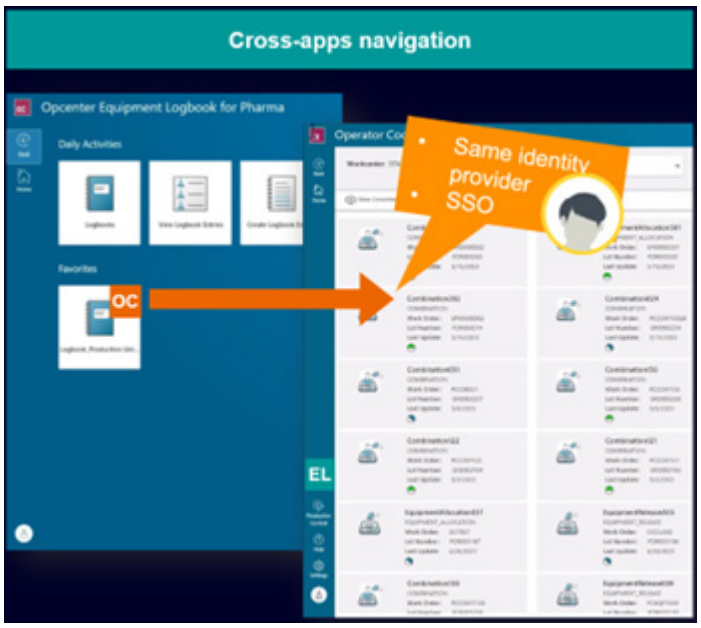
This way, you can use Opcenter EX PH as a unique point of review for the complete batch record, gathering information from the MES and the equipment logbook, which facilitates the job of the quality assurance (QA) user.

From a technical perspective, this integration between the equipment logbook and the MES implements an architectural model involving NATS technology.

Such a NATS architecture allows you to easily implement additional interoperability scenarios, if required (between the equipment logbook app and the MES or any third-party system).

Cross-app navigation

The equipment logbook now includes a direct navigation towards the operator cockpit app.



The equipment logbook to the operator cockpit navigation.

Locking a logbook.

Enhanced logbook management (locking)

In the equipment logbook master data model, it is now possible to decommission equipment, which leads to locking its associated logbook, meaning you cannot add or edit an entry in that logbook.

Benefits:

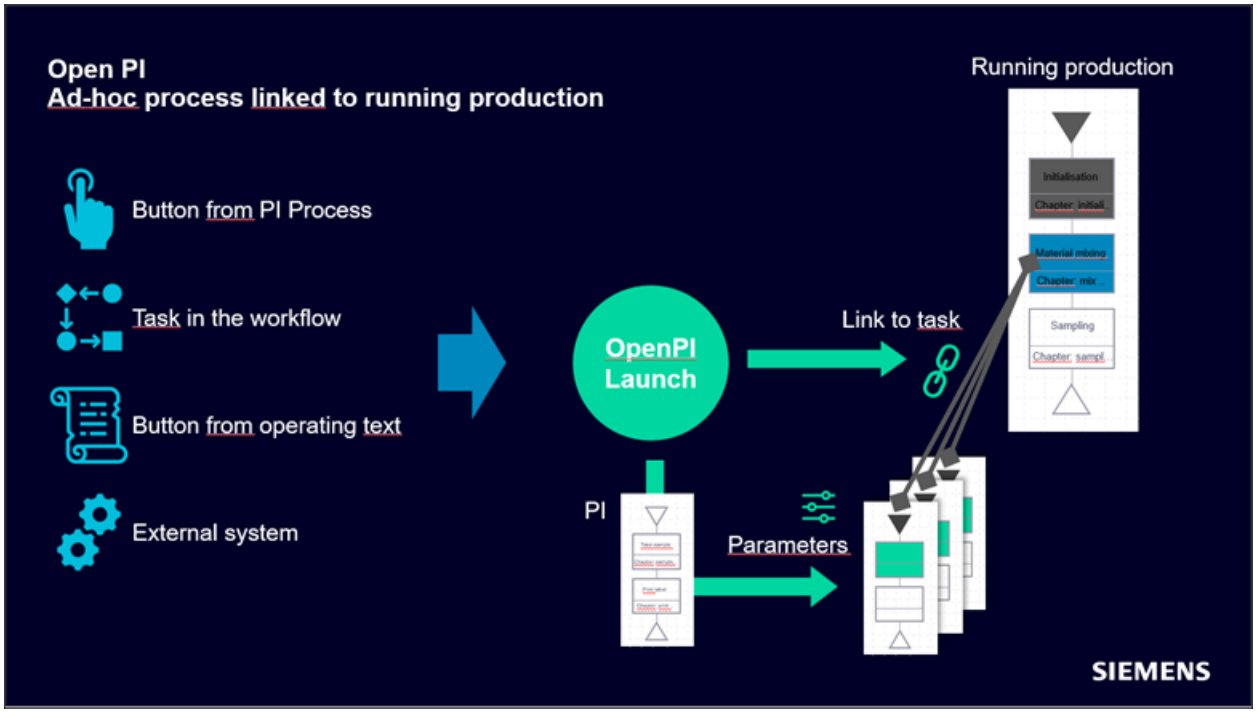
- No additional effort to integrate the equipment logbook app and Opcenter EX PH
- Better operator and assurance quality UX

Ad-hoc process triggering during process execution

With the 2405 release, it is now possible to trigger ad-hoc processes when executing other processes.

You can attach a new process to any task of the on-going production, and the tasks will behave for the operator exactly as the predictive process. The system records all the activities of the ad-hoc process next to the attached process, and you can retrieve them from the same electronic batch record (eBR).

Additionally, you can trigger ad-hoc processes from the process execution via a script from the operating text in the workflow. Alternatively, you can trigger them easily from external systems via an application programming interface (API) or database triggers.



Benefits:

- Simplified process design
- Simplified synchronization with external systems

On-premises weighing bar graph for cloud deployment

The weighing remote bar graph, which shows the weight on a scale, reacts in real time, providing an optimal UX for weighing operators while deploying the system in a cloud environment. With release 2405, we are adding the protocol SICS2 multi protocol to extend the support of scales and deployments.

Benefits:

- An optimal weighing experience while deploying the MES in the cloud
- Reduced TCO by deploying in the cloud

A new level of integration and product extension

This release introduces new approaches to extend the capabilities of the product, including:

- New NATS broker service
- New .NET task software development kit (SDK)

The new NATS broker service allows Opcenter EX PH users to subscribe to various system and component events. Opcenter will trigger API business logic when an external system triggers specific messages.

NATS technology is well known for its reliability and performance. Its native integration into the architecture service of Opcenter EX PH makes it a robust solution to easily integrate systems and components based on a publish and subscribe mechanism.

The publish and subscribe integration mechanism is also used by the product to natively integrate the equipment logbook and Opcenter EX PH. Further, it enables infinite scenarios to support complex project-specific integration requirements, like embedding external devices for augmented or assisted reality or data acquisition and integration with external systems to trigger ad-hoc processes on demand.

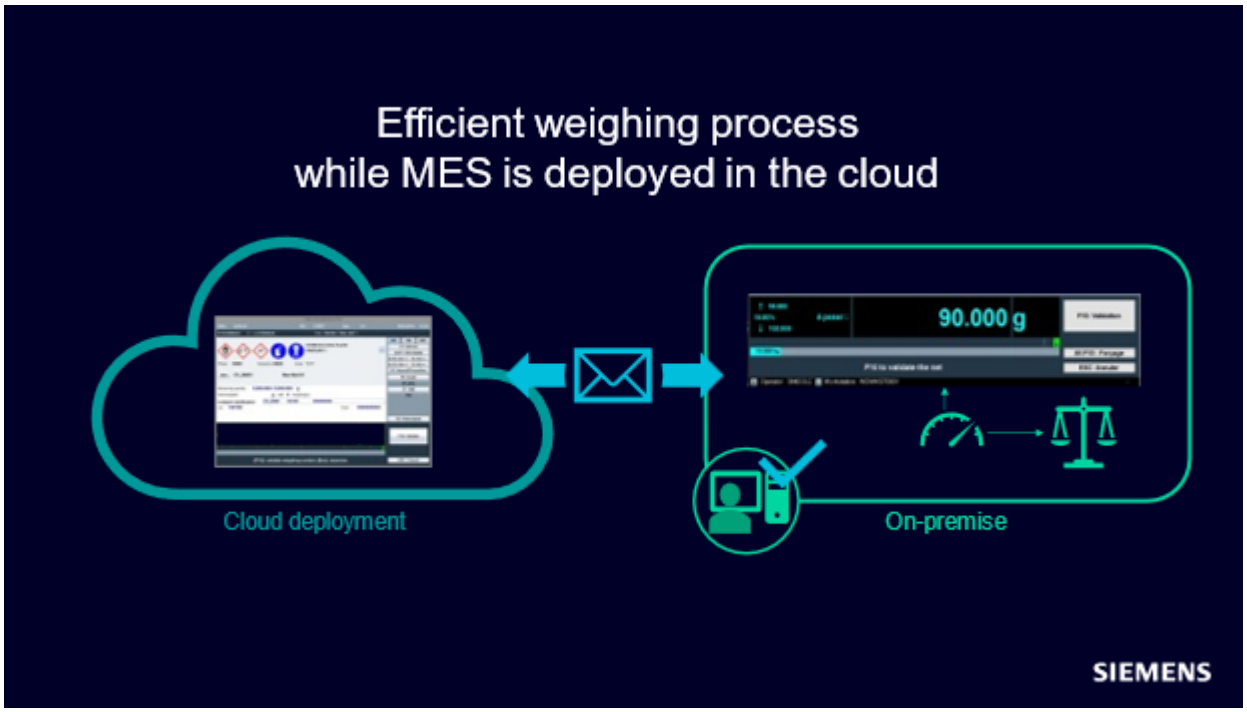
The new .NET task SDK simplifies developing new workflow tasks. It allows integrators to implement new features in the workflow with less code and fewer errors. The .NET task SDK provides the default behaviors of the task (default report, parameters, etc.) that the integrator needs to add only to the expected behaviors.

Using .NET language enables most of the integrators to implement their new tasks but also ensures code quality and reduces maintenance, avoiding recompilation for each product release.

The new .NET task SDK allows you to answer complex requirements by providing dedicated UIs to create complex workflows, scripts and operator instructions.

Benefits:

- Simpler customization capabilities, requiring less effort
- More capabilities to integrate systems and components
- Better UX, providing a best-fit task for operators at a reasonable cost



A perfect weighing experience with the on-premises weighing bar graph.

Improved serviceability, supportability and DAID

With each release, we improve the serviceability and supportability of our product. With Opcenter EX PH 2405, we extended the scripted installation, now having scripts perform most of the product workstations and server installations. This decreases the installation time from 22 minutes to three minutes without additional effort, avoiding possible human errors during installation.

Technical support now covers Windows Server 2022, BIL 8.1 and Opcenter Execution Foundation 2307.

Further, we enhanced the design architecture and infrastructure deployment (DAID) document, providing technical documentation to extend the product via scripts with guidance and an extended object description.

Benefits:

- Easier administration and deployment
- Simpler system definition

Summary of Opcenter EX PH 2405 enhancements

Operator cockpit app

- Equipment transfer and move
- Electronic signature (single/single check) on deviation for combination PBC
- Performance and filtering improvements
- Cross-app navigation

Equipment logbook app

- Enhanced interoperability with Opcenter EX PH
- Enhanced logbook management (locking)
- Cross-app navigation

Shopfloor integration

- Supports batch jump and command recipe structure
- Supports BIL 8.1 and configuration simplification

Scale in the cloud

- Supports SICS2 multi protocol for the remote weighing bar graph

Process Management

- Ad-hoc process triggering

Extensibility

- New NATS client service
- New .NET SDK for tasks

Service and support

- Extends script installation
- Supports Windows Server 2022
- DAID scripting guidance and object description
- Configures agent service level of log

This version also includes several upgrades to technical aspects, enhanced security and bug fixes.

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