DIGITAL INDUSTRIES SOFTWARE

What's new in Opcenter Execution Pharma 2311

Supporting the weighing process while deployed in the cloud

Benefits

- Support weighing process while deployed in the cloud
- Use the Operator Cockpit to execute manufacturing operations
- Reduce paper use by digitalizing processes
- Reduce development effort and risk by integrating MES and DCS
- Standardize, harmonize and implement processes across sites
- Create batch-relevant information reviews faster and safer

Summary

Using 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 expedites the design, execution and review steps and provides flexibility in the master batch record design process.

Leveraging Opcenter EX PH, which is 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

- On-premises weighing bar graph for cloud deployment

- Adaptable PBC in the Operator Cockpit

- Equipment logbook for complex equipment

- Process Instruction management enhancements

- Extended features supported by a PostgreSQL database

- Active Directory multiple domain support

Since this system is fully compliant with the United States (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). You can also systematically control execution at all stages, including human operations or operations controlled via 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 Digital Industries Software, Opcenter EX PH moves to year- and month-based version numbering. Therefore, version 2205 follows version 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.

With Opcenter EX PH 2311, users can access several enhancements, including new OOTB features that ease engineering requirements and reduce the total cost of operation (TCO) of the customer's system.

On-premises weighing bar graph for cloud deployment
In Opcenter EX PH 2311, we enable advanced weighing processes while deploying the system in the cloud.

With the remote weighing bar graph, we provide an advanced user experience (UX) for weighing operators. The bar graph shows that the whole system is installed on-premises. When the operator starts the weighing process, from the system deployed in the cloud, the remote weighing bar graph, installed on-premises, pops up on the operator screen. From the beginning, the remote weighing bar graph establishes communication with the scales, side by side, for

the operator. The remote weighing bar graph supports the weighing process, guiding the operator while communicating with the scales to acquire the weight in real-time. Once the user finalizes the weighing process, the remote weighing bar graph sends back the weight and all relevant information to the MES deployed in the cloud.
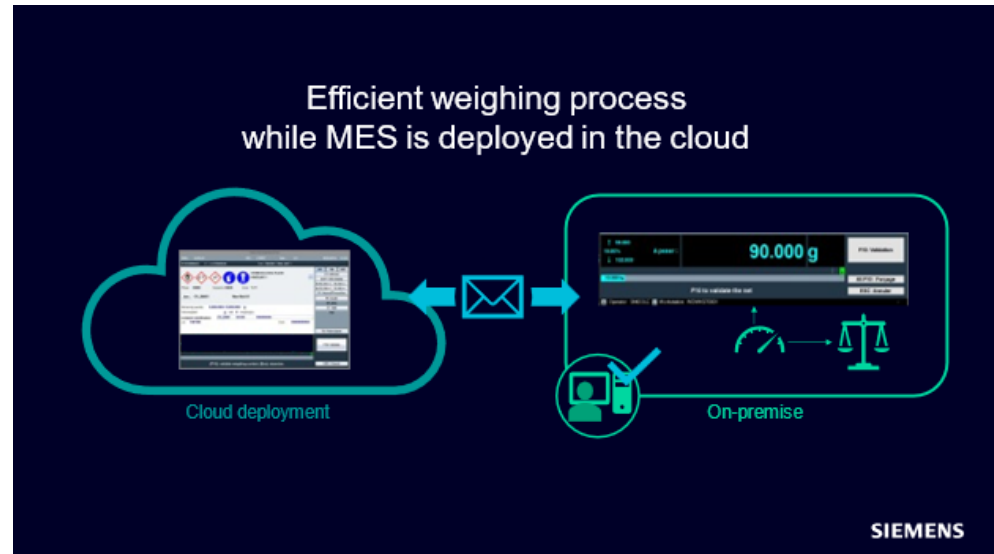
Achieve an advanced weighing experience using the on-premises weighing bar graph.

Benefits:
- Advanced weighing experience while deploying MES in the cloud
- Reduced TCO by deploying in the cloud

Operator Cockpit with adaptable PBC
Using this web-based and cloud-ready application, companies can manage manufacturing task execution across the plant based on the Siemens Xcelerator platform.

With this, you can:

- Display the task list for the connected operator to perform, according to the task orchestration mechanism managed by the Opcenter EX PH workflow engine

- Guide the operator through task execution with a suitable UX

A type of executable task being executable from Operator Cockpit is called a packaged business capability (PBC).

We plan to deliver more standard PBCs in the Operator Cockpit throughout the next product versions.
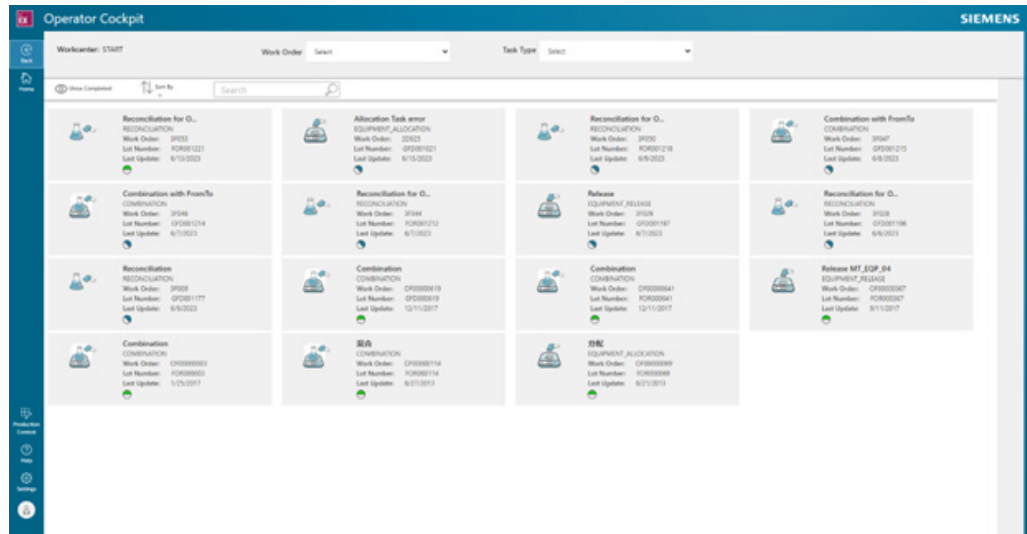
In Opcenter EX PH 2311, the focus is on supporting the adaptive PBC concept by leveraging Mendix™ Low-code platform technology capabilities, which is also part of the Siemens Xcelerator business platform. With these capabilities, project teams can customize or extend their task execution experience to meet customer-specific requirements.
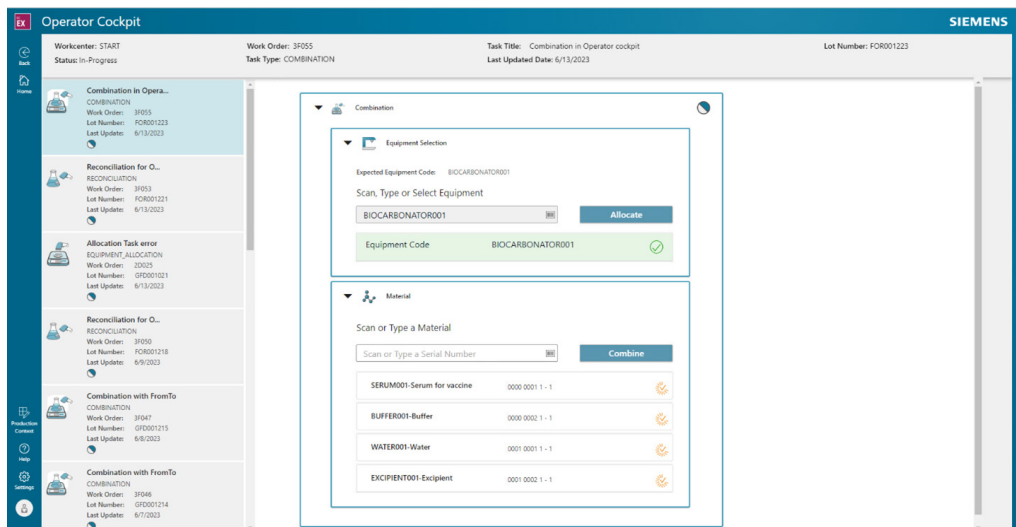
To this extent, we improved the app's architecture to develop a new type of task (PBC) execution experience in the Operator Cockpit. With this, users can:

- Add a new type of task (PBC) in Process Instruction management with the necessary level of configuration

- Manage the related mission creation and execution using the Operator Cockpit during work order execution
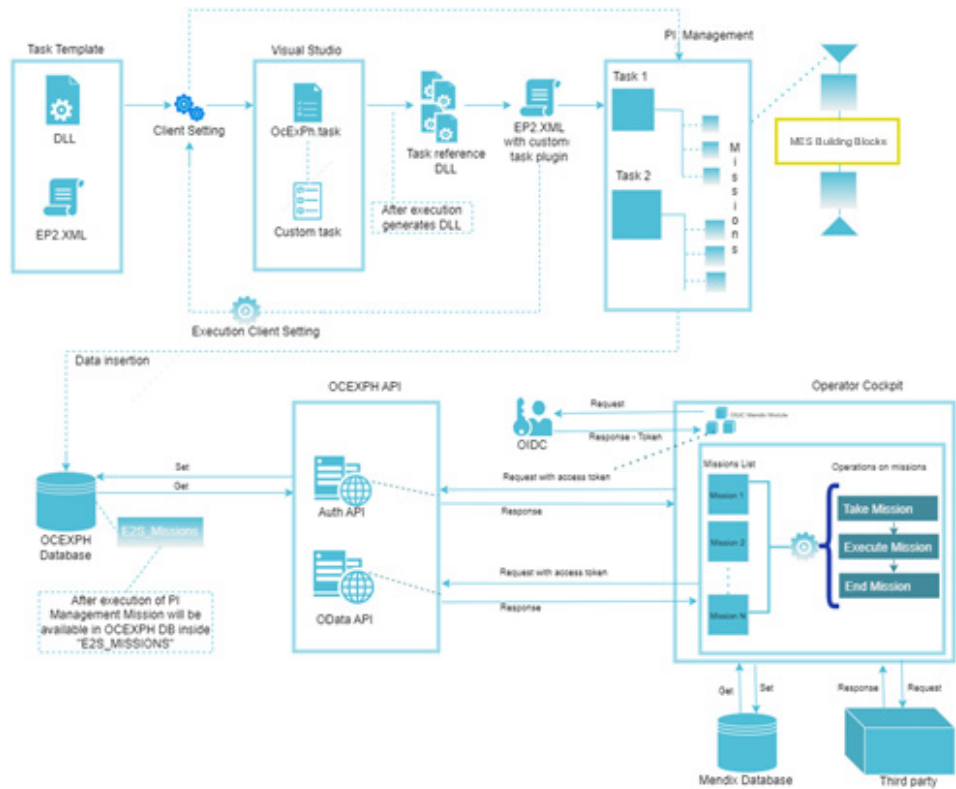
The adaptable Operator Cockpit architecture.

- Manage the authentication mechanism for the new PBC execution

- Develop a new PBC execution user interface (UI) directly with additional Mendix UI components or by injecting a pluggable web widget

Together with this new architecture, we prepared a walkthrough document in Opcenter EX PH 2311 to guide a delivery or project engineer in developing a custom PBC.

Aside from this app architecture improvement, we also improved the combination PBC to manage manual combinations, including dose or sequence configuration restrictions.

The following standard PBCs are available:

- Combination

- Reconciliation

- Equipment allocation or release

Benefits:

- Meets the end user's needs by adding capabilities to the Operator Cockpit

- Boosts adaptability using the Mendix Low-code environment

The new 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, and we designed it to support desktop or mobile tablet devices.

We built this new OOTB feature based on the microservice software architecture design pattern, providing its own UI and database. This way, companies can quickly use it in areas where Opcenter EX PH is not yet deployed, providing value for the end user at a lower cost.
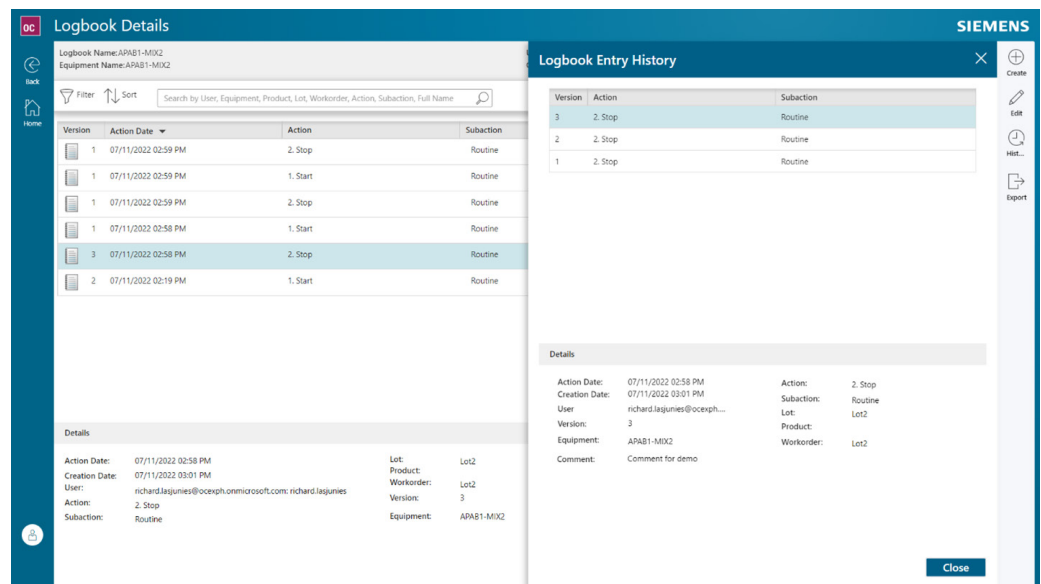
Integrating the customer IT infrastructure is easy using open standards. OpenID and REST API standards are widely used to integrate the customer authentication system and other external systems like ERP, MES and automations.

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

- System logbook

- Two-level entry review

- Electronic signature on logbook entry, modification and/or review upon configuration

System logbook: With this, users can group pieces of equipment into one single system logbook entity to accelerate logbook entry creation for every equipment element that is part of that system simultaneously. For example, in the figure below, creating a cleaning logbook entry in System A creates this same entry in the individual logbooks for the bioreactor, motor and two pumps.
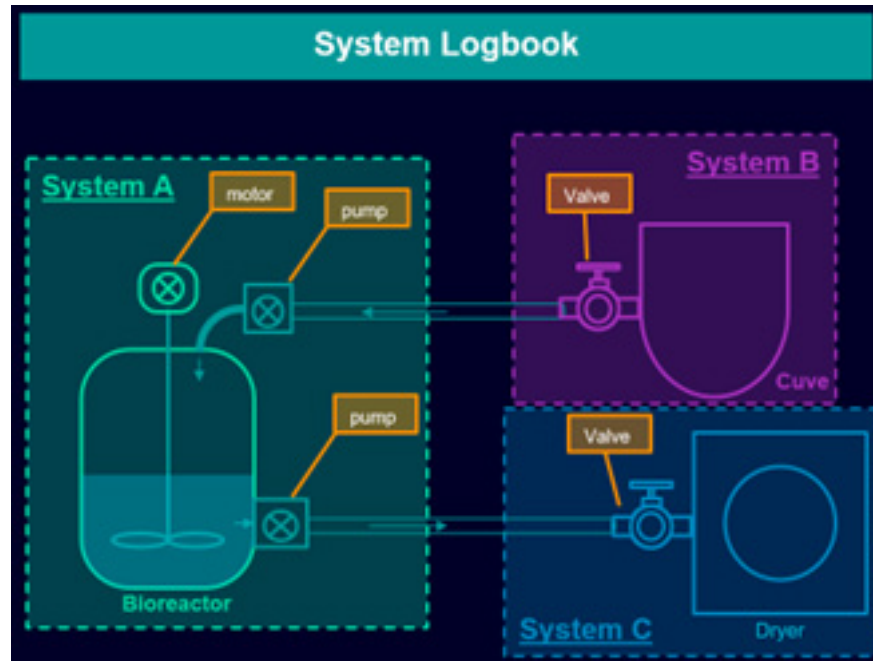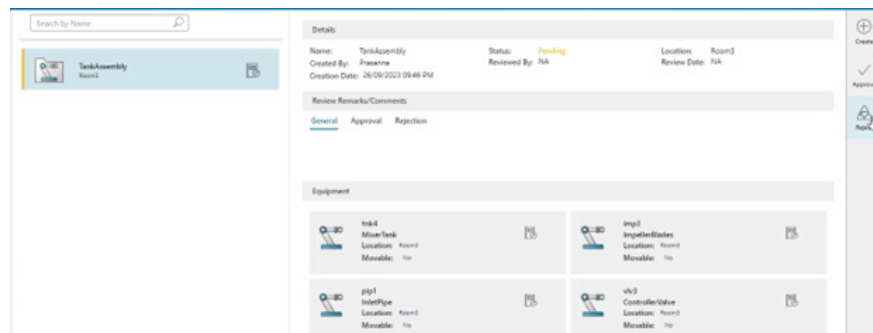
With this version's system logbook enhancement, users also get the following functionalities:
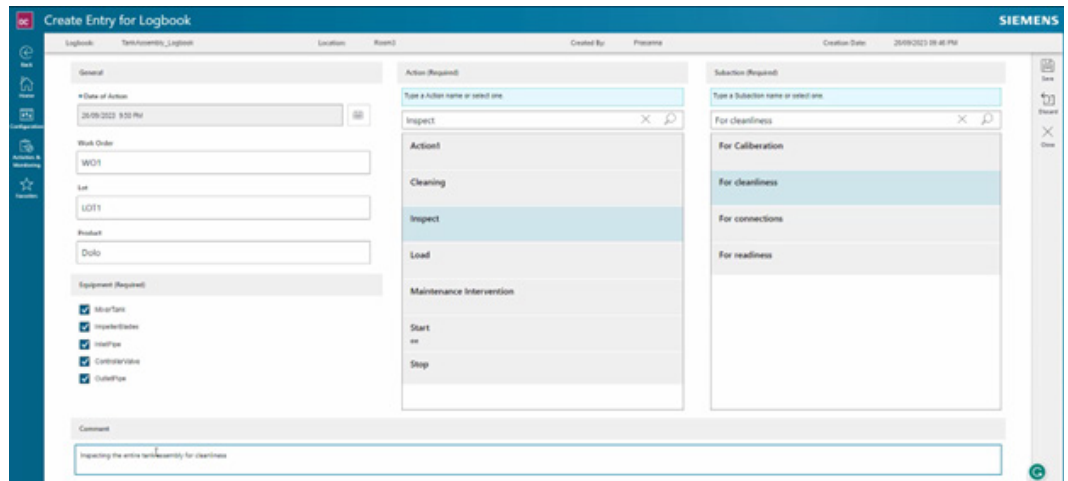
• Sytem logbook creation or modification
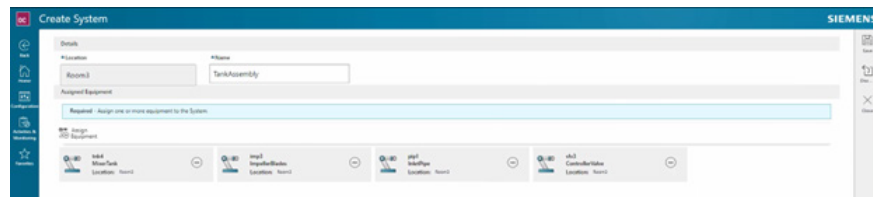
• System logbook approval before use

• Entry creation using a system logbook for a selective equipment list

- System logbook entries display or modifying with searching, sorting and filtering capabilities

- System logbook exporting

Two-level entry review: In the Opcenter EX PH 2305 version, a single-review process was available. With Opcenter EX PH 2311, users can configure a second review level.

Below, we outline the new process:

- During the first review level, users with a technician role can review entries that another user created or modifieded. After this step, the entries switch to a pending review status
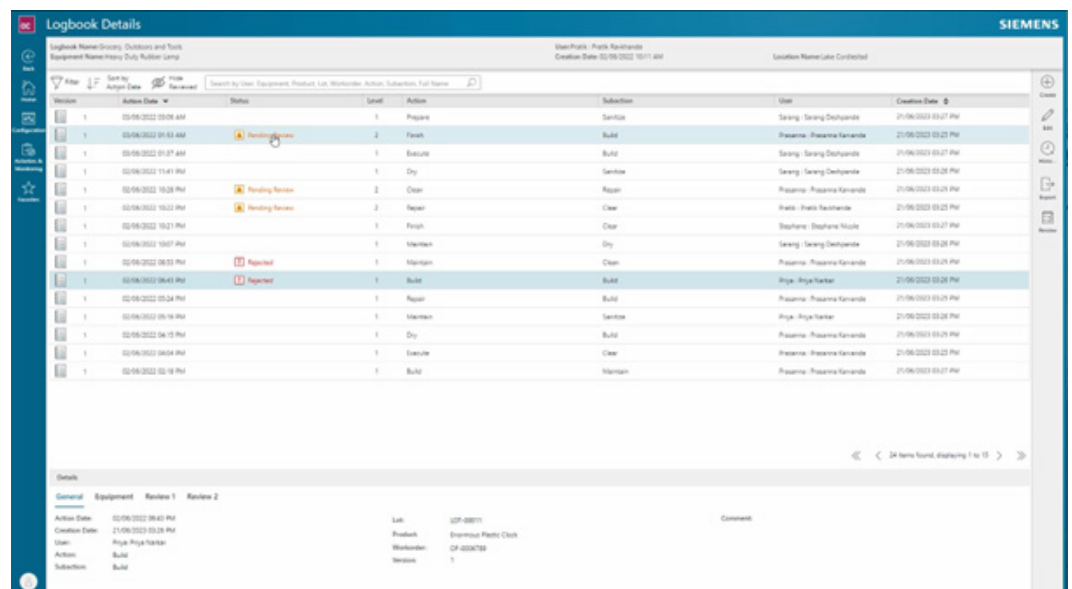
- Afterwards, only users with the quality assurance (QA) role are authorized to perform the second review level on any entries that passed the first review level and were not created, modified and reviewed by the same user previously
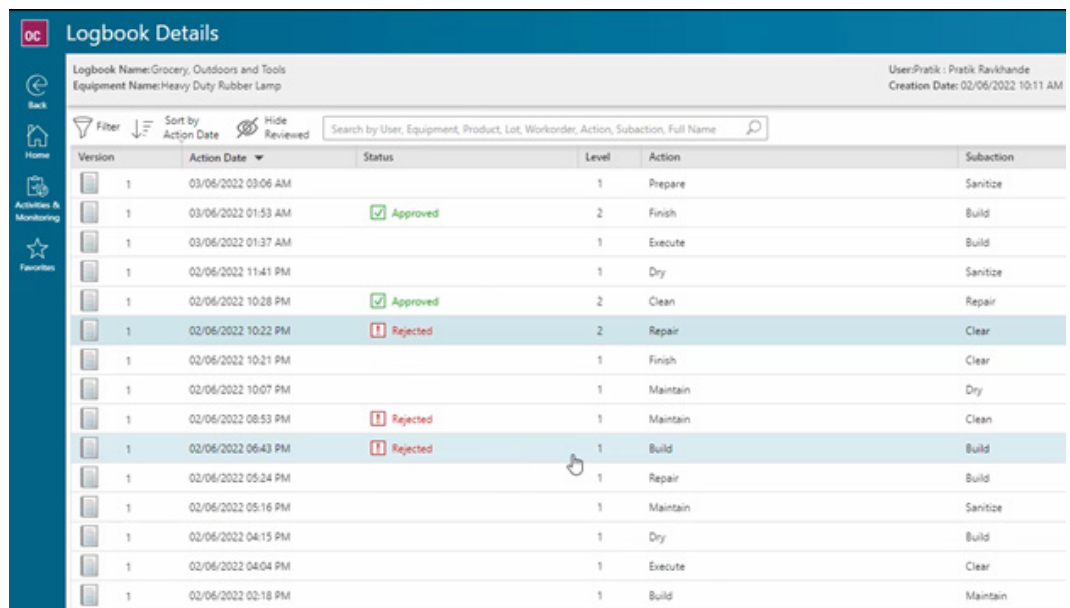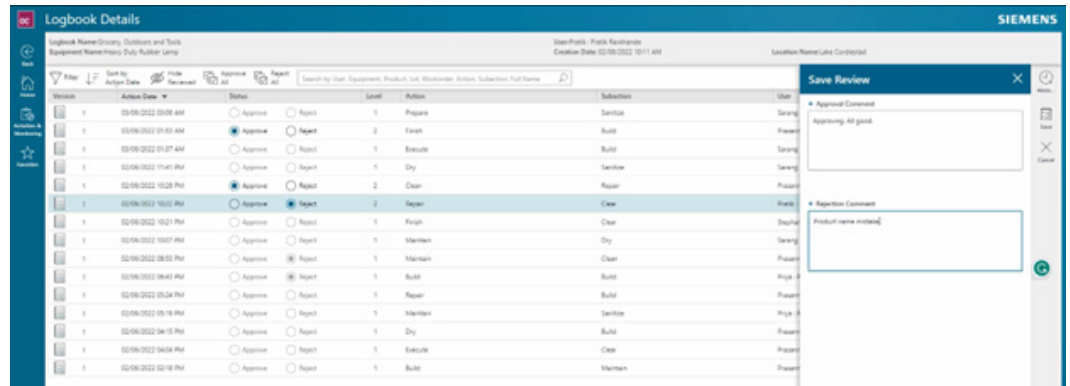
Electronic signature: Another notable enhancement in Opcenter EX PH 2311 is the ability to configure an electronic signature for logbook entry, modification and/or review actions.
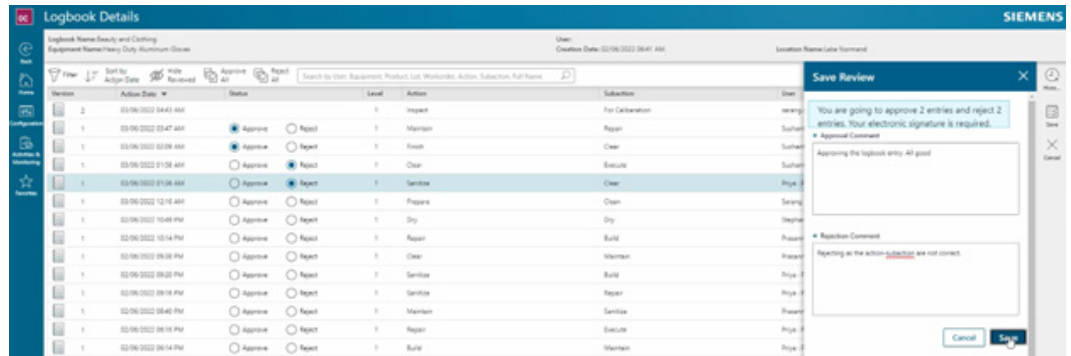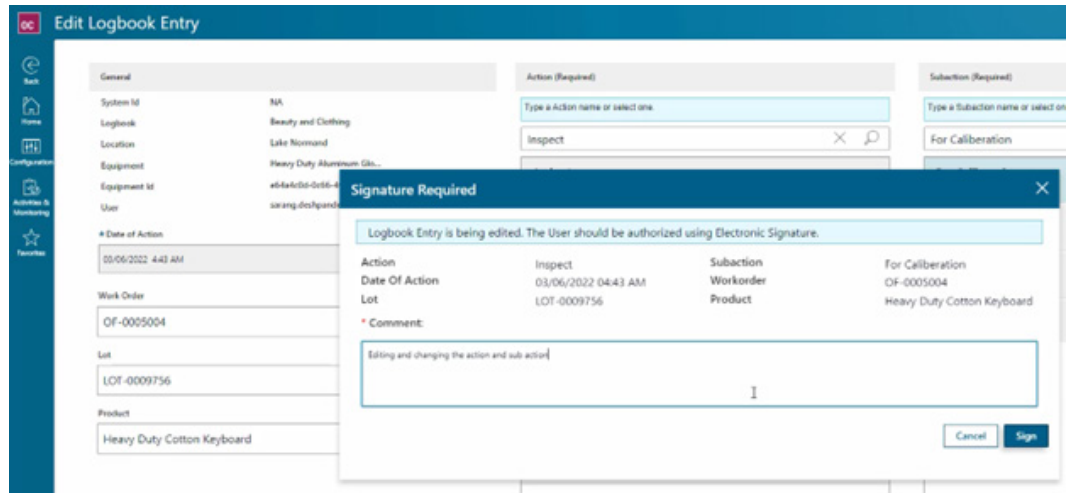
Benefits:

• Complex equipment and use case support

• Better review processes

Process Instruction enhancements

With this version of Opcenter EX PH, we integrated it with the Teamcenter® Share app, which is part of the Siemens Xcelerator business platform. Using Teamcenter Share helps users collaborate on design and engineering projects in the cloud. It allows users to upload, store and download files from the cloud anywhere across the globe. By integrating Teamcenter Share, users can enable Opcenter EX PH in the Teamcenter portfolio to use the Teamcenter cloud platform services.

Users can export process instructions or engineering data directly from the Opcenter EX PH export or import module into Teamcenter Share. These exported files are accessible to specified users directly in Teamcenter Share and can be downloaded.
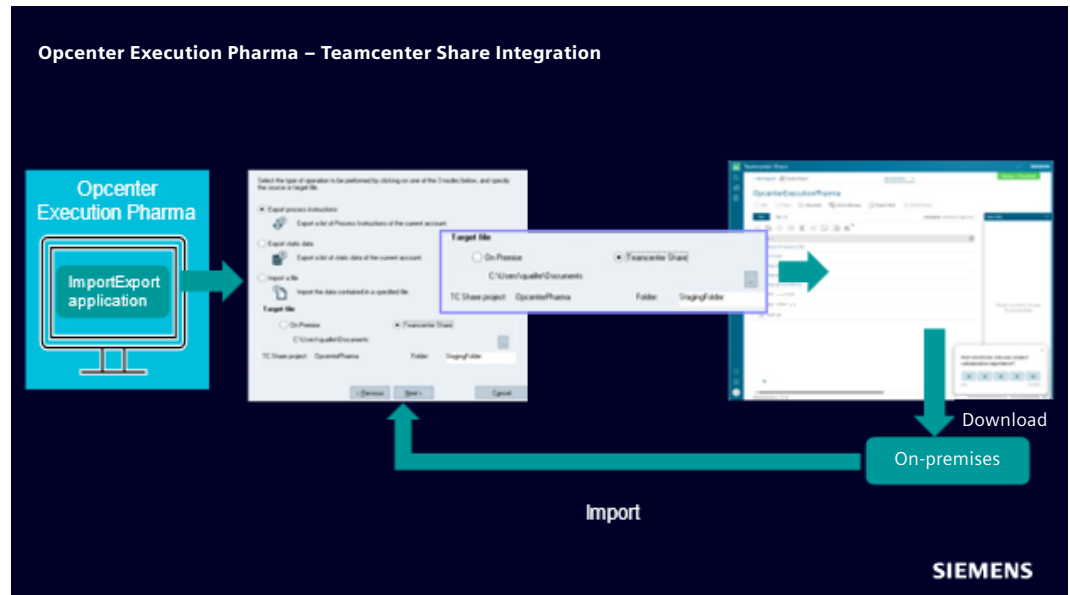
We improved the Process Instruction version upgrade to allow double signature control. By adding an electronic signature for this transaction, the administrator will have several possibilities to control the process instruction version upgrade for none, single or double signatures.

Although the Process Instruction validity period was previously accessible, the system now allows users to control this period when launching a work order. Users can launch a work order only if it is in the Process Instruction validity period.

Another addition is the custom fields (XFields), which users can access from the Process Instruction review application. This allows users access to advanced filtering capabilities for the work order list.

Additionally, we simplified the weighing tag to avoid confirmation pop-up messages. Also, the weighing module now supports weighing up to 99,999 per material request.

Benefits:

• Easy Process Instruction design collaboration between several sites using Teamcenter Share

• More controls for Process Instruction design

• More capabilities and efficient weighing activities

Extended PostgreSQL support
With the release of Opcenter EX PH 2311, PostgreSQL supports:

• Human machine interface (HMI) task list(s)

• Operator Cockpit

With this release, most deployments benefit from the PostgreSQL database, which companies can use to reduce project costs.

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 TCO and make it easier to find companies that provide cost-effective services.

Benefits:

- No acquisition costs
- Lower TCO

Improved serviceability, support and DAID
With each release, we improve the serviceability and supportability of our product. With Opcenter EX PH 2311, you can authenticate users for Active Directory multiple domain configuration.

Furthermore, we enhance the design architecture and infrastructure deployment (DAID) with guidance for better Process Instruction design and add application key performance indicators (KPI) for deploying alongside the PostgreSQL database.

Benefits:

- Easier administration and deployment
- Easier system definition

Opcenter EX PH 2311 enhancements summary

Scaling in the cloud

- On-premises weighing bar graph and scale communication

- Cloud provider and on-premises communication via an MQTT template

Operator Cockpit app

- Adaptable PBC

- Dose and sequence support for combination PBC

Equipment logbook app

- System logbook

- Two-level entry review

- Electronic signature required for logbook entry, modification and/or review upon configuration

Process management

- Increased electronic signatures with the Process Instruction version upgrade

- Process Instruction validity control at work order launch

- XFields accessible in Process Instruction review filters

- Export Process Instructions to Teamcenter Share

- Supports weighing up to 99,999 items per material requirement

Authentication enhancements

- Active Directory for multiple domain support

- Uses OpenID Connect for web portal and application programming interface (API) authentication

PostgreSQL support

- Extended support for HMI task lists and the Operator Cockpit

Service and support

- Simplify runtime deployment in silent mode

- Provide application KPIs for deploying PostgreSQL

This version upgrades technical aspects, enhances security and fixes bugs.