DIGITAL INDUSTRIES SOFTWARE

What's new in Opcenter Execution Pharma version 2205

Simplifying the Process Instruction program rollout

Benefits

- Reduce paper usage until all processes can be handled electronically
- Reduce development effort and risk by integrating MES and DCS
- Standardize processes and facilitate implementation across sites
- Make batch-relevant information reviews faster and safer

Summary

Opcenter™ Execution Pharma software (Opcenter EX PH), formerly known as the SIMATIC IT® suite electronic batch record (eBR), offers native integration between the manufacturing execution system (MES) and distributed control system (DCS) layer. Using Opcenter EX PH expedites the required design, execution and review steps and provides flexibility in the master batch record design process.

Opcenter Execution Pharma has moved to year- and month-based version numbering. Therefore, version number 2205 follows version number 6.2.4. Opcenter Execution Pharma version 2205 introduces several enhancements, increasing out-of-the-box features and simplifying the installation and footprint of the system.

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

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Features

- Process Instruction multilanguage/ translation support
- Work instruction enhancements
- HMI task list
- Design architecture and infrastructure design documentation
- System simplification with new service web console
- Openness of Weighing and Dispensing module

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 operating procedures. It also systematically controls execution at all stages, either human operations or operations controlled by the automation layer.

Using Opcenter EX PH 2205 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 2205 enables manufacturers in the life sciences industries to achieve operational excellence, accelerate time-to-market, reduce compliance costs and improve quality and productivity. Implementing 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. Managing master batch records (MBRs) facilitates the key process parameters.

One of the most requested features, Process Instruction multilanguage, is now available to manage translation end-to-end. The Process Instruction designer application has been improved to support translation of the text instruction, parameters and workflow task title. Translation can be performed directly in the Process Instruction designer application. The correct translation will be displayed when the work order is executed directly via the operator cockpit. The task list, operator instructions and history of tasks (tree view) display the localized instructions. Of course, electronic batch records reflect the localized instructions shown to operators.

To facilitate the lifecycle of the Process Instruction, the Export/Import application has been enhanced to support the transport of the translation by the local teams.

Feature benefits:

- Design once, run everywhere
- Easily manage translation
- Avoid duplicated process instructions
- Validate reduced effort

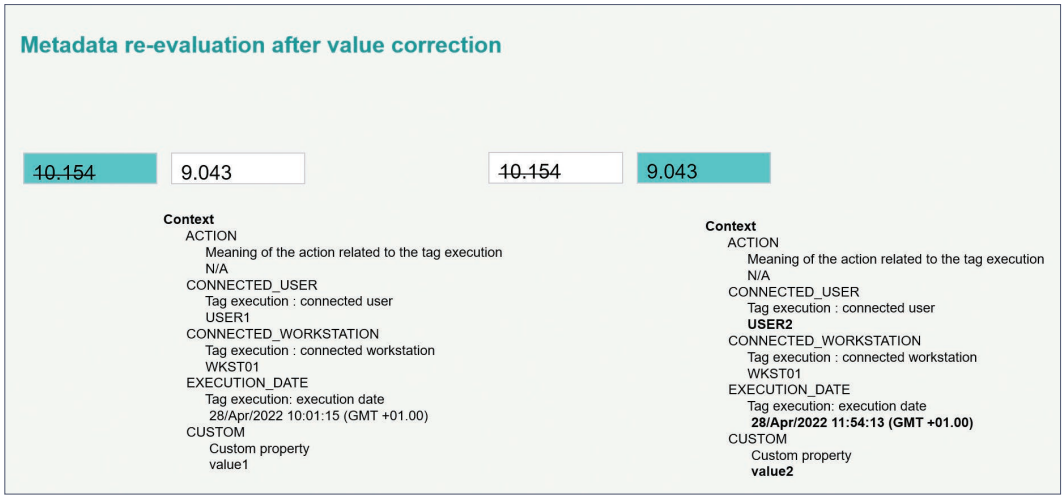
The work instruction engine has been enhanced to fit complex use cases. With this new release, tag metadata is re-evaluated after correcting the linked tag values for better reporting.

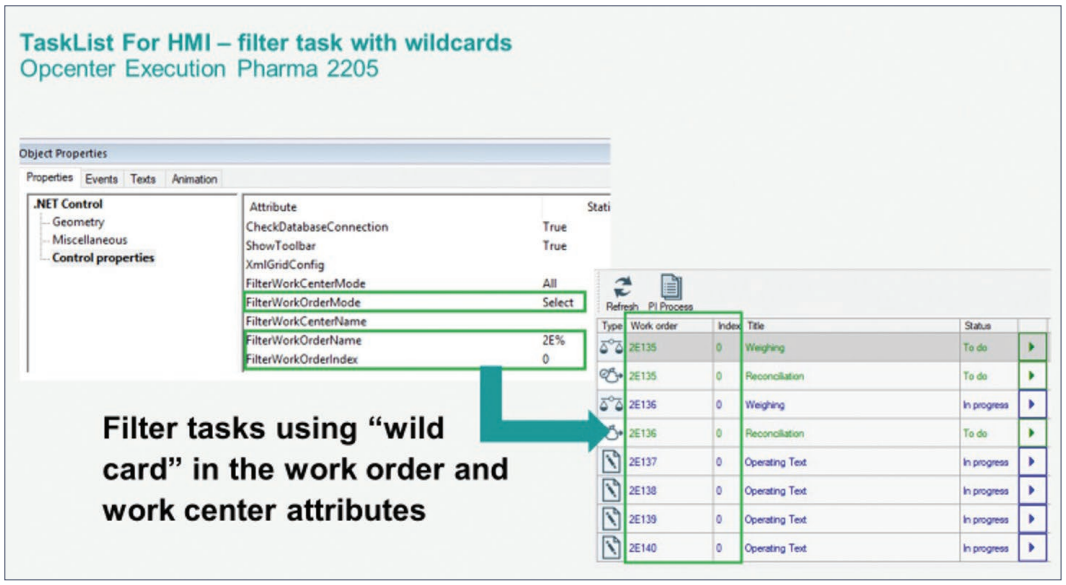
In addition of the work instruction engine enhancements, tag behaviors have been improved. Numeric tags improve the decimal precision check, with an additional mode enforcing minimal precision, preventing less precision than the one defined at design. The bar code reading tag has been refactored to support any type of bar code codification and specifically to support serial shipping container code (SSCC) codification. Equipment-read property tags have been enhanced for easier configuration.

Feature benefits:

- Enhance reporting based on metadata
- Improve data acquisition quality
- Provide more out-of-the-box tag features

For years, Siemens has provided a seamless integration between MES and DCS. With Opcenter Execution Pharma 2205, we have improved the integration with SIMATIC WinCC. It's now easier to filter MES tasks for each SIMATIC WinCC panel based on the work order, work center and the use of wildcards. We have also improved the behavior of the system while the SIMATIC WinCC operator is changing manually or by logging off automatically. Furthermore, the human-machine interface (HMI) task list performance has been improved in case of weak network reliability.





Feature benefits:

- Better performance
- Easier configuration
- More use cases are supported

To improve the serviceability and supportability of the system, we continue to simplify the installation and reduce the footprint, providing a lightweight portal to administrate Opcenter Execution Pharma services. This new option should be of interest to customers not using master batch record features.

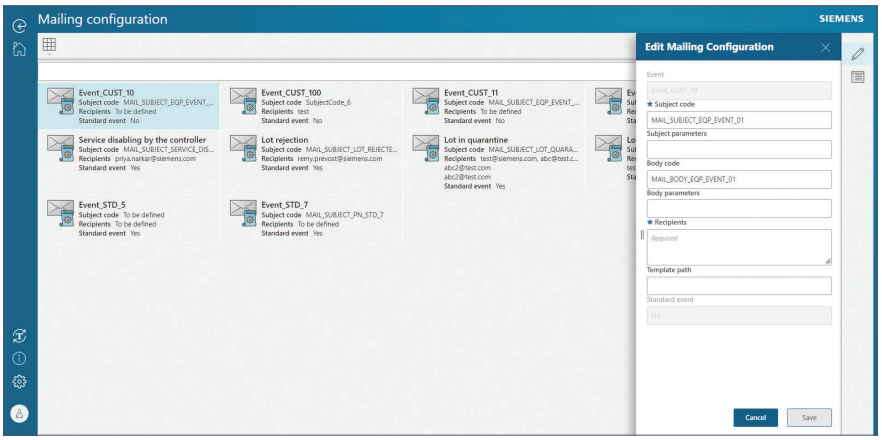
In addition, we are providing guidance to define the best architecture and the infrastructure. In the design architecture and infrastructure deployment (DAID) documents, integrators will find infrastructure templates, sizing tooling, application best practices and guidance on system administration. This documentation is based on performance measures and aggregating the results of dozens of project to avoid pitfalls and effortlessly define the system correctly.

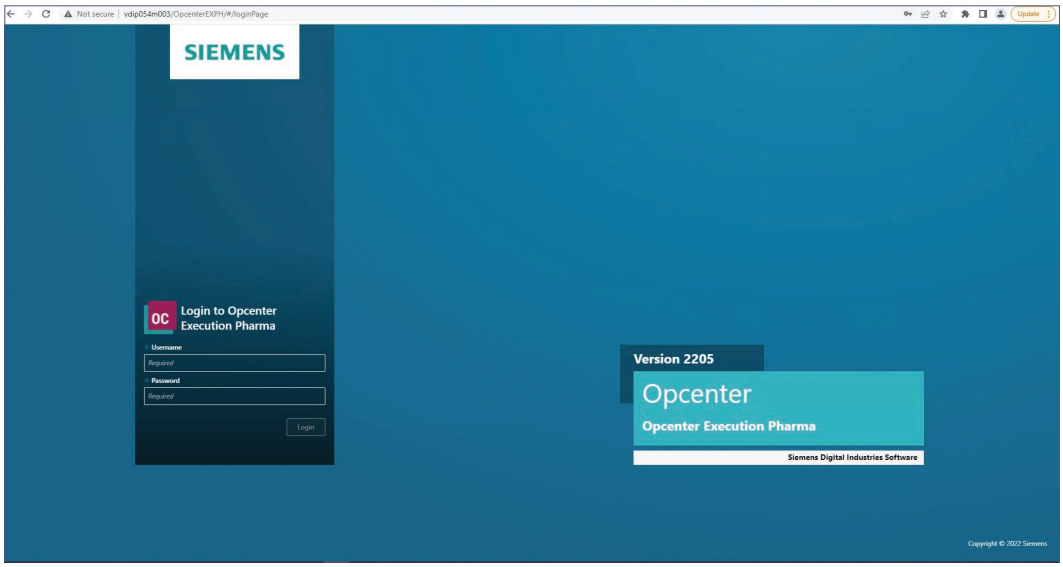
Feature benefits:

- Reduce footprint
- Easily and more effectively define a system

We have extended and simplified the product capability based on the Mendix™ app platform by providing an authenticate endpoint for Opcenter Execution Pharma application programming interfaces (APIs). You just need to configure the Mendix app so you can use the login page to effortlessly retrieve the access token to call the Opcenter Execution Pharma commands and oData endpoints.

It's also now possible to extend the Weighing and Dispensing module to delegate the scale bar graph execution or create specific scale drivers.





Feature benefits:

- Easier integration for external web system
- Support more customer needs

Enhancements to Opcenter EX PH 2205 include:

Process Instruction multilanguage

- Design and translate operating text and workflow
- Dynamic translation when executing work order
- Batch record translated
- Export/Import translated Process Instruction

Work instruction enhancements

- Re-evaluates metadata when correcting tag data
- Numeric tag decimal check
- SSCC support for bar code identification tag

HMI task list enhancements

- Filter tasks using wildcards
- Support multiple screens
- Automatically closes MES tasks when SIMATIC WinCC user logs off or auto logs off
- Performance improvements when network is not reliable

Serviceability and supportability

- Design architecture and infrastructure deployment: examples of default architecture, guidelines to size the system, the application, deployment guidance
- Installation simplification: service console without Opcenter Execution Foundation (EX FN) deployment

Weighing and Dispensing openness – extendable business logic for:

- Weighing remote bar graph
- External scale drivers

Federation authentication

- oAuth2/OpenID login endpoint

Windows 11 support

Technical upgrades and security enhancements

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