Enterprise Server Compliance Pack
EcoStruxure Building Operation

Introduction

Schneider Electric is a leading provider of Facility Automation Management Systems for the Life Science sector including pharmaceutical & medical device manufacturing and Biotechnology. EcoStruxure Building provides HVAC control, alarm monitoring and environmental monitoring for regulated (GxP) facilities worldwide.

The Compliance Pack is an add-on module to EcoStruxure Building to help regulated industries meet the compliance requirements for Electronic Signatures & Electronic Records that are in place in the region. This feature in our EcoStruxure Building Operation software provides facility-wide accountability and traceability of the environmental conditions that can impact the quality and safety of products developed in controlled environments in-line with the 21CFR Part 11 regulation.

Features

The Compliance Pack maintains a complete archive of all system events, consolidated into one reporting structure for effortless search and retrieval. It presents information required by customers and regulators to ensure environmental integrity of the total product manufacturing life cycle.

Controlled Access to the System

Utilizing the built-in security features within EcoStruxure Building, you can comply with 21CFR Part 11, restricting access to authorized & qualified individuals. In addition, the built-in access & security settings can be enhanced by applying further restrictions to the accessibility through the use of change control which can limit access by:

- Time of day
- Day of week
- Operator location
- Scheduling

Critical changes can be restricted to on site even where remote viewing and day-to-day modifications can be done remotely.

Electronic Signature & Audit trail

The Compliance Pack expands the basic activity logging accomplished by EcoStruxure Building by enhancing the the functionality of the standard log, enabling effective and fully configurable change control with the following features:

- Single or dual electronic signature application
- Change control that can be restricted only to specific objects in the system
- Change control that can easily be applied to all objects
- Every associated action is logged with the parameter that was changed
- Before & after parameter values including meta data

For each signature event, the change control signatures contain:

- The unique identifier of the person executing the signature
- The full name of the user who performed the action
- The geographical date & time stamp
- The meaning of the signature, such as approval, review, responsibility, and authorship

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Change control signatures

You can be confident that all changes are approved and explained, with no changes accomplished by a remote viewer. All actions requiring signature are applied contemporaneously within the log.

Long Term Electronic Record Storage with Digital Signing of Reported Data

The Enterprise Server can be configured for long term record and data storage with pdf reports that are protected by digital certificates. There is an assurance of end-to-end data integrity and a knowledge that the reports have not been falsified in any way.

- Historical data, trend log data, event log and audit trail data is stored in a high-capacity, open, PostgreSQL database.

Specifications

Compatibility

EcoStruxure Building Operation software ....version 3.2.1 and later

Part number

Compliance Pack – includes ES level TimescaleDB, Digital PDF Signing, Change Control,
for Enterprise Server and all child level SmartX servers..SXWSWCMPLPK001

- The database is supported with TimescaleDB.

- The capacity is limited only by the size of the selected storage media.

- All historical data and audit trail information is transferred in an encrypted fashion from EcoStruxure Building Operation to the PostgreSQL database.

- The data is available natively to the viewers built into the EcoStruxure Building Operation clients. No other software is required to access the data throughout the full retention period.

- Preformatted, easy to read reports in pdf format and protected with digital certificates can be generated when using the Compliance Pack.

Powered by EcoStruxure Building Operation

By making use of the Enterprise Server with Compliance Pack, it is possible to build a combined yet segregated system that can satisfy the stringent requirements of a validated site while also delivering the economies of using a single system. By segregating the Environmental Monitoring System (EMS) from the Building management System (BMS), day-to-day operations are not burdened by stringent Standard Operating Procedures because the validated data is segregated from the non-validated data.

An Enterprise Server with Compliance Pack can function as the EMS while an Enterprise Server without the Compliance Pack can function as the BMS. Management level activities and sitewide viewing can be accomplished from an EcoStruxure Building Operation Enterprise Central that supervises both the EMS and the BMS. Identical type hardware and software reduce training time and facilitates ease of operation & maintenance.

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