EcoStruxure™
Innovation At Every Level

Compliance Pack

EcoStruxure Building Operation

EcoStruxure™ Building

Introduction

Schneider Electric is a leading provider of Facility Automation Management Systems for the Life Science sector including pharmaceutical ans 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 and Electronic Records that are in place in the region. This feature in our EcoStruxure Building Operation software provides facility-wide accountability and trace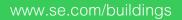ability of the environmental conditions that can impact the quality and safety of products developed in controlled environments in-line with the 21CFR Part 11 regulation.

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 and qualified individuals. In addition, the built-in access and security settings can be enhanced by applying

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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 and Audit Trail

The Compliance Pack expands the basic activity logging accomplished by EcoStruxure Building by enhancing 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 and 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 and time stamp
- The meaning of the signature, such as approval, review, responsibility, and authorship

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

EcoStruxure Building Operation 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 are stored in a high-capacity, open, PostgreSQL database.
- 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.

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- 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.

Based on GAMP5 computer system categorization, EcoStruxure Building Operation is category 4 software.

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

Specifications

Compliance Pack	
Compatibility	
EcoStruxure Building Operation software	version 3.2.1 and later
Part numbers	
Regulated Industries Compliance Pack option For one Enterprise Server or one Enterprise Central * SXWSWCMPLPK001 includes TimescaleDB connection option (SXWSWESDBTS001 or SXWSWECDBTS001) and PDF signing option (SXWSWESPDFSS01 or SXWSWECPDFSS01).	SXWSWCMPLPK001*
Regulated Industries Compliance Pack option For one Enterprise Server for Linux or one Enterprise Central for Linux * SXWSWCMPLPKL01 includes TimescaleDB connection option (SXWSWESDBTSL01 or SXWSWECDBTSL01) and PDF signing option (SXWSWESPDFSSL1 or SXWSWECPDFSSL1).	SXWSWCMPLPKL01*

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