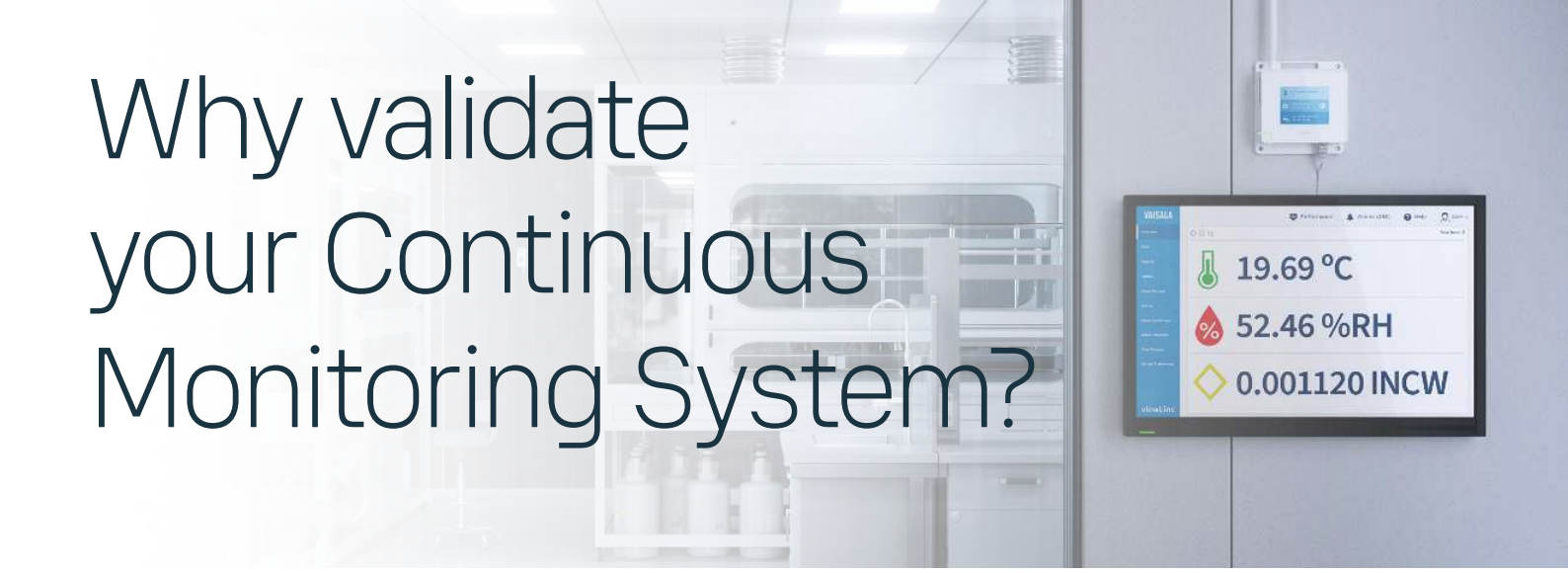
VAISALA

Continuous Monitoring System Validation Solutions

Documentation & services
for GAMP/GxP compliance

Why validate your Continuous Monitoring System?



Validation is essential in pharmaceutical, biological, and medical device manufacturing and distribution. Poorly executed validation is a risk to the quality of your monitoring software implementation, especially with complex computerized systems. Ensuring that your Continuous Monitoring System (CMS) is properly validated proves that the system is fit for its intended use. This in turn helps to protect consumers by ensuring product quality.

Vaisala VaiNet Wireless Temperature & Humidity Data Logger RFL100

To ensure that your system fully complies with Good Manufacturing Practice (GMP) we recommend using the International Society for Pharmaceutical Engineering's Good Automated Manufacturing Practice (GAMP) methodology. GAMP 5 is a risk-based approach to GxP-compliant computerized systems that uses pragmatic and practical guidance to ensure systems are fit for their intended use.

Vaisala simplifies compliance

Vaisala has developed a suite of products and services to help you validate your CMS, ensure quality in your products, and protect both your customers and your reputation. These include:

- A comprehensive set of validation documents that help you integrate your CMS into your Quality Management System
- A standard process for system qualification and documented evidence of control for your auditors
- A comprehensive set of Installation Qualification and Operation Qualification (IQ/OQ) protocols to help you meet your regulatory requirements
- A GxP documentation package to help you implement your system following the guidance set out in GAMP.

All these documents have been designed to complement each other. However, depending on your quality system requirements, you may choose to use the IQ/OQ independently.

IQ/OQ documentation package

As the manufacturer of your Continuous Monitoring System, Vaisala has unmatched insight into the system's architecture, features, and functions and how these relate to GxP processes. We developed these installation and operation protocols based on a solid risk assessment to ensure that you and the end users of your products are protected.

IQ/OQ protocol

Installation Qualification (IQ)

The Installation Qualification details the steps necessary to install the CMS software and documents the installation parameters and variables. This protocol provides you with full documentation of the hardware baseline of the system, including:

- The server
- Sensing instrumentation
- Communication devices

It also verifies the presence of the necessary documentation to support ongoing operation of the system throughout its lifecycle, such as relevant SOPs, calibration certificates, and user manuals.

Operation Qualification (OQ)

The Operation Qualification provides evidence that your CMS functions as it should, meeting the needs outlined in your user requirements specification (URS) and encompassing all GxP-related system capabilities, including:

- Audit trails
- Tamper-proof data
- Other requirements of 21 CFR Part 11, Annex 11 and PFSB 040122

These processes are thoroughly challenged through qualification in the OQ based on the risk assessment included in the GxP documentation package.

"Vaisala validation documentation helps our startup and go-live dates immensely. Their IQ/OQ protocols are aligned with our software quality deliverables. This reduces approval time, which ultimately reduces costs. The test scripts are concise and test pertinent attributes of the hardware and software, ensuring the system's functionality meets its intended use."

Mike Marino, Manager, Facilities Operations

Vaisala VaiNet Access Point AP10

GxP documentation package

The goal of the GAMP approach is to ensure that the monitoring system is fit for purpose and implemented in a controlled manner. The GxP documentation package provides the required specifications, which are then verified within the IQ/OQ. These documents address the typical needs of monitoring system owners in regulated markets but are also adaptable for specialist requirements.

User requirements specification (URS)

- Defines your essential capabilities for the Vaisala Continuous Monitoring System to fulfil its intended role in your process
- Provides a clear and concise list of requirements for a typical continuous monitoring application
- Gives the option to add new requirements according to your unique business processes

Functional specification (FS)

- Outlines all functions of the Vaisala Continuous Monitoring System
- Enables stakeholders to evaluate the CMS as a candidate system by comparing to a URS
- Every requirement in the URS is fulfilled by a function in the FS

Traceability matrix (TM)

- Ensures requirements are traceable through the assessment and testing processes
- Enables verification that each requirement from the URS is fulfilled by a corresponding function in the CMS
- Verifies that each requirement and corresponding function has been fully evaluated through risk assessment, IQ testing, and OQ testing

Risk assessment (RA)

- Outlines the CMS functions that are critical to preserving the safety and efficacy of GxP products
- Provides justification for the items in the Vaisala CMS that will be tested (or not tested)
- Serves as a guide for your testing efforts

Validation services

Vaisala also offers CMS validation as a service. Our expertise and understanding of regulation in the Life Science industries allows us to validate the system quickly and expertly, ensuring your system validation is complete and ready for regulatory scrutiny.

Our validation engineers can collaborate directly with your team to qualify and document your system, providing you with the ideal introduction to the CMS and its place within your regulated environment. Our engineers have executed our IQ/OQ protocols in hundreds of viewLinc applications, and their understanding of best practices in Vaisala instruments, networks, and system functionality is unsurpassed. While onsite, they will ensure your staff become familiar with the CMS and its supporting documentation.

Solutions to suit your resources

Vaisala provides solutions for critical environments with reliable hardware and user-friendly software. Combined with our responsive and knowledgeable customer support, our software and sensors safeguard life science assets in distribution, processing, and manufacturing facilities, laboratories, and cleanrooms. Wherever regulated products require controlled conditions, gap-free environmental data, and presentation-quality records, a fully validated and documented CMS will save on the time and costs of compliance.

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