

VAISALA

Continuous Monitoring System Validation Solutions

DOCUMENTATION & SERVICES
FOR GAMP/GXP COMPLIANCE

VAISALA

Simplicity & Compliance

Continuous Monitoring System Validation



Why Validate Your Continuous Monitoring System?

Validation is essential in pharmaceutical, biological and medical device manufacturing and distribution. A 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 fulfill the ultimate goal of protecting consumers by ensuring product quality.

An inadequately qualified CMS can result in unwanted observations at inspection time, and uncomfortable questions during customer audits.



To ensure that your system complies fully with Good Manufacturing Practice (GMP) we recommend using the ISPE Good Automated Manufacturing Practice (GAMP) methodology as a reasonable and systematic guide to ensure your monitoring system software performs as expected. GAMP 5 specifically is a risk based approach to GxP-compliant computerized systems using pragmatic and practical industry guidance to achieve computerized systems fit for intended use in an efficient and effective manner.

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. We offer a comprehensive set of validation documents that help you integrate your CMS into your Quality Management System, and provide a standard process for system qualification and documented evidence of control to your auditors. We offer a comprehensive set of Installation Qualification and Operation Qualification (IQOQ) protocols to help you meet your regulatory requirements and a GxP Documentation package to help you implement your system following the guidance set out in GAMP. All the documents have been designed to complement each other. However, depending on your Quality System requirements, you may choose to use the IQOQ 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 founded on a solid risk assessment to ensure that you and the end users of your products are protected.



“The Vaisala IQ/OQ protocol is very nicely done... [it's] very complete and saved us 2-3 weeks of work.”

Stephan Montag

“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*



IQ/OQ Protocol

Installation Qualification (IQ)

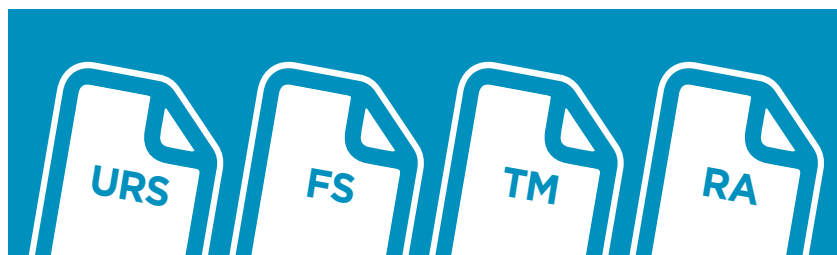
The Installation Qualification details the steps necessary to install the CMS software, and documents the installation parameters and variables. This protocol provides you with full documentation of the hardware baseline of the system including: server, sensing instrumentation, and communication devices. 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 was designed to, meeting the needs outlined in your User Requirements Specification (URS) and encompassing all GxP-related capabilities of the system, including: audit trails, tamper-proof data, and other requirements of 21 CFR Part 11, Annex 11 and PFSB 040122. These processes are thoroughly challenged in the OQ based on the Risk Assessment included in the GxP Documentation Package.

GxP Documentation Package

The goal of the GAMP approach is to ensure the monitoring system is fit for its intended use and implemented in a controlled manner. These goals are achieved through a specification and testing process. The required attributes of the system are described in specifications, and then verified in testing. The GxP Documentation Package provides the required specifications, which are then verified within the IQOQ. These documents cover the typical needs of monitoring system owners in regulated markets, but are also extensible to cover specialized needs.



THE GXP DOCUMENTATION PACKAGE

User Requirements Specification (URS)

The User Requirements Specification defines the capabilities you have deemed necessary for the Vaisala Continuous Monitoring System to fulfil its intended role in your process. This document provides a clear and concise list of requirements for a typical continuous monitoring application, while providing the option to add new requirements according to your unique business processes.

Functional Specification (FS)

The Functional Specification outlines all functions of the Vaisala Continuous Monitoring System. This document can be used by stakeholders to evaluate the CMS as a candidate system by comparison to a User Requirements Specification. Every requirement in the URS is fulfilled by a function in the FS.

Traceability Matrix (TM)

The Traceability Matrix ensures traceability of the requirements through the assessment and testing processes. The Traceability Matrix is used to verify that each requirement from the URS is fulfilled by a corresponding function in the CMS. It verifies that each requirement and corresponding function has been fully evaluated through Risk Assessment, IQ Testing, and OQ Testing.

Risk Assessment (RA)

The Risk Assessment outlines the CMS functions that are critical to preserving the safety and efficacy of GxP products. This Risk Assessment provides justification for the items in the Vaisala CMS that will be tested (or not tested). This analysis serves as a guide for your testing efforts. A central tenet of GAMP philosophy is to leverage supplier involvement. Items identified as not requiring testing in the CMS IQOQ have either been tested thoroughly by Vaisala during system development, or are tested elsewhere during the implementation process.

Validation Services

We also offer CMS Validation as a service. Vaisala's 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.

Let our Validation Engineers become an extension of your Quality organization. Our experts collaborate directly with your team in the qualification and documentation of your system, providing you with the ideal introduction to the CMS and its place within your regulated environment. Our Engineers have executed IQOQ protocols in hundreds of applications, and their understanding of best practices in 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. Choose from documentation and protocols that integrate easily into your Quality System, or bring us into your operations to provide fast, expert execution.



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