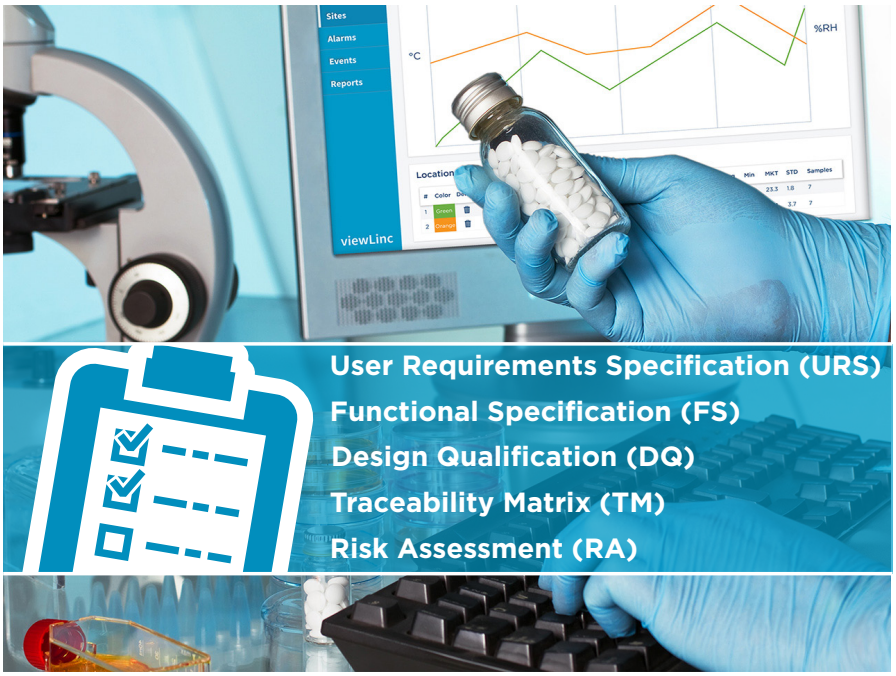
# GxP Documentation Package for Vaisala viewLinc Continuous Monitoring System




## Features

- System validation documentation package designed to provide ISPE Good Automated Manufacturing Practice (GAMP) methodology for viewLinc system validation.
- Available in English, Portuguese, Japanese, and Chinese.
- Specify the required attributes of your viewLinc system using the viewLinc-specific GxP documentation:
  - User Requirements Specification
  - Functional Specification
  - Design Qualification
  - Traceability Matrix
  - Risk Assessment

Vaisala viewLinc Continuous Monitoring System is ideal for GxP-regulated applications and environments that contain high-value products. If you are required to maintain compliant environmental monitoring methods and documentation, Vaisala can provide a GxP System Documentation package for the viewLinc monitoring system to help ensure your system implementation fulfills the recommendations of ISPE Good Automated Manufacturing Practice (GAMP).

## Specify, then verify

The goal of the GAMP approach is to ensure, through specification and testing, that the monitoring system is fit for its intended use and implemented in a controlled manner. The required attributes of the system are described in specifications, and then verified in testing. The GxP Documentation Package provides the required specifications, which can then be verified using the Vaisala IQOQ (Installation Qualification/Operation Qualification) 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.

## Design Qualification (DQ)

The Design Qualification ensures that the Vaisala Continuous Monitoring System is appropriately designed and capable of meeting the requirements of the system user. The DQ compares individual User Requirements in the URS against the system functions, and provides traceable verification that each User Requirement is fulfilled by a function listed 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.

## More information

For more information on the GxP Documentation Package for viewLinc, see www.vaisala.com/gamp-gxp-validation.

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www.vaisala.com

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