

Temperature & humidity mapping/validation service



Current Good Manufacturing Practice requires that environments used to manufacture or process drug products be validated to ensure a high degree of quality and efficacy. According to the FDA's Code of Federal Regulations Title 21, process validation, including the validation of environments, must be performed regularly to ensure conditions match the stability needs of the products.

Mapping service includes:

- Thermal mapping and analysis of environments
- Mapping equipment used during the service
- Mapping study documents

Vaisala mapping service is currently available in Great Britain, Europe, and Japan. However, we offer mapping data loggers, equipment, and expertise in other regions. For more information, please contact your local sales team.

Documentation Features

- Security status of the data is identified on every report
- Each time data is downloaded, vLog generates a unique checksum value, which is the Logger File ID number.
- File ID numbers are referenced in logger file creation reports, data logger files, trend graphs, tabular data, all printed reports

Validation/Qualification Simplified

Vaisala mapping/validation service provides you with an in-depth understanding of the variability of conditions in your controlled environments. Our service technicians will perform studies with Vaisala vLog software and Vaisala high-performance data loggers.

The vLog software provides documentation that is compliant with all global regulations, including:

- 21 CFR Part 11 and Annex 11.
- cGMP and Current USP: 21CFR part 210-211et 11 sections 1079 / 659 / 1118
- ISPE, Good Practice Guide, Cold chain management, 2011
- WHO Technical Report Series, No. 961, 2011 May 2015 Annex 9: Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products.



vLog generates secure files that ensure data has not been altered or modified in any way. Traceability of electronic data is achieved using administrative options (security levels), the Audit Trail report, and data logger File ID Numbers. These features ensure secure and accurate data in the graphs and reports contained in the study documents.



Superior Device Accuracy

Vaisala data loggers provide high accuracy and measurement stability. This allows the devices to reliably map extensive areas without time-consuming and **costly pre- and post-study calibrations**. Another time saver is simple batch setup. Vaisala field service technicians can configure graphs and reports to meet your quality system needs. Simply review, sign, and store your completed validation records.



Vaisala Calibration Means Reliable Mapping Data

All devices used for Vaisala mapping service are calibrated in our regional service centers in Boston, Finland, China, or Japan. Calibrations are accredited to ISO/IEC 17025:2017, ANSI/NCSL Z540-1-1994, and traceable to SI units through national metrology institutes, such as NIST (USA), MIKES (Finland), or equivalent national organizations that maintain measurement standards.

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