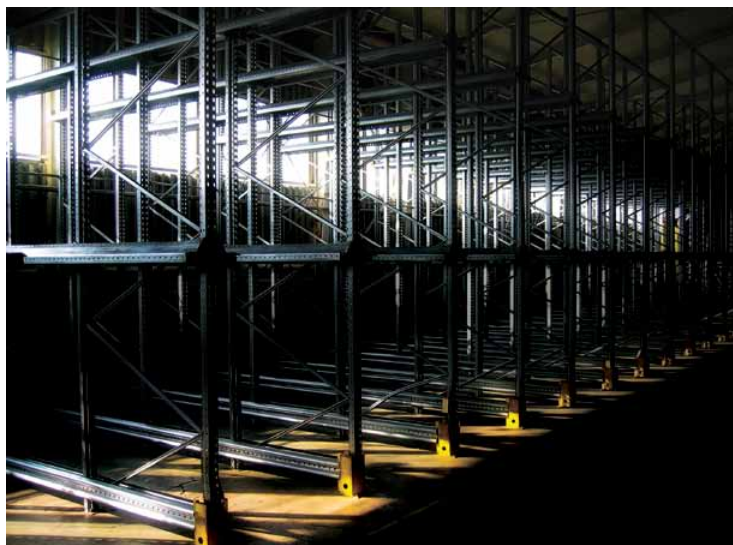


Vaisala Validation Services

/ Efficient, Compliant Temperature & Humidity Mapping

As pharmaceutical, biotechnology and medical device manufacturers and distributors are scrutinized more closely by enforcement agencies around the world, many companies are seeking validation solutions for their controlled environments.

Vaisala reduces your risk of losing product or failing inspections by providing skilled execution of thermal and humidity validation studies that will give you a thorough understanding of the temperature dynamics of your controlled areas. This knowledge will allow you to manage your critical environments more effectively and better validate temperature and humidity over time.



Adding Excellence to your Quality Management System

To ensure compliance with Good Manufacturing Practices, organizations must demonstrate the appropriate control over environmental conditions for storage and distribution areas. Therefore, the first step in your quality plan should be to establish an in-depth understanding of the temperature properties of these areas by performing a mapping study. However, mapping requires both equipment and expertise in validation and calibration.

Vaisala offers world-class validation performed by our skilled technicians that includes a validation plan and detailed mapping protocols to produce mapping studies. In-depth, post-validation reports will increase your knowledge of your controlled environments. The documentation package and expertise will help show that your company is following the current best practices in validation and documentation of controlled environments. We provide the expertise and the equipment for validation so that Quality and Facility managers can focus on their day-to-day work.

Reducing Risk in Life Science Environments

Over the past 20 years we've designed innovative devices and software especially for controlled environments in Life Science industries, including:

- Pharmaceuticals
- Biotechnology
- Medical device
- Nutraceuticals

Applications:

- Refrigerators/Freezers/
Cold rooms
- Incubators
- Stability Chambers
- Warehouses/Storage areas/
Distribution Centers

"Vaisala Validation services were an economical choice, saving us many days of work. We also learned a lot with the Vaisala technician answering questions and providing advice..."

*Senior Director of Facilities,
US-based clinical-stage
biotechnology company*

Detailed, Accurate Documentation

To perform the mapping study, the validation service technician collects and analyzes data in your area, room or chamber, identifying any hot or cold spots in the process. Technicians can perform challenge tests on empty/loaded chambers, or under static/dynamic use for storage areas. The tests can employ thermocouples or sensor-equipped data loggers as the application requires. Vaisala's validation software is used to download and analyze test results. All mapping study documents are secure and presentation quality. Reports include minimum, maximum, and average value statistics and Mean Kinetic Temperature and can be easily exported to generic .csv files for further analysis.

Temperature sensor range:

-90 to 70 °C, up to 0.1 °C accuracy and 0.02 °C resolution

Relative Humidity sensor range:

0 to 90 % RH, up to 1 % accuracy and 0.05 % resolution

Aids Compliance with:

21 CFR Part 11
EU Annex 11



Validation Expertise at your Service

Our experienced validation technicians will review your study with you step-by-step, answering questions about the results and increasing your knowledge of your controlled environments so you will be better prepared to implement a GxP-compliant monitoring system based on the study results. Our validation system is built for fast deployment and will save you time and costs by quickly providing study results in which you can have a high degree of confidence.

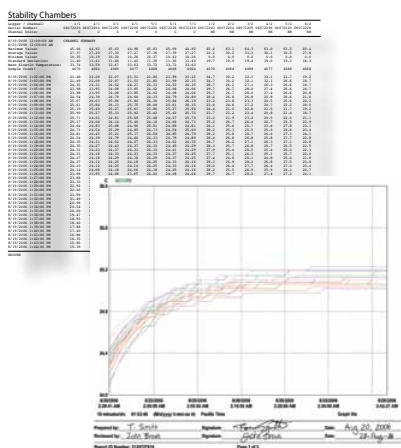
Your validation service includes:

Site Survey	Your validation technician will meet with you to assess your needs, the application to be validated, and any logistical constraints.
Validation Plan	Your validation technician will provide a complete plan for your study(s) as well as a follow up schedule.
Resulting Studies	Your technician will review the mapping study(s) with you in detail, outlining any problem areas and making suggestions for improved monitoring applications.

The Vaisala Difference

For decades Vaisala has advanced the science, accuracy and industry standards of humidity and temperature measurement and documentation for GMP-compliant environments. With our unique system that combines autonomous internal memory and extended battery life for independent recording, we provide the most reliable system wherever data on environmental conditions are critical.

Our environmental validation system is calibrated to a minimum of 5 points to NIST-traceable standards in our own manufacturing facilities. Unlike most mapping equipment, each sensor in our system has a stated accuracy for its humidity and temperature sensors for up to one year of field use.



"The Vaisala validation system reduced the set-up time for temperature mapping by at least 80 %."

- Stephanie Cowan, Validation Specialist

Reliable Solutions, Globally

If your manufacturing or distribution applications are GxP-regulated or subject to other stringent quality compliance guidelines, Vaisala's systems will deliver best-in-class accuracy and reliable data that is customized to the needs of your environment.

In over 140 countries, Vaisala is supported by a worldwide network of direct sales, manufacturing facilities and distributors.

Learn more:

<http://cn.vaisala.com/cn/lifescience/Pages/default.aspx>*

* You are welcome to contact us by emailing chinasales@vaisala.com. Call +86 10 5827 4100 or Fax : +86 10 8526 1155

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Please contact us at
www.vaisala.com/requestinfo



Scan the code for
more information

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