THE ADVANCED GUIDE TO **TEMPERATURE MAPPING**

EVERYTHING YOU NEED TO KNOW, FROM EQUIPMENT SELECTION TO PROCESS STEPS TO STRATEGY DESIGN.

PERFORMANCE VALIDATION
100% EMPLOYEE-OWNED

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Introduction.

Temperature mapping, along with equipment and strategy, plays a role in how pharmaceutical and life science organizations maintain required storage conditions. In this comprehensive guide, our temperature mapping experts provide in-depth insights and guidance on how to get started.

According to the International Society for Pharmaceutical Engineering (ISPE) Good Practice Guide: Controlled Temperature Chambers, "temperature mapping is the process of measuring and documenting temperatures at multiple predefined locations within the storage location over a specified study duration to verify the capability of a controlled temperature chamber to maintain predetermined temperature specifications."

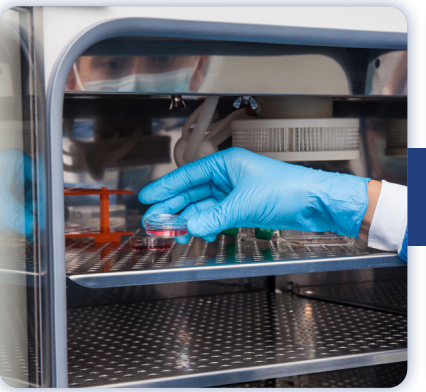
Temperature mapping is critical because it allows you to:

- Verify the facility or chamber is designed and operating properly to maintain required storage conditions.
- Verify storage conditions are continually met for the entire storage space and under extreme conditions (i.e., empty or full, winter or summer).
- Identify hot and cold spots for permanent monitoring/alarming.

Temperature mapping is required within a wide variety of spaces and applications to verify parameters such as temperature uniformity, steam penetration, sterility, and freezing rates.

Warehouses

Ensure optimal storage conditions for sensitive products in storage, shipping, receiving, and packaging warehouses.



Incubators / Stability Chambers

Promote growth conditions and product stability studies that maintain the integrity and efficacy of sensitive materials.

Cryogenic Storage

Provide consistent and ultra-low temperatures throughout the biological or cell storage facility.

Cold Storage

Maintain uniform temperature distribution, minimizing temperature fluctuations and preserving the quality and safety of perishable goods.

Ovens

Ensure accurate and consistent temperature profiles throughout the drying processes and high heat depyrogenation.

Logistics

Maintain consistent temperatures during transportation between the manufacturer, storage, distribution, and retail.

Autoclaves / Steam-in-Place (SIP)

Ensure sterility of equipment and instruments, media, and products with the temperature mapping process.

Controlled Rate Freezers

Monitor temperature gradients and cooling rates, ensuring a controlled freezing profile of material to maintain viability and integrity.

Lyophilizers

Facilitate the controlled freeze-drying of liquid and solid vial products, ensuring optimal conditions for preservation and stability.

TEMPERATURE MAPPING REQUIREMENTS

Temperature mapping is required by regulatory agencies and industry guidelines, which can be challenging since the regulations can be generic and not explain how the actual temperature mapping process should be performed.

For example, the U.S. Food and Drug Administration (FDA) emphasizes in Part 211 of the Current Good Manufacturing Practice for Finished Pharmaceuticals that equipment is needed to control the temperature in buildings and facilities where drug products are manufactured, processed, packaged, and held. However, it does not specify what type of equipment is necessary or how to operate it.

Therefore, temperature mapping regulations are open to interpretation, which can result in inconsistent or inadequate practices. The good news is that this white paper offers equipment and process recommendations to keep your temperature mapping compliant.

Let's get started.

Temperature Mapping Equipment.

Temperature mapping involves using data loggers and instruments to track and log temperature readings at different locations within a designated area for a specific duration. It's important to get the right equipment for temperature mapping to ensure accurate and compliant readings.

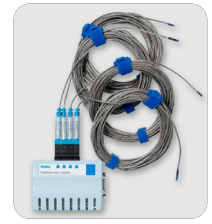
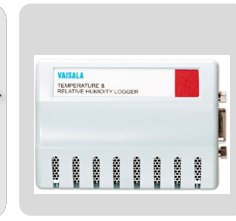
WHAT IS A TEMPERATURE MAPPING DATA LOGGER?

A temperature mapping data logger is a specialized device designed to monitor and record temperature variations across a defined space or area. Unlike standard data loggers that focus on single-point measurements, temperature mapping loggers are strategically placed at multiple locations within an environment to capture temperature distribution patterns accurately.

These loggers are commonly used in industries such as pharmaceuticals, healthcare, food storage, and logistics to ensure regulatory compliance, quality control, and product safety.

Temperature mapping data loggers are crucial in identifying hot or cold spots, assessing temperature uniformity, and optimizing environmental conditions to preserve the integrity and effectiveness of temperature-sensitive products and materials.

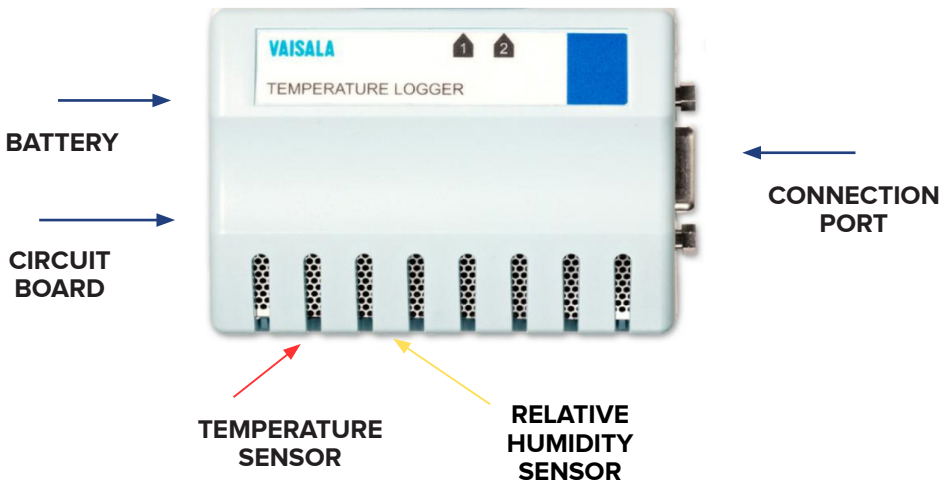
At Performance Validation (PV), our team uses a variety of equipment from top manufacturers to achieve optimal results. **Let's explore them now.**


	Vaisala VL-1000	Vaisala VL-1416	Vaisala VL-2000	Vaisala RFL w/ HMP115	zLogg Mini T/Mini TH	Kaye Validator AVS with Thermocouples	Lives International GMP-RF-F-30H
Range	-25 to +70°C	-90 to +50°C	-25 to +70°C 10 to 90%RH	-40 to +60°C 10 to 90%RH	-40 to +80°C 10 to 90%RH	-196 to +400°C	-90 to +140°C
Accuracy	• ±0.10°C over +20 to +30°C • ±0.20 °C over -25 to +70°C	• ±0.25°C over -90 to +50°C	• ±0.10°C over +20 to +30°C • ±0.20°C over -25°C to +70°C	• ±0.10°C over +15 to +30°C • ±0.20°C over 0 to +40°C • ±0.50°C over -40 to 0°C and +40 to 60°C • ±1.5%RH over 10 to 90%RH at 0 to +40°C • ±2.5%RH over 90 to 100%RH at 0 to +40°C • ±3.0%RH over 10 to 90%RH at -40 to 0 and +40 to +60°C • ±4.0%RH over 90 to 100%RH at -40 to 0 and +40 to +60°C	• ±0.2°C • ±1.8%RH over 10 to 90%RH	• ±(0.003% of reading + 2 counts + 4 microvolts)	• ±0.10°C over -90°C to +140°C
Use For	• Refrigerators • Freezers • Incubators/Stability Chambers (temp only) • Warehouses (temp only) • CRT spaces (temp only)	• Ultra-low temperature freezers	• Incubators/Stability Chambers (temp and RH) • Warehouses (temp and RH) • CRT spaces (temp and RH)	• Incubators • Stability Chambers • Warehouses • Cold Rooms • Freezers	• Incubators • Stability Chambers • Warehouses • Cold Rooms • Freezers	• Steam Sterilizers (autoclaves) • Dry Heat Sterilizers/ Ovens • Steam-in-Place (SIP) • Freeze Dryers/ Lyophilizers • Cryogenic Freezers • Controlled Rate Freezers	• Steam Sterilizers (autoclaves) • Dry Heat Sterilizers/ Ovens • Steam-in-Place (SIP) • Freeze Dryers/ Lyophilizers • Controlled Rate Freezers
21CFR11 Compliant	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Key Considerations	• High accuracy • 10-year lifespan • Calibratable • Wireless • Easy to use	• High accuracy • Low temperature range • 10-year lifespan • Calibratable • Easy to use	• High accuracy • 10-year lifespan • Calibratable • Wireless • Easy to use	• High Accuracy • Calibratable • Wireless • Magnetic Installation • Real-time data views	• High Accuracy • Calibratable • Easy to Use • Magnetic Installation	• High accuracy • Low and high temperature ranges • Calibratable • Wired thermocouples (fast response and can withstand harsh environments) • Up to 48 inputs max	• High accuracy • 10-year lifespan • Calibratable • Wireless • Easy to use • Real-time data view • Maps a larger temperature range

WHAT IS A TEMPERATURE MAPPING DATA LOGGER?

A data logger consists of various parts and components, each playing a part in the monitoring and recording temperature variations. **Let's take a look at these parts.**



CONSIDERATIONS FOR CHOOSING A DATA LOGGER

Before you purchase a data logger for temperature mapping, it's important to take these factors into consideration to ensure it meets your specific needs and requirements:

- **Accuracy:** Choose a high-accuracy data logger to ensure precise temperature measurements, especially in critical applications where temperature variations can impact product quality or safety.
- **FDA Compliance (21 CFR Part 11 Software):** If your industry or application requires compliance with FDA regulations, ensure that the data logger comes with software that meets the requirements of 21 CFR Part 11 for electronic records and signatures.
- **Calibratable:** Opt for a data logger that is calibratable and traceable to national standards, ensuring the reliability and accuracy of temperature measurements over time.
- **Battery Life:** Consider the data logger's battery life, especially if it will be used for long-term monitoring or in remote locations where frequent battery changes may not be practical.
- **Initial Cost vs. Lifetime Cost:** Evaluate the data logger's initial cost and lifetime cost, including maintenance, calibration, and any ongoing subscription fees for software updates or support. The more expensive data loggers offer better accuracy, FDA compliance, lifetime value, and range of use.
- **Range of Use:** Determine the range of temperatures and environmental conditions the data logger can effectively monitor, ensuring it suits your specific application, whether it involves ultra-low temperatures, high temperatures, or other extreme conditions.

If you want a data logger that checks all these boxes, consider one of the devices we listed earlier. These devices offer a comprehensive suite of features and functionalities that address various needs and requirements, ensuring reliable and compliant temperature monitoring and validation.

RENTING VS. BUYING DATA LOGGERS

Depending on your situation, renting data loggers instead of buying may be more beneficial. This is especially true if you are supplementing an existing system to fulfill short-term needs.

While a rented system requires similar considerations as purchasing one, it can often be more cost-effective, especially when factoring in the expenses associated with owning, validating, and servicing a purchased system over time. This makes renting an attractive option depending on the frequency of mapping needs and the overall cost of ownership.

WHERE TO PLACE DATA LOGGERS

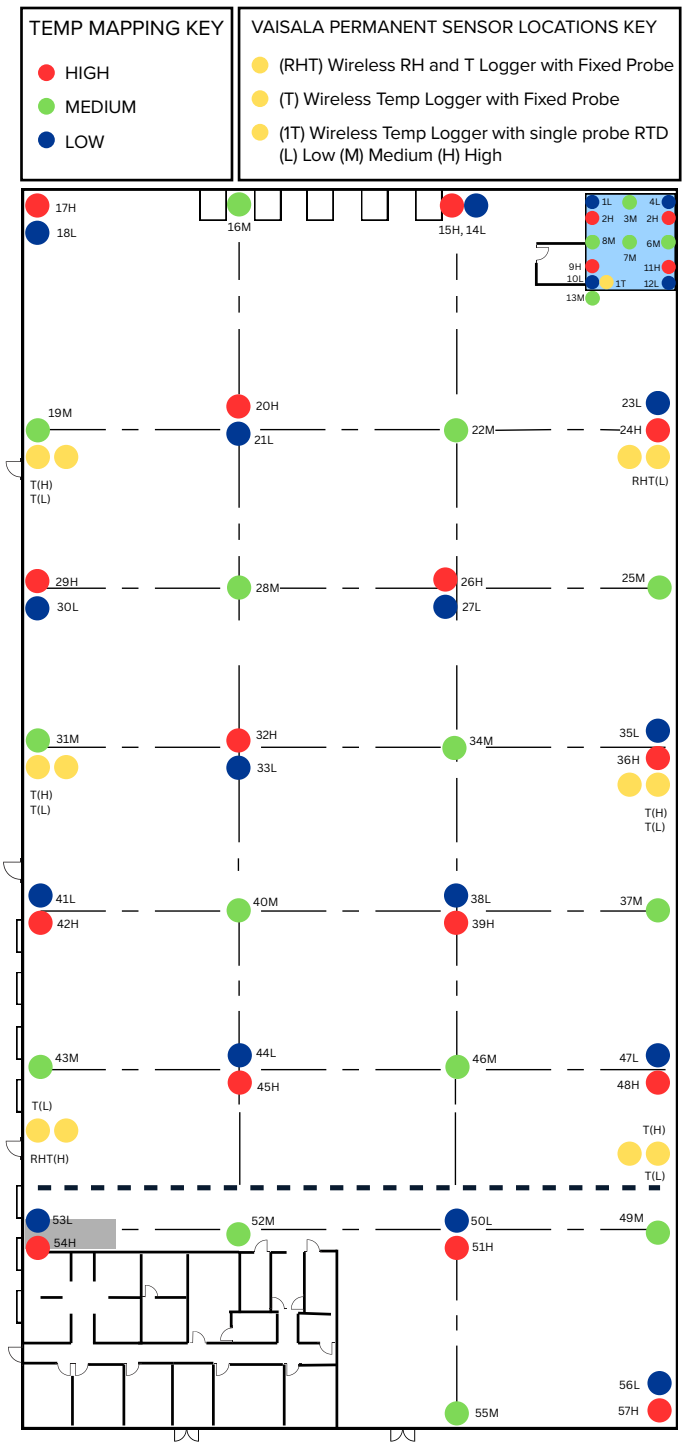
When determining where to place data loggers for temperature mapping, it's crucial to follow guidance and recommendations from reputable organizations such as:

- The World Health Organization (WHO)
- The International Society for Pharmaceutical Engineering (ISPE)
- The Health Products Regulatory Authority (HPRA)
- The European Medicines Agency (EMA)
- Health Canada

These guidelines cover aspects such as the number of data loggers needed, their placement, and the spacing between them.

For example, if you want to place data loggers in a warehouse, you should create a three-dimensional pattern of data loggers throughout the storage space, including the boundary areas, to capture temperature variations effectively. Factors such as heating and cooling sources, such as HVAC vents, windows, doors, and exterior walls, should be considered when placing data loggers to ensure comprehensive monitoring of temperature distribution.

By adhering to these guidelines and considering environmental factors, data loggers can be strategically positioned to provide accurate and reliable temperature mapping data, essential for maintaining product quality and regulatory compliance.



TEMPERATURE MAPPING VS. PERMANENT MONITORING SYSTEMS

If you are new to the industry, it's important to know about permanent monitoring systems. Permanent monitoring systems are critical tools for ensuring the consistent and reliable maintenance of temperature-sensitive environments and are typically separate from temperature mapping systems. The temperature mapping process provides critical inputs to proper installation of a permanent monitoring system. Let's compare the two now.

TEMPERATURE MAPPING

Temperature mapping involves a short-term activity that utilizes a number of data loggers strategically placed to monitor environmental conditions at numerous locations within a given space.

These data loggers, also known as temporary sensors, are instrumental in gathering comprehensive data regarding temperature distribution, identifying potential hot or cold spots, and assessing temperature uniformity across the space. For large spaces, the number of mapping sensors could number in the hundreds.

This process is essential for understanding the thermal dynamics of the environment, especially in critical areas such as pharmaceutical storage facilities, warehouses, or laboratory spaces where maintaining specific temperature ranges is paramount.

PERMANENT MONITORING SYSTEMS

Permanent monitoring entails long-term surveillance using sensors typically installed at the identified worst-case locations determined during the temperature mapping exercise. These worst-case locations are those areas within the space where temperature variations are most likely to occur or where temperatures may deviate significantly from the desired range. Permanent monitoring aims to continuously monitor and record temperature conditions over an extended period, providing ongoing data to demonstrate that conditions are consistently maintained during the operational use of the space.

The primary goal of permanent monitoring is twofold: to ensure that environmental conditions remain within specified limits throughout regular operations and to alert key personnel promptly if conditions deviate from the specified parameters.

This real-time monitoring and alert system is critical for maintaining product quality, safety, and FDA compliance, as it allows for immediate corrective actions to be taken if temperatures are out of specification. Permanent monitoring provides a continuous assessment of temperature conditions, offering peace of mind and assurance that critical areas are being monitored effectively to prevent any potential risks or deviations.

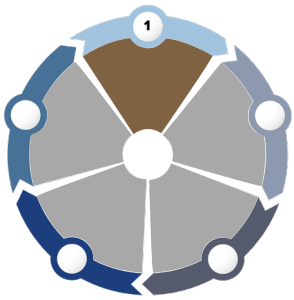
Now that you know what equipment is necessary for temperature mapping, let's explore the process steps.

Temperature Mapping Process.

Following a step-by-step process ensures that temperature mapping activities are conducted thoroughly and methodically. This leads to reliable results that can be used to optimize temperature control systems and maintain product quality and safety in temperature-sensitive environments.

There are five core steps to take:

1. Identify the Mapping Scope



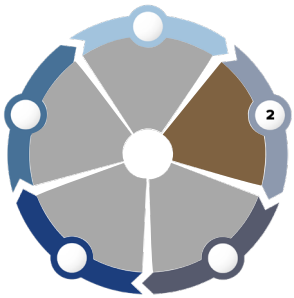
The first step involves gathering information about the space layout where temperature mapping will be performed.

This includes:

- Obtaining dimensions of the space
- Identifying storage racking/locations
- Noting the positions of doors and windows
- Locating HVAC sources such as vents or ducts

This detailed layout information is crucial as it forms the basis for generating the planned mapping layout. Additionally, understanding the layout helps determine the quantity and type of sensors needed for effective temperature monitoring across different space areas.

2. Develop & Approve a Mapping Protocol

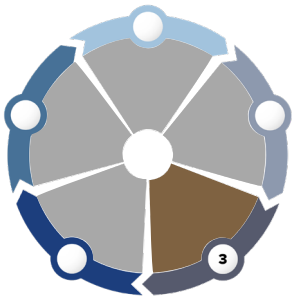


Once the layout information is gathered, the next step is to develop a mapping protocol that outlines the planned approach for the mapping activity. The mapping protocol should include details such as:

- Acceptance criteria
- Duration/types of studies to be performed (empty, loaded, static, dynamic)
- Scenarios for door openings
- Power loss/recovery simulations
- Other relevant parameters

This protocol is a guiding document that ensures consistency, standardization, and compliance with regulatory requirements throughout the mapping process. It can also help you obtain approval from stakeholders, align objectives, and set expectations for the mapping activity.

3. Execute the Mapping Per the Protocol

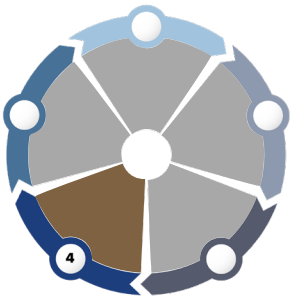


With the approved mapping protocol in place, the mapping activity is executed according to the defined approach. During this phase, mapping sensors are selected based on the protocol specifications, and their calibration is verified to ensure accurate data collection.

Your sensors should be programmed and installed strategically across the space according to the planned mapping layout.

Study start/end times are recorded, and study activities such as door openings, loading/unloading, and power loss/recovery simulations are performed and documented per the protocol guidelines.

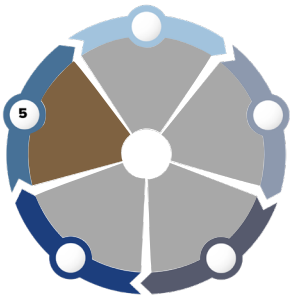
4. Remove Sensors & Review Results



Once the mapping activity is completed, typically the sensors are removed from the space. The data collected by the sensors is then downloaded and analyzed using appropriate software tools. Compare the mapping results against the information recorded in the mapping protocol to ensure that the mapping activity was conducted as planned and that data collection was accurate and reliable.

If using real-time monitoring technology, there is no need to remove and download the sensors first to obtain the results which can provide a time and cost savings if failed results necessitate space adjustments and a remapping.

5. Develop a Summary Report



Based on the analyzed results, a summary report is developed to document the entire mapping process and its outcomes. The report details what was done during the mapping activity, including:

- Any deviations from the protocol
- Study activities performed
- The results of each study type (empty, loaded, static, dynamic)

The report also identifies hot and cold spots within the space that may be considered for permanent monitoring. You can even use it to outline any action items, next steps, and recommendations for ensuring temperature control and compliance within the space.

There are a few different ways PV can support temperature mapping. Let's delve into each of these scenarios to see which one may make the most sense for your needs.

Temperature Mapping Services.

Since every facility or space is unique, there's no one-size-fits-all approach to temperature mapping. The good news is you can tailor your approach based on your budget, team, schedule, or in-house capabilities.

At PV, we support three different types of services for temperature mapping:

1. Equipment Rental

Renting equipment offers a convenient solution for customers who prefer a do-it-yourself approach to temperature mapping activities. With this rental service, you have the flexibility to handle all aspects of the temperature mapping process while obtaining the necessary equipment from Performance Validation. You also benefit from a flexible inventory of calibrated loggers to accommodate varying project sizes and timelines.

To facilitate this service effectively, we ask that you provide the following information:

- The quantity of equipment needed
- The type of data loggers or sensors required for your specific application
- The start date of the rental period
- The duration for which you will require the equipment

By gathering this information upfront, we can ensure you receive the appropriate equipment on time. This option is great for organizations that have an in-house team of temperature mapping experts or to supplement an existing system. PV's equipment is continually maintained in a calibrated and validated state to ensure regulatory compliance.

Performance Validation holds one of the largest temperature mapping equipment inventories in the country, there is no project too big for our team. All of our equipment is maintained in a calibrated and validated state.

2. Remote Service

With our remote service, our experts handle the entire temperature mapping process from our office. We work with the client to develop and approve a temperature mapping protocol. Then, we will send out the necessary equipment and provide instructions on where to place sensors within your designated space.

Once the study is complete, you will remove the sensors and return them to PV. Then, our experts will download and analyze the temperature mapping study data and develop the summary report remotely.

Remote service is particularly popular for studies that last three days to a week and PV does not have a local resource near you. By having you handle the on-site effort, you can save a significant amount of time and money with this option. You also gain access to a versatile inventory of calibrated data loggers and world-class support from our experts.

3. Full-Service

If you prefer a full-service approach to temperature mapping, PV has you covered. With this method, we handle the upfront tasks and take the lead on the installation and removal of loggers. You may need to help us with setting up the data loggers, along with any dynamic activities involving your facility, personnel, or materials. However, our team will lead the efforts and provide any necessary guidance.

This flexible, full-service option is ideal for customers with limited internal resources or who prefer having our PV experts oversee the process in person.

WHAT MAKES THE PV PROCESS UNIQUE?

When you need a temperature mapping partner to help you achieve your goals, consider PV. As an extension of your team, we only succeed when you do.

One key aspect of our PV process is its flexibility. We offer a range of options, such as equipment rentals, remote services, and full-service solutions for temperature mapping projects. This allows you to choose the approach that best suits your needs, budget, and level of involvement in the mapping process.

We also offer an impressive inventory of sensors, including various types and quantities, ensuring we can accommodate diverse mapping requirements across different industries and applications.

With over 35 years of experience in the field, PV has honed its expertise and developed industry-standard approaches to temperature mapping, providing you with reliable and accurate results.

What truly sets PV apart is our collaborative partnership approach with clients. Rather than offering a one-size-fits-all solution, we work closely with you to understand your unique challenges, objectives, and compliance requirements. This collaborative approach allows us to tailor an effective solution that meets your needs, ensuring successful compliance and operational excellence.

WHEN SHOULD YOU PERFORM TEMPERATURE MAPPING?

Temperature mapping should be conducted when initiating operations in a new building, implementing a new production line, introducing new equipment, retrofitting existing facilities, or undergoing revalidation processes.

This practice is crucial during seasonal transitions such as summer and winter to account for any temperature variations that may impact storage conditions. The initial qualification phase involves thorough assessment during these critical periods, ensuring that storage temperatures remain stable and within specified ranges.

Also, requalification should be performed on a regular basis, typically every three years, or whenever significant changes occur:

- Adjustments in setpoints
- Repairs or replacements of equipment
- Relocations
- Modifications in layout or configuration

By following this proactive approach, you can mitigate risks, maintain regulatory compliance, and uphold product quality and safety standards over time.

Temperature mapping requires you to choose the right strategy for your process. Partnering with a temperature mapping expert can help streamline this approach and set you on the path to success.

Conclusion.

Temperature mapping is a critical process for pharmaceutical and life science organizations striving to uphold the required storage conditions essential for product integrity and patient safety. To meet the requirements established by regulatory authorities, it's important to use quality equipment and follow a proven temperature mapping process.

There are many types of temperature mapping equipment available, each with its own benefits. When choosing a data logger, consider factors such as accuracy, software compliance, calibration, battery life, cost, and range of use. Devices that check all these boxes are available from esteemed manufacturers such as Vaisala, Sensitech, and Kaye.

The temperature mapping process involves five fundamental steps: identifying mapping scope, formulating a mapping protocol, executing the mapping operation, analyzing outcomes, and compiling a comprehensive summary report. Following this series of steps can help you achieve optimal results.

PV offers three services for temperature mapping: equipment rental, remote service, and full-service. PV supports all three services through a collaborative partnership that provides tailored solutions, dependable results, and detailed client reports.

Ultimately, effective temperature mapping does more than meet regulatory requirements; it is a commitment to excellence and continuous improvement in temperature-sensitive environments. By embracing best practices, leveraging advanced technologies, and fostering collaborative partnerships, you can navigate the complexities of temperature monitoring with confidence, ultimately contributing to enhanced patient outcomes and industry-wide advancements.

Performance Validation offers cutting-edge equipment and expert services for temperature mapping. When you demand quality and safe products, partner with us to ensure your environment meets the required temperature standards. PV has completed thousands of temperature mapping studies for different clientss across many different industries. Our delivered solutions continuously satisfy internal/external client and regulatory audit expectations.

Contact us to start the conversation.

Temperature Mapping FAQs.

What is the objective of temperature mapping?

To ensure that all storage space meets requirements and to identify the worst-case location(s) for permanent monitoring.

How do you conduct temperature mapping?

Strategically place temperature sensors or data loggers at various locations within a defined space, monitor and record temperature readings over a specified period, and analyze the data to assess temperature distribution and identify potential hot or cold spots.

What is the conclusion of temperature mapping?

To assess temperature distribution, identify potential areas of concern, and ensure regulatory compliance or quality assurance in temperature-sensitive environments.

How often should temperature mapping be performed?

During the initial qualification of a space, empty and loaded if possible. During seasonal extremes. After any physical changes to a space or if permanent monitoring data indicates a lack of adequate control. A regular remapping (i.e., every three years) is recommended.

What are the guidelines for temperature mapping a warehouse?

Several guidelines need to be followed to ensure thorough and accurate assessment:

- Identify critical areas within the warehouse, such as storage zones for temperature-sensitive goods, and strategically place temperature sensors or data loggers in these locations.
- Ensure sensors are distributed evenly to capture variations across the space, considering factors like distance from HVAC systems, proximity to walls or doors, and potential temperature gradients.
- Conduct mapping during different seasons or operational conditions to account for environmental fluctuations.
- Monitor temperatures for a sufficient duration to capture typical temperature patterns and extremes.
- Analyze the collected data to identify areas with temperature deviations and implement corrective measures as needed to maintain consistent and compliant temperature control throughout the warehouse.

Is temperature mapping a calibration?

No. Mapping is measuring temperatures at various locations using a temporary calibrated instrument. Calibration is comparing an instrument reading to a known calibrated standard and adjusting that reading as necessary to within a prescribed tolerance.

How many sensors are needed for temperature mapping?

The number of sensors depends on several factors:

- The size and layout of the space being mapped.
- The complexity of the environment.
- The criticality of temperature-sensitive areas.
- The specific requirements or guidelines of the industry or regulatory standards being followed.

What is thermal mapping?

The process of systematically measuring and analyzing temperature variations across a defined space or area to assess temperature distribution and identify potential hot or cold spots.

What is a hot spot in temperature mapping?

Location(s) displaying the warmest overall temperature and/or warmest average temperature.

What is a cold spot in temperature mapping?

Location(s) displaying the coolest overall temperature and/or coolest average temperature.

PERFORMANCE VALIDATION

Neil Enlow

PRINCIPAL VALIDATION ENGINEER
TEMPERATURE MAPPING SUBJECT MATTER EXPERT