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8-step checklist:

Following WHO's temperature mapping guidelines

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The WHO temperature mapping guidelines are a valuable blueprint for conducting reliable, efficient mapping studies in pharma, logistics, and other GxP-regulated industries – but they can be tricky to navigate.

This checklist translates the guidelines into concrete, easy-to-follow steps that you can easily implement into your next mapping process.

Note

The following is a simplified summary of the guidelines. It also contains other best practice information gleaned from our experience conducting hundreds of GxP mappings. For the complete WHO guidelines, visit their website here.

Why is WHO relevant for temperature mapping in GxP?

The WHO is a respected health authority worldwide, and the WHO mapping guidelines serve as recognized benchmarks for product integrity and universal standards. The guidelines align with other international and national regulations and are continuously updated to reflect the latest advancements. This helps ensure continuous compliance across markets, maintain competitiveness, and uphold high-quality standards.

In other words, applying the WHO frameworks can help your GxP-regulated organization meet regulatory expectations effectively and consistently.

8 steps to implement WHO's mapping guidelines

1 Understand the WHO guidelines

Start by reviewing the WHO temperature mapping guidelines to ensure you get an understanding of the requirements.

Tips:

- Access the latest version of the guidelines directly from the WHO's official website for the most current information.
- Outline your existing mapping practice (if you have one) and conduct a gap analysis to compare this with the WHO standards and identify obvious differences and necessary adjustments.

2 Make a plan

Planning is the key to any successful mapping – and auditors often pay attention to whether or not you have been clear on the scope, requirements, documentation practices, and such *before* you started the study.

Tips:

Risk assessment: Start by doing a risk assessment to identify potential risks and environmental variables that could influence the mapping outcomes, such as location, seasonal changes, and equipment performance. Plan to test under worst-case scenarios, typically during the hottest and coldest months.

Requirements: To avoid deviations, ensure you not only know your current mapping requirements across critical values, product knowledge, and operational knowledge but can also demonstrate that you were aware of them prior to initiating the study.

Protocol: Develop a comprehensive mapping protocol including the scope and purpose of the mapping, method, acceptable temperature ranges and conditions for testing, how you plan to report, etc.
Learn more about how to create a temperature mapping protocol for GxP.

- Clearly define the purpose, scope, and objectives of the mapping exercise.
- Outline the required temperature range and specify critical control points based on product sensitivity and storage conditions.
- Document the methodology to be used, including the placement of data loggers and the frequency of data collection.
- Establish criteria for data evaluation and define what constitutes acceptable results.

Initial training: Train staff on the specific requirements and procedures of the mapping exercise, including how and what to document.

3 Document, document, document (and then document some more)

Documentation is an important part of the WHO's temperature mapping guidelines. Define how you want to handle documentation before you launch your study and keep detailed records from start to finish.

Tips:

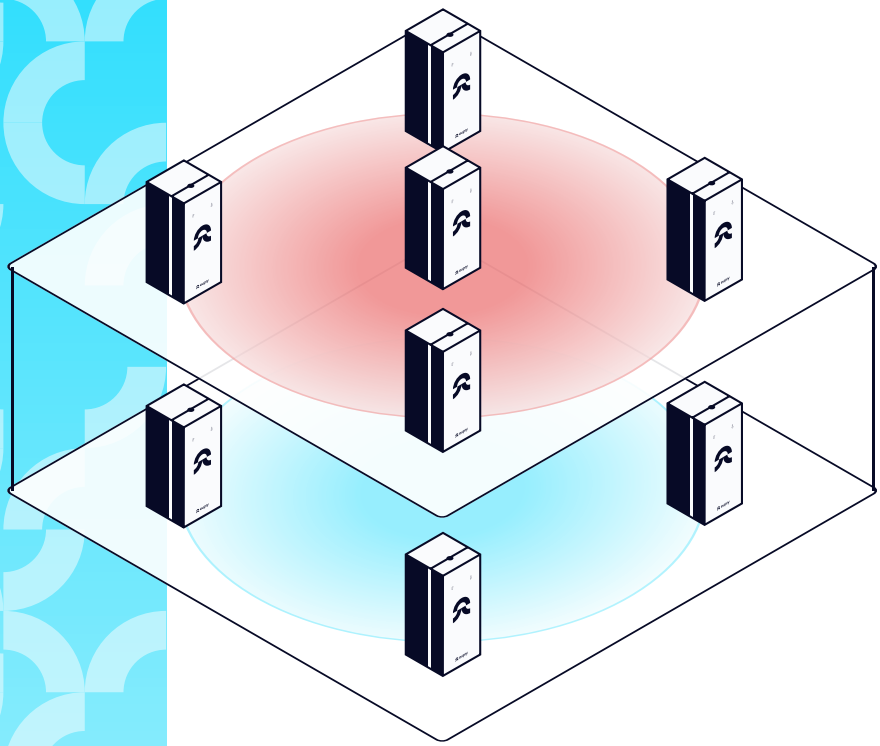
- **Define your strategy:** Clearly define your documentation practice before starting the mapping. Ensure your protocol specifies this documentation strategy, including how you will handle any discrepancies.
- **Conduct training:** Train all relevant personnel on documentation practices.
- **Include other documentation practices:** While the WHO guidelines provide a good foundation, it is often relevant to integrate specialized documentation standards, such as the ALCOA+ principles, and align with your existing SOPs.
- **Document everything throughout the process:** Maintain records of all mapping activities, changes in equipment, personnel, procedures, etc.
- **Include explanations:** Capture deviations and any other abnormality as well as *why* they happened. This will simplify your reporting when needing to justify anomalies.

4 Get the right mapping equipment

Make sure you have the appropriate data loggers and other equipment necessary for your mappings.

Tips:

- **Choose suitable data loggers:** Pick data loggers with the required operational functionality; according to WHO guidelines, loggers should allow programmable data sampling periods, have adequate memory to cover the study duration, and enable data download for analysis.
- **Ensure devices are calibrated:** According to the guidelines, data loggers should be NIST-traceable 3-point calibrated and maintain an error margin no greater than ±0.5 °C at each point. For certain organizations, ISO 17025-accredited calibrations are required. This level of precision confirms that the devices provide accurate and dependable data. Confirm that your data loggers are calibrated according to these standards and include valid calibration certificates in your mapping report.



5

Execute the mapping study

Time to perform the temperature mapping according to your protocol.

Tips:

- Deploy data loggers as specified in the protocol.
- If possible (this will depend on your equipment), monitor the mapping process in real-time to make necessary adjustments and address any anomalies immediately and avoid delays.
- Record all relevant actions, changes, and observations during the mapping for a comprehensive audit trail.

Is real-time data necessary?

The WHO guidelines on temperature mapping emphasize the accuracy and reliability of data but do ***not*** specifically mandate real-time data monitoring.

However, the guidelines do focus on ensuring that temperature-controlled storage areas are mapped effectively – and some level of "live" data can play an important role in securing this.

Although genuine "real-time" data is usually not needed for mappings, having access to continuous data in 5-10 minute intervals can be a valuable tool for immediate detection of deviations, enabling quicker responses to potential issues.

Wireless, Wi-Fi-based data loggers will often provide this data access.

Tip! Check out how Eupry's wireless data loggers work here.

6 Analyse data and create the report

After completing data collection, shift your focus to analyzing and reporting on the findings. Review the gathered data against the established requirements to pinpoint deviations and potential issues.

Tips:

- Collect data from the loggers (if you use wireless loggers, this will most often happen automatically during your study) to determine the temperature distribution.
- Analyze the collected data and compare it with the predefined acceptance criteria.
- Identify and document any deviations from the expected outcomes and requirements, as well as incidents affecting data. Use your ongoing documentation of variations and causes to explain these.
- Prepare a detailed report containing elements like:
    - An in-depth analysis of the data, comparing real-world conditions to the anticipated results.
    - Examination to uncover any discrepancies or anomalies.
    - Proposals for corrective measures and adjustments to storage or handling processes based on the results.

Find a temperature mapping report template here.

7 Implement recommended corrective actions

Based on the findings in the report, define and implement corrective actions to improve your processes and potentially establish an ongoing monitoring setup.

Tips:

- **Turn recommendations into SOPs:** Implement corrective actions for any issues you identify, such as adjustments to HVAC settings or changes in storage configurations, and update or develop new SOPs where needed.
- **Training and operational adjustments:** Train staff on the implications of the results and any new procedures or adjustments.
- **Improve monitoring processes:** A mapping offers an opportunity to refine monitoring processes. It identifies areas with significant temperature fluctuations – cold spots, hot spots, and other susceptible zones – and based on this, you can strategically position your data loggers to provide optimal coverage and make sure they effectively detect deviations. Drawing on your mapping results, it is, therefore, often relevant to adjust your temperature monitoring system to ensure ongoing compliance with identified critical points.

Also read:
A step-by-step guide to choosing the right temperature monitoring system.

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Conduct more mappings in the worst-case scenario

The WHO recommends conducting temperature mappings in "worst-case scenarios". This means that is your facility subject to seasonal changes, one mapping will often not be enough. Although worst case may not always align with summer and winter, conducting two mappings in the coldest and hottest months is the typical case for warehouses and other facilities affected by external temperatures. For facilities like cold rooms and freezers, the WHO notes that mapping in two distinct seasons is usually unnecessary.

Tips:

For areas subject to seasonal fluctuations, perform mappings during the hottest and coldest months to accurately monitor all temperature variations and develop an effective risk assessment strategy.

Learn more

Temperature mapping and validation are complex. Dive into the world of temperature validation and compliance in GxP in our learning universe. For instance, find:

The guides:

For instance, the "Temperature mapping report template" and the checklist "9 mapping mistakes you should avoid

The webinars:

For instance, "How to create a GxP compliant mapping report" and "How to navigate WHO's temperature mapping guidelines" (would you look at that; it is all coming together).