



A 9 Step Guide for Temperature Mapping an Ultra-Low Freezer



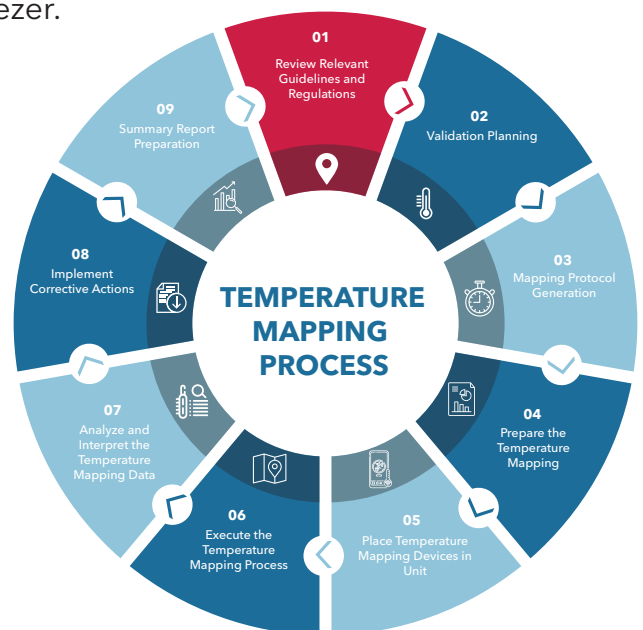
by

Nathan Roman

A Comprehensive Guide to Temperature Mapping Your Ultra-Low Freezer: From Validation Planning to Summary Report Preparation

In the biopharmaceutical industry, [temperature mapping](#) is a crucial step in ensuring that time and temperature-sensitive products are stored and transported under conditions that will preserve their quality and safety. This is especially important for [ultra-low freezers](#), which are used to store temperature-sensitive materials at temperatures below -60°C. The following guide provides step-by-step instructions for temperature mapping an ultra-low freezer.

Note: From this point on; this guide can be adapted for temperature mapping any controlled temperature unit, not just an ultra-low freezer. Simply swap out the term “ultra-low freezer” with the specific type of controlled temperature unit that you are mapping. The same comprehensive process and considerations apply regardless of the type of unit being mapped.



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TEMPERATURE MAPPING AN ULTRA-LOW FREEZER

A Step by Step Guide

Step 1

Review Relevant Guidelines and Regulations

Before starting the temperature mapping process, it is important to understand the relevant guidelines and regulations that apply to your ultra-low freezer. This will help ensure that the mapping process is conducted in compliance with regulations and that the results are meaningful.

Step 2

Validation Planning

Before conducting the temperature mapping, it is important to develop a comprehensive validation plan. This may involve defining the scope and objectives of the mapping process, including worst-case scenarios determining the required resources and personnel, and identifying any potential risks or challenges that may need to be addressed.

Step 3

Mapping Protocol Generation

Once the validation plan has been developed, your next step is to generate a detailed mapping protocol. This protocol should outline the steps involved in conducting the temperature mapping process, including the placement of temperature mapping devices, the methods for collecting and analyzing temperature data, and any required quality control measures.

[Read This Guide for a Basic Temperature Mapping Protocol](#)

Step 4

Prepare the Ultra-Low Freezer for Mapping

Before conducting the temperature mapping, it is important to prepare the ultra-low freezer for the process and always use appropriate PPE (Personal Protective Equipment) when handling and preparing ultra-low freezers to ensure safety. This process involves cleaning the freezer, removing any stored materials, and ensuring that the freezer is [properly calibrated](#) and functioning correctly.



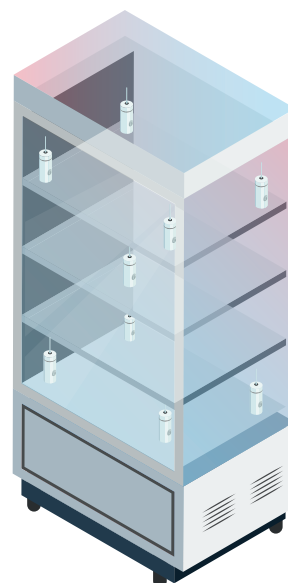
Regulatory Note: Remember to document every aspect of your validation plan meticulously, as GMP regulations emphasize the importance of proper documentation.

Step 5

Place Temperature Mapping Devices in the Ultra-Low Freezer

With the mapping protocol in place, it is time to place [temperature mapping devices](#) in the freezer. This may involve placing temperature data loggers or thermocouples at different locations throughout the freezer according to a predetermined grid, including the top, bottom, and sides, as well as in the door and near any air vents. Also, stabilize the freezer for a specified period before starting the mapping process.

[Discover These Recommended Sensor Locations](#); or [Learn More About Best Practices](#)



Typical Setup

8 corners, with 1 in the center

**Don't forget additional sensor(s) should be placed adjacent to the display, control, and monitoring probe(s), if applicable.*

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Step 6

Execute the Temperature Mapping Process

With the temperature mapping devices in place, it is time to [execute the temperature mapping process](#). This may involve collecting temperature data over a period of several hours or even days, depending on the specific requirements of your operation or equipment and storage area being assessed.

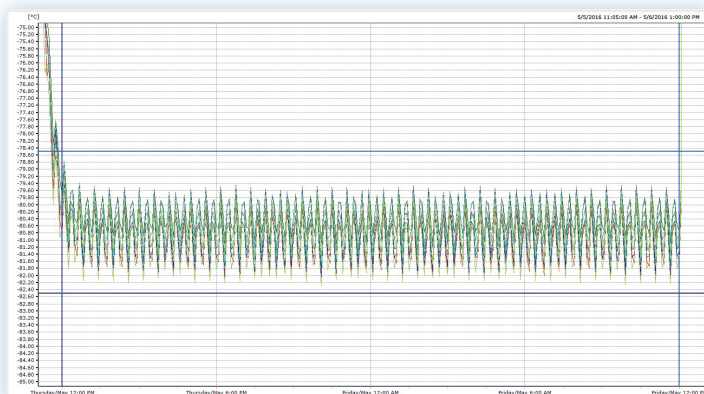
Controlled Temperature Units (CTUs):

- Duration: 24 hours
- Rationale: CTUs require a 24-hour mapping duration to capture multiple temperature cycles, ensuring consistent temperature maintenance.

Step 7

Analyze and Interpret the Temperature Mapping Data

Once the temperature mapping process is complete, it is time to analyze and interpret the data collected. This may involve [generating reports and graphs](#) that show the temperature distribution throughout the ultra-low freezer, as well as identifying any areas of the freezer that are not meeting the required temperature range for root causes.



24hr Temperature Mapping Study for -80 Freezer

Regulatory Note: Ultra-low freezers should be equipped with alarms to alert personnel of temperature deviations. Continuous temperature monitoring systems can also be helpful in maintaining the integrity of stored materials.

Step 8

Implement Corrective Actions

Based on the results of the temperature mapping, it may be necessary to implement corrective actions to ensure that the ultra-low freezer is operating correctly. This may involve making changes to the temperature control system, adding or repositioning temperature mapping devices, or other actions to improve the temperature stability of the freezer.

Regulatory Note: If any changes are made to the ultra-low freezer setup, location, or operating conditions, a revalidation (which includes remapping) may be necessary. A proper change control procedure should be established and followed.

Step 9

Summary Report Preparation

Finally, it is important to prepare a summary report that documents the results of the temperature mapping process, including any corrective actions that were taken. This report should be comprehensive, clearly documenting the methodology used, the results of the mapping process, and any conclusions that can be drawn from the data. Ensure that this report is reviewed and approved by qualified personnel.

Regulatory Note: Good Manufacturing Practice (GMP) regulations emphasize the importance of proper documentation. Every step, observation, and result during the temperature mapping process should be documented meticulously. Documentation provides evidence that the process is consistent and controlled.

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By following this guide, you have taken an important step towards ensuring the safety and integrity of your temperature-sensitive pharmaceutical products. By conducting a temperature mapping of your ultra-low freezer, you are protecting the lives and well-being of the patients who rely on these products.

It can be overwhelming to navigate the complex web of regulations and guidelines, but with a comprehensive approach, you can be confident that your storage area is compliant and that your products are stored at the correct temperature.

[Temperature mapping](#) of ultra-low freezers is crucial for ensuring the integrity and safety of temperature-sensitive biopharmaceutical products. Adherence to regulatory guidelines, thorough planning and protocol development, and data-driven analysis and corrective actions are all vital steps in this process.

Furthermore, the temperature mapping process is adaptable and can be applied to any controlled temperature unit, highlighting its versatility and broad relevance in the biopharmaceutical industry.

In summary, by conducting a detailed temperature mapping of ultra-low freezers, biopharmaceutical companies are better equipped to maintain the quality of their temperature-sensitive products, thereby contributing to the safety and well-being of patients.

Regulatory Note: Backup power generators are crucial for ultra-low freezers. Power interruptions can jeopardize product integrity, despite consistent temperature mapping. Ensure compliance and product safety.



We hope that this guide has provided you with a clear and concise process for temperature mapping your ultra-low freezer. If you have any questions or concerns, please don't hesitate to [contact us today](#) for all your IQ, OQ, and PQ needs. We're here to provide practical solutions and expert guidance that help you navigate the complex regulatory landscape and ensure your success.

Take the next step in securing the safety of your temperature-sensitive products by conducting temperature mapping today!

Written by [Nathan Roman](#)



The following guidelines and regulations should be reviewed as part of the preparation for temperature mapping your ultra-low freezer:

1. World Health Organization (2015). Technical Supplement 8 - Temperature Mapping of Storage Areas
2. USP (2018). USP41-NF36 <1079>. Good Storage and Distribution Practices for Drug Products
3. ISPE (2021) Good Practice Guide: Controlled Temperature Chambers 2nd Edition
4. USP: <659> Packaging and Storage Requirements

These guidelines provide additional guidance on the storage and transportation of various products and can be used as a reference during the mapping process. Ensure that you are referencing the latest available versions of these standards.