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ULT Freezer Mapping: From Planning to Summary Report

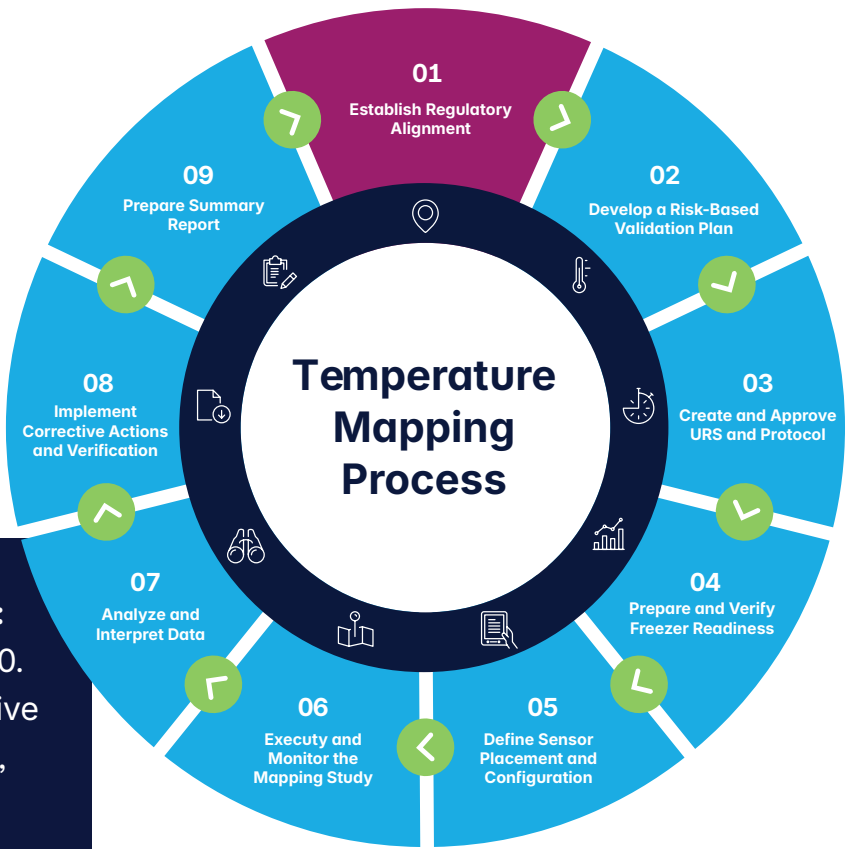
A 9-Step Guide to Temperature Mapping an Ultra-Low Freezer

Temperature Mapping for Ultra-Low Freezers: From Planning to Summary Report

In the biopharmaceutical industry, temperature mapping verifies that time- and temperature-sensitive materials remain within qualified limits during storage. Ultra-low temperature (ULT) freezers, play a critical role in protecting biological samples, reagents, and high-value materials.

For ultra-low temperature (ULT) freezers (–80 °C), temperature mapping provides objective evidence of uniformity and worst-case performance before routine use. This 9-step guide walks from planning through final report, now live-data ready so teams can make timely, documented decisions during OQ/PQ and avoid unnecessary repeats.

While this guide focuses on ultra-low freezers, the same principles apply to any controlled temperature unit (CTU), such as refrigerators, incubators, or cold rooms. Simply substitute the unit type and follow the same structured process.



2025 Update — Real-time visibility: This edition aligns with Validation 4.0. Where appropriate, it incorporates live data during OQ/PQ to enable earlier, documented interventions while maintaining predefined acceptance criteria and Part 11 data integrity.

Step 1

Establish Regulatory Alignment Before Temperature Mapping

Before starting a temperature-mapping study, review all applicable regulations and guidance - such as EU GMP Annex 15, FDA 21 CFR Part 11, USP, and ISPE Good Practice Guides. Aligning your approach with these standards ensures the study is scientifically sound, compliant, and defensible - laying the foundation for reliable results and enduring regulatory confidence.

Step 2

Develop a Risk-Based Validation Plan

Before executing any temperature mapping study, establish a structured, risk-based plan that defines the scope, objectives, and acceptance criteria of the study. Use formal risk assessment tools, such as FMEA, to justify probe placement, mapping duration, and requalification frequency.

Clearly define responsibilities, decision rules, and contingencies to ensure a controlled, compliant, and science-driven qualification process.

Step 3

Create and Approve the URS and Mapping Protocol

After defining your validation plan, outline system requirements in a User Requirement Specification (URS) and develop a mapping protocol detailing device placement, data collection, analysis, and quality control.

The protocol must be reviewed and approved by QA before execution to meet regulatory standards. Finally, configure your software with 21 CFR Part 11 controls to ensure data integrity and traceability.

Step 4

Prepare and Verify Ultra-Low Freezer Readiness

Prior to initiating temperature mapping, ensure the freezer is clean, empty or properly loaded, calibrated, and functioning within specification. Verify all loggers are in calibration and confirm maintenance records. Use appropriate PPE for safety.

If using Frigo UX Sky, test signal coverage, time sync, and buffering. Proper preparation ensures data integrity, operator safety, and GMP compliance.

Regulatory Note:
GMP and 21 CFR Part 11 regulations demand meticulous documentation. This includes establishing a Validation Master Plan (VMP) that is driven by a risk assessment to justify your mapping strategy, sensor placement, and acceptance criteria.

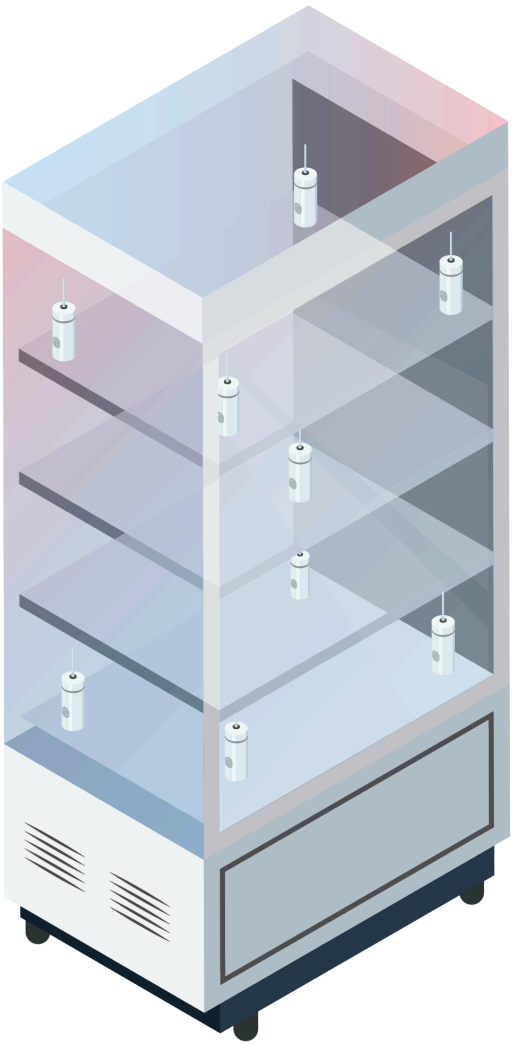
Data integrity must be maintained throughout the process.

Step 5

Define Sensor Placement and Configuration

Accurate sensor placement is the foundation of a successful temperature mapping study. It ensures that the collected data represents the full temperature distribution within the ultra-low freezer and that any potential cold or warm spots are identified.

Follow a systematic, physics-based approach when positioning sensors. Place sensors at the eight corners and center of the freezer, with additional probes near controls and monitoring sensors. Document all placements in the protocol at the time of placement and include a visual map. Thoughtful, risk-based positioning ensures representative data and compliance with Annex 15 and WHO TRS 961.



GxP Best Practices:
GxP best practice calls for a risk-based approach. Place sensors in worst-case locations identified during risk assessment (e.g., door seal, air inlets/outlets, top shelf) and include one next to the control probe for data comparison.

Step 6

Execute and Monitor the Mapping Study

With the sensors installed and the freezer verified as ready, the temperature mapping study can begin. Run the mapping study per the approved protocol, allowing the unit to stabilize before data collection.
For ULT freezers, record for at least 24 hours to capture full temperature cycles.

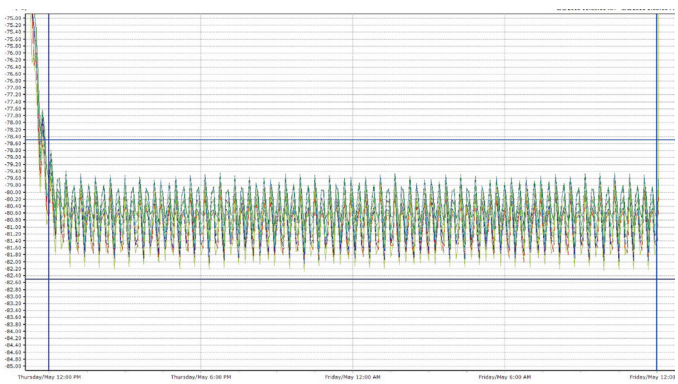
With Frigo UX Sky, monitor live data to detect deviations and act under predefined rules. Document all actions, observations, and events in real time to ensure data integrity and GMP compliance.

Step 7

Analyze and Interpret the Temperature Mapping Data

Once the temperature mapping is complete, the next phase is to analyze and interpret the collected data. First, review all data for completeness and integrity. Use reports and graphs to understand temperature distribution and identify hot and cold spots. Since min/max points can shift over time, select permanent monitoring probe locations based on data collected over time and risk assessment for consistent, compliant monitoring under GMP and Annex 15.

Regulatory Note:
Continuous Temperature Monitoring Systems (CMS) are now standard GxP best practice for critical storage. Utilizing real-time data loggers (like Frigo UX Sky) during qualification is essential, as it allows for immediate corrective action upon deviation detection, minimizing the risk of costly study failure and sample loss.



Step 8

Implement Corrective Actions and Re-Verification

Following data analysis, any deviations, trends, or out-of-specification results must be evaluated and addressed through structured corrective actions. Assess all deviations using a risk-based root cause analysis to determine source and impact.

Apply corrective actions - such as recalibration, repairs, or airflow adjustments - and document each step with rationale and evidence. If changes affect performance, conduct re-verification. A structured CAPA approach ensures the system remains compliant and validated.

Regulatory Note:
A robust Change Control procedure is mandatory. Re-mapping is required for significant changes (e.g., relocation, compressor replacement, major alarm trend). However, maintaining a validated state through Continuous Validation/Monitoring can often eliminate the need for costly periodic re-qualification, satisfying auditors by proving 24/7 compliance.

Step 9

Prepare the Summary Report

The final step is to compile and approve a comprehensive summary report, which serves as the official record of the entire study. This report must document the execution, key results, and the resolution of any deviations, ultimately concluding whether the unit met all acceptance criteria. Formal approval by all departments, including Quality Assurance, serves as the final gate, officially releasing the qualified equipment for operational use. of placement and include a visual map.

Thoughtful, risk-based positioning ensures representative data and compliance with Annex 15 and WHO TRS 961.

Regulatory Note:
Good Documentation Practice (GDocP) is non-negotiable.
Every step, deviation, and observation must be documented meticulously.
This provides an auditable data trail that proves the process is consistent, controlled, and that the data collected is reliable and secure.

Best Practice: Continuous Validation and Requalification

Qualification is not a one-time activity. Maintaining confidence in a controlled temperature unit requires a structured requalification and continuous validation strategy.

Adopt a risk-based approach to trigger requalification after changes, repairs, or recurring alarms. Maintain control through continuous monitoring, data review, and trend analysis. Real-time systems like Frigo UX Sky enable proactive oversight, ensuring data integrity and life cycle compliance.

Regulatory Note:
For critical samples, emergency power (backup generators) is required to mitigate the risk of catastrophic power failure. The qualification protocol (OQ/PQ) must include a Power Failure Test (or Door Opening Test) to demonstrate the freezer's temperature recovery time under a controlled interruption.

Closing Note

By following this guide, you have taken a significant step toward safeguarding the quality, safety, and reliability of your temperature-sensitive products. Temperature mapping is more than a compliance task - it's a commitment to scientific integrity and patient safety.

With a structured, risk-based approach, you can maintain systems that are compliant, controlled, and audit-ready. Each phase, from planning and execution to analysis and improvement, forms a continuous chain of assurance that upholds product integrity. These principles in this guide extend beyond ultra-low freezers and apply to any controlled temperature unit, supporting life cycle validation, regulatory confidence, and data integrity.

At Ellab, we're here to help you achieve and sustain validated performance through practical, compliant solutions for IQ, OQ, and PQ studies. Conduct every mapping study with purpose, precision, and confidence.

About the Author: Nathan Roman

With 25+ years in validation and compliance, Nathan is a recognized thought leader specializing in temperature mapping and equipment qualification.

He has supported more than 100 pharmaceutical and biotech companies worldwide in meeting FDA and EU GMP standards, reducing validation timelines by up to 30%, and shaping industry guidelines, including those from ISPE.

As co-author of the *ISPE Good Practice Guide* and author of *Six Steps to Effective Temperature Mapping*, he has trained professionals globally through articles, sessions, and thought leadership. With over 19K LinkedIn followers, his insights continue to advance best practices in validation, calibration, and compliance.

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

European Commission. (2025). EU GMP Annex 15: Qualification and Validation, Version effective October 1, 2015, with ongoing revisions and updates as of 2025.

United States Pharmacopeia (USP). (2024). USP General Chapter (1079.4) Transport Temperature Zones—Thermal Mapping of Storage Areas, May 2024.

U.S. Food and Drug Administration (FDA). (2025). Title 21 Code of Federal Regulations Part 11: Electronic Records; Electronic Signatures, Current as of 2025.International Society for Pharmaceutical Engineering (ISPE). (2021). Good Practice Guide: Controlled Temperature Chambers, 2nd Edition.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). (2005). ICH Q9: Quality Risk Management, Current edition.

ASTM International. (2024). ASTM E2500-24: Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment, 2024 edition.

World Health Organization (WHO). (2011, supplemented through 2025). WHO Technical Report Series No. 961, Annex 9: Model Guidance for the Storage and Transport of Time- and Temperature-Sensitive Pharmaceutical Products (TTSPPs), with technical supplements issued through 2025.

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TrackSense® Frigo UX Sky – Confidence in Every Degree

Throughout each step of this guide, accuracy, traceability, and compliance form the foundation of a successful ultra-low freezer qualification. **TrackSense® Frigo UX Sky** brings these principles to life.

Engineered for performance down to –90 °C, it enables real-time visibility and risk-based control during mapping studies. By combining precise wireless measurements with intuitive data management in ValSuite®, Frigo UX Sky helps you detect deviations early, minimize repeat studies, and maintain full regulatory confidence.

Empower your validation process with technology designed to uphold data integrity and ensure end-to-end compliance across your equipment life cycle.