

Temperature Mapping Studies

Mesa Labs Temperature Mapping Studies – an evidence-based approach to understanding the temperature and/or humidity distribution of your storage environments while demonstrating compliance.



“Drug products must be transported, handled and stored in a manner that mitigates the risk of exposure to temperatures outside labelled storage conditions; potentially impacting the safety, quality and effectiveness of the drug product”. **Guidelines for Temperature Control of Drug Products during Storage and Transportation (GUI-0069) – January 28, 2011. Statements with similar meaning can be found in FDA, EU and WHO regulations and guidance.**

How does your company demonstrate compliance?

The Supply Chain Challenge

The shipment and storage of pharmaceuticals is highly regulated throughout North America and most of the world under such guidelines as GUI-0069 in Canada, and 21 CFR Part 11 in the United States. As well, guidelines such as USP <1079>, provide additional direction to companies to ensure good storage and shipping practices. Whether you are a manufacturer, third party logistics firm, distributor or wholesaler, compliance with these regulations is essential to your business.

Mesa Labs Temperature Mapping Overview

The objective of a Temperature Mapping Study is to document temperatures within defined areas where temperature sensitive products are stored or shipped. This can range in size from a small refrigerator to transport trailers and large warehouses. Using our proven analytical process, the Infitrak team works with your staff to not only conduct a temperature study, but also to empower your staff with the know-how to improve your processes and environments.



Cold Chain - Transport Monitoring

The Infitrak temperature mapping process follows a comprehensive and proven methodology, including:

- Mapping protocols adapted to the unique needs of your environment, and its conditions. Before a study begins, protocols are reviewed and pre-approved by your staff
- Calibrated and independent N.I.S.T. traceable temperature data loggers (no hardwiring)
- Documentation of environmental conditions that identify the temperatures recorded over the life of the Study, and the thermal variations within the studied areas at any given time
- Calculation of mean kinetic temperature (MKT) within each unique area being studied
- Multi-seasonal comparisons that can include winter, summer, spring and fall
- Pre-qualification studies that can pave the way for new or expanded storage areas
- Identification of locations within the studied area that demonstrate high and low temperatures (hot and cold spots) as compared to the desired temperature range for the area
- Location of temperature collection points for on-going monitoring
- Follow-up with your staff to address any adverse situations identified as part of the study

Expertise and Knowledge Transfer

With more than 15 years of experience in pharmaceutical and supply chain analysis, Infitrak offers a comprehensive range of Cold Chain services that do not end with temperature mapping. We specialize in the identification, design and implementation of solutions for all Cold Chain related issues. Our end goal is to empower our clients with the knowledge and skills required for continual improvement, self sufficiency and the internal management practices necessary for SOPS and regulatory compliance.

Benefits:

- Mesa's expertise and proven track record of success
- Time-tested methodologies that meet regulatory requirements
- Cost-effective routes to compliance
- Knowledge transfer to ensure your team is empowered with a complete understanding of the work being completed and the appropriate responses to audit and regulatory questions
- Post-study products and services to assist you in responding to any identified deficiencies

For further guidance on cold chain management and good distribution practices, please contact the Mesa Labs team.