“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 (GDPs).

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 cGMP in the United States. As well, regulations such as USP <1079>, GDP and PDA Technical reports provide additional direction for 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.

Infitrak Transport Mapping Overview

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

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

- Mapping protocols adapted to the unique needs of your transport environments and their conditions of exposure. Before a study begins, protocols are reviewed and pre-approved by your staff. The location of temperature collecting points for mapping are also reviewed and pre-approved
- Calibrated and independent N.I.S.T. traceable temperature data loggers (calibration certificates included)
- Documentation of environmental conditions that identity the temperatures recorded over the life of the Study, and the thermal variations within the studied areas at any given time.
- Multi-seasonal comparisons that can include winter, summer, spring and fall
- Identification of locations within the studied area that demonstrate high and low temperatures (hot and cold spots) compared to the desired temperature range for the area
- The location of temperature collection points for on-going monitoring, as required
Infitrak Transport Qualification and Validation Overview

Transport Qualification (IQ/OQ/PQ) and Validation Studies are comprehensive studies that also incorporate Mapping. Transport Qualification and Validation Study documents show how the transport system, operations and processes are performed according to predetermined specifications and criteria. Infitrak provides experience and value-added knowledge around cGMP and GDP compliance and regulatory inspections for trailer qualification and transport validation for controlled-environment logistics worldwide.

The Infitrak qualification and validation process follows a comprehensive and proven methodology:

- Qualification and validation protocols adapted to the unique needs of your transport environments and their conditions of exposure. Before a study begins, protocols are reviewed and pre-approved by your staff. Documentation, verifications and tests, acceptance criteria, and location of temperature collecting points are also reviewed and pre-approved.

- Qualification and validation protocols document a list of documentation, verifications and tests to be performed on the transport system. These documentation, verifications and tests are done to ensure the transport system is properly installed, and operates according to given specifications. Results from the verifications and tests must comply with pre-approved acceptance criteria.

**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 a transport mapping study. 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 regulatory compliance.

**Benefits:**

- Infitrak’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 Infitrak team.