



Facility Thermal Mapping

Prove You are in Control of Your Facility

Compile, Analyze and Document Temperature Variances

“Observation of temperature variations in a warehouse should be made over a period of time to establish a meaningful temperature profile, including the temperature variations and conditions in the different parts of the warehouse. Such observations provide

data and information as to where various products should and should not be stored.”

**General Chapter USP <1079>
Good Storage and Shipping Practices
November 2005**

Challenges

Each drug has stability data that indicates its temperature storage requirements. The FDA requires drug products to be stored under appropriate conditions, including temperature and humidity, so that their identity, strength, quality and purity are not affected (21 CFR 211.142).

While regulatory requirements around product quality have always been important, the publishing of U.S. Pharmacopeia <1079> “Good Storage and Shipping Practices” in November 2005 has had a significant impact on the industry by providing detailed requirements for thermal mapping of facilities.

The document, sponsored by this science-based public-health organization, is geared toward manufacturers, distributors, wholesalers, repackagers and transport logistics providers—thus, covering the entire pharmaceutical supply chain.

Sensitech has been providing analysis of cold chain storage and distribution systems for more than 15 years. Sensitech can help organizations evaluate how these new guidelines may affect existing systems and provide the documentation required to support those systems.

Solutions

Industry-leading pharmaceutical manufacturers, wholesalers and distributors have historically turned to **Sensitech’s Life Science Professional Services™** for **Facility Thermal Mapping**.

The Professional Services team provides comprehensive mapping services in strict accordance

with current regulatory requirements. The success of our monitoring and analysis program is dependent on working closely with customers upfront to identify and document specific needs and requirements. Sensitech’s project management methodology is based on quality execution and detailed documentation of deliverables.

Programs range from mapping a facility to implementing a comprehensive validation project.





Service Offering Overview

- Provides documented temperature or temperature and humidity profiles over time that comprehensively identify conditions and variations across the unit being mapped
- Documents recommendations for use of each area and identifies areas unsuitable for storage of specific Pharmacopeial articles
- Documents compliance with regulatory and standards-based guidelines
- Includes the development of both summer and winter temperature profiles
- Incorporates Mean Kinetic Temperature (MKT) calculations for separate areas
- Identifies potential problem areas and works with the customer to develop, implement, and test recommendations for reduction of variability in those areas
- Provides development of a monitor placement protocol for hard-wired environmental control

Characteristics of the Program

- Efficient, timely and cost-effective
- Independent documentation to support internal Standard Operating Procedures (SOPs) and overall regulatory requirements
- Education of industry best practices: Good Cold Chain Management Practices™ (GCCMP)
- Sensitech's temperature and humidity monitors are wireless self-contained units, eliminating the need to hardwire monitors for the study
- All monitors are tested to NIST traceable standards and include a Certificate of Validation—per USP guidelines

For More Information

- Call Sensitech's Life Science Professional Services group at 1-800-843-8367
- Contact your Sensitech regional sales manager
- Visit Sensitech on the Web at www.sensitech.com

As the world's leading provider of cold chain visibility solutions, Sensitech enables global leaders in Food and Pharmaceuticals to track and monitor assets across the supply chain to protect the integrity of temperature-sensitive products. Sensitech is an ISO 9001:2000 company and is based in Beverly, Massachusetts, with offices in Amsterdam, Boston, Calgary, Melbourne, Mumbai, Redmond, Santiago and Shanghai as well as service and distribution offices around the world. Sensitech is a unit of Farmington, Conn.-based Carrier Corp., the world's largest provider of heating, air conditioning, and refrigeration solutions with operations in 172 countries. Carrier Corp. is part of United Technologies Corp. (NYSE:UTX), a Hartford, Conn.-based provider of a broad range of high technology products and support services to the aerospace and building systems industries worldwide. For additional information, please call +1-978-927-7033 or visit www.sensitech.com. © 2009. Sensitech Inc. All Rights Reserved. All trademarks and service marks are the property of Sensitech Inc.