



Shipping Studies

Real Environment. Real Data. Real Decisions.

"Each month we perform hundreds of thermal package qualification tests for clients in the biopharmaceutical, diagnostic, and blood industries. Our client's most difficult issue is always selecting the 'right' ambient profile."

"Valuable temperature-sensitive cargo is put at risk if thermal packages are under-engineered, i.e., are not designed and tested using realistic ambient temperature extremes. On the other hand, you end up with an over-engineered costly package when

test ambient profiles are more extreme than would be found in the actual shipping routes.

"To select the best ambient profile, we recommend customers carry out a well-defined shipping study. Clients that have actually measured their transit temperatures through a shipping study are able to build a database so test profiles can be adequately defended."

Tom Pringle,
Technical Director, SCA Thermosafe

Challenges

In November 2005 the U.S. Pharmacopeia published General Chapter <1079> "Good Storage and Shipping Practices." It states that Shippers and Distributors should follow proper storage and shipping requirements as indicated by the manufacturer. And, that "manufacturers and distributors should work together to establish proper distribution and product-handling requirements for the purpose of ensuring appropriate product maintenance in-transit."

<1079> "Good Storage and Shipping Practices" developed by the U.S. Pharmacopeia, a service-based public health organization, is geared toward manufacturers, distributors, wholesalers, repackagers, and transport logistics providers. The overall goal is to provide guidance for ensuring a product's "identity, strength, quality, and purity" across the entire distribution channel.

Also stated in USP <1079>: "Shipping of temperature sensitive articles presents a special challenge...unlike shock, vibration, and other physical hazards, thermal hazards tend to be unique to a given system."

The variables that make each cold chain system unique include:

- Points of origin and destination
- Article and container sensitivities to cold
- Accidental freezing or heat
- Transit mode (e.g. air, truck, rail, or a combination)
- Time
- Weather or season
- Carrier type (e.g. integrated carrier, freight forwarder, or small package carrier)

To determine appropriate packaging specifications for a specific product, it is first critical to have an accurate "ambient temperature profile" for the specific trade lane in question. The only way to develop a temperature profile is to conduct a Shipping Study because there are many factors that contribute to determining the thermal variability of a specific trade lane, including carriers, delivery times, service levels, and routes.



Solutions

Sensitech's Life Sciences Professional Services team has 15 years of experience providing comprehensive **Shipping Study** services for leading worldwide pharmaceutical manufacturers. Sensitech's in-depth monitoring and analysis includes specific recommendations for process improvements that comply with regulatory guidance. The result is highly detailed documentation to support risk management decisions and to identify the optimal balance between controllable costs and uncontrollable risks.

Sensitech works closely with customers to identify and document the customer's specific needs and requirements. Sensitech's project management methodology is based on quality execution and detailed documentation of deliverables.



Service Offering Overview

- Includes the development of a qualification protocol based on actual field tests that include load configurations, conditions, expected environmental extremes, and the projected transportation channel
- Provides documented temperature or temperature and humidity profiles over time that identify conditions and variations in a comprehensive manner
- Documents evidence to support the distribution of specific products in compliance with regulatory and standards-based guidelines
- Develops, documents and executes consecutive replicated field transportation tests
- Includes both temperature and humidity data—per USP guidelines
- Includes the development of both summer and winter temperature profiles



Characteristics of Program

- Efficient, timely and cost effective
- Third-party documentation to support internal Standard Operating Procedures (SOPs) and overall regulatory requirements
- Education of industry best practices—Good Cold Chain Management Practices (GCCMP)
- 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 1-800-834-8367.
- Contact your Sensitech regional sales manager.
- Visit Sensitech on the Web at www.sensitech.com

Sensitech Inc. is a leading provider of supply and cold chain visibility solutions that enable our customers—global leaders in the food, life sciences, and industrial markets—to track, monitor and protect the quality and integrity of their temperature-sensitive products across complex supply chains. Through its logistics security division, FreightWatch International, Sensitech also offers origin-to-destination services that provide customers with real-time cargo transparency, helping them to mitigate such risks as theft, diversion, counterfeiting, and chain of custody. Sensitech Inc. is an ISO 9001:2008 company based in Beverly, Mass., with more than 30 sales, service and distribution locations around the world. Sensitech is a part of UTC Building & Industrial Systems, a unit of United Technologies Corp., a leading provider to the aerospace and building systems industries worldwide. Visit www.sensitech.com for additional information. © 2013. Sensitech Inc. All Rights Reserved. Unless otherwise indicated, all trademarks and service marks are the property of Sensitech Inc.