

# <1079> Overview

## Revised Pharmaceutical ‘Storage and Shipping Practices’ Regulation Warrants a Review of Existing Processes and Documentation

### Understand Changes in the Regulatory Environment

The regulatory environment for the storage, handling and distribution of pharmaceutical products has changed dramatically with the publication of U.S. Pharmacopeia (USP) <1079> “Good Storage and Shipping Practices”.

As a result of this publication, pharmaceutical manufacturers should review their current processes and documentation for supporting a well-developed cold chain management program.

### What is USP General Chapter <1079>?

USP <1079> “Good Storage and Shipping Practices” outlines guidance for manufacturers, distributors, wholesalers, repackagers, and transport logistics providers handling pharmaceutical products. The document provides requirements for ensuring a product’s “identity, strength, quality, and purity” across the entire distribution channel — from manufacturer to end user.

USP <1079> covers the handling and storage of products in:

- Warehouses
- Pharmacies
- Trucks
- Shipping Docks
- Other Locations

### What Does USP Guidance Actually Say?

*“Operational and performance testing should be parts of a formal qualification protocol”*

*“Validated temperature- and/or humidity-monitoring technologies can be used to monitor the overall environmental effect on compendial articles during shipment and distribution.”*

*“Observation of the 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 different parts of the warehouse.”*

*Temperature profiling “should be conducted in both summer and winter” and “the temperature profile report should provide recommendations.”*



### What Do I Need to Do?

As a result of these recommendations, detailed quality reports are required to support appropriate internal processes and regulatory requirements.

Three key drivers must be considered when re-evaluating cold chain distribution systems and documentation:

1. Protecting patient safety by ensuring product quality
2. Upholding brand equity through product quality
3. Complying with increased regulatory guidance and scrutiny of cold chain management programs and documentation

### What is Sensitech's Solution?

**Sensitech's Life Sciences Professional Services™** team has an in-depth knowledge of the changing regulatory landscape. Furthermore, as the pharmaceutical industry's leading provider of comprehensive cold chain visibility solutions, Sensitech has the experience to help you audit your current processes and documentation to support Good Cold Chain Management Practices.

Sensitech is able to monitor and analyze the entire pharmaceutical supply chain from raw materials through final distribution at the pharmacy. Each of Sensitech's temperature monitors receives a Certificate of Validation and is traceable to NIST standards.



ISO 9001:2000-certified Sensitech provides three types of professional services to monitor and analyze a product's adherence to desired conditions:

1. Facility Thermal Mapping
2. Trailer and Container Thermal Mapping
3. Shipping Studies

These services enable us to deliver highly detailed documentation to support risk management decisions and to identify the optimal balance between controllable costs and uncontrollable risks. Sensitech's highly detailed reports provide the necessary documentation to support internal process improvements required by regulatory and compliance bodies.



**About U.S. Pharmacopeia:** The United States Pharmacopeia (USP) is the official public standards-setting authority for all prescription and over-the-counter medicines, dietary supplements, and other healthcare products manufactured and sold in the United States. USP sets standards for the quality of these products and works with healthcare providers to help them reach the standards. USP's standards are recognized and used in many other countries outside the United States.

**About Sensitech:** Sensitech is the world's leading provider of cold chain visibility solutions enabling global leaders in Food and Pharmaceuticals to track and monitor assets across the supply chain, protecting the integrity of their temperature-sensitive products. Sensitech is an ISO 9001:2000 registered company. The company is based in Beverly, Massachusetts, and has offices in Amsterdam, Calgary, Melbourne, Redmond and Santiago with service and distribution offices around the world. For additional information about Sensitech, call 978-927-7033 or visit [www.sensitech.com](http://www.sensitech.com). ©2006. Sensitech Inc. All Rights Reserved. All trademarks and service marks are the property of Sensitech Inc.