

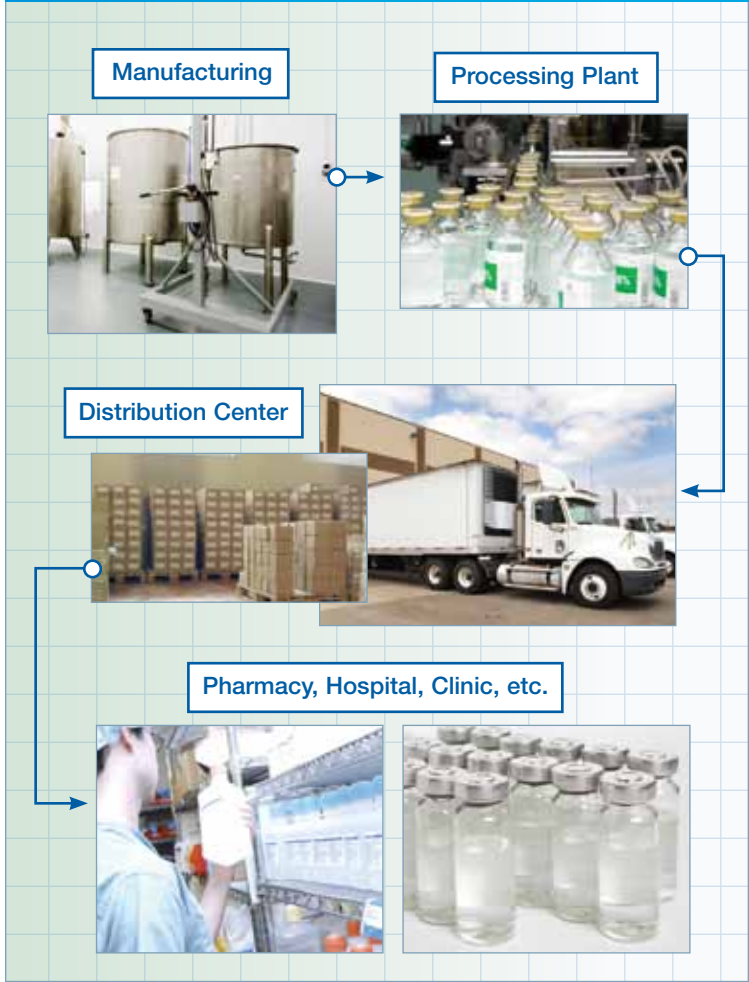
# Temperature Sensitive Supply Chain Services



# Temperature Sensitive Supply Chain Services

## Ensure Product Quality and Patient Safety through Control of Your Cold Chain

### The Cold Chain Process



### Sensitech delivers the tools, people and expertise

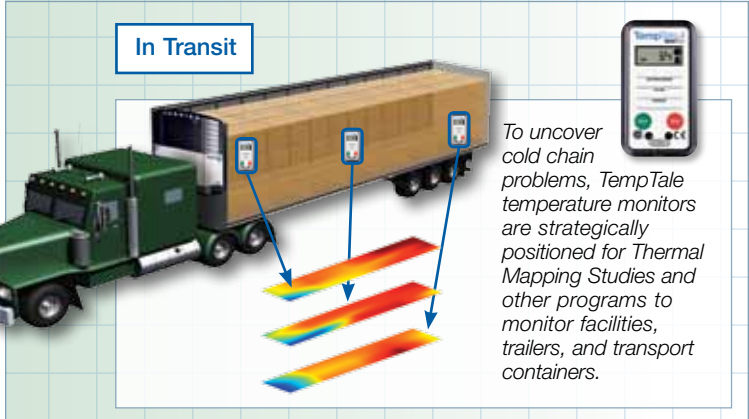
In the business of temperature-controlled medicinal products, there is a direct correlation between your cold chain data and the quality of the products you deliver. For decades, cold chain data has been underutilized. It has been used purely for the purposes of evaluating the integrity of individual shipments by facilitating the dock-level accept or reject decisions. The same cold chain data can and should be accumulated and used to identify systemic weaknesses and variability in your process, which can help to identify problems before they occur. Meaningful and measurable improvements will help to insure product quality, patient safety, and cost savings while protecting brand equity.

Sensitech collects and aggregates cold chain data for the purpose of evaluating processes. We apply statistical methodologies, including statistical process control (SPC), and analyze your cold chain as a process, rather than as sets of independent transactions. We follow a sound methodology and utilize proprietary analysis tools to identify and help to resolve problems that cost your organization valuable resources. Additionally, Sensitech delivers findings in easy-to-interpret graphs and tables so that you can communicate issues effectively and take action. Finally, we continue to work with you to ensure that your actions have had the intended effect.

### Our Team of Experts

Sensitech's Professional Services Team has years of experience in analyzing cold chains in the biological, pharmaceutical, chemical, and clinical sciences markets.

The team is strategically positioned around the world for direct customer interaction and appreciation of geographic considerations. Professional backgrounds include: validation and packaging engineers, industrial engineers, statisticians, logisticians, and packaging experts.



## ColdStream™ “Process Framework”

Sensitech takes a scientific approach to problem solving. By applying a disciplined methodology to the analysis of your cold chain, we can help you identify weaknesses before they become systemic problems. Sensitech evaluates your temperature-sensitive supply chain as a process focusing on continuous improvement.

## Six Steps to an Improved Cold Chain

**Step 1: Define** Our Professional Services advisors utilize a risk-based approach when defining goals and objectives. We then develop and articulate a clear operational plan to outline what will be observed and measured.

**Step 2: Plan** We develop a detailed data collection plan that is reliable and statistically valid. Sensitech relies on years of experience and standards-based guidance in determining the precise sampling size and Monitor Placement Protocol for the appropriate level of granularity and accuracy of data collection.

**Step 3: Measure** Our Professional Services advisors are seasoned project managers who strive to manage every project with absolute precision. Utilizing our validated TempTale® monitors, the advisors manage the collection of an unbroken chain of clean and comprehensive data.

**Step 4: Analyze** Understanding the reams of raw data collected requires a team of experts and the right tools. Our Professional Services advisors evaluate the data using proprietary software and apply extensive industry experience to identify cold chain weaknesses. The team applies statistical process control (SPC) for understanding variability in your cold chain data.

**Step 5: Recommend** Improving your decision making is our goal. Sensitech’s team delivers clear and concise reports that make sense of your data. We then turn information into an action plan, giving you the ability to prioritize changes that can drive meaningful and measurable impact on your temperature-sensitive supply chain.

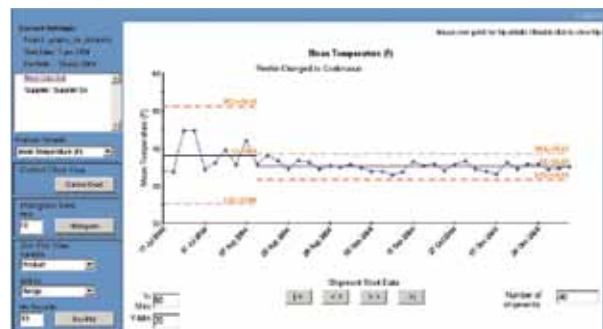
**Step 6: Verify** Ensuring that process changes maintain the desired outcome is the ultimate goal. We work with you to facilitate communication across your supply chain for improved cold chain management, including collaboration between you and your customers, suppliers, and, partners.



*Sensitech’s integrated six-step methodology is used to monitor cold chain processes for improved operational efficiencies and product quality.*

## Statistical Process Control (SPC)

SPC is a proven methodology that has typically been applied to quality-conscious manufacturing environments. The methodology measures variation in processes over time and helps to distinguish routine variation from exceptional variation. As an industry thought leader in Good Cold Chain Management Practices, Sensitech has applied these same concepts to the temperature-sensitive supply chain. The key is to reduce variation, making your process more stable, and enabling you to document that your process is in control and operating within allowable tolerances. This documentation of control can be used to meet regulatory requirements and to reduce costs.



*Control Chart showing Mean Temperature for Supplier over time. Note the reduction in variation once a change was implemented.*

# Temperature Sensitive Supply Chain Services

## Temperature Sensitive Visibility Services

Sensitech's Temperature Sensitive Visibility Services are designed to help improve your cold chain performance.

Partner with us to:

- Assess your current cold chain practices.
- Complete root cause analysis of cold chain issues.
- Develop practical solutions to improve your cold chain.
- Evaluate the effectiveness of your current SOPs.
- Work with supply chain partners to develop quality agreements.
- Provide support to meet regulatory standards.
- Improve efficiencies to control temperature-sensitive distribution costs.

Sensitech will work with you to develop the level of involvement appropriate for a single project, multiple projects, or for ongoing continuous improvement programs. Regardless of the scope of an individual project, our Professional Services advisory team applies the same discipline and rigor.

## Validation and Qualification Services

Validation and Qualification Services include documented testing performed under highly controlled conditions, demonstrating that processes, methods, and systems consistently produce results meeting pre-determined acceptance criteria.

## Thermal Mapping Studies

Thermal Mapping Studies determine and document temperature profiles and variability within any storage or transportation location including: facilities, trailers, intermodal containers, air cargo holds, etc.

## Shipping Studies – Ambient Thermal Profile Development

In order to perform Operational Qualification (OQ) testing of shipping systems, which are designed to maintain product temperatures within predefined specifications, an ambient profile must be created. Ambient thermal profiles are designed to evaluate ambient temperatures across shipment lanes as well as for various methods of transportation and seasonal variation.

## Shipping Studies – Performance Qualification

Performance Qualification (PQ) studies are designed to evaluate if the shipping system is maintaining the product temperature as per design specifications and requirements in the actual distribution environment.

## Continuous Improvement – Life Sciences Programs

Continuous Improvement Programs ensure consistent quality throughout your temperature sensitive supply chain. Sensitech offers full service programs that encompass ongoing data collection, management, and storage of temperature sensitive supply chain data, as well as the analysis, reporting, and interpretation required to translate your data into actionable information.

## Choose the Right Partner

Sensitech's Professional Services protect the value, integrity, and efficacy of medicinal products by working with our customers to improve the efficiency of their cold chain processes. Sensitech is the global leader in temperature-sensitive supply chain data management services.

As the world's leading provider of cold chain visibility solutions, Sensitech Inc. enables global leaders in the food, pharmaceutical, and industrial markets to track and monitor assets across the supply chain in order to protect the integrity of temperature-sensitive products. Sensitech is an ISO 9001:2008 company based in Beverly, Mass., with offices in Amsterdam, Calgary, Hong Kong, Melbourne, Mumbai, Redmond, and Santiago, and additional service and distribution locations around the world. Sensitech is a wholly owned subsidiary of Farmington, Conn.-based Carrier Corp., the world's leader in high technology heating, air-conditioning and refrigeration solutions with operations in 172 countries. Carrier Corp. is a unit 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](http://www.sensitech.com). © 2011 Sensitech Inc. All Rights Reserved. Unless otherwise indicated, all trademarks and service marks are the property of Sensitech Inc.

## A Carrier Corp. Subsidiary

09/11 00



Amsterdam Boston Calgary Hong Kong Melbourne Mumbai Redmond Santiago

Sensitech Inc. • 800 Cummings Center • Suite 258X • Beverly, MA 01915-6197 • 1-800-843-8367 • +1-978-927-7033 • Fax: +1-978-921-2112 • [www.sensitech.com](http://www.sensitech.com)