



Qualification Services for Transportation

Global regulatory agencies are pushing for cold chain monitoring programs to expand their focus beyond distribution and include the entire pharmaceutical supply chain. Pressure is mounting for life sciences supply chains to adopt a more comprehensive program that starts with monitoring raw materials and extends all the way through to distribution to the patient. According to Chapter V, section 501 of the Federal Food, Drug, and Cosmetic Act, the U.S. Food and Drug Administration (FDA) has stated that a drug is deemed “adulterated” if its manufacture, processing, packing or “holding” do not conform to current Good Manufacturing Processes (cGMP). In the Act, “holding” is defined as the phase of the supply chain process during which a drug is being distributed, transported, or warehoused for distribution or transfer. The European Union, Ireland, Canada, India, Mexico and Argentina are among the many regions that are adopting more comprehensive monitoring practices. To demonstrate the necessary cGMP control, proper qualification for transportation has become a necessary step for the life sciences industry.

Sensitech Inc. has been providing cold chain analyses of distribution systems for more than two decades. Our customers can now choose from a range of options to assist with their qualification needs, ranging from full-service engagements to self-implementation solutions. Customize a combination of services to meet your needs, and we will help you to ensure compliance and control.

Qualification Services

Distribution environments are highly variable because they depend upon a range of factors including but not limited to: product, packaging, carrier, trip duration, transit mode, and weather conditions. Consequently, obtaining qualification services has become a necessary step to ensure that those involved in the temperature-controlled supply chain are maintaining the quality of products throughout their distribution environments. Documented testing must be performed to demonstrate that transport processes, methods, and systems consistently produce results meeting pre-determined acceptance criteria for storage against label claims.

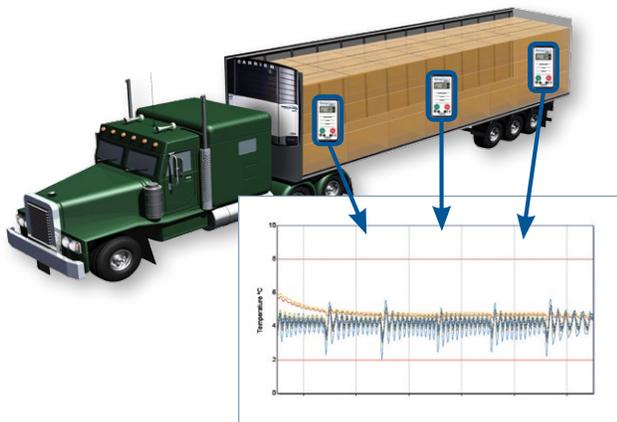
Sensitech has the equipment, materials, and personnel with the requisite experience and training needed to provide different types of qualification services for equipment utilized in managing the temperature-controlled supply chain.

Sensitech’s services include:

- Operational Qualification (OQ) and Performance Qualification (PQ) protocol generation
- Collection of temperature data using NIST® traceable TempTale® temperature monitors
- Complete Qualification Report generation including:
 - Executed protocols
 - Summary reports
 - Project execution data
 - Observations
 - Recommendations
- Verification assistance using thermal mapping



Qualification Services for Transportation



Thermal Mapping Services

- Thermal mapping is a key component to qualification certifications and requires professional background knowledge, broad implementation experience and in-depth analysis capabilities. Sensitech makes this step in the certification process easy by offering full service thermal mapping, as well as self-implemented thermal mapping kits. Regardless of the method you choose, all thermal mapping services offer the same high-quality components:
- Qualification mapping protocol designed exclusively for specific transportation environments to ensure that results accurately reflect actual conditions and expected environmental extremes
- Documented temperature profiles over time to comprehensively identify conditions and variations across the unit being mapped
- Evidence to support the distribution of specific products to show compliance with Good Distribution Practices (GDPs) and the regulatory bodies that govern your distribution network
- Mean Kinetic Temperature (MKT) calculations for separate areas to show the effect of temperature fluctuations during transport
- Identification of problem areas to help reduce variability within your distribution network

Full-Service Thermal Mappings

Sensitech can map any transport vehicle as part of a qualification process. Full-service thermal mappings are conducted by Sensitech's Professional Services team on-site. The complete service includes fully implemented protocols, all necessary equipment and personnel to execute the study, a complete data analysis, and a comprehensive Qualification Report.

Thermal Mapping Kits

Transportation Thermal Mapping Kits are a great way to benefit from Sensitech's years of experience at a significantly lower cost. The kits include mapping protocols, easy-to-follow execution instructions, and a complete set of materials including NIST traceable TempTale monitors. Once the protocols are executed and the data is gathered, customers can simply send the monitors back to Sensitech. Sensitech's Professional Services team will analyze the data and deliver a complete data analysis and a comprehensive Summary Report.

Kits are supported for the following:

- Trailers
- Air and sea containers
- Trucks and lorries
- Vans

About Sensitech Services

Our Services are backed by Sensitech's world-class support infrastructure and feature:

- ISO-certified, NIST traceable TempTale temperature monitors, and ColdStream®, an Internet-enabled application platform built to comply with 21 CFR Part 11 guidance
- A field support team that has 20+ years of experience placing monitors and implementing protocols, and has successfully passed regulatory scrutiny from the FDA, Irish Medicines Board (IMB), Health Canada, and Medicines and Healthcare Products Regulatory Agency (MHRA)
- A Professional Services team for expert data analysis and expertise in cold chain management
- A Technical Support team strategically positioned globally for optimal coverage should you have any questions

Sensitech Inc. is focused on delivering supply chain visibility solutions that track, monitor and protect products for global leaders in the food, life sciences, consumer goods, and industrial markets. Our solutions are focused in three key areas: quality and compliance, supply chain security, and logistics performance management. Quality and compliance solutions address temperature-sensitive, complex supply chains focused on delivering the highest quality possible, while our supply chain security solutions help to mitigate risks associated with theft, diversion and chain of custody. Sensitech's logistics performance solutions deliver origin-to-destination, real-time transparency to any in-transit journey. Sensitech Inc. is an ISO 9001:2008 company, headquartered in Beverly, Mass., with more than 35 sales, service and distribution locations around the world. Sensitech is a part of UTC Climate, Controls & Security, a unit of United Technologies Corp., a leading provider to the aerospace and building systems industries worldwide. Visit www.sensitech.com for additional information. © 2017 Sensitech Inc. All Rights Reserved. Unless otherwise indicated, all trademarks and service marks are the property of Sensitech Inc. NIST is a registered trademark of The National Institute of Standards and Technology Agency of the United States Government.