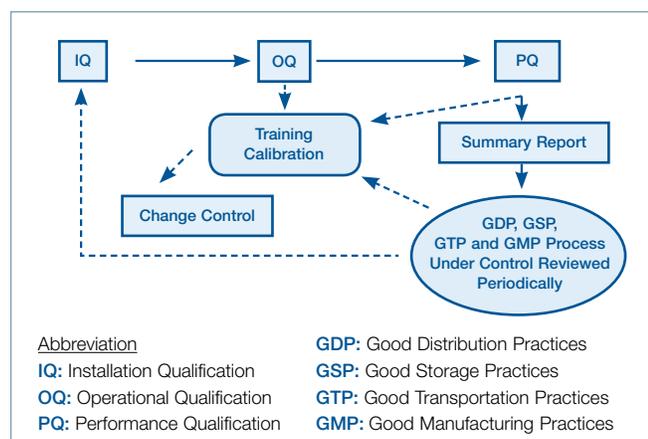# Validation and Qualification Services for Storage

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 of storage facilities 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 variety of options to assist with their validation 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.

Validation Services

| Abbreviation	
IQ: Installation Qualification	**GDP:** Good Distribution Practices
OQ: Operational Qualification	**GSP:** Good Storage Practices
PQ: Performance Qualification	**GTP:** Good Transportation Practices
	GMP: Good Manufacturing Practices

Obtaining validation 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 highly-controlled environments. Documented testing must be performed under controlled conditions and must demonstrate that processes, methods, and systems consistently produce results meeting pre-determined acceptance criteria.

Sensitech's services include:

- Review and evaluation of equipment or facility data including: manuals, mechanical drawings, piping and instrumentation diagrams (P&IDs), calibration information, etc.
- Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) protocol generation
- Collection of temperature data using NIST® traceable TempTale® temperature monitors or Kaye® Validator® thermal validation system
- Complete Validation Report generation including:
  - Executed protocols
  - Summary reports
  - Project execution data
  - Observations
  - Recommendations
- Verification assistance using thermal mapping
- Validations for the following:
  - Warehouses
  - Cold rooms
  - Refrigerator & freezer
  - HVAC systems
  - Incubator and stability chambers

SENSITECH
United Technologies
SUPPLY CHAIN VISIBILITY

Validation and Qualification Services for Storage
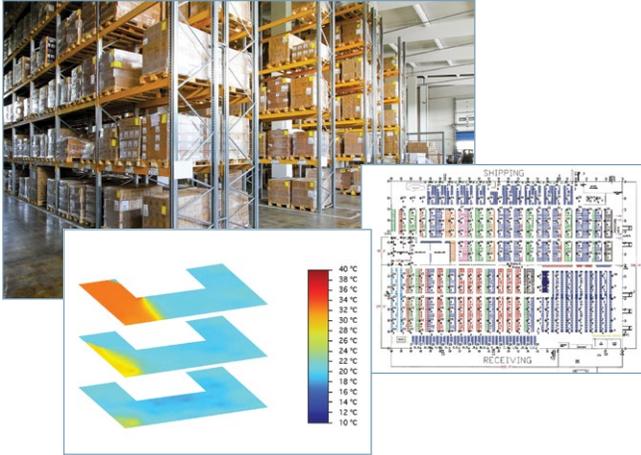
Thermal Mapping Services

Thermal mapping is a key component to validation certifications and requires professional background knowledge, broad implementation experience, and in-depth analysis capabilities. Execution protocols can be complicated and tedious, depending on the storage area being evaluated. In order to meet this challenge, as well as limitations in staff availability and financial constraints, Sensitech offers you the choice of either full-service or self-implementation thermal mapping kits.

Both options offer the same high-quality components:

- Thermal mapping protocol designed exclusively for specific storage 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 storage area being mapped

- Evidence to support the storage of specific products in specific locations to show compliance with Good Distribution Practices (GDPs) and the regulatory bodies that govern your storage locations

- Mean Kinetic Temperature (MKT) calculations for separate areas to show the effect of temperature fluctuations during storage

- Identification of problem areas to help reduce variability

Full-Service Thermal Mappings

Sensitech can map any location, facility or storage space as part of a validation process. Full-service 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

Storage Thermal Mapping Kits are a great way to benefit from Sensitech's years of experience at a significantly lower cost. A kit includes 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:

- Stand-alone refrigerators and freezers
- Incubators
- Environmental chambers

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.com

🐦 @sensitech

06/17

SENSITECH
United Technologies
SUPPLY CHAIN VISIBILITY

Sensitech Inc. • 800 Cummings Center • Suite 258X • Beverly, MA 01915-6197 • 1-800-843-8367 • +1-978-927-7033 • Fax: +1-978-921-2112 • clientservices@sensitech.com
Sensitech EMEA • Tel: +31 (0)252 211 108 • Fax: +31 (0)252 231 032 • info@sensitech.eu