

# Validation & Qualification Services

## Validation and Qualification Services for Your Temperature Controlled Supply Chain

*Do you have documentation to support that "facilities or controls used for, its [the drugs] manufacturing, processing, packing, or holding" conform to Current Good Manufacturing Practices (cGMP)?*

**Federal Food, Drug, and Cosmetic Act [501 (a)(2)(B)]**

### Challenges

In the Life Science industry, validation has become a necessary step to ensure that you are maintaining the quality of temperature controlled medicinal products throughout the manufacturing, storage, handling, and distribution environments.

Regulatory requirements dictate that cGMPs apply not only during the manufacturing process but also while a drug is being distributed, transported, or warehoused for distribution or transport. Therefore, validation of equipment used in the distribution, transportation, and warehousing of drugs is required.

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

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

### Solutions

Sensitech has provided analysis of cold chain storage, handling, and distribution environments for over 15 years. We have also conducted validations of equipment used for transportation and storage.

We can provide you with the documentation needed to help you comply with global regulatory expectations and standards-based guidance.

### The Guideline on General Principles of Process Validation authored by the FDA states:

*"Process Validation is a requirement of the Current Good Manufacturing Practices Regulations for Finished Pharmaceuticals, 21 CFR Parts 210 and 211."*

*"After process equipment is designed or selected, it should be evaluated and tested to verify that it is capable of operating satisfactorily within the operating limits required by the process."*

*"It is important that equipment qualification simulate actual production conditions, including those which are 'worst case' situations."*



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## Service Offering Overview

**Validation**—Sensitech has a well-defined process for executing a validation.

- 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.
- Configuration of TempTale® temperature monitors or Kaye Validator thermal validation system.

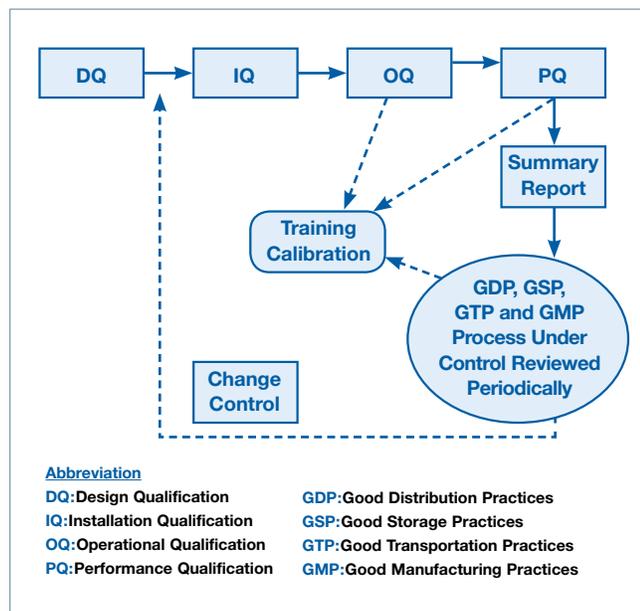
Final Validation Report generation consists of the executed protocol, which depicts data collected from the study observations and actions. In addition, the validation report includes testing support data compiled from temperature mapping, data summaries, equipment data reports, recording charts, and conclusions.



## Validation and Qualification services offered are:

- Process Validation
- HVAC Systems Validation
- Autoclaves Validation
- Refrigerator & Freezer Validation
- Incubator Validation
- Cold Room Validation
- Walk-In & Stability Chamber Validation
- Transportation Qualification
- Trailer Qualification
- Sea & Air Container Qualification
- Package Performance Qualification

## Characteristics of Program



## Features

- Designed to comply with industry guidelines and standards.
- Based upon industry best-practices.
- Supports internal and external audit procedures as well as Standard Operating Procedures (SOPs).
- Documentation is written to support cGMP compliance.
- Our experienced Project and Program Managers aim to deliver timely and accurate execution of all projects.
- All monitors used are tested to NIST® traceable standards and include a Certificate of Validation.

## For more information

- Call Sensitech's Life Science Professional Services group at 1-800-843-8367.
- Contact your Sensitech regional sales manager.
- Visit Sensitech on the Web at [www.sensitech.com](http://www.sensitech.com).

As the world's leading provider of cold chain visibility solutions, Sensitech enables global leaders in Food and Pharmaceuticals to track and monitor assets across the supply chain to protect the integrity of temperature-sensitive products. Sensitech is an ISO 9001:2008 company and is based in Beverly, Massachusetts, with offices in Amsterdam, Boston, Calgary, Melbourne, Mumbai, Redmond, Santiago and Shanghai as well as service and distribution offices around the world. Sensitech is a subsidiary of Farmington, Conn.-based Carrier Corp., the world's largest provider of heating, air conditioning, and refrigeration solutions with operations in 172 countries. Carrier Corp. is part 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). © 2010. 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.

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