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" confirm 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.

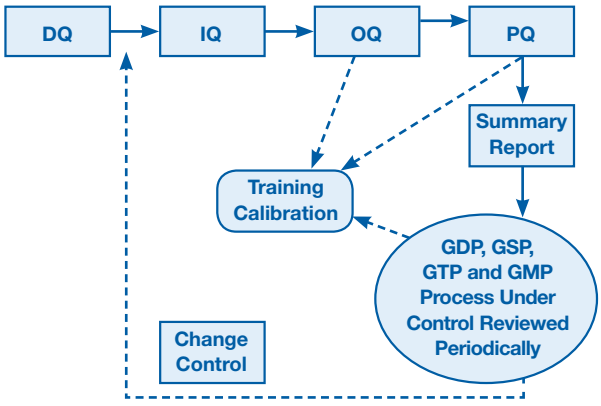
- Review and evaluation of equipment or facility data including: manuals, mechanical drawings, Piping and Instrumentation Diagrams (P&IDs), calibration information, etc.
- Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) protocol generation.
- Configuration 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



Abbreviation

DQ:Design Qualification
IQ:Installation Qualification
OQ:Operational Qualification
PQ:Performance Qualification
GDP:Good Distribution Practices
GSP:Good Storage Practices
GTP:Good Transportation Practices
GMP:Good Manufacturing Practices

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.

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SENSITECH COLD CHAIN VISIBILITY

Amsterdam Boston Calgary Melbourne Redmond Santiago Shanghai

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