



GMP Warehouse Qualification & Compliance Services

Ensuring that warehouses are compliant and well-controlled, confidently ready for customer audits.

Who We Are

cGMP Consulting offers decades of practical experience in assisting GMP-regulated storage facilities within the pharmaceuticals, biotech, and related sectors. Our team knows how FDA expectations impact real-world operations so we can recommend practical, risk-based strategies that align with both your customer's requirements and regulatory requirements. We work with you to develop sustainable systems, aligning with your business objectives, that prepare you for customer audits.

Our Process

Assess & Plan

We will assess your facility using a risk-based approach. This process will typically include a gap analysis and a review of existing SOPs to effectively determine the best course of action.

Build Documentation Package

A series of documents will be created for your qualification needs, including temperature/humidity mapping, risk assessments, and execution protocols like IQQ/PQ or IOPQ, depending on your needs. A Validation Master Plan (VMP) will also be developed as warranted.

Execute Qualification Studies

In larger facilities, the process involves IQQ/PQ, while in smaller facilities, IOPQ is more common. PQ, or Performance Qualification, consists of temperature and humidity mapping your facility or cold unit.

Analyze Data / Manage Deviations

We review and interpret all data to confirm compliance with defined acceptance criteria. If deviations are identified, we lead the investigation, perform root cause analysis, and develop corrective actions aligned with regulatory expectations.

Prepare and Deliver Final Report

We deliver a complete, clearly documented final report that summarizes results, conclusions, and any required actions. We present it within your established timeline to support timely review and informed decision-making.

Our Services

Qualification

- Warehouses
- Cold Units
 - Refrigerators
 - Freezers
 - Cold Rooms
- Systems
 - Document Control, Temperature Monitoring, Warehouse Monitoring, ASRS, WMS, etc.

Supporting Offerings

- GMP Gap Assessment
- Existing SOP Review
- Quality Management System Development
- Audit Preparation/Response
- Mock Audits
- GMP Training
- GMP Certification

Notable Clients



Contact Us

 312-420-7682

 cGMPConsulting.com