GPS CAPABILITIES PROFILE

stability chambers

Your stability chamber qualification team

IQ, OQ, PQ Validation Studies; Temperature and Relative Humidity

Stability Chamber Validation
The stability chamber is the backbone of a new drug development program. In today's era of high stakes development, there is no room for risk. Let us bring the Gavin standard of excellence to your stability chamber qualification program.

Gavin Integration
We come to your site, and start with the programs you have established. We study your Standard Operating Procedures for validation, your validation protocols, your documentation practice, and other established written procedures. We apply the results by creating the appropriate validation protocols for your stability chambers, new or used. The protocols will be presented for management approval.

Chamber IQ, OQ Studies
With the approved protocol as the study plan, we proceed to execute the appropriate level of Installation Qualification analysis and documentation. We focus on special requirement control systems, especially temperature and relative humidity controls. Operational testing will demonstrate the proper functionality of all control and monitoring systems, including any special integrated monitoring and alarm systems. If appropriate, we test the ability of the system to notify personnel of problems by remote dialing, pager messaging, or related alarm mechanisms.

Performance Qualification
The performance qualification (PQ) phase typically includes repetitive time and temperature studies to demonstrate that all samples stored in the chamber will experience the required conditions. Our high quality thermocouple calibration is conducted before and after the study for the study integrity you can count on. Because the chambers will store your samples for months at a time, our PQ studies span appropriate lengths of time to support the normal use of the chamber. We collect the data, analyze it, and present it to demonstrate a sound stability program.

At a Glance

Service: *Stability Chamber Validation*
Compliance: *21CFR Part 211*
Capability: *Full Capability*
Best at: *High Quality Validation*
Project Scope: *Full or Partial*
Contact: *Blair Conley*
Sales: **1-800-700-5147**

Relative Humidity Mapping
Most stability chambers are required to control relative humidity as well as temperature. This is especially critical for accelerated storage studies, designed to stress packaging as well as the dosage form itself. Our state of the art real time humidity logging instrumentation generates the high quality data you need to document the humidity control performance of each of your chambers. Don't rely on the monitoring instruments alone. Let us create the data you need to demonstrate humidity control.

Special Studies
Power failure studies and open door recovery studies are just two of the special studies we recommend. If you could use expert help with your stability chambers, why not turn to the experts at GPS? We can give you the support, the professional service, and the dedication to high quality validation which assures your success.

Act Today
Call today to discuss your stability chamber validation project!

1-800-700-5147