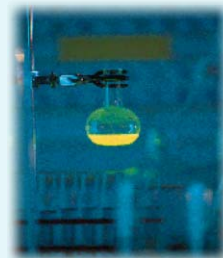




Laboratory Services

Your partners at **Quality Compliance Partners, Inc. (QCP, Inc.)** are a dedicated, dependable team of professionals who hold the experience and the technical competence required to successfully implement any laboratory project in support of research, development, and commercial production. Services we offer include:

- ✓ **Laboratory Validation Services**
- ✓ **Laboratory Vendor Software Services**
- ✓ **Laboratory Procedures Development Services**
- ✓ **Laboratory Personnel Training Services**



Laboratory Validation Services

QCP, Inc. can provide complete Laboratory and Equipment Validation Services to ensure that your lab systems and equipment meet GLP, GMP and GCP standards along with 21 CFR Part 11 and other industry standards, guidance documents, and regulations. Our laboratory validation services include, but are not limited to:

- Development and Implementation of Master Validation Plans
- Develop and Execute IQ/OQ/PQ for Laboratory Systems and Equipment
- Validation/Qualification studies on new transferred methods of new products
- Method Development
- Conduct GAP Analysis and Risk Assessments and Develop Remediation Plans
- Evaluation of Current Compliance States



Laboratory Instrument Validation Services

Include, but are not limited to:

- | | |
|-------------------------------|--|
| • HPLC, GC / LC | • Dissolution Apparatus |
| • Mass Spec. / NMR | • Calorimeters |
| • FTIR, NIR, UV-Vis | • Densitometers |
| • Fluorometers | • Auto-titrators |
| • Plate Readers | • Gamma Counters |
| • Cell Sorters, Cell Counters | • Chromatography System |
| • TOC Analyzers | • Refrigerators, Freezer, and Cyro Units |





Laboratory Systems Validation Services

Laboratories typically have many instruments that generate large volumes of data. The authenticity and reliability of this data must be assured. We can assist your laboratory by conducting a compliance assessment of all of your systems, or help with individual systems or instruments. Include, but are not limited to:

- Most Major LIMS Validation
- Chromatography Data Systems (Waters, Agilent, PeakPro, Turbochrom)
- Networked Data Acquisition Devices
- Laboratory Systems Interfaces
- Clinical Data Management Systems
- Document Management Systems

Laboratory Vendor Software Services

Leveraging vendor provided qualification services and documents can be useful but only if the following are satisfied:

- ✓ Protocol pre-approved by client
- ✓ Tests and acceptance criteria meets your intended use
- ✓ Tools used during the qualification are calibrated and certificates are provided
- ✓ Good documentation practices meet guidelines
- ✓ Security requirements tested
- ✓ Workgroup or user configurations verified and tested
- ✓ Data locations and interfaces to other equipment or systems has been verified and tested



Only by having a documented process for leveraging vendor provided qualification service can the client fully meet validation and qualification regulations. QCP, Inc. can support the execution of these systems and can ensure compliance with current regulatory requirements.

Laboratory Procedures Development Services

Include, but are not limited to:

- System Life Cycle Procedure
- System Categorization Procedure
- System Logbook Procedure
- Equipment out of Tolerance (OOT) Procedure
- System Change Control Procedure
- Laboratory Document Control
- Ensuring Data Traceability
- Control of Laboratory Data and Software Data Integrity
- Purchase, Storage, and Evaluation of Supplies and Services
- Laboratory Housekeeping/ Laboratory Maintenance to Support Activities and Test Results

Laboratory Personnel Training Services

- Best Practices for GLP (Good Laboratory Practices)
- Analytical Techniques and Instrumentation
- Computer System Validation for Laboratory Systems
- Good Documentation Practices
- Laboratory Equipment & Method Validation
- Laboratory Investigation Reports
- Thermal Mapping (using Kaye Validator 2000) for Stability Rooms, EM Chambers, Ovens, Sterilizers, and Freezers



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