PHCbi

Life Science
Innovator
Since 1966

LABORATORY EQUIPMENT VALIDATION SERVICES

Seamless Integration for Qualification Solutions

PHC Corporation of North America

www.phchd.com/us/biomedical

Turnkey Solutions

Advanced technology and contemporary processes assure compliance through in-depth validation.

PHC Corporation of North America offers a turnkey, systemized approach to validation and compliance.

We provide turnkey solutions using NIST/ISO calibrated instrumentation for validation and qualification in accordance with current GxP regulations (GMP, GLP, GCP), local standards and other regulations.

Professional Validation

Our team of experienced factory trained validation service professionals have earned a reputation for professional performance, detailed documentation and outstanding support for our customers.

Validation solutions incorporate a data collection and analysis protocol to provide complete and accurate validation reports. All archived data is customer specific with secure backup. We meet international requirements for inspection of pharmaceutical, biotechnology and medical device manufacturing.

We use a wired process validation system designed around measurement and reporting requirements of the most intensely regulated industries.

PHC offers a "Café Plan" of services that allow the customer to select site-specific options that are needed and/or required.

Available Validation Services

On-Site Validation/Qualification

- IOQ (IQ/OQ) Protocol Execution
- Calibration (NIST/ISO)
- Temperature mapping
- Dynamic Testing (PQ)
- Validation support
- Consultation

Pre-Delivery Services

- Factory Acceptance Testing (FAT)
- Calibration (NIST/ISO)
- Temperature mapping
- Dynamic Testing (PQ)
- Validation support
- Consultation

Custom Validation

Customized options include but are not limited to:

- Loaded Chamber mapping
- Open Door/Recovery mapping
- Power Failure/Recovery mapping (temperature pull-up)
- Temperature pull-down
- Additional temperature sensor positions
- Extended logging periods – greater than 24 hours

Validation Protocols

- Unit specific manufacturer authorized protocol documents
- Traceable to unit model and serial number
- Customizable testing procedures to meet customer specific requirements
- May be purchased separately for in-house or local vendor execution

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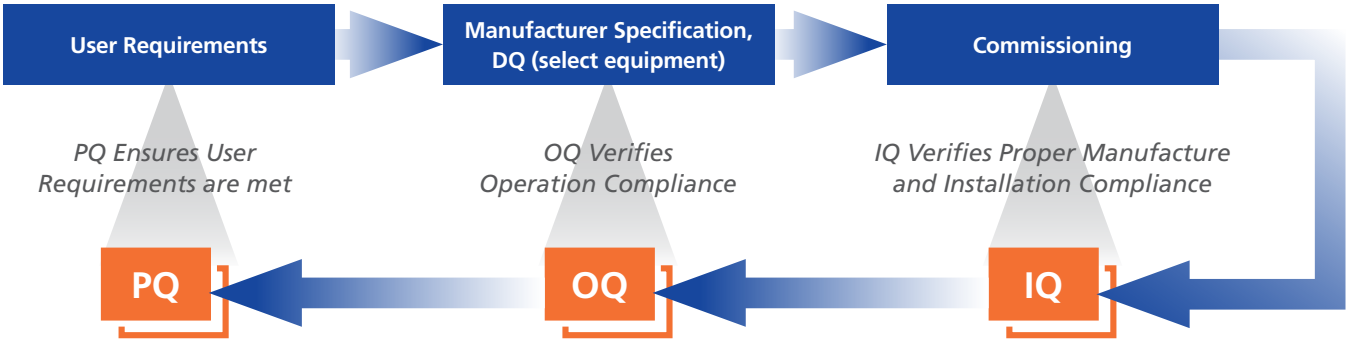
Validation Solutions



Installation/Operation Qualification (IOQ)

IOQ is performed on the equipment at the customers facility. IOQ covers verification of unit conformance to manufacturing specifications including verification of unit assembly and installation (IQ) and verification of unit operation (OQ).

Dynamic Testing (PQ)

Dynamic testing challenges the unit by subjecting it to "real world" operational situations for data capture and evaluation, Dynamic testing may be executed as either a pre-delivery service or at the customer facility. Dynamic testing may include any combination of Loaded Chamber Temperature Mapping, Open Door/Recovery Testing and Power Failure/Recovery Testing.

Factory Acceptance Testing (FAT)

Factory Acceptance Testing is performed on the equipment at the manufacturer prior to delivery to the customers facility. FAT covers virtually all testing as performed in an on-site IOQ process. Save time and money with FAT, which minimizes or eliminates the need for on-site testing. Equipment is delivered to your facility fully validated and ready for use.

Unique Solutions

Our flexibility to meet your needs and our knowledge of regulatory expectations guide our mission to provide professional and successful completion of our services.

Beyond meeting established standards, guidelines and tolerances, we accommodate unique customer application needs. If a service, validation or qualification you require is not listed, please contact us for assistance.

Laboratory Equipment Parameters

Whatever your validation needs, we can provide comprehensive expertise in laboratory equipment to meet your needs.

Laboratory Equipment Parameters

Product	Temperature	CO_2	O_2	Humidity -%RH	Pressure
ULT Freezers	●	—	—	—	—
Cryogenic Freezers	●	—	—	—	—
LN_2 Storage	●	—	—	—	—
Laboratory Freezers	●	—	—	—	—
Pharmaceutical Storage Freezers	●	—	—	—	—
Plasma Storage Freezers	●	—	—	—	—
Laboratory Refrigerators	●	—	—	—	—
Blood Bank Refrigerators	●	—	—	—	—
Pharmaceutical Refrigerators	●	—	—	—	—
Incubators	●	—	—	—	—
CO_2 Incubators	●	●	—	—	—
CO_2/O_2 Incubators	●	●	●	—	—
Environmental Chambers	●	—	—	●	—
Ovens	●	—	—	—	—
Autoclaves	●	—	—	—	●

Regular scheduling of calibration and preventive maintenance is required to trace performance and ensure the accuracy of your equipment.

Calibration

Validation Services offer compliant calibration to meet your validation and qualification needs. Calibration confirms and verifies that all displayed values and control parameters are within the manufacturer's tolerances to ensure proper operation at exact setpoints.

Validation instruments are calibrated to NIST/ISO standards and adhere to a regular schedule of calibration and preventive maintenance for ongoing compliance. Test equipment calibration certificates are available on all projects.

Our Professional Expertise

Our validation staff can help you with planning and developing your validation strategies. With our deep knowledge and experience we offer:

- Emphasis in validation services that meet regulatory guidelines and standards such as ICH, USP, AABB, WHO
- More than 30 years of combined validation experience in the strictest GxP environments
- Field service and service engineering
- 60 years of combined service experience in the laboratory equipment market
- Unbiased testing of competitive equipment

PHCbi Laboratory Products

As a leader in environmentally controlled products, PHC Corporation of North America offers a full line of laboratory equipment designed for use in the life science market. Our level of standards for product safety, reliability and high performance are well known in the industry.

Self-diagnostics, included on our products, permit authorized service technicians to determine how and when service calls are required. Because our products are sold and serviced worldwide, products acquired in one country under grant or facility-sharing programs are easily supported if moved to facilities in the next city or around the world.

Choosing PHCbi brand as an equipment and validation service provider can greatly reduce the time and cost of equipment compliance verification. We also offer training to selected facility biomedical engineers and service staff authorized in warranty and post-warranty repairs.

PHC Corporation of North America offers detailed protocols, including all required specifications, service manuals, operation manuals, support documentation, FAT and IOQ Protocols. This information will assist your validation group or our Validation Services team in the qualification process.

Terms and Definitions

Terms	Definitions
Dynamic Testing	Loaded Chamber, Open Door and Power Failure testing
GxP	Good (x = anything) Practice - guidelines for pharmaceutical industry
GMP	Good Manufacturing Practices
cGMP	Current Good Manufacturing Practices
GLP	Good Laboratory Practices
GCP	Good Clinical Practices
ISO	International Organization for Standardization (International Standards Organization)
FAT	Factory Acceptance Testing
NIST	National Institutes of Standards and Technology
ICH	International Conference of Harmonization
USP	United States Pharmacopeia (compendium of drug information)
WHO	World Health Organization
IQ*	Installation Qualification
OQ**	Operation Qualification
IOQ	Combined Installation and Operation Qualification
PQ***	Performance Qualification
DQ	Design Qualification
SOP's	Standard Operating Procedures
Commissioning****	Operation Qualification

*IQ (Installation Qualification) verifies and documents the equipment installation is compliant with the manufacturer's requirements and specifications as well as testing critical utilities.

**OQ (Operation Qualification) verifies and documents the full functional operation of the installed equipment. Temperature performance is mapped over a continuous 24-hour period. Data produced is compared with manufacturer's published equipment specifications. Specific product parameters are included in the OQ protocol.

***PQ (Performance Qualification) is a testing protocol commonly conducted and performed by an independent validation service company in the customer's production processing area. The PQ will test and validate the performance of equipment in its actual working environment with loaded product. The PQ will make reference to the customer's Standard Operating Procedure (SOP) documents, e.g. product identification, specific storage requirements, loading patterns, etc. The validation report is unique to the customer's specific production process.

****To ensure equipment is designed and installed in a way that follows established codes and regulations as well as sound engineering practices. Commissioning checklist also aims to address issues related to safety, health and environmental impact. The checklist document provides a record of each installation and review as required by law.

For more information contact: **service@us.phchd.com**

PHC Corporation of North America
1300 Michael Drive, Suite A, Wood Dale, IL 60191
Toll Free USA (800) 858-8442, Fax (630) 238-0074
www.phchd.com/us/biomedical

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