



VALIDATION SERVICES

Help support regulatory requirements and industry standards for equipment compliance

Validation Services

Validation Services help meet and mitigate risk in both regulated and non-regulated environments. These services, including Commissioning, Installation Qualifications, Operational Qualifications and Performance Qualifications are among the suite of Services DLR offers.

Validation helps support regulatory requirements and industry standards for equipment compliance with manufacturer documentation.

Upon completion of the validation service, you can feel confident that your equipment is installed, operating, and performing according to manufacturer's specifications.

- Qualifications are required for facilities that operate within a quality management system, comply with global standards, and/or follow country-specific regulations.
- All test equipment used during validation, such as multimeters and probes, are maintained and calibrated by NIST traceable devices.
- DLR offers a consultative approach, reviewing and approving protocols with customers before execution.

Who We Are

Diversified Laboratory Repair (DLR) is an ISO 9001:2015 accredited, full-service laboratory service provider with a full suite of biopharma, healthcare, and research laboratory services a wide variety of equipment types and brands.

A La Carte Service

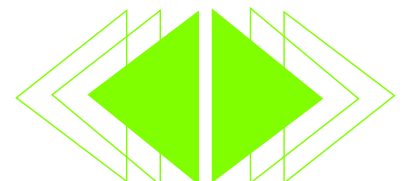
DLR can accommodate modifications and suggestions to Validation protocols with customized protocols to meet customer specification.

Brands Serviced

All Brands Eligible

Equipment & Applications Supported

Reach-in Refrigerators & Freezers
Wlk-in Refrigerators & Freezers
Liquid Nitrogen Storage Tanks
Liquid Nitrogen Back-up Systems
Controlled Rate Freezers
Environmental Chambers
Cell Washing Equipment
CO2 Incubators
Water Baths
Any Equipment used in Regulated Critical Processes (e.g. Manufacturing or Storage Products)





Validation Offer for 24-Hour Mapping

(Longer mapping studies also available)

Commissioning

Bringing a new piece of equipment into GMP operational state.

- Calibrate any control instruments that are part of the equipment being commissioned.
- Adjust equipment's cycles and settings where necessary.
- Provide customer a commissioning report with details of adjustments made and final equipment settings.

Installation Qualification (IQ)

The first test of the equipment validation or qualification process and verifies the equipment has been installed correctly and adheres to design specifications.

- Identification of equipment components.
- Verification of all critical utilities that run the equipment, such as electrical power, steam and water pressure (if applicable).
- Verification of documentation including operations and maintenance manuals and component cutsheets.
- Verification of security and access (if applicable).
- Provide customer executed protocol and final report that summarizes tests and results.

Operational Qualification (OQ)

Operational qualification follows installation qualification and serves to confirm whether the equipment is operating within range and help identify any hot or cold spots within the unit.

- Temperature Mapping of the equipment with

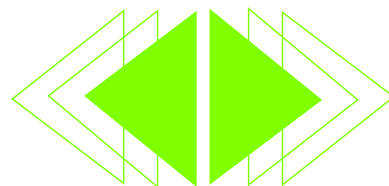
NIST traceable probes.

- Open Door Study to simulate equipment's temperature decay and recovery when accessed.
- Power Loss Study to simulate equipment's temperature decay and recovery when power is lost.
- Provide customer executed protocol, including graphic, statistical, and detailed reports of all probe readings and a final report that summarizes tests and results.

Performance Qualification (PQ)

PQs include a loaded chamber with simulated products in the equipment during testing to validate the performance of the equipment simulating day-to-day usage.

- Temperature mapping of the equipment with NIST traceable probes.
- Open Door Study to simulate equipment's temperature decay and recovery when accessed.
- Power Loss Study to simulate equipment's temperature decay and recovery when power is lost.
- Provide customer executed protocol, including graphic, statistical, and detailed reports of all probe readings and a final report that summarizes tests and results.



Contact us for more information on how we can help with your validation efforts. info@dlrepair.com

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