Thermo Scientific Validation Services for Laboratory Equipment

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Thermo Scientific Services

Validation Services for Laboratory Equipment

Selecting the right validation supplier for your equipment is important for the success and efficiency of your laboratory. With our services you receive a full range of cGMP/GLP validation capabilities along with:

Improved Productivity
Our factory-developed IQ, OQ, PQ protocols allow you to start the review process before the equipment arrives, increasing product uptime.

Single-Vendor Convenience
We offer installation, validation and annual re-qualification of your laboratory equipment.

Peace-of-Mind
Our factory-certified validation technicians are product experts with experience and knowledge in cGxP environments.

No Charge, Re-qualification
After our initial qualification, we will re-qualify your unit at no charge if a key component fails while under warranty or an approved service contract.

"Our team has been thoroughly impressed with the level of technical knowledge, quality and responsiveness of Thermo Scientific Services.

Their ability to successfully complete this PQ validation project within the specified time period has enabled our Company to achieve increased compliance levels in an efficient manner."

– Project Manager

Validation Case Study

Read about how a world leading biotech company improved GMP compliance with Thermo Scientific validation services.

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The world leader in serving science

CASE STUDY

A world leading Biotech company improves GMP compliance with Thermo Scientific - Validation Services

As part of its focus on continuous quality improvement, the Customer sought to increase GMP compliance levels through Performance Qualification (PQ) validation and thermal mapping of all QA equipment in one of its facilities. The project involved multiple brands and types of lab equipment and required completion within a tight timeline. Deep technical expertise, project management and thorough knowledge of regulatory standards were key requirements.

Solution

Thermo Scientific Services was selected to perform PQ validation and temperature mapping services based on their in-depth experience and technical expertise of lab equipment, knowledge of compliance, quality of services, and competitive pricing.

The PQ validation and temperature mapping solution included an initial needs assessment, development of a customized protocol, on site mapping work, data analysis and delivery of a professional final report. The protocol, developed in collaboration with the Client, established the procedure for testing and validating the accuracy, uniformity and stability of more than 100 Incubators, Lab Refrigerator / Freezers and -86°C ULT Freezers. The temperature data was generated with state-of-the-art precision recording equipment to ensure full compliance with FDA 21 CFR Part 11 standards. A customized final report, prepared by Thermo Scientific Services, summarized the recorded results for proof of compliance in an easy to read format.

Results

The PQ validation and temperature mapping project was successfully executed and completed on time. GMP procedural requirements for PQ validation are easily accessible and consistently documented across all manufacturers.

The Client can easily demonstrate the Company's adherence to Pharmaceutical and Biologics cGMP's for laboratory equipment.

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> "The validation services are impeccable. The technician that we had on site was personable and knowledgeable. The quality of the validation packages that you receive at the end of the process are of very high quality and have stood up to regulatory scrutiny during audits."
>
> – Associate Director, QC Operations

> "Thermo Scientific Validation Services has enabled our company to save critical time by not only providing us with quality validation documents for our project but performing the testing and assembling a professional validation package at the end of the process, which enabled us to exceed our customers' TAT (turn around time) goals."
>
> – Senior Validation Specialist

Our validation services include:

- Certified validation technician with factory direct equipment expertise and in-depth experience in cGxP environments
- Factory-developed protocols approved by our design engineers and written to FDA standards
- Validation Package includes:
  - Specification sheet with tests and deliverables
  - IQ, OQ, PQ protocols for cGxP requirements
  - Unit specific Operations Manual
  - Critical pass/fail analysis
  - Performance charts
  - Pre and post qualification reports for temperature recording devices
  - Certificates of training on cGxP validation principles and Good Documentation Practices
  - Certificates of calibration for all test equipment

Product Families

Biosafety Cabinets
Centrifuges
CO_2 Incubators
Cryopreservation
Environmental Chambers
Freeze Dryers
Furnaces
General Purpose Incubators
Refrigerators and Freezers
Ultra-low temperature freezers
Microplate Instrumentation
Molecular Biology
Ovens and Vacuum Ovens
Shakers, Stirrers and Mixers
Vacuum Concentrators
Water Baths
Water Purification

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