



Source BioScience

Stability Storage and Validation Services

Your Laboratory Service Partner for Stability Storage and Validation Services





Stability Storage – Keeping your Samples Safe, Stable and Controlled

Source BioScience has over 30 years of experience offering a full range of Stability Storage Solutions with FDA-registered and cGMP, MHRA, HPRA and DEA compliant equipment, to the UK, Ireland and USA.

Our facility with 21 CFR part 11 monitored equipment offers long and short shelf life studies under specified ICH or non-ICH conditions. Our extensive Quality Management System provides overall management, accuracy and control over the Stability and Storage of your samples.

Disaster Recovery

Our Stability Storage facility provides protection of your samples when facing internal threats, such as power outages or equipment failure, as well as external threats such as natural disaster flooding or earthquake disruption. You will have the option to reserve space in our stability storage suites in house, or to hold sample overflow should you require a secure holding facility to meet your environmental specifications.

Photostability

Under the ICH Q1b guidelines, photostability testing is a requirement for photo-sensitive products being produced or under evaluation in pharmaceutical product development. Our photostability testing services are performed in line with the ICH 1Qb specification in normal ambient temperatures of up to 21°C, with capabilities of achieving a minimum of 1.2 million lux hours and 200-watt hours per square metre in fewer than 14 days.

Thermal Cycling

Thermal Cycling facilitates sample testing to ensure adverse effects can be avoided during product transportation, such as potential damages from deviating conditions, such as temperature changes from shipment to storage. Source BioScience provides a variety of cycling equipment capable of reproducing deviating temperature conditions and cycle at various hour periods without the disruption of product movement between chambers.

Service and Validation

Service and Maintenance Services

With over 30 years of experience in Service and Maintenance services, Source BioScience offers full range equipment preservation solutions that are tailored to individual customer requirements.

Benefits

- Service Level Agreements (SLA)
- Technical Support
- Emergency call-out

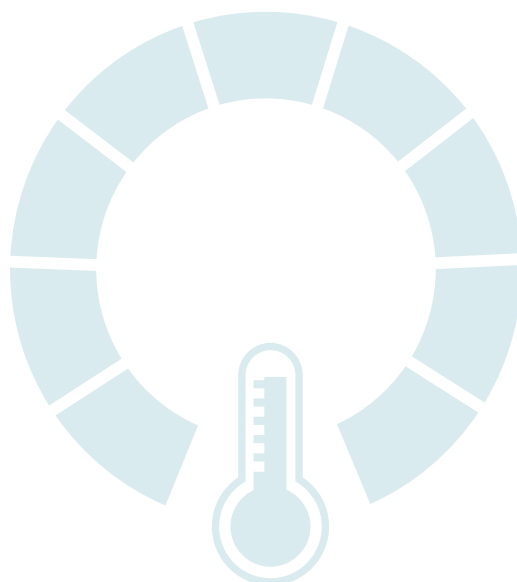
Validation Services

Our Field Service Validation Engineers provide uniformity enhancement to ensure all equipment is performing optimally. All data acquisition systems used by our Field Validation Engineers are fully configurable to customer requirements, conforming with 21 CFR Part 11 and ensure data integrity throughout the validation process.

Our use of standard templates and custom documentation allows us to generate comprehensive validation protocols that will demonstrate compliance to both ICH/MHRA guidelines and FDA requirements.

Source BioScience offers a solution encompassing all aspects of validation and calibration, including:

- IQ (Installation Qualification)
- OQ (Operational Qualification)
- CQ (Calibration Qualification)
- PQ (Performance Qualification)



Why Outsource Stability Storage?

CAPEX vs. OPEX

Instead of large Capital Expenditure Projects, manage your stability projects as part of an operational budget. Typically, a customer pays only for the space used against a pay per use model.

Physical Space

Stability storage equipment can be sizeable, with walk-in rooms requiring a large footprint. Many companies do not have the physical space to accommodate such equipment without the requirement for laboratory refurbishments / extensions so choose to outsource their stability trials.

On-going Management

Stability equipment must be managed and maintained to safeguard against equipment failure and therefore the associated processes and documentation which can occur should a piece of equipment go out of specification. By outsourcing your stability studies to a trusted partner, routine tasks, such as data monitoring, stock inventory tracking and environmental surveillance, are carried out and recorded for the upkeep of your trial.

Focus on Core Activities

Stability studies are typically long-term projects whereby space, maintenance, and staff monitoring are required across the entire length of the project. More companies are now choosing to outsource stability studies, allowing internal teams to drive other projects for maximum revenue generation of the business.

Redundancy and Back-up

To preserve sample quality and enforce data protection, back up generators are installed to preserve the integrity of the sample storage area in the event of a power loss. Walk-in rooms and cabinets are validated across a range of temperatures to provide redundancy in the unlikely event of a room failure to provide complete coverage against external interferences.

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Contact the team

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