

Europe's Leading Stability Storage Experts

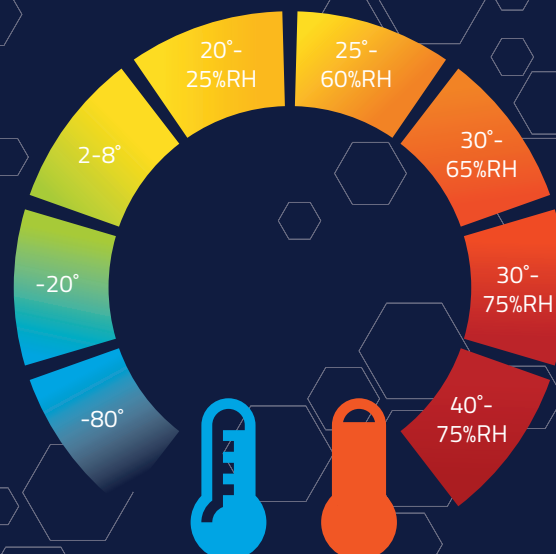
The Q1 Scientific GMP Certified facility provides state of the art environmentally controlled and monitored stability storage to meet all ICH requirements.



STABILITY STORAGE SERVICES

ICH Recommended Storage Conditions:

-80°C	Ultra-low – used mainly for storage of Biological samples eg. DNA, serum & plasma.
-20°C	For long-term storage of retains reference standards and also biologics.
2-8°C Refrigerated	Long term storage of Active Pharmaceutical Ingredients (APIs) or trial batches, Injectables and some Biologics, Retain samples and Reference Standards
25°C/60% RH	Used for Bulk, Retain & Heritage Storage and Medical devices. (Storage of one's DNA long term for possible future use). This condition is used for long term storage.
30°C/65% RH	Used for pharmaceutical and medical device product for either long term or intermediate storage.
30°C/75% RH	Used mainly for trial batches for product being distributed to hot/humid climate conditions.
40°C/75% RH	Product held at this accelerated condition is normally stored for 6 months only.



OTHER SERVICES PROVIDED

Photo Stability

ICH Q1B guideline is the harmonized effort to standardize photostability testing on new pharmaceutical drug substances and drug products. For companies developing or manufacturing pharmaceutical drugs, a robust photostability testing process is essential to ensure product quality and regulatory compliance. Inadequate or substandard testing equipment can result in costly delays and lost revenue.

Q1 Scientific carries out photo stability studies to the client specifications.

Freeze/Thaw – Thermal Cycling

Temperature Sensitive Medicinal products should be transported in a manner which ensures product quality is not adversely affected during transport and that product will be maintained within an acceptable range. Transportation of product takes place within a commercial environment and factors such as traffic events and unforeseen weather conditions can delay shipments and have a deleterious effect on product. This range may differ from that which is specified for long term storage ascertained from stability studies. Temperature excursion and thermal cycling studies evaluate the potential effects of temperature deviations that may occur during the transport process.

Q1 Scientific caters to specific client requirements for freeze thaw studies.

The Case for Outsourcing Stability Storage

'It makes sense to outsource your stability storage'

Argument for the outsourcing of stability storage including:

- **It costs less** – with Q1Scientific's 'Pay for use' model you only pay for the space you need, when you need it.
- **Reduces headcount** – you can prioritise core laboratory activities without additional resources to manage and maintain equipment - no late night calls for OOS's
- **Flexible Capacity** – space available as required
- **Reduced Risk** – Q1Scientific is GMP certified and offers a solution to any disaster recovery situation
- **Eliminate non-value-add activities:** equipment maintenance, capacity constraints & down time.

ICH Zones

ZONE I

ZONE II

ZONE III

ZONE IV

Interactive map available on the Q1Scientific website

www.q1scientific.com