Mapping Services

KELSIUS

PRIMARY AUTHORITY
Worcestershire Regulatory Services
Supporting and protecting you

- ✓ ISO 9001 Accredited
- ✓ ISO 14001 Accredited
- ✓ ISO 27001 Accredited through AWS partners
- ✓ Mapping systems are 21 CFR Part 11 compliant and ISO 17025 calibrated
- ✓ HPRA Compliant
- ✓ MHRA Compliant

What is temperature mapping?

Temperature mapping is the process of collecting and analysing temperature data from different locations within a facility, storage space or temperature-controlled equipment to ensure it is operating within pre-determined limits and to identify any deviations from those limits.

This means you are confirming that the temperature controlled space is suitable for its intended use and that the area, space, cold room or chiller is capable of storing temperature-sensitive products under the appropriate conditions.

You can perform a temperature mapping exercise in any temperature-controlled area.

This could be:

- ✓ Refrigerator or freezer (including ULTs).
- ✓ Incubators.
- ✓ Walk in cold room.
- ✓ Warehouse or other storage area.
- ✓ Temperature-controlled transportation vehicles such as vans or articulated lorries.
- ✓ Ovens.

kelsius.com sales@kelsius.com +44 (0)2045 799 048

Mapping Services

KELSIUS

PRIMARY AUTHORITY
Worcestershire Regulatory Services
Supporting and protecting you

Why is temperature mapping important?

Temperature mapping is a requirement in the context of the GDP / GMP regulations for each space intended for the storage and handling of products with a specific allocated storage temperature. It is required by HPRA, MHRA and other regulators. This includes freezers, cold rooms, conditioned storage areas, quarantine areas and loading bays.

When should I carry out temperature mapping?

If you are mapping a warehouse, it is a good idea to map before items are stored (i.e. an empty warehouse) and when it is full of stock. This is the same for mapping a piece of equipment like a refrigerator. If you do not want to compromise your temperature sensitive items, you may want to put dummy boxes inside your equipment to mimic the actual product.

✓ An initial temperature mapping exercise should be carried out on the storage area before use, under representative conditions. The mapping exercise should be repeated according to the results of a risk assessment exercise or whenever significant modifications are made to the facility or the temperature controlling equipment (EU GDP/GMP; Commission guideline 2013/C 343/01, Chapter 3.2.1).

✓ It is also recommended to perform the mapping exercise at least twice a year: once during the summer and once during the winter. Regulatory bodies (HPRA, MHRA and others) expect twice-yearly mapping exercises to be completed and data available during inspection.

kelsius.com sales@kelsius.com +44 (0)2045 799 048

Mapping Services

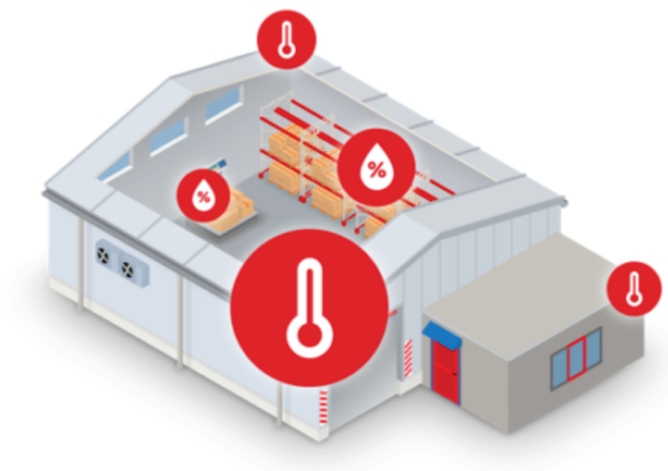
KELSIUS

PRIMARY AUTHORITY
Worcestershire Regulatory Services
Supporting and protecting you

Why should you perform temperature mapping?

Below are some examples of why you would need to perform a temperature mapping exercise:

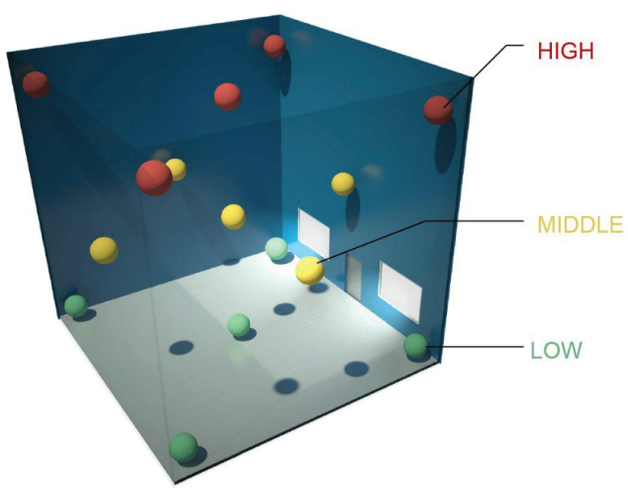
1. Ensuring that the equipment you are using, such as a refrigerator, is working properly.
2. Identify hot and cold spots in a storage area.
3. It is a crucial element for the production, transport and storage of drugs.
4. Identify any infrastructure or design issues such as problems with the HVAC system or insulation.
5. To meet regulatory standards such as those set by the MHRA, HPRA and other regulatory bodies.
6. To protect your business from financial loss due to gaps in cold chain traceability where stock may need to be disposed of.
7. Protect your customers.



What do we provide to you?

We provide a temperature mapping report that includes:

- ✓ Full analysis report
- ✓ Full graphs for each point with minimum, maximum and average
- ✓ Mapping area description
- ✓ Mapping area risks and alarm points
- ✓ External weather conditions for location
- ✓ Area maps with logger locations
- ✓ Photos of mapped areas
- ✓ Sensor reference list
- ✓ Statistical analysis including minimum, maximum, average, standard deviation and MKT
- ✓ Specification of logging equipment used
- ✓ Calibration certificates for equipment used
- ✓ Any recommendations based on findings
- ✓ Full unedited data is available in CSV format
- ✓ Data will be shared and made available through our secure Kelsius Portal



kelsius.com sales@kelsius.com +44 (0)2045 799 048