ABB MEASUREMENT & ANALYTICS | WHITE PAPER

Service

Why it pays to grill your cold chain services supplier

When it comes to ensuring that your cold storage operation and maintenance meets MHRA requirements, it pays to make sure your service supplier knows what they're doing. Here are some of the key factors you should consider when selecting a supplier of cold chain mapping services.

Measurement made easy

by Dave Head, Service Product Manager ABB Measurement & Analytics, UK

Introduction

The Medicines and Healthcare Products Regulatory agency (MHRA) places stringent requirements on the way that cold storage facilities are monitored and maintained in UK hospitals and medical establishments. All designated blood bank fridges must comply with appropriate standards and all hospitals can be subject to an MHRA audit, to ensure they comply.

In the absence of any auditing procedure by the MHRA to check the capabilities of cold chain mapping and calibration suppliers, the onus is on the user to make sure that their supplier is fully competent to perform the work.

Despite taking every effort to comply with the MHRA expectations, many hospitals and medical establishments throughout the UK have suffered 'deficiencies' during an audit, with many cases directly attributable to their supplier lacking the skills and resources to do the job properly.

So what's the answer? How can you ensure that you take every step to make sure you pick the right supplier?

Get to know your supplier

There are a number of key areas where errors are frequently made. Questioning your supplier about their approach to these areas will help you to get a better picture of their competence to survey your equipment.

A first step is to check that they are ISO 9001 accredited and that they can offer proof of past work where the MHRA auditor has been satisfied. Can they offer customer references?

It's important to make sure your supplier is using the correct equipment with suitable traceability, accuracy and stability for the task. All of the test equipment must have a valid calibration certificate and the supplier needs to provide evidence of this for your records.

...Get to know your supplier

Temperature mapping of temperature controlled equipment should be undertaken annually. Another key consideration during the mapping process is to ensure the correct number of probes are used for the size of device being measured. MHRA expectations are that the number of probes used must be scientifically justified with guidance indicating a minimum of three probes for small, conventional size units, up to 18 or more for very large walk-in facilities.

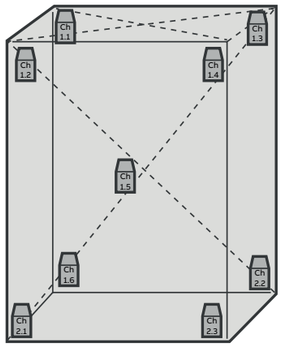

Figure 1 Ensure the correct number probes and positions

A cold chain mapping survey should also be carried out for a sufficient period of time. As a minimum, a survey should last for minimum of 24 hours, with added time for the temperature measurement equipment to stabilize and for a good snapshot of operating efficiency under normal conditions to be achieved. In this respect, it is important to ensure that the logging frequency of the data recording device is properly set, to enable a detailed picture of the equipment thermal uniformity to be obtained.

An expert supplier should be aware of other factors that can affect fridge mapping. In particular, usage of the plant during the testing process, such as loading with warm samples, for example, can distort results, showing variations in temperature that might not otherwise have occurred. These factors should be noted and detailed in the supplier's final report, together with data on the loading of the cold chain asset before the start of the mapping survey. The ambient temperature should be within World Health Organisation Guidelines.

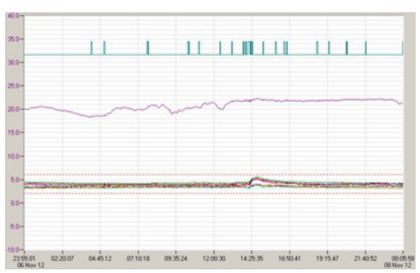

Figure 2 24 Hour trace

Different cold storage methods

Another key factor to consider is the different control requirements needed for various cold storage methods of pharmaceutical products. For example, some blood products for biotechnology should be stored at freezing temperatures of -5 °C or even below -30 °C. A mapping process must take into account that storage units should be capable of maintaining the required temperature in all parts of the asset and recommend that temperatures are monitored and recorded.

Low volume

The quantity of products needed for storage will also determine the manner in which they are kept. For example, domestic refrigerators may be suitable for low volumes of products, like eye drops, which are less susceptible to the effects of storage in less controlled environments. However, they would not be suitable for high-risk goods as they may not have the precise electronic control to maintain the temperature within the 5 °C±3°.

The minimum requirement for monitoring is a calibrated max/min thermometer. In a domestic refrigerator a supplier should ensure these devices are placed within the load or a suitable buffer and positioned so that measurements are not affected by opening and closing of fridge doors (intrusions). Care should also be taken not to place goods next to or in contact with the chiller plate, or coil, as this could reduce their temperature and impacting on product quality.

High risk products

For high risk products in particular, monitoring should be performed using electronic thermometers with an accuracy of at least ±0.5 °C, with the temperature preferably being readable from outside of the refrigerator. If mains-powered, these devices should also include a battery back-up to ensure continued traceability of product temperature in the event of a power failure. Though it is recommended for all cold storage facilities, a power failure alarm is especially essential for high risk products.

Recording and reporting

Another good indicator of supplier competency is the quality of their survey report. This document will be your evidence to an inspector that you took every reasonable step to comply. You should therefore ensure that it contains details on all aspects of the survey, including details of the supplier's test equipment and a full description of the testing process.

Part of ABB's mapping toolkit includes advance videographic data recorders. These devices can collect a wealth of mapping data, which can quickly be compiled into a detailed post survey report. Compliant with FDA's CFR21 Part 11 requirements for secure electronic data storage, videographic recorders feature a host of protective measures to eliminate the risk of unauthorized data tampering both during recording and the post-recording data gathering stage. Standard security features include the ability to configure and allocate multiple users with individual password and access rights. There is also the option of an internal security switch protected by a tamper-proof seal preventing unauthorized personnel from altering the recorder configuration.

Data integrity is further protected by an internal audit trail, which logs any configuration changes made and records who made the changes and when, as well as the details of all datafiles created and many other events key to process data security, such as calibration changes.

These are just some of the key factors that need to be considered. As a responsible and experienced supplier of temperature mapping and calibration services, ABB gives you everything you need to meet MHRA expectations. For more information, including quotations, please email abb.service@gb.abb.com or call 01480 488080, ref. 'cold chain services'.

Figure 3 ABB is your cold chain mapping service provider

Suggested pull-out piece

Ensure you are using your cold chain storage facilities correctly by following these simple tips:

- Large refrigerators (in excess of 6m3) and walk-in cold rooms used in high volume operations should be fitted with an electronic temperature recording device that measures load temperatures. With high volumes it is important that the chart, printout or direct reading should be checked daily and the examination recorded, in this instance it may be easier to install an electronic recorder, with a calibrated max/min thermometer placed inside the unit as a backup.

- In large storage facilities, recording probes should be placed within the load for routine monitoring and if air distribution is not fan-assisted the probe should be located in the part of the load at the highest risk from low temperatures.

- The placement of goods within walk-in units is also critical. Any goods sensitive to temperatures greater than 8°C should not be stored next to the door and goods susceptible to temperatures below 2 °C should not be placed in the airflow of the refrigeration unit.

- With high risk products it is important that temperatures are recorded on a daily basis and that probe(s) are placed within the load (or within a suitable buffer) to record the load rather than the air temperature. These facilities should also be based in an external environment where the ambient temperature does not affect the temperature control within the unit.

- A small but increasing number of blood and biotechnology products must be stored frozen. Storage units must be capable of maintaining the required temperature in all parts of the load, and temperatures should be monitored within the load and recorded daily.

ABB Limited
Measurement & Analytics
Service
Howard Road
St. Neots
Cambridgeshire PE19 8EU
UK
Tel: +44 (0)1480 488080
Fax: +44 (0)1480 470787
Mail: abb.service@gb.abb.com

abb.com/measurement

WP/SERVICE/001-EN Rev. A 10.2018