



Measurement & Analytics, ABB UK & Ireland

Cold Chain Mapping and Calibration Considerations

Understanding the basics



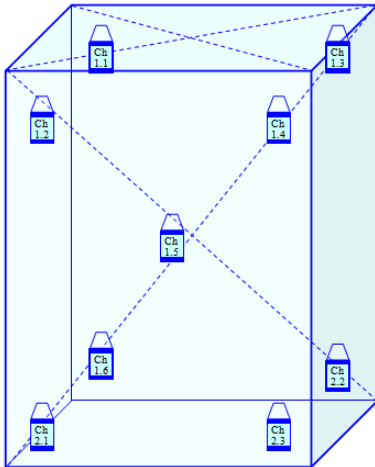
- The MHRA are an executive agency of the department of health.
- Responsible for ensuring medicines and medical devices work and are acceptably safe.
- In 2009 of the 70 Hospital's inspected 17% had Critical failings and 97% had more than one failing, 1 site was closed for a short period.
- MHRA expect mapping and calibration of blood fridges (and temperature controlled equipment) annually
- Focus is on blood fridges as they are a 'medical device'
- No 'guidelines' – although there is some 'guidance'
- Some hospitals do the work 'in house' some 'outsource'



Mapping and Calibration



- Calibration done annually appears to satisfy MHRA (however NHS Scotland specify 6 monthly)
- Mapping is used to prove the ‘thermal uniformity’ of the storage device – this has been undertaken for many years in the aerospace industry (TUS – thermal uniformity survey)
- Mapping to be undertaken ‘regularly’ – annually or after a major change to prove ongoing performance
- Mapping for a minimum of 24 hours
- Mapping to use sufficient number of probes to comprehensively cover the area – min. of 3.
- Probe logging interval less than or equal to 5 minutes



Mapping and Calibration



- Accuracy of test probes should be ± 0.5 degC. Note: this is the accuracy of the test 'system' not just the probe.
- A test protocol should be developed and followed (or agreed with outsourced service provider)
- Mapping of new equipment should be done empty and then full as part of validation process.
- Persons undertaking the exercise should be trained and able to provide documented training evidence.
- Any outsourced maintenance, calibration or mapping should be reviewed and signed by staff.

Outsourcing – pros/cons



Pros of outsourcing

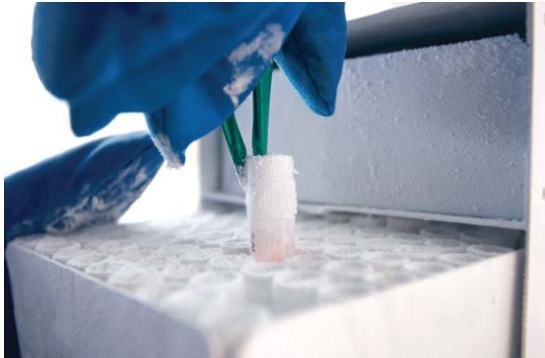
- Less work for busy staff
- No competency training required for internal staff
- Experienced company are likely to satisfy MHRA audit
- No capital outlay for test equipment
- No recalibration costs/management of test equipment



Cons of outsourcing

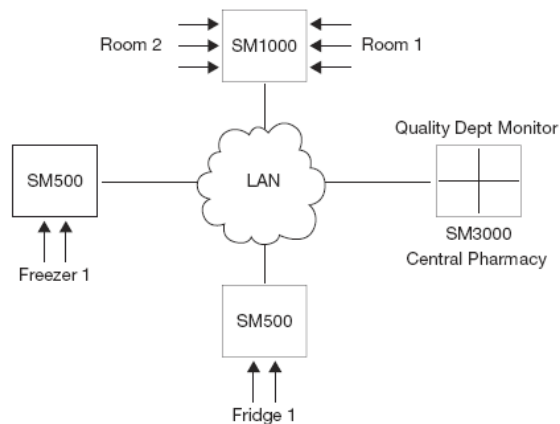
- You are still ultimately responsible!
- Cost
- Another contract to manage..
- Potential for mistakes – not under your control
- Still requires some input from you – check protocol etc.

Outsourcing – considerations



Considerations when choosing a service provider

- Is health and safety as a key part of their business process? (e.g. risk assessments)
- Proven track record – able to provide references/case studies/examples
- ISO 9000 accredited quality system essential (as their QA system has to be externally audited)
- Will they provide a testing protocol/SOP and demonstrate probe justification?
- Quality of report – contains all relevant info (details of test equipment, ambient temperature, calibration traceability)
- Good timekeeping (turning up on the scheduled date and delivering reports on time).



Outsourcing – considerations



Considerations when choosing a service provider

- Are their engineers competency trained?
- Do they have a reasonable sized team? – if you need someone quickly will they be able to provide an engineer – smaller companies may not.
- Do they actually undertake the work – or do they just send you the equipment for you to use?

Why ABB?



- We have a proven track record with over 125 years experience in temperature measurement
- ABB are ISO 9000 Accredited
- We use the MHRA guidance and where not applicable we use our experience from our work in the aerospace industry.
- Our report quality has been described as “Best in class” and has been viewed many times by MHRA inspectors.
- The data collected is verified and can be used in a system complying with FDA CRF21 Part 2 (data integrity).

Why ABB?



- ‘Pass Guarantee’ – if an MHRA audit finds any problems with the service we have provided, we will ensure that we correct this. This guarantee is limited to the work we have done and obviously doesn’t cover your internal quality system.
- Our engineers are competency trained and contribute to continuous improvement during regular ‘knowledge sharing workshops’.
- All our test equipment is UKAS calibrated traceable
- Health and Safety is a key focus, our engineers are audited at random during unannounced worksite inspections.
- We can provide references on request

Power and productivity
for a better world™

