

6.5 Supplier Selection

Suppliers used for supply of calibration instrumentation or services should be assessed and approved for use. The nature and extent of the assessment should be risk-based and appropriate to the equipment or service being provided. The purpose of the assessment is to ensure that the equipment or service provided meets the quality standards expected of the pharmaceutical industry. The postal audit document (Attachment 22, provided on the ISPE Web Site – see Appendix 6) is useful in three ways:

1. To give an initial assessment of companies who could provide a service. For low criticality/risk, this could be all that will be necessary, particularly if there is relevant experience of working in the pharmaceutical industry.
2. To use as the basis for a physical audit and elicit those areas requiring more focus.
3. It may disqualify a potential provider before the expenditure of an on-site audit.

6.5.1 Calibration Laboratories

Calibration laboratories should provide measurements that are traceable to a recognized national or international standard. Laboratories selected to perform the calibration of critical or reference instruments should operate a quality management system in accordance with the principles of (Reference 10, Appendix 16) 17025, and preferably, should be formally accredited (for the relevant measurement field with an appropriate measurement capability), by the officially-appointed national body (e.g., UKAS in the UK) belonging to International Laboratory Accreditation Cooperation (ILAC).

Evidence of accreditation is normally sufficient to ensure that an effective Quality Management System is in place and a further assessment may not be deemed necessary. However, further assessments may be required to ensure that specific aspects of management, appropriate to the pharmaceutical industry, are in place. For example, systems for GxP awareness and contamination control plus any other company specific requirements would not form part of normal accreditation.

6.5.2 Instrumentation Suppliers

Although there are no specific requirements to assess the Quality Management System of instrumentation suppliers, it may be beneficial. It is desirable to have clear evidence for:

- a. change control systems, particularly with regard to the control/inspection of materials for wetted parts
- b. systems to ensure the calibration of supplied product (where required) is adequate and meets the traceability requirements
- c. complex instrumentation, software, and hardware processes are properly documented

6.5.3 Calibration Services

Suppliers providing on-site calibration activities should be assessed to ensure that the following elements of effective calibration and quality management are in place:

- quality management systems in compliance with ISO 9001 and ideally ISO 17025 (References 11 and 10, Appendix 16)
- training and competence of engineers/technicians performing the calibration activities
- management of reference standards