

obtained documenting the vendor's software quality assurance program (e.g., an ISO certificate or similar industry certification).

4. The Process for Assessing Laboratory Equipment should be established and documented (e.g., SOP, VMP). Assessment for new GMP equipment should be completed prior to use of the equipment.

Equipment that has been previously qualified or calibrated and is in a change control/maintenance program may be excluded from the assessment.

5. Post Qualification Changes That Might Impact the Equipment Qualification Status should be addressed by established change control and/or investigation SOPs.
6. When Performing Re-qualification Activities, an assessment of the original equipment qualification documentation should be performed to determine which qualification tasks need to be re-executed to demonstrate suitability of the equipment for continued use. The re-qualification activity should be documented and approved by the system owner and Site Quality Team.

7. Equipment Qualification Documents should include the following equipment information, at a minimum:

- Description, and
- Unique Identifications.

Qualification documentation package for equipment should include the following information, at a minimum:

- Required documents as specified in Appendix 1 based on the equipment classification;
- Intended end-use of the equipment, and
- Equipment classification.

A process or procedure should exist to ensure all documents related to individual equipment qualifications are retrievable.

8. Installation Qualification (IQ) should ensure that the instrument has been installed as specified, (e.g., plugged-in), located and configured in accordance with the manufacturer's guidelines.

The IQ instructions or protocol for a Simple, Moderate, or Complex off-the-shelf piece of equipment should be approved by the Quality Authority prior to execution including vendor provided documentation.

9. Operational Qualification (OQ) should ensure that the instrument is operating as specified by the manufacturer: