General Discussion
This procedure provides guidance in the qualification of simple, moderate, and complex laboratory equipment that is used in an analytical laboratory in a Good Manufacturing Practices (GMP) environment associated with products in or intended for the market place.

1. Exemption of Equipment from Qualification and the rationale for the exemption should be documented (e.g., in the VMP or SOP). Examples of exempt equipment include, but are not limited to, the following:

    - Equipment that does not require installation for use (e.g., thermometers, hand-held thermocouples, certified equipment); or
    - Equipment that is a non-critical factor in the generation of a result.

2. Documentation of Qualification Activities Performed at the Site by a Vendor (e.g., protocols and results) should be obtained, reviewed, and approved by the Quality Authority.

3. The System Owner should ensure that the equipment vendor follows a quality system approach. This can be accomplished by one of the following:

    - Site approved vendor;
    - Previous industry and/or experience with the vendor and/or system;
    - Vendor assessment -vendor assessment may include documentation provided by the vendor or specific request for information that may include vendor surveys; or
    - Vendor audits.

For example, simple or moderate laboratory equipment obtained from common well-known manufacturers, and models used throughout the industry, do not require vendor audits. When purchasing complex off-the-shelf equipment from well-known manufacturers, a vendor audit may not be required, if a statement from the vendor is 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

