4.3.2 Quality Assurance is responsible for ensuring that all equipment used to test product is validated.

4.3.3 Quality Assurance is responsible for ensuring that the GMP aspects of the equipment validation programme are in accordance with relevant procedures and those critical parameters and report conclusions are supported.

5.0 PROCEDURE

5.1 Equipment Validation Rationale

The qualification and validation process should establish and provide documentary evidence that:

5.1.1 The equipment and the processes have been designed in accordance with the requirements of GMP. This normally constitutes Design Qualification or DQ.

5.1.2 The equipment has been built and installed in compliance with their design specifications. This constitutes Installation Qualification or IQ.

5.1.3 The equipment operated in accordance with the design specifications. This constitutes Operational Qualification or OQ.

5.1.4 A specific process will consistently produce a product meeting its predetermined specification and quality attributes. This constitutes Process Validation. The term Performance Qualification or PQ may also be used.

5.1.5 The extent of the validation should be based on risk assessment, such that critical aspects and other system components or functions are verified to be fit for intended use. The risk assessment should be based on the impact to product quality and patient safety. Additional items for consideration include the level of standardization, level of complexity, configuration, customisation, intended use, and vendor quality system assessment where applicable.

5.2 Equipment Validation Requirements

5.2.1 Protocols for each type of qualification will be written as per approved SOP. (See all types of protocol templates from the site http://www.gmpsop.com). Depending on the size of the system or item to be validated IQ and OQ may be combined into one protocol and one report.

5.2.1.1 Assessment of vendor quality system, as a component of the risk assessment, shall be considered to determine the extent of validation and potential leveraging of vendor documentation to support the validation effort. The assessment method chosen shall be based on the criticality of the system, the complexity of the system, and previous experience with the vendor.

5.2.1.2 The validation team will make additions to the vendor documentation as necessary to meet Site Quality Standards. Vendor protocols must be pre approved by the validation committee to meet site requirement as outlines in this document. A validation report will be issued for vendor protocols.

5.2.1.3 When there is more than one identical piece of equipment, each item has to be qualified, however identical protocols can be used.

For legacy equipments with critical aspects that are not validated, gaps in qualification activities in the existing documentation shall be identified. If there are gaps, remediation activities shall be developed and implemented.

5.8 **Qualification of Equipment with Computer Systems**

Equipment containing Programmable Logic Controllers and or computer systems must also conform to the Site computer system guidelines. Usually the computer system will be qualified as part of the equipment qualification. Separate protocol and report are not required.

5.9 **Re-Qualification**

5.9.1 Modifications to, or relocation of, validated equipment must be authorised through the change control system. Modification or relocation will require full or partial re- qualification.

5.9.2 Re-qualification is not required if mobile equipment is moved however procedures for operating of this equipment must contain extensive checks on the equipment prior to its operation and operation of any instrumentation must be verified prior to use.

5.10 **Maintaining the Validated State**

All processes and systems once validated will be maintained in a validated state through the life cycle of the process / system. Maintaining the validated state will be achieved by the change control system, re-qualification, training, SOPs, calibration and engineering maintenance programmes.

6.0 DEFINITIONS / ACRONYMS

DQ	Design Qualification
EH&S	Environmental, Health and Safety
FAT	Factory Acceptance Test
GMP	Good Manufacturing Practice
IQ	Installation Qualification
OHS	Operational Health and Safety
OQ	Operational Qualification
PQ	Performance Qualification
VPP	Validation Project Plan

7.0 REFERENCES

LAB-120 *Qualification of Laboratory Instruments*

8.0 SUMMARY OF CHANGES

Version #	Revision History
VAL 090	New