

## DEFINITIONS

### **Acceptance Criteria:**

The product specifications and/or conditions such as acceptance plans with an associated sampling plan, that are necessary for making a decision to accept or reject a lot or batch (or any other convenient sub-groups of manufactured units).

### **Accuracy:**

The closeness of agreement between an observed or measured value and an accepted reference value.

### **Adequate Standard:**

An instrument that is capable of measuring the full range of and with accuracy four times better than the instrument under test (IUT). If the accuracy of the IUT is +/- 4 psi, then the accuracy of an adequate standard is +/-1 psi.

### **Calibration:**

Comparison of a measurement standard or instrument of known accuracy with another standard or instrument to detect, correlate, report, or eliminate by adjustment any variation in the accuracy of the item being compared.

### **Certification:**

Documented statement by qualified authorities that a validation event has been done appropriately and that the results are acceptable. Certification is also used to denote the acceptance of the entire manufacturing facility as validated.

### **Change Control:**

A formal monitoring system by which qualified representatives review proposed or actual changes that might affect validated status and take preventive or corrective action to ensure that the system retains its validated state of control.

### **Computer System**

Computer hardware components assembled to perform in conjunction with a set of software programs, which are collectively designed to perform a specific function or group of functions.

### **Computerized System**

The computer system plus the controlled function which it operates.

**Computerized System Validation:**

Establishing documented evidence that provides a high degree of assurance that a specific computerized system will consistently operate in accordance with predetermined specifications.

**Current Good Manufacturing Practices (cGMPs):**

The minimum requirements by law for the manufacture, processing, packaging, holding or distribution of a material as established in Title 21 of the Code of Federal Regulations. Examples are Part 211 for Finished Pharmaceuticals, Part 606 for Blood and Blood Components, Part 820 for Medical Devices and Quality System Regulations (QCR).

**Design Qualification (DQ)**

The Design Qualification provides documented verification that the system, equipment or process has been designed adequately to ensure proper function and performance. The Design Qualification protocol evaluates the operational and performance requirements as well as the capability of the design to meet specifications. Through this review, problems can be identified and solutions proposed before system, equipment, or process commissioning.

**Facilities:**

Facilities are areas, rooms and spaces such as receiving/shipping, quarantine, rejected materials storage spaces, approved materials warehouse, staging areas, process areas, etc.

**Installation Qualification (IQ)**

The Installation Qualification establishes documented evidence that all key aspects of a system or equipment installation adhere to approved design requirements and that all manufacturer's recommendations have been considered. The protocol contains the documented plans and details of procedures that verify specific static attributes of a facility, utility system, or process equipment. The executed IQ protocol provides verification that all aspects of the installation adhere to the approved design intentions and that the manufacturer's recommendations have been reviewed and considered.

**Life Cycle:**

The time frame from early stages of development until commercial use of the product or process is discontinued.

**Master Plan:**

The Master Plan describes the validation of a specific facility and its equipment and processes. It includes the cGMP requirements for a validation program. It also provides the outline and scope of such a program. The Master Plan includes the following elements:

- Definition of the systems, equipment, and processes that the company regards as requiring validation.
- General methods to be used and issues to be addressed in each validation protocol.
- The existence of systems which support and maintain the validation status of certified items such as calibration, training and preventative maintenance programs.
- The assignment of responsibilities to different functional groups within the company for accomplishment of various tasks associated with validation activities.

**Measurement Tractability:**

The ability to relate individual measurement results to national (or other) standards through an unbroken chain of comparisons.

**Operational Qualification (OQ)**

The documented evidence that the system or equipment performs as intended throughout all anticipated operating ranges. The Operational Qualification protocol contains the procedures to verify specific dynamic attributes of a system or equipment throughout its operating range, which may include "worst case" conditions. Applicable Standard Operating Procedures and training procedures are documented in the appropriate protocol section. The executed operational qualification protocol verifies that the system or equipment performs as intended.

**Performance Qualification (PQ)**

The documented evidence that the system, equipment or process is capable of consistently producing a safe product of high quality. The Performance Qualification protocol describes the procedures that verify the specific capabilities of a process equipment/system through the use of simulation material and/or actual product.

**Protocol**

A protocol is a documented set of instructions designed to confirm specific static and/or dynamic attributes of the installation, operation or performance of a utility/system, equipment or process.

**Processes:**

A Process is defined as a series of steps and/or actions, controlled by a written procedure, which are used to accomplish or produce a desired result. Sterilization is an example of a routine process.

**Process Equipment:**

The equipment that is necessary to execute a given process according to a specific procedure. Examples would include tanks, mixers, filters, etc.

**Process Validation:**

Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes.

**Prospective Validation:**

Validation conducted prior to the distribution of either a new product, or product made under a revised manufacturing process, where the revisions may have affected the product's characteristics. It is also to ensure that the finished product meets all release requirements for functionality and safety.

**Quality Assurance:**

The activity of providing evidence that all the information necessary to determine that the product is fit for the intended use meets cGMP requirements. The Quality Assurance Department executes this function.

**Quality Control:**

The activity of measuring process and product parameters for comparison with specified standards. This activity is to assure that they are within predetermined limits and therefore, the product is acceptable for use. The Quality Control Department executes this function.

**Revalidation:**

Repeating the validation process or portions of it in order to demonstrate that no changes have occurred which could alter the performance of the original validated equipment or process.

**Retrospective Validation:**

Validation of a process for a product already in distribution based upon establishing documented evidence. The review and analysis of historical manufacturing and product testing data that verifies a specific process can be consistently produced meeting its predetermined specifications and quality attributes.

**Specifications:**

Documents which define and set acceptable and/or authorized modifications.

**Utilities:**

The physical supporting systems used to operate plant equipment and processes. Examples would include HVAC, Electrical System, Purified Water System, etc.

**Validation:**

Validation is establishing documented evidence which provides a high degree of assurance that a specific system (an interacting or interdependent group of items that function together to achieve a specific function), process, or facility will consistently produce a product meeting its predetermined specifications and quality attributes. Validation can be subdivided into three activities; installation, operational, and performance qualifications.

**Validation Program:**

The collective activities that are related to validation.

**Validation Scope:**

The boundaries of the equipment use or process application intended to be addressed by that particular document. For example, a protocol's scope might include challenging the capacity of a glassware washer to remove process residuals but not to qualify the washing process for depyrogenation.

**Worst Case:**

A set of conditions encompassing upper and lower processing limits and circumstances, including those within standard operating procedures, which pose the greatest chance of process or product failure when compared to ideal conditions. Such conditions do not necessarily induce product or process failure.