VALIDATION POLICY

1. PURPOSE

The purpose of this procedure is to define validation principles and establish the policy for validation.

2. SCOPE

This policy applies to all items requiring validation, including facilities, utilities, equipment, processes, quality control methods, and computerized systems that could potentially impact the purity, potency, or quality of a product, or are used for GxP functions, and/or to generate, store, manipulate or retrieve electronic quality records.

This policy includes all such items at the company and at subcontractor locations.

3. REFERENCE DOCUMENTS

[Note to the purchaser of this document: Most of the procedures, and templates referenced here are available at www.BPAconsultants.com]

3.1. EQUP004 – Equipment Qualification

3.2. RISK002 – Risk Management Procedure

3.3. VAL003 – Validation of Off-The-Shelf Computer Systems

3.4. VAL005 – Change Control for Validated System

3.5. 21 CFR Part 11 – Electronic Records; Electronic Signatures. Federal Register: March 20, 1977, Volume 62, Number 54.

3.6. "Guidance for Industry - Computerized Systems Used in Clinical Trials," FDA, April 1999.

3.7. "Guidance for Industry Part 11, Electronic Records; Electronic Signatures – Scope and Application," August 2003.

4. DEFINITIONS

4.1. Computer system: A computer system consists of the software components and associated hardware designed and assembled to perform a specific function or group of functions. Each computer system is defined in the validation plan developed for it. Such systems typically include, but may not be limited to:

4.1.1. Hardware dedicated to the system or used by the system.

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VALIDATION POLICY

The purpose of validation is to establish documented evidence providing a high degree of assurance that a specific system or item will consistently perform to specified requirements under the range of specified conditions. Validation is a component of a total process designed to ensure the proper performance of the item throughout its life. The total process generally includes:

- Identification of user and technical requirements.
- Selection, procurement, and/or building of an item that is capable of meeting the requirements. Vendor qualification.
- Proper installation and appropriate testing of the item to ensure that it functions properly under specified conditions (i.e. validation).
- Appropriate calibration, maintenance, and use of the item.
- Implementing changes by means of a documented change control process.
- Appropriate requalification in conjunction with change or in the event of certain circumstances.

6.2. When validation is performed

6.2.1. Validation is performed when required by relevant regulations and standards.

6.2.2. Pre-clinical research

6.2.2.1. This phase of product development includes:

- All research activities including animal studies covered by GLPs.
- Feasibility studies in which the product created is not used in clinical trials, or to make decisions concerning the production or testing of the product for clinical trials or commercial use.
- Methods, equipment and computer systems used to release product for animal studies have to be qualified, that is, calibration and/or other methods are used to demonstrate that the equipment/method can perform at the required level of accuracy and precision. Full validation is not required. Facilities, utilities, and equipment need to be calibrated and maintained as appropriate.

6.2.2.2. Computer systems that create, modify, maintain, or transmit records in electronic format required by the GLP regulations must meet Part 11 requirements.

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