VALIDATION MASTER PLAN ITEM INFORMATION FORM

1. PURPOSE

The purpose of this work instruction is to provide a form for collecting the information needed about an item to determine if validation is required and, when used in conjunction with a validation master plan, to assign a priority to the validation, as required by VAL001.

2. SCOPE

This work instruction applies to uses of the attached form for recording information regarding items that need to be validated, including facilities, utilities, equipment, processes, and computer systems.

3. REFERENCE DOCUMENTS

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

3.1. VAL001 - Validation Policy

3.2. VAL003 – Validation of Computer Systems Used in Production and Quality Systems

3.3. VAL003 – Life Cycle for the Selection, Implementation, Validation and Use of Computer Systems

4. DEFINITIONS

4.1. Business harm: The impact a failure/hazard will have on an item itself, other assets, or company efficiency.

4.2. Clinical harm: The impact a failure/hazard will have on the quality of the product and, as a result, the safety of the patient.

4.3. Compliance harm: The impact of a failure/hazard on compliance with the Company's policy, and/or external standards and regulations.

4.4. EIN: Equipment Identification Number

4.5. GXP: GXP is a generic designation for all FDA regulations for an industry practices, including GLP, GCP, and GMP, as applicable to the industry.

4.6. Item: An item requiring validation, including facilities, utilities, equipment, processes, analytical or test methods, and computerized systems that could

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For example, if a HPLC is used to determine the amount of active ingredient in a drug lot manufactured for commercial use or clinical trials, it must be validated. However, if another HPLC is used only to perform quantitative analyses in conjunction with scale-up studies for the transfer of technology to commercial scale batches, it does not need to be validated as long as the product manufactured is not used for clinical trials or commercial use.

6.3.1. In determining the uses of any data or records, make sure that all of the uses throughout the lifecycle of the data are examined.

6.3.2. Include data integration, that is, situations where the data flow from this system into another system is automated.

For example, if a database on incoming materials were a stand-alone system used only for managing inventory, it would not need to be validated. However, if another system pulled information about a lot of raw material from such a database and inserted it into a batch record for use in traceability, the incoming material database would need to be validated.

6.4. The Item Owner indicates if any electronic records are created, maintained, archived, retrieved, or transmitted using the system. This information is used in the section called “Part 11 Applicability” to determine if Part 11 applies to the item.

6.4.1. QA indicates if the record is required by predicate rule, that is, is there an FDA regulation that requires the record.

6.5. The Item Owner describes the most serious consequences that could occur because of the item’s failure, and identifies the type of harm. A consequence can be of one of three types:

6.5.1. Harm to user or patient (clinical harm). For example, death of a patient or user, or a severe injury requiring medical attention.

6.5.2. Business loss (business harm). Loss of a major business system (e.g., manufacturing system, or corporate network) for an intolerable period of time.

6.5.3. Noncompliance with regulations (compliance harm). Loss of control of product documentation (e.g., specifications, drawings, assembly instructions), quality control procedures, and all other controlled documents because the document control system allowed uncontrolled employee access to the documentation.

6.6. The Item Owner determines a risk level for each of the potential harms following the guidelines provided in VAL003. The type of harm is recorded (clinical,

business, or noncompliance). A risk level can be given for more than one type of risk.

6.7. QA or designee checks the appropriate item regarding Part 11 applicability. See VAL001 for information regarding Part 11 applicability.

6.8. The Item Owner or QA records the validation history. If the system has been validated in the past, record the validation report number and the date of the validation. Indicate the scope of the last validation. (If the use of the system has, or will be expanded, additional validation or a complete revalidation may be necessary.)

6.9. QA or designee indicates if validation is required and why by checking the appropriate items in the "Validation Requirement" box. If validation is not required, indicate why.

6.10. QA or designee summarizes the decisions made concerning the item in the "Summary of Regulatory Information" table.

6.11. Any notes that need to be recorded about the item or the decisions reached are written in the "Notes" space. Attach additional pages as needed.

6.12. QA or the designee records the validation priority in the box at the top of the first page of the form. The individual recording the priority initials and dates the entry in the space provided.

6.13. The Item Owner, QA and IT as well as those involved in making the decisions regarding the information put on the form, sign the form. The functions signing the form ordinarily include at least QA or Validation, and IT.

7. QUALITY RECORDS

The completed forms are not considered to be a quality record; rather, they are used to support the validation master plan that is a quality record. The forms ought to be retained nevertheless as long as the Validation Master Plan in retained.

Record Name	Record Format	Record Owner	Storage Location	Filing Method
None				

8. SUMMARY OF REVISION CHANGES AND JUSTIFICATION