# VALIDATION OF COMPUTER SYSTEMS USED IN PRODUCTION AND QUALITY SYSTEMS

## 1. PURPOSE

The purpose of this procedure is to define the requirements for the validation of off-the-shelf computer systems used for GxP activities (including production and quality systems) and/or in conjunction with FDA required quality records.

## 2. SCOPE

This procedure applies to all off-the-shelf computer systems that require validation, that is:

- Computer systems used as part of production or the quality system (21 CFR 820.70 i)
- Computer systems used for production and service provision that affect the ability of the product to conform to specified requirements (ISO 13485 2003, Section 7.5.2.1)
- Computer systems that pharmaceutical companies introduce "into systems of manufacturing, including storage, distribution and quality control." (EC, Commission, 2003, Annex 11)

This procedure does not include the development and validation of custom software, or the development and validation of spreadsheets or applications using database packages such as SAS and Access.

## 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. 21 CFR Part 11 – Electronic Records; Electronic Signatures. Food and Drug Administration. Federal Register: March 20, 1977, Volume 62, Number 54

3.2. 21 CFR 820, Medical Devices; Current Good Manufacturing Practices (CGMP) Final Rule; Quality System Regulation, Federal Register 52602 (October 7, 1996) 2005 Revision.

3.3. ISO 13485, Medical Devices – Quality Management Systems – System Requirements for Regulatory Purposes, 2003

3.4. EC Commission Directive, The Rules Governing Medicinal Products in the European Union, Vol. 4. Good Manufacturing Practices, Annex 11, Computerised Systems, October 8, 2003

3.5. MIS001 – IT Policy

3.6. RISK006 - Computer System Risk Evaluation for Determining Risk Mitigations, Validation Activities, and the Extent of Testing

4.1.3. Application software.

4.1.4. Data storage devices and software.

4.1.5. Peripheral devices, such as data collection devices and output devices dedicated to the system.

4.2. Function risk level: The level of risk associated with the failure of a computer system to meet a specific functional requirement

4.3. GxP: A generic designation for all FDA regulations, including GLP, GCP, cGMP, and the Quality System Regulations, as applicable to an industry.

4.4. Intensity: The scope of analysis, across all normal and abnormal system operating conditions, performed in a validation activity.

4.5. MDR: Medical Device Reportable event, also known as an adverse event, see for example, 21 CFR 820.198 d.

4.6. Off-the-shelf systems: A software product that is commercially available and has not been specifically designed to meet an individual purchaser's specifications or modified through the creation of custom program code. The product is used as developed with minimal or no configuration.

4.7. Quality record: A record required by a regulatory body, in conjunction with quality systems, as documentation that an event occurred.

4.8. Record owner: The function that is responsible for the maintenance of a particular record.

4.9. Rigor: The formality of the methods used for validation activities and recording their results.

4.10. Supportive operations: Operations used by the system to perform the functions mandated in the user requirements. For example, if it is a user requirement to be able to approve a record with an electronic signature, some of the supportive operations the system must perform are: determining if the signer has authority, recording the date and time that the signature was entered, and protecting the signature from change.

4.11. System Owner: The manager, or designee, of the department that is most impacted by, or is the primary user of, the system.

4.12. User requirements: Requirements that a user has for the operation and functioning of an instrument, piece of equipment, or computer system.

4.13. Validation environment: Hardware and software used for conducting the installation and operational qualifications.

## 5. RESPONSIBILITIES

5.1. Project Team

5.1.1. A project team is typically formed and assigned responsibility for the selection, procurement, installation, and obsolescence of computer systems. A project team may not be needed for simple systems.

5.1.2. The Project Manager, if one is appointed, heads the project team. The team also includes, at least, the System Owner, Information Systems (IT), QA, and Validation.

5.1.3. Except for approval requirements specified in this procedure, the responsibility for approving documents is defined in the validation plan for a system.

5.2. The System Owner is responsible for:

5.2.1. Ensuring that the system meets user requirements by:

5.2.1.1. Creating and appropriately revising the user requirements during the validation.

5.2.1.2. Managing the selection process.

5.2.1.3. Planning mitigation measures to mitigate risk and to harmonize the system and user requirements.

5.2.2. Obtaining management approval to purchase and implement the system.

5.2.3. Participating in the development of deliverables, as defined in this procedure or the validation plan for the system.

5.2.4. Assuring that the system is used in a compliant manner, including: preparing user and administrative procedures, training users, participating in the assessment, approval and implementation of changes, and taking appropriate corrective actions to resolve any compliance issues.

5.3. Quality Assurance (QA) is responsible for:

5.3.1. Ensuring that the system is compliant with appropriate regulations.