# VALIDATION OF OFF-THE-SHELF COMPUTER 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. MIS001 – IT Policy

3.5. RISK002 - Risk Management Procedure

3.6. Stein, R. Timothy. *Computer System Risk Management and Validation Life Cycle*, Paton Press, 2006.

3.7. TEMP002 – Validation Plan Template

3.8. TEMP004 – IQ Template

3.9. TEMP005 – OQ Template

3.10. TEMP006 – PQ Template

3.11. TEMP007 –Validation Final Report

3.12. TEMP008 – Computer System Technical Requirements Template

3.13. TEMP009 – Computer System Specification Template

3.14. VAL001 – Validation Policy

3.15. VAL004 – Requirements for Computer System Requirements, Validation Plans, Protocols and Reports

3.16. VAL005 - Change Control for Validated Systems

3.17. VAL006 – Computer System Project Proposal

3.18. VAL007 – Computer System Vendor Qualification and Management

3.19. VAL008 – Computer System Vendor Audit Checklist

3.20. VAL015 – Guidance - Items to Evaluate in an IQ, OQ, or PQ for a Computer System

3.21. VAL019 – Computer System Risk Evaluation for Determining the Rigor and Intensity of Validation Activities and Testing

## 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 components typically include, but may not be limited to:

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

4.1.2. Operating systems and system software.

4.1.3. Application software.

4.1.4. Data storage devices and software.

5.4. Validation is responsible for:

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

5.4.2. Assuring that the validation deliverables are fit to serve as part of the validation record.

5.4.3. Assuring that the system is appropriately validated based on the risk level of the system.

5.4.4. Participating in the assessment, approval, validation and implementation of changes as appropriate.

The responsibilities assigned to the validation function are performed by QA if a separate validation function does not exist.

5.5. IT is responsible for:

5.5.1. Managing the system implementation

5.5.2. Ensuring that technical requirements for the system are defined and met, including: ensuring that proper equipment is selected or purchased, configuring the hardware, system software, and infrastructure applications, such as email, as needed to meet the technical requirements.

5.5.3. Participating in the validation as defined in this document, or the validation plan for the system.

5.5.4. Preparing an IQ protocol, executing the protocol, preparing the IQ report, and using the IT protocol for subsequent installations of the system as appropriate.

5.5.5. Documenting and following IT policy and procedures for the proper security, maintenance, and support of the computer system.

5.5.6. Participating in the assessment, approval, and implementation of changes.

## 6. METHOD

### 6.1. Validation record

6.1.1. The items given in italics in this Method section form the validation record.