1 Purpose

This procedure describes the validation process for software tools used at MBio in the Quality Management System (QMS), production of product, and/or monitoring and measurement of requirements.

2 Scope

A software tool either developed or acquired for QMS processes (including Design Control processes) or manufacturing processes for regulated products and/or inspection thereof must be validated for its intended use. This requirement applies to any software used to automate device design, testing**,** component acceptance, manufacturing, labeling, packaging, distribution or complaint handling.

Included among the computerized applications that must adhere to this validation process are:

Off-the-shelf (OTS) software for those uses for which it is intended (Only the used features must be validated).

A previously validated application moved to a different hardware or software platform.

Customized software for use in the QMS or as part of a piece of equipment.

New equipment with software (embedded)[1]

Excel spreadsheet formulas that inform acceptance or rejection of product

The following shall not require validation:

Word processing applications and editors

Operating systems, operating system environments and network management systems

Previously validated portable equipment being moved from one location to another that does not require installation other than reconnection of connectors.

Previously validated applications to be installed on equivalent computer platforms.

Software used exclusively for Research and Development (R&D) purposes

This procedure complies with MBio's Quality Management System and with all relevant standards and applicable regulations as listed in the Quality Manual (QM001). Additional regulatory standards or guidance documents may be referenced within this procedure.

3 Additional Regulatory Standards or Guidance Documents Referenced

N/A

[1] (IQ/OQ/PQ may be reviewed against the requirements to determine if a separate validation is required. If the IQ/OQ/PQ process does not provide full coverage of the requirements, separate tool validation is required, although it may have more limited scope. That is, it may rely on the IQ/OQ/PQ results to support part of the validation.)

4 Overview

4.1 Each software tool must be evaluated using this procedure prior to initial use, and as appropriate after changes to the software tool or its application. It is acceptable to document a group of software tools with a single documentation package.

4.2 Each software tool is identified for its scope of use: within a discipline (e.g., Engineering), within a project or product (e.g., Workspace.com), within a department (e.g., manufacturing), or within the entire company. Within this procedure, “management” means the management appropriate for the scope of the software tool.

4.3 If a single documentation package is used for a group of software tools, the software tools should have the same scope.

5 Procedure

5.1 Users identify software tools. This may happen at the direction of functional area management or spontaneously. See FM-6000-005.1 Software Tool Validation Form.

5.2 The users determine the software tool’s intended use. Design qualification documentation or a procedure may include guidance for the intended use.

5.3 The users propose if the software tool:

5.3.1 does not require validation (document the rationale),

5.3.2 will be verified by output (a subsequent output is fully reviewed or tested during normal use: document the rationale, e.g., measurement of a physical part could verify CAD software tool correctly generated a 3D model), or

5.3.3 will be validated by test (its output is not expected to be reviewed or tested in normal use).

5.4 The risk associated with use of the software tool, including the effect on the ability of product to conform to specifications shall be considered and documented on FM-6000-005.1. The approach and activities associated with validation and revalidation shall be proportionate to the risk.

5.5 If the provider of the software tool has supplied sufficient evidence of validation, document the evidence and skip to step 5.12.

5.6 If the software tool is verified by output, management assures that procedures require the expected review or test. In the case of software tool requiring no validation, validated by provider or verified by output, skip to step 5.12.

5.7 If the software tool is to be validated by test, the user authors the Software Tool Requirements Specification for the software tool. Requirements must be testable.

5.8 Items for consideration in the requirements include:

5.8.1 System inputs

5.8.2 System outputs

5.8.3 Functions that the system will perform

5.8.4 Performance requirements that the software tool will meet (e.g., data throughput,

5.8.5 reliability, timing, etc.)

5.8.6 External and user interfaces; software tool to system interfaces

5.8.7 What constitutes an error; how errors should be handled

5.8.8 Required response times

5.8.9 Ranges, limits, defaults and specific values that the software tool will accept

5.8.10 Safety related requirements, specifications, features, or functions

5.9 Users also author the Software Tool Validation Protocol for the software tool's requirements.

5.10 The Software Tool Validation Protocol shall be reviewed and approved for use per SOP-5000-001 Document and Records Control.

5.11 Test staff (i.e., someone sufficiently independent of the writing of the requirement and validation protocol writing) runs the protocols and documents the results in a Software Tool Validation Report. If any tests fail, the failure modes are discussed with users and either the procedures for use are modified, the requirements are modified, or a new software tool is selected.

5.12 Software tools must have all documentation of the validation effort stored with the appropriate Software Tool Validation Report per SOP-5000-001 Document and Records Control. The documentation will include:

5.12.1 The name of the software tool

5.12.2 The revision of the software tool

5.12.3 Reference to the documentation containing risk assessment and validation methodology

5.12.4 Documentation of validation results, conclusion of validation, and necessary actions including any restrictions on use due to failures.

5.13 Users must be trained in the proper use of the software tool. This training will include review or test steps used for software tool validated through output or approved use for software tool approved through test. Any restrictions placed on provider-validated software tool are also to be covered. This training must be completed in compliance with SOP-11000-001 Training Procedure.

6 Responsibility:

Role	Responsibility
Software Tool Users	• Initiate the validation process • Perform and document risk assessment associated with software tool • Identify the software tool's requirements • Author validation protocols
Quality Assurance (QA)	• Coordinate and ensure that the validation process is completed per this procedure • Approve the assessment, requirements, validation protocols, and reports
Functional Area Managers	• Approve the assessment, requirements, validation protocols, and reports • Coordinate training on the software tool's use based on the test results and the requirements list

Role	Responsibility
Test Staff (various departments)	• Perform tests and report results, including any restrictions on the software tool's use, depending on the results

7 Referenced QMS Procedures and Work Instructions (not external documents)

The following documents are cross-referenced in this SOP.

QM001 Quality Manual

SOP-5000-001 Document and Records Control

SOP-11000-001 Training Procedure

8 Attachments, Associated Forms, and Associated Controlled Spreadsheets

8.1 The following form(s) is associated with this SOP: may be revised separately from this SOP.

FM-6000-005.1 Software Tool Validation Form

SS-6000-005.1 Software Tool Validation Form Log

9 Revision History

Revision	Effective Date	DCO Number
01	12MAY2020	643
00	10JAN2020	601