

Standard Operating Procedure

Title: **Guideline for the Validation of Excel Spreadsheets**

Department	Validation/Technical Services	Document no	VAL-170		
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1 Purpose

The purpose of this document is to provide guidelines for a suitable approach for the qualification of Excel spreadsheets used in direct, or in-direct, GxP related activities at all GMP facilities.

2 Scope

The procedure applies to the initial qualification and re-qualification of Excel spreadsheets, designed and used for making quality based decisions in GxP environments at the GMP facility. These areas include but are not limited to:

- Quality Operations
- Manufacturing Operations
- Development
- Planning
- Regulatory Affairs

The scope does not include those spreadsheets which are single use only (prepared for a specific, one off tasks) or those which are used for organisation of personal, or departmental work plans. These should be verified at each time of use as appropriate.

3 References

- Good Automated manufacturing Practice Guide (GAMP), Version 4, ISPE
- David Harrison and David A Howard, A Pragmatic Approach to the [Validation of Excel Spreadsheets](#), Pharma IT Journal, Vol1 No.4 October 2007

4 Introduction

Spreadsheets can be used to record and manipulate (change, delete, add) GxP data and as such need to be managed to ensure the continued integrity and security of that data. While some are no more than fancy calculators others are embedded with special features and use intricate logic in the form of Macros that are in effect computer programs.

Spreadsheets can be classified into GAMP categories depending on use and contents of the spreadsheet. This will impact the level of validation effort that is applicable just as with other computerized systems. Spreadsheets which fall into [GAMP Category 3 guidelines](#) (Table 1) do not require full validation activities but should be held under appropriate security conditions.

Standard Operating Procedure

Title: **Guideline for the Validation of Excel Spreadsheets**

5.3.2 Operation/ Performance

The **Operational/ Performance Qualification** shall be written to document the instructions for the testing. The Operation Qualification shall include the following tests:

- Calculation Test to verify that correct formulas are entered
- Logical Values Test to verify Boolean algebra formulas.
- Range/Precision Test to verify calculations will still be accurate when extremely large or small values are entered
- “Challenge condition” testing for the program and application (e.g., invalid inputs, stress testing)
- Boundary and limit checking, failure analysis and confirmation of appropriate error trapping.

Acceptance criteria shall be established for each test and written into the Operation Qualification Protocol. Typical tests with associated acceptance criteria are:

5.3.2.1 Calculation Test

These are performed to verify that correct formulas are entered. Enter sample values in all fields that are included in the input range of all mathematical functions. Restrict the input to whole numbers at this time for aggregate functions (sum, max, etc.) use different values for each field. Document the step, include a printout of the spreadsheet application indicating the test values, and compare the printout to that obtained from a calculator.

Acceptance Criteria

Calculated values from the spreadsheet application must be identical to those obtained from a calculator (preferably with printout capabilities).

5.3.2.2 Logical Values Test

These are performed to verify Boolean algebra formulas. Print the spreadsheet application cells containing Boolean (logical values) and calculate the results manually. Print the results from the spreadsheet application calculation.

Acceptance Criteria

For logical values (e.g. Pass/Fail or True/False) verify the displayed value is the same as the expected value, calculated manually.

5.3.2.3 Range/Precision Test

These are performed to verify calculations will still be accurate when extremely large or small values are entered. Enter extremely large values at the correct precision (e.g. enter 99.99 for 0.01 precision). For aggregate functions, enter 0 in one or more fields with non-zero values in other fields. Duplicate the formula calculations using a calculator and compare the results/printouts. Repeat this test with extremely small values, and report the results.

Acceptance Criteria:

Calculated values from the spreadsheet application must be identical to those calculated manually using a calculator (with correct precision and consistent with agreed Rounding principle).

Standard Operating Procedure

Title: **Guideline for the Validation of Excel Spreadsheets**

6 Usage of Spreadsheet Applications

6.1 Availability of Spreadsheet Application:

The Spreadsheet applications shall be protected from unauthorized modification of the master copy. For example, the spreadsheet application shall be available to authorized users as “read only”.

Authorized users will be given access after they have been trained on the use of the spreadsheet application (which shall include proper GMP handling of the files and documentation practices).

Where networks are employed for spreadsheet application use, spreadsheet applications will typically be stored in a network directory that allows access by authorized users. In this instance, the storage of a copy of the spreadsheet application on the hard drive of the local computer shall be forbidden by policy.

6.2 Training of Users

Users shall be trained to use the spreadsheet application. As appropriate, training objectives shall include learning:

- How to use the spreadsheet application, including how to print the Spreadsheet Application Report
- The procedure for storing Spreadsheet Application Reports (if applicable)

Training may be conducted earlier based on a preliminary review of the Final Report.

6.3 Storage of Completed Electronic Files:

When data have been entered into the spreadsheet application, the calculated results become a new [electronic file](#).

If site policy requires storage of an electronic copy of the spreadsheet application file, the file should be stored under a new name in a designated area of the LAN server.

- Files should be named using a convention agreed between the user and site Quality Assurance
- The file name of the completed spreadsheet application electronic report should be recorded in notebook or other similar documentation system as a cross-reference.
- During review of notebook or other similar documentation system data, the reviewer should assure that the electronic file has been stored correctly.

7 Re-qualification of Spreadsheet Application Formulas

Spreadsheet applications in the library will be reviewed / verified every 3 years to address the validity of the validation documentation which includes formula integrity. Reviews will be managed via the Validation Manager program.

Re-qualification may also be triggered by the installation of an upgrade of the spreadsheet program (Change Control System), or by changes in the LAN (e.g., system crashes).

8 Change Control:

If changes are required in a spreadsheet application, it is the responsibility of the Department Manager to manage the change using the site Change Control procedures.