
Standard Operating Procedure

Validation of Spreadsheet Applications



This is an example of a Standard Operating Procedure. It is a proposal and starting point only. The type and extent of documentation depends on the process environment. The proposed documentation should be adapted accordingly and should be based on individual risk assessments. There is no guarantee that this document will pass a regulatory inspection.

Publication from
www.labcompliance.com

Global on-line resource for validation and compliance

Copyright by Labcompliance. This document may only be saved and viewed or printed for personal use. Users may not transmit or duplicate this document in whole or in part, in any medium. Additional copies and licenses for department, site or corporate use can be ordered from www.labcompliance.com/solutions.

While every effort has been made to ensure the accuracy of information contained in this document, Labcompliance accepts no responsibility for errors or omissions. No liability can be accepted in any way.

Labcompliance offers books, master plans, complete Quality Packages with validation procedures, scripts and examples, SOPs, publications, training and presentation material, user club membership with more than 300 downloads and audio/web seminars. For more information and ordering, visit www.labcompliance.com/solutions

1. PURPOSE

Quality standards, regulatory agencies and some company policies require software used for evaluation of critical data to be properly validated. Spreadsheet applications are considered as software and should be validated to demonstrate suitability for their intended use. The purpose of this operating procedure is to ensure that Spreadsheet applications are validated during their development and installation and periodically reevaluated during operation.

2. SCOPE

Validation of Spreadsheet applications used in regulated environments. Examples are Excel™ Spreadsheets. The procedure applies whenever firms develop Spreadsheet applications with and without VBA scripts.

3. GLOSSARY/DEFINITIONS

VBA - Visual Basic for Applications, Macro programming language for Microsoft Office Products.

Note: For other definitions, see www.labcompliance.com/glossary.

4. REFERENCE DOCUMENTS

- 4.1. "Validation Master Plan for Equipment and Computer Systems".
(Not part of this SOP, example can be ordered from
www.labcompliance.com/books/masterplan.htm)
- 4.2. SOP ###: "Risk-Based Validation of Equipment and Computer Systems".
Available through: www.labcompliance.com/solutions/sops.
- 4.3. SOP ###: "Change Control of Software and Computer Systems".
Available through: www.labcompliance.com/solutions/sops.
- 4.4. SOP ###: "Development and Use of Spreadsheets in GxP/Part11
Environments".
Available through: www.labcompliance.com/solutions/sops.