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## 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.

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## 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](http://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](http://www.labcompliance.com/books/masterplan.htm))
- 4.2. SOP ###: "Risk-Based Validation of Equipment and Computer Systems".  
Available through: [www.labcompliance.com/solutions/sops](http://www.labcompliance.com/solutions/sops).
- 4.3. SOP ###: "Change Control of Software and Computer Systems".  
Available through: [www.labcompliance.com/solutions/sops](http://www.labcompliance.com/solutions/sops).
- 4.4. SOP ###: "Development and Use of Spreadsheets in GxP/Part11 Environments".  
Available through: [www.labcompliance.com/solutions/sops](http://www.labcompliance.com/solutions/sops).