

Making Excel Spreadsheets Compliant:

Foolproof Methods for Validation

Table of Contents

Introduction	
What Needs to Be Validated.....	5
Problems with Excel Spreadsheets	7
The Planning Process	9
The Validation Process – Path I.....	11
Execute Spreadsheet Qualification	15
The Validation Process – Path II	19
Change Control	21
Software Tools	23
Common Pitfalls	25
FAQ.....	27
Conclusion	31

Appendices (*can be found on the CD in the back of this report*)

- A. Spreadsheet Design and Validation for the Multi-User Application for the Chemistry Laboratory Part I
- B. Spreadsheet Design and Validation for the Multi-User Application for the Chemistry Laboratory Part II
- C. 21 CFR Part 11
- D. Part 11, Electronic Records; Electronic Signatures — Scope and Application
- E. General Principles of Software Validation; Final Guidance for Industry and FDA Staff
- F. Guidance for Industry: Computerized Systems Used in Clinical Investigations