

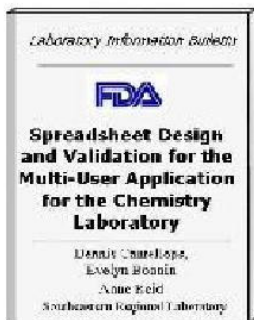
**Best Practices – Macro and Spreadsheet Quality Package** is economically priced at \$499 which includes shipping and handling plus all the contents listed below:

**1. Interactive video for fast and intuitive familiarization with various topics. Includes:**

- 50 Video Clips on CD
- With MS PowerPoint, it comes with PowerPoint Viewer
- Contents include:
  - ✓ FDA requirements and inspection findings
  - ✓ Problems with spreadsheet programs and Macros
  - ✓ Policies and procedures for development and use of spreadsheets and Macros
  - ✓ Strategy and example for risk assessment and management
  - ✓ Validation of Macro programs
  - ✓ Validation of spreadsheet calculations
  - ✓ Case study using functions included in the spreadsheet to increase reliability, integrity, and security

**2. FDA's 40-page *Laboratory Information Bulletin on Design and Validation of Spreadsheets* – a validation master plan for equipment, computer systems, and networks.**

- For effective, complete and consistent implementation
- Includes chapter on Macro programs and spreadsheets



**3. Inclusive Manual – a 42-page handbook used for extensive background and reference information using Macros and spreadsheets in regulated environments.**

- FDA requirements and inspection observations
- Problems with spreadsheet programs and Macros
- Policies and procedures for development and use of spreadsheets and Macros
- Risk assessment and management: examples for risk factors and preventive actions
- Validation of spreadsheet calculations and Macros
- Boundary testing, stress testing, error testing
- Example using functions built into spreadsheets to increase reliability, integrity and security

**4. An extensive 7-page gap analysis/checklist using spreadsheets in regulated environments.**

- Useful in preparation for audits. Helps to avoid inspectional observations and Warning Letters. The checklist is updated on a regular basis and includes suggestions from recent FDA guidance documents, industry task forces, FDA inspection findings and the author's own experience.

**5. FDA Warning Letters and 483 inspection observations and full follow-up inspection report (EIR) describing corrective actions.**

- FDA Warning Letters and 483 inspection reports related to macros and/or spreadsheet calculations
- A full FDA report of follow-up inspections demonstrating accepted corrective actions

**6. Standard Operating Procedures/Test Procedures for development, validation and use of Macros and spreadsheets for highest efficiency and consistency.**

- Validation of Macro Programs and other application software
- Using Macros and spreadsheet applications in a regulated environment
- Change control of computer systems
- Verifying limited access
- Risk assessment for Part 11
- Training for GxP and computers

**7. Excel Macro example with validation documentation which includes a project plan, inventory list, requirement specifications, test plan, traceability matrix and test scripts for fast implementation.**

- Example can be used as templates for other macros and spreadsheet calculations
- Templates improve efficiency and ensure consistent implementation
  - ✓ Project schedule (helps not to forget anything and for resource planning)
  - ✓ 21 User Requirement Specifications for spreadsheets – example
  - ✓ Additional User Requirements Specifications for Macros – example
  - ✓ Test Plan
  - ✓ 12 Test scripts for functional testing, includes boundary testing, out of range testing
  - ✓ Test traceability matrices: tests vs. specifications, specifications vs. test cases
  - ✓ Test summary sheet

**8. Excel template example demonstrating record integrity (user can enter and re-enter data, print and exit, nothing else, menu and CTRL items are removed).**

- This example can be used as templates for other macros and spreadsheet calculations
- Templates improve records integrity and traceability

**9. Excel functions that help comply and reduce errors.**

- Excel has a lot of functions, that when used appropriately, help to defend your data
- Examples with user instructions, screen captures, etc.
- Input validation, tracking function, plausibility checks, conditional cell colors, printing file directory, path, file name, and date

**10. MD5 example software to verify the file proper software installation and integrity of the spreadsheets.**

- Makes it easy to audit and verify that the spreadsheet is “original”
- Comes with validation documentation (DQ, IQ, OQ,)

**11. FDA's 40-page *Laboratory Information Bulletin on Design and Validation of Spreadsheets*.**

**12. Procedures for risk assessment and limited access.**

**13. Two years on-line updates through password protected website which includes:**

- FAQ's
- Future SOPs, templates and checklist upgrades
- Updates on regulations and guidance
- Links to useful Internet sites

You'll have everything you need to overcome the compliance limitations of Excel.