


A Step-by-Step Guide to Excel Spreadsheet Validation

VALIDATION OF  Excel
CALCULATION SHEETS

PRODUCT :					
B.NO.					
CONDITION :					
CONTENT :					
Purity %					%
Label Claim					
Factor					
<i>For Assay :</i>					
Av.Wt.:					Mg.
Std.Con					
Spl.Con					
					Mean Area
Assay %					%

No.	Area/Abs.	Standard Mean Area/Abs.	RSD %
1			
2			
3			
4			
5		Mean Std.	
6		0	

Step 1: Develop Functional Requirements

1. Define the Purpose

Clearly state the purpose of the spreadsheet, such as calculating analytical results or generating reports.

Ensure the purpose aligns with the specific needs of the GMP environment.

Identify the key outputs the spreadsheet will produce.

Understand how these outputs will be used in decision-making processes.

Document the purpose to guide the development and validation processes.

2. List Formulas and Macros

Detail all mathematical and logical formulas that will be used.

Describe any macros that automate repetitive tasks.

Ensure all formulas and macros align with the spreadsheet's purpose.

Document each formula and macro for future reference and validation.

Include explanations of how each formula and macro contributes to the spreadsheet's functionality.

3. Data Handling and Reporting

Explain how data will be entered (manual entry or automated import).

Specify how data will be sorted and rearranged for reporting purposes.

Define the format and content of the reports generated by the spreadsheet.

Ensure data handling processes maintain data integrity and accuracy.

Document data handling and reporting procedures to ensure consistency.

4. Performance Requirements

Establish criteria for performance, such as calculation speed and application availability.

Define acceptable performance thresholds for various spreadsheet functions.

Ensure performance requirements align with user needs and regulatory standards.

Document performance requirements to guide testing and validation.

Include requirements for handling large datasets and complex calculations.

Step 2: Develop the Excel Spreadsheet Application

1. Data Entry Methods

Define whether data will be entered manually or imported automatically from instruments.

Ensure data entry methods maintain data integrity and accuracy.

For manual entry, implement a verification process by a second individual.

Document the data entry process and any verification steps.

Ensure automated data import processes are validated and reliable.

2. Formula Development

Implement and verify all formulas and logical functions.

Use diagnostic tools to check for errors and ensure accuracy.

Document each formula and its intended purpose.

Ensure formulas are robust and handle a range of input values.

Regularly review and update formulas to maintain accuracy.

3. Data Arrangement

Develop procedures for sorting and rearranging data to produce the desired reports.

Document these procedures clearly for consistency.

Ensure data arrangement processes maintain data integrity.

Test data arrangement procedures to ensure they meet user needs.

Update procedures as necessary based on user feedback and testing results.

4. Macro Programming

Record macros to automate repetitive tasks.

Ensure that macro steps are documented and tested during qualification.

Verify that macros function as intended and do not introduce errors.

Regularly review and update macros to ensure continued functionality.

Train users on how to use and troubleshoot macros.

5. Report Generation

Create or modify the spreadsheet to generate automated reports.

Ensure reports include necessary metadata, such as analyst identifiers and version control.

Test report generation to ensure accuracy and completeness.

Document the report generation process for consistency.

Regularly review and update report formats based on user needs.

Step 3: Qualification Testing

Installation Qualification (IQ)

1. Verify Installation

Confirm that all necessary features and addins are installed.

Ensure compatibility with the system's hardware and network configurations.

Document the installation process and any configurations.

Implement security measures to protect the spreadsheet.

Verify that the installation meets user requirements and specifications.

2. Security Measures

Implement access controls to restrict unauthorized access.

Encrypt data to protect against unauthorized modifications.

Store the master copy in a secure, readonly environment.

Regularly review and update security measures.

Train users on security protocols and access controls.

Operational Qualification (OQ)

1. Calculation Test

Verify that all formulas and functions produce correct results.

Compare spreadsheet outputs with calculator results for validation.

Document test procedures and results for each formula.

Ensure that test results meet predefined acceptance criteria.

Regularly review and update test procedures as needed.

2. Logical Values Test

Test Boolean functions (IF, AND, OR) to ensure they return expected results.

Manually verify and compare results.

Document test procedures and results for each logical function.

Ensure that logical functions handle a range of input values.

Regularly review and update logical functions to maintain accuracy.

3. Range/Precision Test

Enter extreme values to test the precision of calculations.

Ensure that the spreadsheet handles these values accurately.

Document test procedures and results for each precision test.

Verify that results meet predefined acceptance criteria.

Regularly review and update precision tests as needed.

4. Challenge Condition Test

Input boundary and extreme values to see how the spreadsheet handles unexpected data.

Ensure the spreadsheet processes these inputs correctly or provides appropriate error messages.

Document test procedures and results for each challenge condition.

Verify that the spreadsheet handles edge cases effectively.

Regularly review and update challenge condition tests as needed.

5. Performance Test

Assess the spreadsheet's performance with large datasets.

Ensure it completes calculations and processes data without crashing or significant delays.

Document test procedures and results for performance tests.

Verify that performance meets predefined acceptance criteria.

Regularly review and update performance tests as needed.

6. Error Handling and Recovery Test

Introduce intentional errors to test error messages and recovery mechanisms.

Verify that the spreadsheet manages errors gracefully without data loss.

Document test procedures and results for error handling tests.

Ensure that error handling procedures are effective.

Regularly review and update error handling tests as needed.

7. Integration and Interface Test

Verify that data imported from external sources is accurate and timely.

Ensure integration with other systems works correctly.

Document test procedures and results for integration tests.

Verify that integration processes meet predefined acceptance criteria.

Regularly review and update integration tests as needed.

8. Audit Trail and Version Control Test

Ensure that all changes, edits, and deletions are logged with timestamps and user IDs.

Verify that previous versions can be retrieved and changes are traceable.

Document test procedures and results for audit trail tests.

Ensure that version control processes are effective.

Regularly review and update audit trail and version control tests as needed.

9. Backup and Restoration Test

Test the effectiveness of backup mechanisms by restoring deleted or corrupted data.

Ensure that restored data matches the original without any loss.

Document test procedures and results for backup tests.

Verify that backup and restoration processes are effective.

Regularly review and update backup tests as needed.

Performance Qualification (PQ)

1. End User Operation Test

Verify that the spreadsheet performs correctly when used by its intended users.

Ensure standard operational tasks are completed without errors.

Document test procedures and results for end user operation tests.

Verify that user feedback meets predefined acceptance criteria.

Regularly review and update end user operation tests as needed.

2. LongTerm Stability and Performance Test

Assess the spreadsheet's performance over extended periods.

Ensure it maintains consistent performance as data accumulates.

Document test procedures and results for longterm stability tests.

Verify that longterm performance meets predefined acceptance criteria.

Regularly review and update longterm stability tests as needed.

3. RealWorld Data Test

Input actual data sets to validate processing and output integrity.

Ensure the spreadsheet handles realworld complexities accurately.

Document test procedures and results for realworld data tests.

Verify that realworld performance meets predefined acceptance criteria.

Regularly review and update realworld data tests as needed.

4. Scalability Test

Test how the spreadsheet performs as data volume increases.

Ensure it does not crash or slow down significantly.

Document test procedures and results for scalability tests.

Verify that scalability meets predefined acceptance criteria.

Regularly review and update scalability tests as needed.

5. Environmental Conditions Test

Assess performance under varying conditions, such as network interruptions or power fluctuations.

Ensure autosave and recovery features work correctly.

Document test procedures and results for environmental conditions tests.

Verify that environmental performance meets predefined acceptance criteria.

Regularly review and update environmental conditions tests as needed.

6. User Acceptance Test

Collect feedback from endusers to confirm the spreadsheet meets their needs.

Make adjustments based on user feedback.

Document test procedures and results for user acceptance tests.

Verify that user acceptance meets predefined criteria.

Regularly review and update user acceptance tests as needed.

Step 4: Execute Qualification Protocols

1. Follow Testing Protocols

Execute IQ, OQ, and PQ protocols meticulously and document all results.

Ensure all tests are performed according to predefined procedures.

Address any deviations with root cause analysis and corrective actions.

Document any changes made to the testing protocols.

Regularly review and update testing protocols as needed.

2. Error Analysis and Resolution

Analyze any errors that occur during testing.

Modify the spreadsheet to resolve errors and repeat tests as necessary.

Document the error analysis process and any corrective actions taken.

Ensure that all issues are resolved before finalizing validation.

Regularly review and update error analysis procedures as needed.

Step 5: Prepare Final Report

1. Summarize Results

Compile results from all tests, explaining any deviations and resolutions.

Ensure that all test results are documented and meet predefined acceptance criteria.

Attach associated records and submit the report for review and approval.

Include a summary of the validation process and key findings.

Regularly review and update the final report based on feedback.

Managing Validated Spreadsheets

1. Prevent Unauthorized Access

Protect the master copy from unauthorized modifications.

Implement access controls to restrict user access to readonly mode.

Store spreadsheets in secure network directories.

Regularly review and update security measures.

Train users on access control protocols.

2. Training

Train employees on proper use of validated spreadsheets.

Include instructions on data entry, report generation, and storage procedures.

Document training sessions and ensure all users are adequately trained.

Regularly review and update training materials based on user feedback.

Ensure ongoing training to maintain user proficiency.

3. Storage

Save completed files with approved naming conventions.

Ensure proper documentation and crossreferencing of stored files.

Regularly review and update storage procedures to ensure data integrity.

Train users on proper storage protocols.

Implement regular audits to ensure compliance with storage procedures.

ReValidation

1. Periodic Review

Review the spreadsheet every three years or after significant changes.

Ensure the effectiveness of validation parameters and the integrity of the formula.

Manage changes through a change control committee and revalidate as necessary.

Document the revalidation process and any changes made.

Regularly review and update revalidation procedures based on feedback.

Pro Tips for Excel Spreadsheet Validation in GMP Environments

Define Clear Objectives: Clearly outline the purpose and objectives of your spreadsheet to guide development and validation.

Document Everything: Maintain thorough documentation at every stage, from initial requirements to final validation reports.

Use Template Spreadsheets: Start with pre-approved templates to ensure consistency and compliance with validation standards.

Lock Critical Cells: Protect cells containing formulas and critical data to prevent accidental modifications.

Implement Version Control: Use version control to track changes and maintain a history of spreadsheet revisions.

Automate Repetitive Tasks: Use macros to automate repetitive tasks, but ensure they are thoroughly documented and validated.

Test Under Real Conditions: Perform validation tests using real-world data to ensure the spreadsheet handles actual scenarios accurately.

Regularly Update Documentation: Keep all documentation up-to-date, reflecting any changes or updates made to the spreadsheet.

Conduct Peer Reviews: Have peers review the spreadsheet and validation protocols to catch errors and ensure completeness.

Train All Users: Provide comprehensive training for all users on the proper use of the spreadsheet and the importance of validation.

Use Data Validation Rules: Implement data validation rules to restrict invalid data entries and ensure data integrity.

Set Up Audit Trails: Enable audit trails to track changes and identify who made modifications and when.

Validate External Data Sources: Ensure data imported from external sources is accurate and validated.

Perform Stress Tests: Test the spreadsheet's performance with large datasets to ensure it can handle high data volumes.

Regularly Revalidate: Schedule regular revalidation intervals, especially after software updates or significant changes.

Backup Regularly: Implement regular backup procedures to protect against data loss and ensure data can be restored.

Use Conditional Formatting: Highlight critical data or errors using conditional formatting to improve data visibility and accuracy.

Simplify Formulas: Keep formulas as simple as possible to reduce the risk of errors and make validation easier.

Test Error Handling: Introduce intentional errors to test the spreadsheet's error handling and recovery capabilities.

Ensure Security Compliance: Implement security measures to comply with GMP requirements and protect sensitive data.

Limit Access: Restrict access to the spreadsheet to authorized personnel only to prevent unauthorized changes.

Perform Integration Testing: Test the integration of the spreadsheet with other systems to ensure seamless data flow and accuracy.

Use Consistent Naming Conventions: Apply consistent naming conventions for files, formulas, and macros to enhance clarity and organization.

Conduct User Acceptance Testing: Involve end-users in testing to ensure the spreadsheet meets their needs and expectations.

Monitor Spreadsheet Usage: Regularly monitor how the spreadsheet is used to identify potential issues and areas for improvement.

Implement Error Tracing Tools: Use error tracing tools to identify and fix issues in formulas and data entries.

Validate Calculations: Regularly cross-check calculations against manual calculations or external tools to ensure accuracy.

Plan for Contingencies: Develop contingency plans for potential issues, such as system failures or data corruption.

Document Validation Procedures: Clearly document validation procedures and protocols to ensure consistent application.

Review and Update Regularly: Regularly review and update the spreadsheet, validation protocols, and documentation to adapt to new requirements or changes in regulations.