Ofni Systems

VALIDATION SUMMARY REPORT

FOR THE

EXAMPLE VALIDATION SPREADSHEET

SERVING

OFNI SYSTEMS
RALEIGH, NORTH CAROLINA

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Thank you for downloading this sample validation document.

Ofni Systems can validate all of your software, databases, spreadsheets and computer systems, and develop the appropriate documentation for all phases of the software life cycle. We can provide any level of service required, from executing test scripts generated from your existing specifications to writing the entire validation package. Ofni Systems will perform risk assessments to focus the validation effort on the most appropriate sections of your system.

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Ofni Systems validation specialists have experience working within the compliance requirements of established regulated companies. Our specialists are experts in industry validation standards and will produce validation documents which will meet or exceed your exacting standards.

Ofni Systems is a leader in providing regulatory compliance solutions for pharmaceutical, biotech and medical device companies. They are the creators of ExcelSafe for Excel spreadsheet security and the Part 11 Toolkit for compliant databases. They also are the creators of the FastVal validation software for generating and executing validation documents, and have been providing professional validation services using FastVal since 2006. Their products for Part 11 compliant databases and spreadsheets are used by pharmaceutical, biotech and medical device companies across the globe, while it's products for computer validation, auditing and FDA submissions ensure that their clients meet every requirement for electronic records and electronic signatures.

How can we help you? Contact Ofni Systems at by email or by phone (919) 844-2494.

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Produce validation documents, manage validation projects and execute testing protocols electronically in 70% less time.

ExcelSafe™
Makes existing MS Excel spreadsheets compliant with all the technical requirements of 21 CFR Part 11.

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Transform MS Access programs into powerful, secure systems that meet all requirements of Part 11.

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Assess all of your computer systems for compliance, perform gap analysis and create corrective action plans.

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Part 11 Assessments
Determine the compliance status of your computer systems.

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Validate new or updated software, database and computer systems.

Custom Programs
Develop a compliant computer system specific to your requirements.

Data Migration
Convert existing legacy data to an Access or SQL Server database.

Compliance Training
Learn to build a fully Part 11 compliant electronic record system.

SIGNATURES

Author:	
Signature:	Date:
System Owner:	
Signature:	Date:
Quality Assurance:	
Signature:	Date:

REVISION HISTORY

Rev #	Description	Date Approved
0	Initial Issue.	

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1. Executive Summary

This Final Summary Reports summarizes the results obtained during the execution of the Installation/Operational (IOQ) Qualification (IOQ-001), for the validation of the Example Validation spreadsheet. This Summary Report documents that the Example Validation spreadsheet performed in accordance with its intended use as indicated in the Functional Requirements Specification and the Software Design Specification.

Protocol # IOQ-001 was performed for the qualification of the Example Validation spreadsheet. Successful completion of the qualification activities described in protocol # IOQ-001 demonstrates that the Example Validation spreadsheet is installed and operated according to specifications as outlined in FRS-001 and SDS-001.

Test Case 7.1: Verification of ExcelSafe Installation

Test Case 8.1: Calculation Worksheet and the Plotting Mass vs. Volume Chart

Test Case 8.2: Accurate Record Generation

Test Case 8.3: Program Timeouts

Test Case 8.4: Audit Trails

Test Case 8.5: Electronic Signature Manifestations

Test Case 8.6: GenUsers

Test Case 8.7: DataEntry

Test Case 8.8: Managers

Test Case 8.9: Administrators

All sections of the Installation/Operational Protocol for the Example Validation Spreadsheet were executed and successfully completed. The Ofni Systems, Raleigh, NC, Example Validation spreadsheet functioned in accordance with the approved System Specifications and adhered to site specific standards to ensure system specifications. The Example Validation spreadsheet is considered qualified and can be used for its intended use.

2. Summary Report Introduction

2.1. Objectives

This Final Summary Reports summarizes the results obtained during the execution of the Installation/Operational (IOQ) Qualification (IOQ-001), for the validation of the Example Validation spreadsheet. This Summary Report documents that the Example Validation spreadsheet performed in accordance with its intended use as indicated in the Functional Requirements Specification and the Software Design Specification.

Protocol # IOQ-001 was performed for the qualification of the Example Validation spreadsheet. Successful completion of the qualification activities described in protocol # IOQ-001 demonstrates that the Example Validation spreadsheet is installed and operated according to specifications as outlined in FRS-001 and SDS-001.

2.2. Scope

This Report applies to the validation of the Example Validation spreadsheet. The scope of this Summary Report is limited to Ofni Systems (Raleigh, NC) and the testing to demonstrate Example Validation functionality.

2.3. Assumptions

The validation will be performed on a properly functioning Ofni Systems workstation, with MS Excel and ExcelSafe properly installed.

2.4. Exclusions

This validation applies to the Example Validation spreadsheet, and not to MS Excel, ExcelSafe, the workstation or computer environment.

3. Acronyms and References

3.1. Acronyms and Definitions

Code of Federal (US) Regulations

3.2. References

21 CFR Part 11, Part 210, Part 211

GAMP 5 Guide for Validation of Automated Systems

VCP-001, Validation and Compliance Plan for the Example Validation Spreadsheet

FRS-001, Functional Requirements Specification for the Example Validation Spreadsheet

SDS-001, Software Design Specification for the Example Validation Spreadsheet

IOQ-001, Installation/Operational Protocol for the Example Validation Spreadsheet

4. Testing Summary

4.1. General

The IOQ protocol provided the necessary documented verification that all key aspects of the Example Validation spreadsheet were properly installation/operation. The following items applied to all test steps in this Installation/Operational Qualification Protocol:

4.1.1. Each test case was read prior to performing the test.

4.1.2. Qualification entries were completed using cGxP documentation practices.

4.1.3. Test steps were followed as listed in each test case.

4.1.4. For each test instruction, results were documented in the actual results column.

4.1.5. For each test instruction, Pass or Fail was recorded for each step.

4.1.6. The person performing the test recorded their initials/date in the Performed By/Date Column.

4.1.7. Any event where there was an inability to meet the approved protocol requirements was addressed on the Deviation Log.

4.1.8. Adhere to all Ofni Systems (Raleigh, NC) site emergency response and safety procedures.

4.1.9. The testing included in this Installation/Operational Protocol met or exceeded all criteria listed in the individual test procedures. Each individual test:

4.1.9.1. The acceptance criteria for each individual test procedure was met and all required documentation in this protocol was properly executed.

4.1.9.2. All test procedures were executed and corresponding test tables were completed.

4.1.9.3. All deviations were recorded on the appropriate Deviation Log. All deviations were addressed, resolved and approved.

4.2. Documentation

The following documentation practices apply to this Installation/Operational Protocol

4.2.1. All qualification reviews, inspections and verifications were documented at the time they were performed.

4.2.2. All qualification work required by this IOQ Protocol was performed.

4.2.3. Each protocol page containing support data was signed and dated.

4.2.4. When applicable, all deviations encountered during the execution of this protocol were documented on the appropriate Deviation Log.

4.2.5. Pages added to the qualification were properly identified, signed, dated and carried the Protocol number.

4.3. Equipment/Materials

No additional materials besides the Example Validation spreadsheet and the ExcelSafe application were required.

4.4. Testing Exclusions

4.4.1. Hardware Identification

The only hardware associated with the database are Ofni Systems Standard Workstations.

4.4.2. Equipment Installation

The database is accessed by PCs used in ambient office environments via the LAN. There was no additional environmental verification or testing.

4.4.3. System Documentation

There are no specific manuals or documentation associated with this application. MS Access provides online help files for user.

4.4.4. Preventative Maintenance and Calibration

There are no maintenance or calibration functions associated with this database application.

4.4.5. Verification of Drawings and Installation

Not Applicable. There are no drawings associated with this software.

4.4.6. Prerequisites for Software Installation

Example Validation is an MS Excel spreadsheet, running in a standard windows environment. No further testing is required.

5. Results of Validation Testing

5.1. Installation Qualification Tests

5.1.1. Test Case 1, Verification of ExcelSafe Installation

Purpose: To verify proper installation of ExcelSafe.

5.1.1.1. Acceptance Criteria

The test case will demonstrate that:

All documentation required to operate and maintain the system is present.

Microsoft Excel, Version 2000 or higher is installed.

The operating system required for use is MS Windows 2000, MS Windows XP or MS Vista.

All required ExcelSafe files are loaded.

Microsoft Access, Version 2000 or higher is installed.

Microsoft DAO, Version 3.51 or higher is installed.

The Example Validation spreadsheet is properly loaded in ExcelSafe.

The Example Validation spreadsheet can use local or networked printers.

Will not open from outside ExcelSafe.

Opens correctly from inside ExcelSafe.

5.1.1.2. Test Results

This test case met or exceeded the "Expected Results" listed in the individual test procedures. The test passed without reported deviations.

5.2. Approval to Proceed to Operational Qualification

Before proceeding with Operational Testing, acceptance of Installation Qualification was provided prior to execution of the Operational Qualification.

5.3. Operational Qualification Tests

5.3.1. Test Case 2, Calculation Worksheet and the Plotting Mass vs. Volume Chart

Purpose: To demonstrate functionality of the Calculation Worksheet and the Plotting Mass vs. Volume chart.

5.3.1.1. Acceptance Criteria

The Calculation Worksheet:

Allows users to enter appropriate values for Sample, Mass and Volume.

Calculates Maximum(Volume), Minimum(Volume) and Average(Volume).

Calculates Volume^2.

Allows users to secure and unsecure data by adding or removing electronic signatures.

Is properly formatted for printing.

Records changes in user data to the ExcelSafe audit trail.

The Plotting Mass vs. Volume Chart:

Plots Mass (X-axis) vs. Volume (Y-axis).

Plots Volume and Volume^2.

5.3.1.2.   Test Results

This test case met or exceeded the "Expected Results" listed in the individual test procedures. The test passed without reported deviations.

5.3.2.   Test Case 3, Accurate Record Generation

Purpose: To demonstrate Example Spreadsheet compliance with accurate record generation requirements.

5.3.2.1.   Acceptance Criteria

Test for the following requirements:

ExcelSafe and the Example Validation spreadsheet have the ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review and copying by regulatory agencies.

The functionality meets the following requirement of 21 CFR 11:

11.10.b The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform review and copying of the electronic records.

The Example Validation spreadsheet will meet the following requirements:

5.3.2.2.   Test Results

This test case met or exceeded the "Expected Results" listed in the individual test procedures. The test passed without reported deviations.

5.3.3.   Test Case 4, Program Timeouts

Purpose: To demonstrate Example Spreadsheet compliance with program timeout requirements.

5.3.3.1.   Acceptance Criteria

Test for the following requirements:

ExcelSafe provides the Example Validation spreadsheet with will automatically time-out after 10 minutes of non-activity.

The functionality meets the following requirements of 21 CFR 11:

11.10.d Limiting system access to authorized individuals.

11.300.d Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.

The Example Validation spreadsheet Program Timeouts meets the following requirements:

5.3.3.2. Test Results

This test case met or exceeded the "Expected Results" listed in the individual test procedures. The test passed without reported deviations.

5.3.4. Test Case 5, Audit Trails

Purpose: To demonstrate Example Spreadsheet compliance with audit trail requirements.

5.3.4.1. Acceptance Criteria

The Example Validation spreadsheet audit trail will meet the following requirements:

Audit Trail records are computer generated.

Audit Trail records are secure (read-only access).

Audit Trail records have an accurate Time/Date stamp.

Audit Trail performs a journal function and records the Time/Date of operator entries and actions that create, modify and delete electronic records.

The Audit Trail is unalterable and changes to Audit Trail records do not obscure previously recorded information.

5.3.4.2. Test Results

This test case met or exceeded the "Expected Results" listed in the individual test procedures. The test passed without reported deviations.

5.3.5. Test Case 6, Electronic Signature Manifestations

Purpose: To demonstrate Example Spreadsheet compliance with electronic signature requirements.

5.3.5.1. Acceptance Criteria

The Example Validation spreadsheet electronic signatures will meet the following requirements:

Application of an electronic signature requires use of the User ID and password.

Data secured with an electronic signature cannot be edited or deleted unless the electronic signature is removed.

Multiple electronic signatures can be applied to a single workbook page.

Electronic signatures include the printed name of the user applying the electronic signature.

Electronic signatures include the Date/Tune when the electronic signature was applied.

Electronic signatures include the Meaning of the electronic signature.

The Electronic signature is human-readable.

5.3.5.2. Test Results

This test case met or exceeded the "Expected Results" listed in the individual test procedures. The test passed without reported deviations.

5.3.6. Test Case 7, GenUsers

Purpose: To demonstrate proper functionality of the GenUser security group in the Example Validation spreadsheet.

5.3.6.1. Acceptance Criteria

Members of the GenUsers group:

Can open the spreadsheet.

Cannot add spreadsheet data.

Cannot edit spreadsheet data.

Cannot delete spreadsheet data.

Cannot sign pages within the spreadsheet.

Cannot remove electronic signatures from the spreadsheet.

5.3.6.2. Test Results

This test case met or exceeded the "Expected Results" listed in the individual test procedures. The test passed without reported deviations.

5.3.7. Test Case 8, DataEntry

Purpose: To demonstrate proper functionality of the DataEntry security group in the Example Validation spreadsheet.

5.3.7.1. Acceptance Criteria

Members of the DataEntry group:

Can open the spreadsheet.

Can add spreadsheet data.

Can edit spreadsheet data.

Can delete spreadsheet data.

Cannot sign pages within the spreadsheet.

Cannot remove electronic signatures from the spreadsheet.

5.3.7.2. Test Results

This test case met or exceeded the "Expected Results" listed in the individual test procedures. The test passed without reported deviations.

5.3.8. Test Case 9, Managers

Purpose: To demonstrate proper functionality of the Managers security group in the Example Validation spreadsheet.

5.3.8.1. Acceptance Criteria

Members of the Managers group:

Can open the spreadsheet.

Can add spreadsheet data.

Can edit spreadsheet data.

Can delete spreadsheet data.

Can sign pages within the spreadsheet.

Cannot remove electronic signatures from the spreadsheet.

5.3.8.2.   Test Results

This test case met or exceeded the "Expected Results" listed in the individual test procedures. The test passed without reported deviations.

5.3.9.   Test Case 10, Administrators

Purpose: To demonstrate proper functionality of the Administrators security group in the Example Validation spreadsheet.

5.3.9.1.   Acceptance Criteria

Members of the Administrators group:

Can open the spreadsheet.

Can add spreadsheet data.

Can edit spreadsheet data.

Can delete spreadsheet data.

Can sign pages within the spreadsheet.

Can remove electronic signatures from the spreadsheet.

5.3.9.2.   Test Results

This test case met or exceeded the "Expected Results" listed in the individual test procedures. The test passed without reported deviations.

6.   Conclusion

All sections of the Installation/Operational Protocol for the Example Validation Spreadsheet were executed and successfully completed. The Ofni Systems, Raleigh, NC, Example Validation spreadsheet functioned in accordance with the approved System Specifications and adhered to site specific standards to ensure system specifications. The Example Validation spreadsheet is considered qualified and can be used for its intended use.