OPERATIONAL QUALIFICATION PROTOCOL
FOR THE
EXAMPLE VALIDATION SPREADSHEET
SERVING
OFNI SYSTEMS
RALEIGH, NORTH CAROLINA

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REVISION: 0

PREPARED BY
DANIEL WATERMAN
VALIDATION ENGINEER
OFNI SYSTEMS
Thank you for reviewing 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.

These sample validation documents were produced with the FastVal Validation Document generator software, which allows us to complete validation projects in 70% less time than traditional validation methods, with more time spent testing your software and less time preparing documentation. Our goal in all software validation projects is to improve the quality and value of your computer system.

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 its 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.

<table>
<thead>
<tr>
<th>Tools for Compliance</th>
<th>Consulting and Services</th>
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<tbody>
<tr>
<td><strong>FastVal</strong>&lt;sup&gt;™&lt;/sup&gt;</td>
<td><strong>Part 11 Assessments</strong></td>
</tr>
<tr>
<td>Produce validation documents, manage validation projects and execute testing protocols electronically in 70% less time.</td>
<td>Determine the compliance status of your computer systems.</td>
</tr>
<tr>
<td><strong>ExcelSafe</strong>&lt;sup&gt;™&lt;/sup&gt;</td>
<td><strong>Computer Validation</strong></td>
</tr>
<tr>
<td>Makes existing MS Excel spreadsheets compliant with all the technical requirements of 21 CFR Part 11.</td>
<td>Validate new or updated software, database and computer systems.</td>
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<tr>
<td><strong>Part 11 Toolkit</strong>&lt;sup&gt;™&lt;/sup&gt;</td>
<td><strong>Custom Programs</strong></td>
</tr>
<tr>
<td>Transform MS Access programs into powerful, secure systems that meet all requirements of Part 11.</td>
<td>Develop a compliant computer system specific to your requirements.</td>
</tr>
<tr>
<td><strong>Part 11 Advisor</strong>&lt;sup&gt;™&lt;/sup&gt;</td>
<td><strong>Data Migration</strong></td>
</tr>
<tr>
<td>Assess all of your computer systems for compliance, perform gap analysis and create corrective action plans.</td>
<td>Convert existing legacy data to an Access or SQL Server database.</td>
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<td><strong>Compliance Training</strong></td>
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<td>Learn to build a fully Part 11 compliant electronic record system.</td>
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SIGNATURES

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<th>Author</th>
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REVISION HISTORY

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<tr>
<th>Rev #</th>
<th>Description</th>
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<td>Initial Issue.</td>
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</tr>
</tbody>
</table>
TABLE OF CONTENTS

1. INTRODUCTION .............................................................................................................................. 5
  1.1. Objectives ....................................................................................................................................... 5
  1.2. Scope ............................................................................................................................................... 5
  1.3. Assumptions .................................................................................................................................. 5
  1.4. Exclusions ...................................................................................................................................... 5

2. ACRONYMS AND REFERENCES .................................................................................................. 5
  2.1. Acronyms and Definitions............................................................................................................. 5
  2.2. References ...................................................................................................................................... 6

3. RESPONSIBILITIES ........................................................................................................................ 6
  3.1. System Owner ................................................................................................................................ 6
  3.2. Ofni Systems Validation Representative ..................................................................................... 6

4. SYSTEM DESCRIPTION ................................................................................................................. 6

5. PROCEDURE TEST PLAN ............................................................................................................. 6
  5.1. General ............................................................................................................................................ 6
  5.2. Documentation ............................................................................................................................... 7
  5.3. Equipment/Materials ...................................................................................................................... 7
  5.4. Exclusions ...................................................................................................................................... 7

6. OPERATIONAL TESTS .................................................................................................................. 9
  6.1. Test Case #2: Calculation Worksheet and the Plotting Mass vs. Volume Chart ..................... 9
  6.2. Test Case #3: Accurate Record Generation .............................................................................. 14
  6.3. Test Case #4: Program Timeouts ............................................................................................... 18
  6.4. Test Case #5: Audit Trails ........................................................................................................... 21
  6.5. Test Case #6: Electronic Signature Manifestations ................................................................. 27
1. Introduction

1.1. Objectives
The purpose of this Operational Qualification protocol is to define the requirements and acceptance criteria for the operation of the Example Validation spreadsheet. The spreadsheet (and associated ExcelSafe software) will reside on the Ofni Systems LAN. Successful completion of this OQ will provide the necessary documented evidence to assure that the Example Validation spreadsheet has been properly operated in accordance with Ofni Systems procedures and complies with all cGxP requirements.

1.2. Scope
This OQ protocol verifies the operation of the Example Validation spreadsheet. Functional requirements for the Example Validation spreadsheet are detailed in the Functional Requirements Specification for the Example Validation Spreadsheet (FRS-001). Design requirements for the the Example Validation spreadsheet are detailed in the Software Design Specification for the Example Validation Spreadsheet (SDS-001).

1.3. Assumptions
The validation will be performed by Ofni Systems. The validation will be performed on a properly functioning Ofni Systems workstation.

ExcelSafe has been previously installed and validated by Ofni Systems before performing this validation.

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

2. Acronyms and References

2.1. Acronyms and Definitions
CFR - Code of Federal (US) Regulations
cGxP - Abbreviation which includes current Good Manufacturing, Clinical and Laboratory Practices
Closed System - An environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.
FRS - Functional Requirements Specification
GUI - Graphical User Interface
OQ - Operational Qualification
LAN - Local Area Network
Open System - An environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.
SDS - Software Design Specification
SOP - Standard Operating Procedure
Spreadsheet - Generic term for application containing rows and columns of cells, with functions to manipulate data within those cells.
Workbook - A group of one or more worksheets contained within a spreadsheet file. The workbook may also include code modules.
Worksheet - One of possibly multiple data sheets within a workbook.

2.2. References

21 CFR Part 11, Part 210, Part 211
GAMP 5 Guide for Validation of Automated Systems
FRS-001, Functional Requirements Specification for the Example Validation Spreadsheet
SDS-001, Software Design Specification for the Example Validation Spreadsheet
Validation Package for ExcelSafe, V2.0

3. Responsibilities

3.1. System Owner

3.1.1. Supplies all procedures, data, manuals, drawings and documentation necessary for the generation of protocols and the completion of final reports.

3.1.2. Reviews test data, including deviation resolutions.

3.1.3. Assembles the test data and documentation for post-execution approval.

3.2. Ofni Systems Validation Representative

3.2.1. Reviews and pre-approves this protocol.

3.2.2. Coordinates protocol execution upon pre-approval.

3.2.3. Executes approved protocol.

3.2.4. Notifies System Owner of issues or deviations rising during protocol execution.

4. System Description

The Example Validation spreadsheet is a Microsoft Excel 2003 Application. The Example Validation spreadsheet is stored on the Ofni Systems LAN. This database can be accessed from any workstation with network capabilities given the user has the privileges to access the network folder. The Example Validation spreadsheet is GAMP Category 5 (Customized MS Excel spreadsheet) GMP.

The Example Validation spreadsheet is stored within the ExcelSafe system. ExcelSafe provides the technological tools for regulatory compliance to Excel spreadsheets, including audit trails and electronic signatures.

5. Procedure Test Plan

5.1. General

This OQ protocol will provide the necessary documented verification that all key aspects of the Example Validation spreadsheet has been properly tested. The following items apply to all test steps in this Operational Qualification Protocol:

5.1.1. Read each test case prior to performing the test.

5.1.2. The qualification entries should be completed using cGxP documentation practices.

5.1.3. Follow the test steps listed in each test case.

5.1.4. For each test instruction, documents the results in the actual results column.

5.1.5. Records Pass or Fail for each step in the test.

5.1.6. Record the initials/date of each person performing the test under the Performed By/Date Column.
Qualification Type: OQ

**Section #** | **Test Case #** | **Title**
---|---|---
8.1. | 2 | Test Case: Calculation Worksheet and the Plotting Mass vs. Volume Chart

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

**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.

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

<table>
<thead>
<tr>
<th>Step #</th>
<th>Procedure</th>
<th>Expected Result</th>
<th>Actual Result</th>
<th>P / F</th>
<th>Init.</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Open the Example Validation spreadsheet through ExcelSafe. Navigate to the Calculation worksheet.</td>
<td>The Example Validation spreadsheet opens without error. The Calculation worksheet opens without error.</td>
<td>The Example Validation spreadsheet opens without error. The Calculation worksheet opens without error.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The Calculation Worksheet allows users to enter appropriate values for Sample, Mass and Volume.

The Calculation Worksheet calculates Maximum(Volume), Minimum(Volume) and Average(Volume).

<table>
<thead>
<tr>
<th>Step #</th>
<th>Procedure</th>
<th>Expected Result</th>
<th>Actual Result</th>
<th>P / F</th>
<th>Init.</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Navigate to the cell G6, Max(Volume). Record the calculation cell G6 should perform.</td>
<td>Calculation in cell G6 recorded.</td>
<td>Calculation in cell G6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Record the formula in cell G6. Verify that the formula correctly models the intended calculation.</td>
<td>Formula in cell G6 recorded. The formula correctly models the intended calculation.</td>
<td>Calculation. Calculation:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Manually perform the calculation in cell G6. Verify that the manual calculation matches the spreadsheet calculation.</td>
<td>The manual calculation matches the spreadsheet calculation.</td>
<td>The manual calculation matches the spreadsheet calculation. Manual Calculation: Spreadsheet Calculation:</td>
<td></td>
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</tr>
<tr>
<td>8</td>
<td>Navigate to the cell G8, Min(Volume). Record the calculation cell G8 should perform.</td>
<td>Calculation in cell G8 recorded.</td>
<td>Calculation in cell G8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Record the formula in cell G8. Verify that the formula correctly models the intended calculation.</td>
<td>Formula in cell G8 recorded. The formula correctly models the intended calculation.</td>
<td>Calculation. Calculation:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Manually perform the calculation in cell G8. Verify that the manual calculation matches the spreadsheet calculation.</td>
<td>The manual calculation matches the spreadsheet calculation.</td>
<td>The manual calculation matches the spreadsheet calculation. Manual Calculation: Spreadsheet Calculation:</td>
<td></td>
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