

OPERATIONAL QUALIFICATION PROTOCOL FOR THE EXAMPLE VALIDATION SPREADSHEET SERVING

OFNI SYSTEMS
RALEIGH, NORTH CAROLINA

DOCUMENT NUMBER: OQ-001 DATE ISSUED: 8/12/2013 REVISION: 0

PREPARED BY
DANIEL WATERMAN
VALIDATION ENGINEER
OFNI SYSTEMS

Ofni: Example Validation Spreadsheet Operational Qualification Protocol		Doc. #: OQ-001 Rev. #: 0
Department Validation	Author Daniel Waterman	Page 2 of 7

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 <u>FastVal Validation Document generator</u> software, which allows us to complete validation projects in <u>70% less time</u> 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 <a href="ExcelSafe for <a href="ExcelSafe

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

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

Ofni: Example Validation Spreadsheet Operational Qualification Protocol		Doc. #: OQ-001 Rev. #: 0
Department Validation	Author Daniel Waterman	Page 3 of 7

SIGNATURES

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

REVISION HISTORY

Rev#	Description	Date Approved
0	Initial Issue.	

Ofni: Example Validation Spreadsheet Operational Qualification Protocol		Doc. #: OQ-001 Rev. #: 0
Department Validation	Author Daniel Waterman	Page 4 of 7

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

Ofni: Example Validation Spreadsheet Operational Qualification Protocol		Doc. #: OQ-001 Rev. #: 0
Department Validation	Author Daniel Waterman	Page 5 of 7

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.

Ofni: Example Validation Spreadsheet Operational Qualification Protocol		Doc. #: OQ-001 Rev. #: 0
Department Validation	Author Daniel Waterman	Page 6 of 7

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. 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.

Step #	Procedure	Expected Result	Actual Result	P/F	Init.	Date
he Calo	culation Worksheet allows users to enter appropriate values for	r Sample, Mass and Volume.				
1	Open the Example Validation spreadsheet through ExcelSafe. Navigate to the Calculation worksheet.	The Example Validation spreadsheet opens without error. The Calculation worksheet opens without error.	The Example Validation spreadsheet without error. The Calculation worksheet without error.			
2	Navigate to cell range A6:A36, Sample. Verify that the cell range accepts data entry.	Cell range A6:A36 accepts data entry.	Cell range A6:A36data entry.			
3	Navigate to cell range B6:B36, Mass. Verify that the cell range accepts data entry.	Cell range B6:B36 accepts data entry.	Cell range B6:B36data entry.			
4	Navigate to cell range C6:C36, Volume. Verify that the cell range accepts data entry.	Cell range C6:C36 accepts data entry.	Cell range C6:C36data entry.			
ne Calo	culation Worksheet calculates Maximum(Volume), Minimum	(Volume) and Average(Volume)	me).			
5	Navigate to the cell G6, Max(Volume). Record the calculation cell G6 should perform.	Calculation in cell G6 recorded.	Calculation in cell G6 Calculation:			
6	Record the formula in cell G6. Verify that the formula correctly models the intended calculation.	Formula in cell G6 recorded. The formula correctly models the intended calculation.	Calculation Calculation: models the intended calculation.			
7	Manually perform the calculation in cell G6. Verify that the manual calculation matches the spreadsheet calculation.	The manual calculation matches the spreadsheet calculation.	The manual calculation the spreadsheet calculation. Manual Calculation: Spreadsheet Calculation:			
8	Navigate to the cell G8, Min(Volume). Record the calculation cell G8 should perform.	Calculation in cell G8 recorded.	Calculation in cell G8 Calculation:			
9	Record the formula in cell G8. Verify that the formula correctly models the intended calculation.	Formula in cell G8 recorded. The formula correctly models the intended calculation.	Calculation Calculation: models the intended calculation.			
10	Manually perform the calculation in cell G8. Verify that the manual calculation matches the spreadsheet calculation.	The manual calculation matches the spreadsheet calculation.	The manual calculation the spreadsheet calculation. Manual Calculation: Spreadsheet Calculation:			

Monday, August 12, 2013 Page 7 of 7