



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

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PREPARED BY
DANIEL WATERMAN
VALIDATION ENGINEER
OFNI SYSTEMS

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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.

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

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SIGNATURES

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

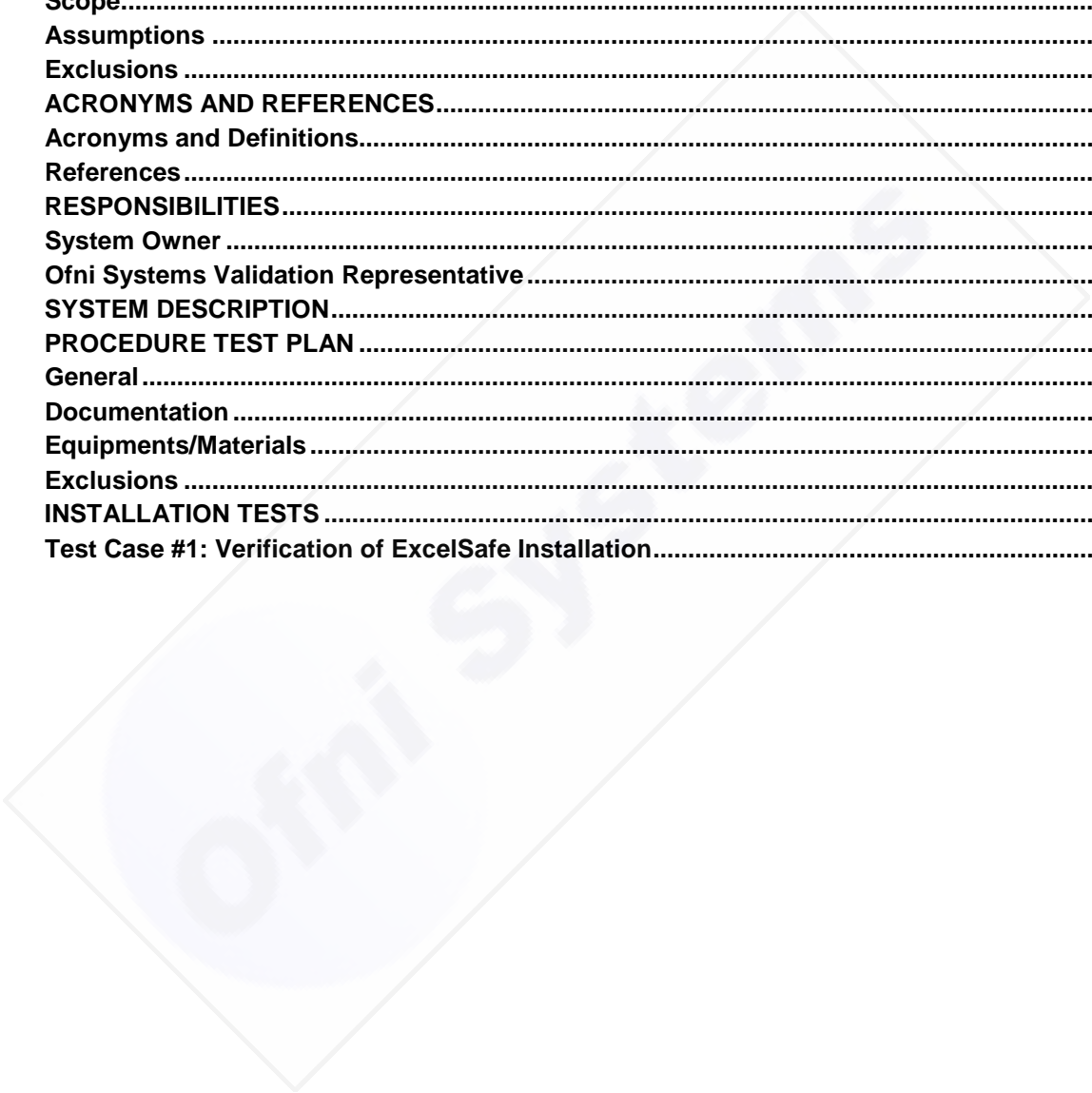
REVISION HISTORY

Rev #	Description	Date Approved
0	Initial Issue.	

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1. Introduction

1.1. Objectives

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

1.2. Scope

This IQ protocol verifies the installation 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). Design requirements for the the Example Validation spreadsheet are detailed in the Software Design Specification for the Example Validation Spreadsheet (SDS).

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

IQ - Installation/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.

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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 IQ 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 Installation/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.
-

Installation / Operational Qualification

Qualification Type: IQ

Section # Test Case # Title

7.1. 1 Verification of ExcelSafe Installation

Purpose

To verify proper installation of ExcelSafe.

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.

Test Case: 1. Verification of ExcelSafe Installation

<u>Step #</u>	<u>Procedure</u>	<u>Expected Result</u>	<u>Actual Result</u>	<u>P / F</u>	<u>Init.</u>	<u>Date</u>
All documentation required to operate and maintain the system is present.						
1	Verify that all documentation required to operate and maintain the system is present.	All documentation required to operate and maintain the system is present.	All documentation required to operate and maintain the system is _____. Document Title: _____ Doc ID: _____ Revision: _____ Date Approved: _____			
Microsoft Excel, Version 2000 or higher is installed.						
2	Open Microsoft Excel. Under the Help item on the menu, select About Microsoft Excel.... Verify the version of Microsoft Excel. Close Microsoft Excel.	Microsoft Excel is Version 2000 or higher.	Microsoft Excel _____ Version _____.			
The operating system installed for use is either MS Windows 2000 or MS Windows XP or MS Vista.						
3	On the desktop, right click the MY Computer icon and select Properties from the menu. Verify the version of Microsoft Windows that is currently running. Close the Windows property screen.	The version of Microsoft Windows currently running is either Windows 2000, Windows XP or MS Vista.	The version of Microsoft Windows currently running _____ Windows _____.			
All required ExcelSafe files are loaded.						
4	Record file location for ExcelSafe.mde program.	File location for ExcelSafe.mde program recorded.	File location for ExcelSafe.mde program _____. File Location: _____			
5	Record file location for ESData.tdb.	File location for ESData.tdb recorded.	File location for ESData.tdb _____. File Location: _____			
6	Record file location for P11Toolkit.mde (P11 Toolkit).	File location for P11Toolkit.mde (P11 Toolkit) recorded.	File location for P11Toolkit.mde (P11 Toolkit) _____. File Location: _____			
7	Record file location for the ExcelSafe security workgroup (EsSec.mdw).	File location for EsSec.mdw recorded.	File location for EsSec.mdw _____. File Location: _____			
Microsoft Access, Version 2000 or higher is installed.						
8	Open Microsoft Access directly. Under the Help item on the menu, select About Microsoft Access.... Verify the version of Microsoft Access	The version of Microsoft Access is Access 2000 or higher.	The version of Microsoft Access _____ Access _____.			