



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

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**SIGNATURES**

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

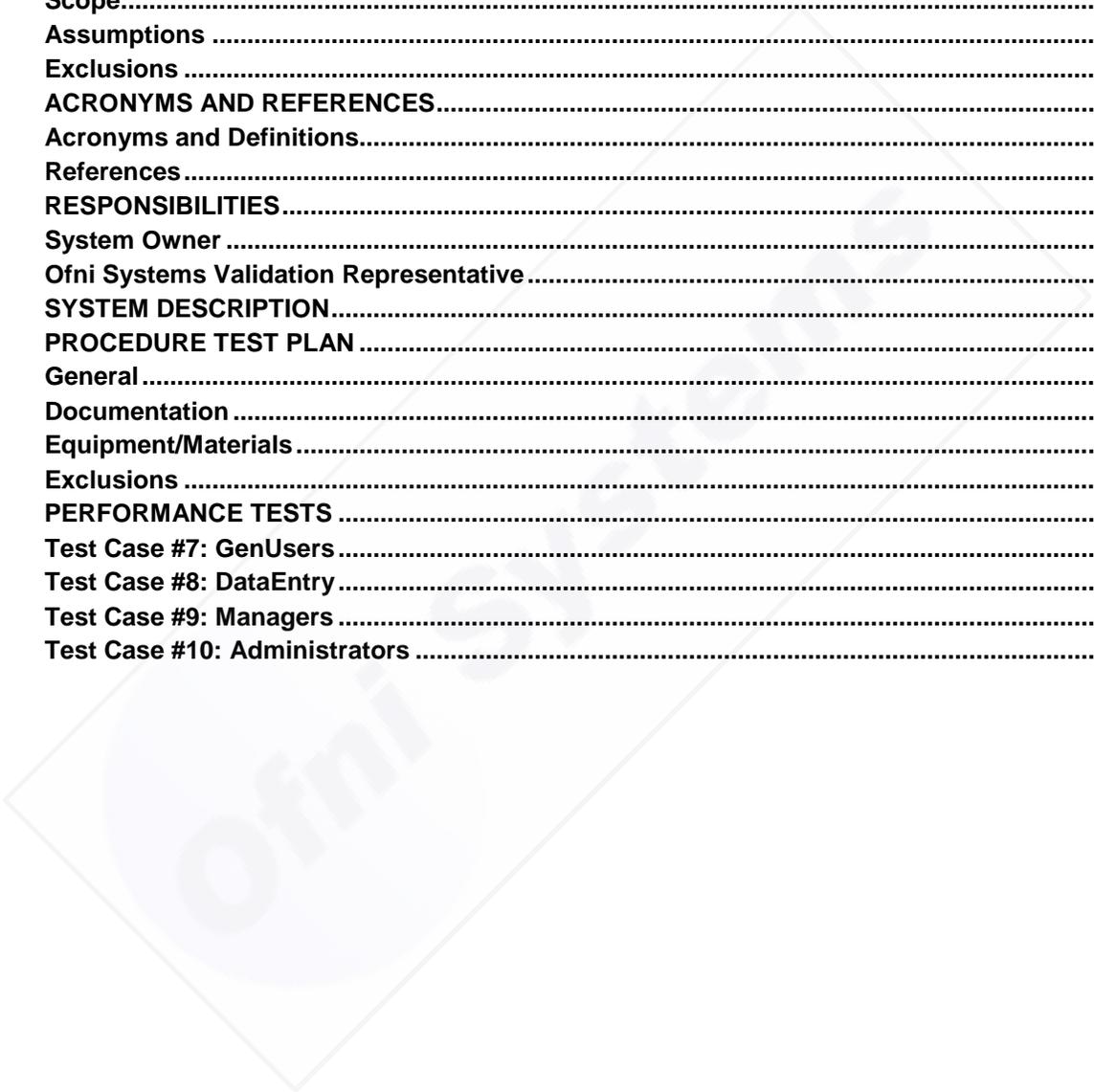
**REVISION HISTORY**

Rev #	Description	Date Approved
0	Initial Issue.	

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## 1. Introduction

### 1.1. Objectives

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

### 1.2. Scope

This PQ protocol verifies the performance 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 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

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.

PQ - Performance Qualification

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 PQ 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 Performance 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: PQ

**Section #**      **Test Case #**   **Title**  
 8.6.                      7      Test Case: GenUsers

**Purpose**

To demonstrate proper implementation of the GenUser security group in the Example Validation spreadsheet.

**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.

**Test Case:** 7. Test Case: GenUsers

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
<b>Members of the GenUser group can open the spreadsheet.</b>						
1	Open ExcelSafe as an Administrative user. Open the User Administration screen. Select a user who is a member of the GenUser (and only a member of the GenUser) user group.	The selected user is a member of the GenUser (and only a member of the GenUser) user group.	The selected user _____ a member of the GenUser (and only a member of the GenUser) user group. User: _____			
2	Login to the spreadsheet as the user selected in the previous step.	The user successfully logs into ExcelSafe.	The user _____ logs into ExcelSafe.			
3	Select the spreadsheet. Verify that members of the GenUser group can open existing instances of the spreadsheet.	Members of the GenUser group can open existing instances of the spreadsheet.	Members of the GenUser group _____ open existing instances of the spreadsheet.			
4	Verify that spreadsheets opened by members of the GenUser group are identified as Read-Only.	Spreadsheets opened by members of the GenUser group are identified as Read-Only.	Spreadsheets opened by members of the GenUser group are _____ as Read-Only.			
<b>Members of the GenUser group cannot add spreadsheet data.</b>						
5	Attempt to add data to the spreadsheet.	The user cannot add data to the spreadsheet. A message appears on the lower left corner of the spreadsheet informing the user that the workbook is read-only.	The user _____ add data to the spreadsheet. A message _____ on the lower left corner of the spreadsheet inform the user that the workbook is read-only.			
<b>Members of the GenUser group cannot edit spreadsheet data.</b>						
6	Attempt to edit data within the spreadsheet.	The user cannot edit data in the spreadsheet. A message appears on the lower left corner of the spreadsheet informing the user that the workbook is read-only.	The user _____ edit data in the spreadsheet. A message _____ on the lower left corner of the spreadsheet inform the user that the workbook is read-only.			
<b>Members of the GenUser group cannot delete spreadsheet data.</b>						
7	Attempt to delete data from the spreadsheet.	The user cannot delete data from the spreadsheet. A message appears on the lower left corner of the spreadsheet informing the user that the workbook is read-only.	The user _____ delete data from the spreadsheet. A message _____ on the lower left corner of the spreadsheet inform the user that the workbook is read-only.			
<b>Members of the GenUser group cannot sign pages within the spreadsheet.</b>						
8	Navigate to the Active Sheets Utility screen. Verify that the Sign Active Sheet field is inactive.	The Sign Active Sheet field is inactive. Members of the GenUser group cannot sign pages within the spreadsheet.	The Sign Active Sheet field is _____. Members of the GenUser group _____ sign pages within the spreadsheet.			