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

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REVISION HISTORY

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<tr>
<th>Rev #</th>
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<td>Initial Issue.</td>
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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 performed 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.
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**

### 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: GenUsers

<table>
<thead>
<tr>
<th>Test Case</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 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.</td>
<td>The selected user is a member of the GenUser (and only a member of the GenUser) user group.</td>
<td>The selected user is a member of the GenUser (and only a member of the GenUser) user group.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>2</td>
<td>Login to the spreadsheet as the user selected in the previous step.</td>
<td>The user successfully logs into ExcelSafe.</td>
<td>The user successfully logs into ExcelSafe.</td>
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<tr>
<td>3</td>
<td>Select the spreadsheet. Verify that members of the GenUser group can open existing instances of the spreadsheet.</td>
<td>Members of the GenUser group can open existing instances of the spreadsheet.</td>
<td>Members of the GenUser group can open existing instances of the spreadsheet.</td>
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<tr>
<td>4</td>
<td>Verify that spreadsheets opened by members of the GenUser group are identified as Read-Only.</td>
<td>Spreadsheets opened by members of the GenUser group are identified as Read-Only.</td>
<td>Spreadsheets opened by members of the GenUser group are identified as Read-Only.</td>
<td></td>
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<tr>
<td>5</td>
<td>Attempt to add data to the spreadsheet.</td>
<td>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.</td>
<td>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.</td>
<td></td>
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</tr>
<tr>
<td>6</td>
<td>Attempt to edit data within the spreadsheet.</td>
<td>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.</td>
<td>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.</td>
<td></td>
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<tr>
<td>7</td>
<td>Attempt to delete data from the spreadsheet.</td>
<td>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.</td>
<td>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.</td>
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<tr>
<td>8</td>
<td>Navigate to the Active Sheets Utility screen. Verify that the Sign Active Sheet field is inactive.</td>
<td>The Sign Active Sheet field is inactive. Members of the GenUser group cannot sign pages within the spreadsheet.</td>
<td>The Sign Active Sheet field is inactive. Members of the GenUser group cannot sign pages within the spreadsheet.</td>
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</tr>
</tbody>
</table>