



**USER REQUIREMENTS SPECIFICATION
FOR THE
EXAMPLE VALIDATION SPREADSHEET
SERVING**

**OFNI SYSTEMS
RALEIGH, NORTH CAROLINA**

Ofni Systems

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Ofni Systems: Example Validation Spreadsheet User Requirements Specification		Doc. #: URS-001 Rev. #: 0
Department: Validation	Author: Daniel Waterman, Validation Manager, Ofni Systems	Page 2 of 14

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SIGNATURES

Author: _____
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Signature: _____ Date: _____
Quality Assurance: _____
Signature: _____ Date: _____

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1. Introduction

1.1. Objectives

This is the User requirements Specification for the Example Validation Spreadsheet, for use by the Validation Department at Ofni Systems (Raleigh, NC).

The User Requirements Specification for the Example Validation Spreadsheet (URS-001) the business needs for what users require from the Example Validation spreadsheet. These requirements will assure that Example Validation spreadsheet will correctly and reliably perform its intended functionality.

1.2. Scope

This User requirements Specification applies to the Example Validation spreadsheet. The URS will address the functions the Example Validation spreadsheet must be able to perform to successfully perform primary business functionality. This document also addresses regulatory and Ofni Systems requirements for spreadsheets.

1.3. Assumptions

The validation will be performed on a properly functioning Ofni Systems workstation, with MS Excel and ExcelSafe properly installed.

1.4. Exclusions

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

2. Acronyms and References

2.1. Acronyms and Definitions

Cell - An individual square in a spreadsheet grid.

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.

GUI - Graphical User Interface

IOQ - 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.

URS - User requirements Specification

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.

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2.2. References

21 CFR Part 11, Part 210, Part 211
 GAMP 5 Guide for Validation of Automated Systems
 Validation Package of the ExcelSafe System, V2.0

3. Spreadsheet Description

3.1. Spreadsheet Software

The Example Validation spreadsheet needs to be an MS Excel template. In order to maintain the spreadsheet in compliance with 21 CFR 11, the following documentation needs to be approved and software needs to be installed:

- 3.1.1. All documentation required to operate and maintain the system is present.
- 3.1.2. Microsoft Excel, Version 2000 or higher is installed.
- 3.1.3. The operating system required for use is MS Windows 2000, MS Windows XP or MS Vista.

3.2. ExcelSafe

The Example Validation spreadsheet needs to be able to work with ExcelSafe. ExcelSafe is a proprietary software package from Ofni Systems. ExcelSafe provides the Example Validation spreadsheet and MS Excel with technological tools to be compliant with 21 CFR Part 11.

- 3.2.1. All required ExcelSafe files are loaded.
- 3.2.2. Microsoft Access, Version 2000 or higher is installed.
- 3.2.3. Microsoft DAO, Version 3.51 or higher is installed.

ExcelSafe provides the following functions to the Example Validation spreadsheet:

- 3.2.4. The Example Validation spreadsheet is properly loaded in ExcelSafe.
- 3.2.5. The Example Validation spreadsheet will not open from outside ExcelSafe.
- 3.2.6. The Example Validation spreadsheet will open correctly from inside ExcelSafe.

3.3. System Hardware

The Example Validation spreadsheet is accessible through an Ofni Systems standard PC workstation or Laptop PC with ExcelSafe properly installed. Reports may be printed out on local or networked printers. The Example Validation spreadsheet does not affect the Ofni Systems LAN. The Example Validation spreadsheet can use local or networked printers.

3.4. Security Description

The Example Spreadsheet is only accessible through ExcelSafe. The Example Validation spreadsheet:

4. System Interfaces

4.1. Introduction Worksheet

The Introduction worksheet provides a general introduction to the Example Validation worksheet. It also provides links to the validation documents. This is a non-regulated section of the workbook and has no requirements.

4.2. Calculation Worksheet

The Calculation worksheet accepts data for Sample ID, Mass and Volume, and performs calculations on the data. The worksheet also calculates Maximum(Volume), Minimum(Volume), Average(Volume) and Volume². The worksheet also includes the Plotting Mass vs. Volume chart,