USER REQUIREMENTS SPECIFICATION
FOR THE
EXAMPLE VALIDATION SPREADSHEET
SERVING
OFNI SYSTEMS
RALEIGH, NORTH CAROLINA

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Thank you for downloading 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 it's 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.
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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 addresses 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.
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 Volume$^2$. The worksheet also includes the Plotting Mass vs. Volume chart.