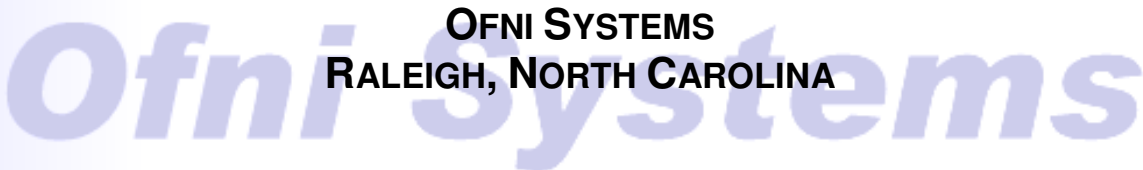




**FUNCTIONAL REQUIREMENTS SPECIFICATION
FOR THE
EXAMPLE VALIDATION SPREADSHEET
SERVING
OFNI SYSTEMS
RALEIGH, NORTH CAROLINA**



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1. Introduction

1.1. Objectives

This is the Functional Requirements Specification for the Example Validation Spreadsheet, for use by the Validation Department at Ofni Systems (Raleigh, NC). The Example Validation spreadsheet has been identified a Category 5 cGxP system (customized MS Excel spreadsheet).

The Functional Requirements Specification for the Example Validation Spreadsheet (FRS-001) details the capabilities and functions that the Example Validation spreadsheet must be capable of performing. These requirements will assure that Example Validation spreadsheet will correctly and reliably perform its intended functionality. This specification will provide general, as well as specific requirements to be used in the design, testing and validation of the application. The focus is on what the spreadsheet must do; details on how the spreadsheet components will be developed and how it will operate will be defined in the Software Design Specification for the Example Validation Spreadsheet (SDS-001).

1.2. Scope

This Functional Requirements Specification applies to the Example Validation spreadsheet. The FRS 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. The focus is on what the spreadsheet must do; details on how the spreadsheet will be developed and how it will operate will be defined in the Software Design Specification for the Example Validation Spreadsheet (SDS-001).

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.

FRS - Functional Requirements Specification

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

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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

Validation Package of the ExcelSafe System, V2.0

3. Spreadsheet Description

3.1. Spreadsheet Software

The Example Validation spreadsheet is an MS Excel template, with file name Example Validation.xlt. To function properly, Example Validation.xlt requires:

- 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

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.

ExcelSafe requires:

- 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.
- 3.2.4. The Example Validation spreadsheet is properly loaded in ExcelSafe.

3.3. System Hardware

The Example Validation spreadsheet name runs on the minimum standard PC workstation or Laptop PC configurations specified by Ofni Systems. 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.

- 3.3.1. 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:

- 3.4.1. Will not open from outside ExcelSafe.
- 3.4.2. Opens correctly from inside ExcelSafe.

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3.5. Process Description

Example Validation is accessible through ExcelSafe, which in turn is accessed through a Ofni Systems standard PC workstation or Laptop PC. The Example Validation.xlt spreadsheet is loaded in ExcelSafe. Users create instances of the Example Validation spreadsheet in the ExcelSafe.

The Example Validation spreadsheet is designed to provide an example validation of an Excel 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 includes the Plotting Mass vs. Volume chart, described below. The Calculation worksheet:

- 4.2.1. Allows users to enter appropriate values for Sample, Mass and Volume.
- 4.2.2. Calculates Maximum(Volume), Minimum(Volume) and Average(Volume).
- 4.2.3. Calculates Volume².
- 4.2.4. Allows users to secure and unsecure data by adding or removing electronic signatures.
- 4.2.5. Is properly formatted for printing.
- 4.2.6. Records changes in user data to the ExcelSafe audit trail.

4.3. Plotting Mass vs. Volume Chart

The Plotting Mass vs. Volume chart plots Mass, Volume and Volume². The Plotting Mass vs. Volume chart:

- 4.3.1. Plots Mass (X-axis) vs. Volume (Y-axis).
- 4.3.2. Plots Volume and Volume².

5. Regulatory Requirements

5.1. Controls for Closed Systems (21 CFR 11 B Sec. 11.10)

There are five technical requirements for systems in order to be compliant with 21 CFR Part 11 guidelines for closed systems. The Example Validation spreadsheet will meet or exceed all five of these requirements.

5.1.1. Accurate Record Generation

ExcelSafe and the Example Validation spreadsheet have the ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review and copying by regulatory agencies.

The functionality meets the following requirement of 21 CFR 11:

11.10.b The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions

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regarding the ability of the agency to perform review and copying of the electronic records.

The Example Validation spreadsheet will meet the following requirements:

- 5.1.1.1. Users are able select search queries.
- 5.1.1.2. Users are able to customize the criteria used to view data from the search.
- 5.1.1.3. Users are able to view resulting data on a standard report created by the developer for the search being used.
- 5.1.1.4. Users are able to export data to MS Excel.

5.1.2. Program Timeouts

ExcelSafe provides the Example Validation spreadsheet with will automatically time-out after 10 minutes of non-activity.

The functionality meets the following requirements of 21 CFR 11:

- 11.10.d Limiting system access to authorized individuals.
- 11.300.d Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.

The Example Validation spreadsheet Program Timeouts meets the following requirements:

- 5.1.2.1. The program provides users with the ability to secure the program without exiting.
- 5.1.2.2. If the current user cannot re-enter the session, the only other option is to close the program.
- 5.1.2.3. Only the current user may have the ability to unsecure the program to continue the current session.

5.1.3. Audit Trails

ExcelSafe provides the Example Validation spreadsheet with an audit trail, recording changes to all spreadsheet data.

The functionality meets the following requirements of 21 CFR 11:

- 11.10.e Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.
- 11.10.k.2 Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.

The Example Validation spreadsheet audit trail meets the following requirements:

- 5.1.3.1. Computer Generated
The spreadsheet audit trail records are computer generated.
- 5.1.3.2. Secure

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The spreadsheet audit trail records are secure (read-only access).

5.1.3.3. Date/Time Stamp

The spreadsheet audit trail records have an accurate Date/Time stamp.

5.1.3.4. Journal Function

The spreadsheet audit trail records the Date/Time of operator entries and actions that create, modify and delete electronic records.

5.1.3.5. Unalterable

Changes to the spreadsheet audit trail do not obscure previously recorded information.

5.1.3.6. Retention

Audit-trail records are maintained for at least as long as the retention of the underlying records. The audit trail is imbedded within the record and cannot be separated.

5.1.3.7. Accessibility

Audit trail records are available for FDA review and copying. The audit trail is accessible by clicking Changes on the appropriate record.

5.1.4. Operational System Checks

The Example Validation spreadsheet uses operational system checks to enforce permitted sequencing of steps and events, as appropriate.

The functionality meets the following requirements of 21 CFR 11:

11.10.f Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.

5.1.5. Device Checks

The Example Validation spreadsheet uses device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.

The functionality meets the following requirements of 21 CFR 11:

11.10.h Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.

5.2. Electronic Signature Manifestations (21 CFR 11 B Sec. 11.50, 11.70)

ExcelSafe has the ability to secure data in the Example Validation spreadsheet through electronic signatures. Data secured with an electronic signature cannot be edited or deleted unless the electronic signature is removed. Application of an electronic signature requires use of the users ID and password. This functionality will be provided by ExcelSafe, supplemented by the Example Validation System Administration SOP.

5.2.1. Electronic Signature and Meaning

Electronic signatures within the Example Validation spreadsheet include the printed name of the signer, the date/time the signature was added and the meaning of the electronic signature.

The functionality meets the following requirements of 21 CFR 11:

11.50.a Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:

11.50.a.1 The printed name of the signer;

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11.50.a.2 The date and time when the signature was executed; and

11.50.a.3 The meaning (such as review, approval, responsibility, or authorship) associated with the signature.

The electronic signatures will meet the following requirements:

- 5.2.1.1. Application of an electronic signature requires use of the User ID and password.
- 5.2.1.2. Data secured with an electronic signature cannot be edited or deleted unless the electronic signature is removed.
- 5.2.1.3. Multiple electronic signatures can be applied to a single workbook page.
- 5.2.1.4. Include the printed name of the user applying the electronic signature.
- 5.2.1.5. Include the Date/Time when the electronic signature was applied.
- 5.2.1.6. Include the Meaning of the electronic signature.
- 5.2.1.7. Electronic signature is human-readable.

5.2.2. Electronic Signature Compliance

Electronic Signatures within the Example Validation spreadsheet meets all requirements for 21 CFR 11 identified in this document, including audit trails and password controls.

The functionality meets the following requirements of 21 CFR 11:

11.50.b The items identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).

5.2.3. Signature/Record Linking

Electronic Signatures within the Example Validation spreadsheet are linked to the respective electronic records in such a manner that the record and the electronic signature cannot be separated, copied, transferred or otherwise falsified.

The functionality meets the following requirements of 21 CFR 11:

11.70 Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.

5.3. User Password Controls

ExcelSafe allows users to update their passwords. ExcelSafe also provides the ability for administrators to control user access and security group membership, define password complexity and time limits, add new users and reset the passwords of existing users. The functionality should also meet the following requirements of 21 CFR 11:

11.10.d Limiting system access to authorized individuals.

11.10.g Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.

11.300.a Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.

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11.300.b Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging).

11.300.d Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.

Passwords will meet the following technical requirements:

5.3.1. Limited Access and Unauthorized Access

ExcelSafe limits system access to the Example Validation spreadsheet to authorized individuals. User passwords prevent unauthorized access to the system. The Example Validation spreadsheet cannot be accessed without an active UserID and password to ExcelSafe. Example Validation permits the detection of and report in an immediate and urgent manner any attempt at unauthorized access to the system and may notify the security unit, and/or organizational management.

5.3.2. Authority Checks

ExcelSafe provides the Example Validation spreadsheet uses authority checks to ensure that only authorized individuals can use the system, electronically sign a record or remove an electronic signature.

5.3.3. Password Uniqueness

ExcelSafe maintains the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.

5.3.4. Password Periodic Review

ExcelSafe ensures that identification code and password issuance's are periodically checked, recalled, or revised (e.g., to cover such events as password aging). User passwords expire after a certain period of time, in according with Ofni Systems rules or a system administrator.

5.3.5. Password Expiration

User passwords will expire after a certain period of time, in according with Ofni Systems rules or a system administration SOP.

5.4. Additional System Controls

5.4.1. Event Logging

ExcelSafe records significant Example Validation spreadsheet events, including system log-ins, log-outs, system errors and failed log-in attempts

5.4.2. System Access

Access to the ExcelSafe and the Example Validation spreadsheet must be controlled by User Access to the LAN controlled by System Identification and Password, i.e. the folder in the LAN must be set up to allow users to read/write the data files from the folder as well as set up to deny access to personnel not on the user list. This functionality is controlled by the LAN.

5.4.3. Input Checks

Where appropriate, entries may be programmatically checked before being accepted by Example Validation. This includes the use of combination boxes to restrict allowed values into text boxes, programmatic checks of numerical values (For example, no negative values accepted for number of donors)

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5.5. User-Level Security Requirements

The Example Validation spreadsheet is protected by ExcelSafe, which uses four levels of user security:

5.5.1. GenUsers

Members of the GenUsers group:

- 5.5.1.1. Can open the spreadsheet.
- 5.5.1.2. Cannot add spreadsheet data.
- 5.5.1.3. Cannot edit spreadsheet data.
- 5.5.1.4. Cannot delete spreadsheet data.
- 5.5.1.5. Cannot sign pages within the spreadsheet.
- 5.5.1.6. Cannot remove electronic signatures from the spreadsheet.

5.5.2. DataEntry

Members of the DataEntry group:

- 5.5.2.1. Can open the spreadsheet.
- 5.5.2.2. Can add spreadsheet data.
- 5.5.2.3. Can edit spreadsheet data.
- 5.5.2.4. Can delete spreadsheet data.
- 5.5.2.5. Cannot sign pages within the spreadsheet.
- 5.5.2.6. Cannot remove electronic signatures from the spreadsheet.

5.5.3. Managers

Members of the Managers group:

- 5.5.3.1. Can open the spreadsheet.
- 5.5.3.2. Can add spreadsheet data.
- 5.5.3.3. Can edit spreadsheet data.
- 5.5.3.4. Can delete spreadsheet data.
- 5.5.3.5. Can sign pages within the spreadsheet.
- 5.5.3.6. Cannot remove electronic signatures from the spreadsheet.

5.5.4. Administrators

Members of the Administrators group:

- 5.5.4.1. Can open the spreadsheet.
- 5.5.4.2. Can add spreadsheet data.
- 5.5.4.3. Can edit spreadsheet data.
- 5.5.4.4. Can delete spreadsheet data.
- 5.5.4.5. Can sign pages within the spreadsheet.
- 5.5.4.6. Can remove electronic signatures from the spreadsheet.

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6. Additional Requirements

6.1. Procedural Regulatory Requirements

There are four procedural requirements for systems in order to be compliant with 21 CFR Part 11 guidelines. Compliance with these requirements will be done through verification of the appropriate established Ofni Systems policies and procedures. The Example Validation spreadsheet will meet or exceed all four of these requirements.

6.1.1. System Validation

The Example Validation spreadsheet will be validated.

The functionality meets the following requirement of 21 CFR 11:

11.10.a Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.

6.1.2. System Documentation

Ofni Systems Standard Operating Procedures covering operation, maintenance, security, backup and recovery, and data archival and retrieval will be created before the system is considered validated. The system operational procedure will outline the responsibilities associated with the electronic signatures, including that each electronic signature must only be used by their genuine owners.

The functionality meets the following requirement of 21 CFR 11:

11.10.j The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.

11.10.k.1 Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.

6.1.3. System Training

All personnel using the Example Validation spreadsheet will be adequately trained. This training will be documented per Ofni Systems procedure.

The functionality meets the following requirement of 21 CFR 11:

11.10.i Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.

6.1.4. Archive and Backup/Recovery

The archive of Example Validation spreadsheet will follow Ofni Systems Record Retention and Backup/Recovery policies.

The functionality meets the following requirement of 21 CFR 11:

11.10.c Protection of records to enable their accurate and ready retrieval throughout the records retention period.

6.1.5. Software Version Control

Changes to the Example Validation spreadsheet can be recorded on a Software Version Control plan. All changes should be made and tested in a controlled version of Example Validation in a development environment. A testing protocol, appropriate to the changes being proposed should be written. Both the software version control and testing protocols need to be in accordance with Ofni Systems requirements for Qualification and Validation. Once the software version control plan and testing protocol are written, a change control can be opened. If changes to the Functional Requirements Specification

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or Software Design Specification are required, these revisions should be included in the change control. The testing protocol is then executed. If the testing is successful, Example Validation can be updated and the change control closed.

6.2. Ofni Systems Requirements

6.2.1. System Interactions

The Example Validation spreadsheet does not interact with any other validated computer systems beyond those described in this document.

6.2.2. System Performance

There are no system performance requirements for the Example Validation spreadsheet.

6.2.3. System Availability

The system is available during normal business hours 800-1700 EST. The Example Validation spreadsheet will be maintained by the Validation group, supported by IS, where appropriate. When changes to the spreadsheet required, they should be scheduled outside of business hours, if possible.

6.2.4. Backup/Recovery

6.2.4.1. The Example Validation spreadsheet will be backed up daily on the LAN.

6.2.4.2. The Example Validation spreadsheet will be 100% recoverable within one business day.

6.2.4.3. A master copy of the MS Excel, ExcelSafe and the Example Validation spreadsheet must be securely maintained.

6.2.4.4. The method to load MS Excel, ExcelSafe and the Example Validation spreadsheet exists.

6.2.5. Physical Environment

Example Validation uses standard Ofni Systems PC workstation located in a typical office environment.