Verification and Validation Summary Report - <Offering ID>
Document Number: <Document #>
Version Number: <Version #>

How to Use the Form:

1. All BLACK text shall remain in the document. **BLUE** text serves as instructions, description, or examples and is to be deleted, modified and replaced. All **GREY** text is to be evaluated for relevance within the SOP, if the **GREY** text is relevant the text shall be turned BLACK, if the **GREY** text is not relevant it shall be deleted.

2. All text shall be BLACK when completed.

3. Delete this page after creating the document.

Verification and Validation Summary Report for <Offering ID>

VERIFICATION AND VALIDATION SUMMARY REPORT APPROVALS

The following Testing Review Committee acknowledge that:

1) The appropriate validation activities have been conducted for the <Offering ID>, and the accompanying validation documents adequately demonstrate that the system/offering performs its intended functions accurately and reliably;

2) This Validation Summary Report accurately reflects the results of the validation process and activities conducted for delivery of the <Offering ID>; and

3) The <Offering ID> is ready to be implemented in the <pre-production> environment.

<Add signature lines and roles as needed>

<FULL NAME> <APPROVER ROLE>	Date
<FULL NAME> <APPROVER ROLE>	Date
<FULL NAME> <APPROVER ROLE>	Date

1 Purpose

Describe the purpose of this document and what purpose it serves in terms of the overall project. It should answer the question of whether the Testers followed through with what was originally planned (in the Verification and Validation Plan) or were there changes (e.g., to personnel, processes, strategy, etc.)? Are there residual risks that could not be addressed?

Discuss whether any additional test cases were developed and summarize the testing effort in terms of the number of tests executed, number of failed test cases, resolutions to failed test cases, and outstanding issues still needing to be remediated.

This Verification and Validation Summary Report documents the results of the <Offering ID> verification and validation effort and includes a description of the testing results as well as any deviations from the original Verification and Validation Plan.

2 Roles/Responsibilities

Roles and their associated responsibilities with respect to this report are listed below.

Add roles as necessary, the table should be sorted by Role, alphabetically.

Identify all individuals who actually participated in the validation effort. If everything went as originally planned (per the Verification and Validation Plan), then the Development Team and other departments representatives identified in the Verification and Validation Plan will be the same. If not then this is the place to make note of that fact.

Role	Responsibility
Development Team	Individuals directly involved with the technical aspects of developing the Offering; specifying and analyzing Design Inputs and Design Outputs, implementation of the Offering and/or components and subsystems of the Offering (e.g., software coding and programming).
Functional Head	An executive within a functional group who is responsible for a document specific process.
Functional Manager	An individual within a functional group with oversight of personnel or a process.
Project Leader	Ensures that all project team members and personnel working within the overall scope of Design Control are trained on the Design Control SOPs.

Quality and Regulatory (Q&R) Representative	Ensures that quality and regulatory requirements are met by providing quality and regulatory input and perspective in the Design and Development Plan, Design Inputs, and Design Outputs, and Reviews. Works with all involved project functions to assure that documentation is compiled as described in the Design Control SOPs to demonstrate product performance and safety. Responsible for ensuring that the content is compliant with quality standards and regulatory requirements.

A RACI chart may be added to clarify who is responsible and accountable for each procedure step and decision point. If a RACI is not provided, the procedures should clearly document who is responsible and accountable for each step in the procedure and process flow.

3 Deliverables

Identify all deliverable verification and validation documents that were produced during the validation effort. Specific versions and dates should be noted for each document/record that is listed here. If everything went as originally planned (per the Verification and Validation Plan) then the deliverables will be the same as the documents that were outlined in the Verification and Validation Plan. If not (and perhaps decisions were made along the way to simplify or combine certain documents) then this is the place to make note of that fact.

Design Input Specification

Design Output Specification

Verification and Validation Test Protocols

Validation Summary Report (this document)

Standard Operating Procedures

- List of IQ (if applicable)
  IQ (Installation Qualification - A protocol describing detailed system component information (e.g., make, model, version numbers) and how the system components are installed and configured, as well as the methods for determining if the installation and configuration was done correctly))

4 Personnel

Provide a list of the personnel involved in the development and testing of the Offering

5 Test Results

The results of the <OFFERING NAME and version> verification and validation testing activities are summarized below.

<Include the Risk mitigation verifications and reference the Risk Management report. State the conclusions of the Risk analysis.>

<add rows as needed>

Protocol ID	Test Case ID.	Title of Test Case	Run #	Pass/Fail	Defect #
<ID number>	1234	Confirm that access to file is permitted for authorized user	1	Pass	N/A
<ID number>	1245	Confirm that write access to a file is denied for a user with read only access to the file.	2	Fail	123

The corresponding Defect Reports identified in the table below provides additional details of the test failure and recommended corrective actions.
If no discrepancies were encountered, enter "N/A" or "Not Applicable" or delete table. Add rows as needed.

Defect No.	Defect status	Test Case ID	Brief Description of defect
<Defect No.>	<Open / closed>	<Test Case ID>	<Summarize the problem from Defect Report>
#14732	closed	1234	Test User created for QA role allowed file to be modified.

6 Planned Deviations (if applicable)

Describe the planned deviations and an update of the planned deviations

7 Deviations from the Verification and Validation Plan

Describe any deviations from the Verification and Validation Plan or Verification and Validation Test Protocol(s). This includes explaining why test cases were not executed (if applicable) of why additional test cases were included (if applicable).

If no deviations occurred, enter “Not Applicable”.

8 Additional Notes

Insert any additional notes

9 Summary of Results

<The Test Team asserts their recommendations to Management regarding the results of the verification and validation effort.>

All validation activities have been concluded to the satisfaction of the Test Team. Based upon the performance of the system/Offering as demonstrated by the verification and validation testing conducted, the Test Team approves this <Offering ID> for use in the pre-production environment.

10 Records Management

<List all DHF records associated with the project and where the documents reside>

Document Number	Document Name	Location
<Requirement ID>	<Product/Risk/Regulatory ID>	<Location>

11 Traceability Matrix

<Include all requirements associated in the Offering and Version, add rows as needed>

High Level User Requirement ID	Product Requirement / Risk Control Measure / Regulatory ID	Detailed Requirement ID	Verification and Validation Protocol ID	Test Case ID
<Requirement ID>	<Product/Risk/Regulatory ID>	<Detailed Requirement ID>	<Protocol ID>	<Test Case ID>

12 Revision History

Tracks changes made to this record, including original version

Version	Change	Revised By	Date (dd-MMM-yyyy)
1.0	Original	N/A	

2.0	<Describe the changes that were introduced and where in the report such changes were made.>	<Author Name>	