**Operational Qualification Protocol**

**for the**

**XXX**

**Document Revision History**

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision** | **Date** | **Author / Company** | **Description of Revision Changes** |
| 001 |  |  | Initial Version |
|  |  |  |  |

**Table of Contents**

1. Purpose/Scope 3

2. Description 3

3. References 3

3.1 Definitions 3

4. Responsibilities 3

5. Execution Materials And Equipment 3

6. Execution Instructions 3

7. Protocol Deviations Resolution 3

7.1 Signature Record 4

8. Operational Qualification 5

8.1 Technical Requirements Testing 6

8.2 User Functional Requirements Testing 8

8.3 Electronic Records / Compliance Requirements Testing 10

9. Approvals 12

# Purpose/Scope

This protocol covers the Operational Qualification for the XXX. Describe any specific functions of the system that are to be tested i.e. workflow.

# Description

See Validation Plan for details (If a Validation Plan was written otherwise, reference an appropriate document with the system description or include it here.

# References

### Supporting Documentation (All validation documents written that are associated with the system)

|  |  |
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| **Document ID** | **Title** |
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## Definitions

| **Term** | **Definition** |
| --- | --- |
|  |  |
|  |  |

# Responsibilities

It is the responsibility of XXX to execute this protocol and XXX, XXX to approve the executed results.

# Execution Materials And Equipment

List any items that may be required to complete execution i.e. temperature/humidity gauge.

# Execution Instructions

Recording of data or other required information in any test document must be done pee, Good Documentation Practices. Blue or Black ink must be used (no pencil). If an error is made in the documentation, use one line to line out the error and write in the correct information along with a reason for the change and initial and date the correction.

# Protocol Deviations Resolution

All protocol deviations must be documented using VAL008\_01.

## Signature Record

| **Printed Name** | **Signature** | **Initials** | **Date** |
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# Operational Qualification

**Test Purpose:**

The purpose of this test is to verify the operation of the XXX

**Test Method:**

Record the results in the appropriate row of the test table. Where possible, screenshots or other documented evidence may be included as supporting evidence and attached to the test protocol and marked with the appropriate protocol number, attachment page number (as x of y), test page number, test step number references, and initials and date.

**Acceptance Criteria:**

All Expected Results must match the Actual Results for each test step.

| Technical Requirements Testing | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Step** | **Test Step** | **Expected Result** | **Actual Result** | **Pass / Fail** | **Reference** | **Initial and Date** |
|  |  |  |  |  |  |  |

| **8.1 Technical Requirements Testing** | | | | |
| --- | --- | --- | --- | --- |
| **Comments/Additional Information:** | | | | |
| **Conclusion:**  Did the Actual Results for each test step match the Expected Results listed? | | Yes | | No |
| **Completed By:** |  | **Date:** |  | |
| **Reviewed By:** |  | **Date:** |  | |

| User Functional Requirements Testing | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Step** | **Test Step** | **Expected Result** | **Actual Result** | **Pass / Fail** | **Reference** | **Date and Initial** |
|  |  |  |  |  |  |  |

| **8.2 User Functional Requirements Testing** | | | | |
| --- | --- | --- | --- | --- |
| **Comments/Additional Information:** | | | | |
| **Conclusion:**  Did the Actual Results for each test step match the Expected Results listed? | | Yes | | No |
| **Completed By:** |  | **Date:** |  | |
| **Reviewed By:** |  | **Date:** |  | |

| Electronic Records / Compliance Requirements Testing | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Step** | **Test Step** | **Expected Result** | **Actual Result** | **Pass / Fail** | **Reference** | **Date and Initial** |
|  | | | | | | |
|  |  |  |  |  |  |  |

| **8.3 Electronic Records / Compliance Requirements Testing** | | | | |
| --- | --- | --- | --- | --- |
| **Comments/Additional Information:** | | | | |
| **Conclusion:**  Did the Actual Results for each test step match the Expected Results listed? | | Yes | | No |
| **Completed By:** |  | **Date:** |  | |
| **Reviewed By:** |  | **Date:** |  | |

# Approvals