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# PURPOSE

The purpose of this Validation Final Report (VFR) is to summarize the validation activities and results of <system name>. Furthermore, this VFR also provides the conclusion that <system name> has been validated and meets its documented requirements.

# SCOPE

The scope of this Validation Final Report (VFR) is limited to the activities performed during the validation of <system name>. This VFR includes a summary of the validation documentation and the results of the test protocols, including any errors or limitations encountered and their resolutions. It also states a conclusion as to whether the validation effort was successful and whether the system should be released for continued production use.

# REFERENCES

|  |  |
| --- | --- |
| **Document #** | **Document Name** |
|  |  |
|  |  |

# DEFINITIONS

|  |  |
| --- | --- |
| **Acronym/ Term** | **Definition** |
| SRS | Software Requirements Specification |
| RTM | Requirements Traceability Matrix |
| FS | Functional Specification |
| CFR | Code of Federal Regulations |
| cGMP | Current Good Manufacturing Practices |
| FDA | Unites States Food and Drug Administration |
| OTS | Off-the-Shelf |
| SME | Subject Matter Expert |
| QA | Quality Assurance |
| VP | Validation Plan |
| VFR | Validation Final Report |

# PROCEDURE

## Validation Strategy

The validation activities for <system name> have been performed in accordance with Company’s Computerized System Validation Procedure (xxx). This encompasses all validation activities for the computer system to ensure proper installation and operation according to predefined acceptance criteria.

## Protocol Deviation Summary

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Deviation Summary Table** | | | | | |
| Deviation # | Protocol (IQ/OQ/PQ) | Deviation Description | Resolution/ Corrective Action | Severity | Status |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

## Protocol Results Summary

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Protocol Results Summary** | | | | | | | |
| Protocol | Approved Date | Execution Start Date | Execution End Date | Minor Deviation Count | Moderate Deviation Count | Major Deviation Count | Total # of Deviations |
| IQ |  |  |  |  |  |  |  |
| OPQ |  |  |  |  |  |  |  |

## Validation Deliverables

This section lists all the documents included in the validation package, as defined in the Validation Plan.

### Deliverables Matrix

| **Deliverable** | **Document #** | **Revision** | **Submitted/ Approved Date** |
| --- | --- | --- | --- |
| Software Requirements Specification (SRS) |  |  |  |
| GxP Validation Assessment |  |  |  |
| Validation Plan (VP) |  |  |  |
| Validation Protocol(s)   * Installation Qualification (IQ) |  |  |  |
| * Operational and Performance Qualification (OPQ) |  |  |  |
| Requirements Traceability Matrix (RTM) |  |  |  |
| Validation Protocol Report(s)   * Installation Qualification (IQ) |  |  |  |
| * Operational and Performance Qualification (OPQ) |  |  |  |
| Protocol Deviation Reports |  |  |  |
| Test Supporting Documentation   * Installation Qualification (IQ) |  |  |  |
| * Operational and Performance Qualification (OPQ) |  |  |  |
| Validation Final Report (VFR) |  |  |  |

### Additional Deliverables

Not Applicable

## Acceptance Criteria

The following acceptance criteria have been satisfied:

* The validation activities were performed in accordance with Company’s *Computerized System Validation Procedure (xxx)*.
* The validation deliverables identified in the Validation Deliverables Matrix have been reviewed and approved. Testing is considered to be adequate, sufficient, and complete. Testing has shown that the computerized system is accurate, consistent, and reliable.
* All deviations experienced during protocol execution have been resolved through correction of the protocol, retesting, transfer of an unresolved deviation to change control, procedural workaround, or in another approved manner.

## Conclusion

|  |  |  |  |
| --- | --- | --- | --- |
| **Conclusion**  Based on the test results and supporting system documentation within the validation package: | | | |
| The system functions as specified. It is the recommendation that the <system name>  system be certified for continued operational use.  The system is ready for release: | | The system does not function as specified. It is the recommendation that the <system name> ***NOT*** be certified for operational use.  The system cannot be released: | |
| Executed By (Name): |  | Date: | 06/11/2019 |
| Reviewed By (Name): |  | Date: | 06/11/2019 |

## Maintaining Compliance and Fitness for Intended Use

Once the system has been accepted and released for use, there is a need to maintain compliance and fitness for intended use throughout its operational life.

Operational Controls present practical and relevant guidance to ensure that areas relating to maintaining compliance and fitness for intended use of GxP regulated computerized systems throughout their life cycle are covered.

The following processes shall be utilized to maintain that the computerized system stays within a state of compliance:

| **Process** | **Description** | **SOP** | **Company Process Document** |
| --- | --- | --- | --- |
| Change Management | Change Management is the process of controlling the life cycle of changes. The primary objective of change management is to enable beneficial changes to be made, without compromising regulated processes or records and with minimum disruption to services. | SOP Change Management | IT Change Management Policy (IT00-00250) |
| Backup and Restore | Backup is the process of copying records, data and software to protect against loss of integrity or availability of the original.  Restore is the subsequent restoration of records, data, or software when required. | SOP Backup and Restore | IT Back Up Policy (IT00-00001) & COMPANY Server Back Up and Monitoring (IT00-00023) |
| Document Management | Management of documentation includes preparation, review, approval, issue, change, withdrawal, and storage. | SOP Document Management | General Document Authoring Fundamentals (DC00-00019) & Good Documentation Practices (IS.RC.012) |
| Training | Training is the process that ensures that persons who develop, maintain, or use computerized systems have the education, training, and experience to perform their assigned tasks. | SOP Employee Training | Personnel Training (GP00-00008) |

**END OF DOCUMENT**