COMPUTER SYSTEM VALIDATION MASTER PLAN

Department:	
Equipment Name:	
Equipment ID:	
Make:	
Model:	
Serial No.:	
Location:	
Effective Date:	

COMPUTER SYSTEM VALIDATION MASTER PLAN

DOCUMENT APPROVAL

The signing of this document is a joint responsibility from the following functional areas of ……. and Client Name, Client Address.

Prepared By: (Vendor)	**Name**	**Sign/Date**
M/s. …….		

Client Name		
Reviewed By: (Department Name)	**Name**	**Sign/Date**
Production		
Engineering		
Quality Assurance		
Approved By:	**Name**	**Sign/Date**
Head – Operations		
Head – Quality Assurance		

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REVISION HISTORY:

Revision	Reason for change
00	Initial Document

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TABLE OF CONTENTS

VALIDATION PLAN 1
DOCUMENT APPROVAL 2
REVISION HISTORY 3
1. INTRODUCTION 6
2. PURPOSE 6
3. SCOPE 6
4. REFERENCES 6
5. ACRONYMS 7
6. SYSTEM DESCRIPTION 7
7. SYSTEM CLASSIFICATION 7
8. VALIDATION APPROACH 8
8.1 SYSTEM CATEGORIZATION 8
8.2 VALIDATION PLAN (VP) 8
8.3 USER REQUIREMENT SPECIFICATION (URS) 8
8.4 FUNCTIONAL DESIGN SPECIFICATION (FDS) 9
8.5 FUNCTIONAL RISK ASSESSMENT (FRA) 9
8.6 INSTALLATION QUALIFICATION (IQ) 10
8.7 OPERATIONAL AND PERFORMANCE QUALIFICATION (OPQ) 10
8.8 ERES ASSESSMENT (ERES) 10
8.9 TRACEABILITY MATRIX (TM) 10
8.10 VALIDATION SUMMARY REPORT (VSR) 11
8.11 SYSTEM DESCRIPTION 11
8.12 SYSTEM RELEASE CERTIFICATE 11
9. VALIDATION RESPONSIBILITIES 12
10. SUPPORTING PROCESS AND CONTROLS 13
10.1 STANDARD OPERATING PROCEDURES 13
10.2 TRAINING 13
10.3 DISCREPANCIES REPORTING 14
10.4 PROTOCOL DISCREPANCIES FORM 15
10.5 DISCREPANCIES REPORT LOG 16

10.6 CHANGE CONTROL..... 17

10.7 MAINTENANCE..... 17

10.8 ACCEPTANCE CRITERIA 17

COMPUTER SYSTEM VALIDATION MASTER PLAN

1. INTRODUCTION:

The validation plan is to describe the approach for the validation of System name placed in system location at client name. This document will define the fundamental requirements and standard that must be followed for validation of System name.

2. PURPOSE:

This document is prepared to establish uniform terminology and definitions that are to be used in validation documents, detail approach to be followed when implementing this plan and present the chronology of validation activities for validation of System name.

3. SCOPE:

This document is applicable for validation of computerized system of System name, Equipment ID – XX placed in system location at client name.

4. REFERENCES:

S.No.	Document Description
1.	Initial Risk Assessment/ GxP Assessment for System name; Protocol No.:
2.	ISPE GAMP-5, A Risk-Based approach to GxP Compliant Laboratory Computerized Systems
3.	US FDA 21 CFR Part11 (Rule for Electronic Records and Electronic signatures)
4.	EudraLex Volume 4 Annex 11: Computerized Systems

5. ACRONYMS:

Acronym	Definition	Acronym	Definition
CFR	Code of Federal Regulations	QA	Quality Assurance
FMECA	Failure Mode Effect and Criticality Analysis	QRM	Quality Risk Management
GxP	Good x Practices	RP	Risk Priority
GAMP	Good Automated Manufacturing Practices	SOP	Standard Operating Procedure
HMI	Human Machine Interface	TM	Traceability Matrix
IQ	Installation Qualification	URS	User Requirement Specification
IT	Information Technology	VP	Validation Plan
OPQ	Operational and Performance Qualification	VSR	Validation Summary Report
PLC	Programmable Logic Controller	NA	NA

5. SYSTEM DESCRIPTION:

5. SYSTEM CLASSIFICATION:

The System Classification Assessment is documented in XX, and is summarized below:

System classification assessment summary	
GxP Assessment	Yes
GAMP - Software Category	Category 4
Electronic Records Applicability	Applicable
Electronic Signature Applicability	Not applicable

8. VALIDATION APPROACH:

This Validation Plan (VP) is developed to outline the requirements that shall demonstrate and document that the application is appropriate for regulatory requirements and applicable regulations, guidelines & accepted practices for validation. Below mentioned lifecycle phase will be used for validating the system name. Validation strategy described in VP and computer system life cycle for category 4 system shall be used to validate this system. It also elaborates the responsibility of various roles involved in the system validation life cycle. This plan also provides details of various project deliverables those are required to support the implementation.

8.1 SYSTEM CATEGORIZATION:

The System is categorized based on Initial risk assessment/GxP assessment (XX) and concluded that system falls under category 4 of GAMP 5.

8.2 VALIDATION PLAN (VP):

The Validation Plan (VP) establishes the approach of the validation / compliance effort, summarizes the activities that will be performed in the entire validation project, identifies the measures of success and clearly defines the criteria of final acceptance. This plan specifies all validation requirements and deliverables for the validation effort inclusive of the different types of reports that will be produced in this project to cover the progress made, issues raised and the acceptance of the different phases of the Validation Plan (VP).

8.3 USER REQUIREMENT SPECIFICATION (URS):

The User Requirements Specification (URS) will define the exact business needs, the intended usage and the required features for the system name leveraging the business process description. Each requirement in the URS will be numbered to facilitate the development of a Traceability Matrix.

8.4 FUNCTIONAL DESIGN SPECIFICATION (FDS):

This document shall combine Functional/Technical Specifications, Design and Configuration Specifications. This document will also serves as System Requirement Specification.

The FDS shall contain testable description of various components, access privileges and configurations. It provides the detailed descriptions of each of the final design and configuration for the computerized system.

The FDS is a living document that must be prepared and maintained throughout the instrument's validation and operational usage. The FDS shall be prepared based on manual/design specification provided by vendor or by physical verification of control system.

The Functional Design Specification is a combination of software and hardware specification developed jointly by the User and Supplier. This document shall be based on the URS.

8.5 FUNCTIONAL RISK ASSESSMENT (FRA):

Functional Risk Assessment shall be carried out initially to identify the major risk and issues which may arise during life cycle of system name. A formal risk analysis will be performed utilizing FMECA as the Quality Risk Management (QRM) tool. This assessment is to identify, assess risks and to establish mitigation plan to reduce the severity of the identified risks to an acceptable level (RP) for system name.

This risk assessment serves as, the Functional Risk Assessment for Systems, as well as a traceability between URS, potential risk, and measure to control risk (e.g. specific test specification, additional requirement to mitigate risk, SOP).

Functional risk assessment shall be assessed based on Occurrence, Severity, and Detectability.

The identified risks are mitigated and tested in relevant IQ and OPQ documents. Procedural controls shall be in place (if needed) to identify and manage risks to patient safety, product quality, and data integrity that arise from failure of the function under consideration as mentioned in URS.

8.6 INSTALLATION QUALIFICATION (IQ):

Installation Qualification Protocol shall be developed & executed to qualify the installation of system name.

The tests to be performed during the IQ shall be described in detail in the IQ protocol, which will be approved before execution. The results of the IQ will ensure that the system name has been installed according to pre-approved specifications.

8.7 OPERATIONAL AND PERFORMANCE QUALIFICATION (OPQ):

Operational and Performance Qualification Protocol shall be developed & executed to qualify the operation of system name.

The tests to be performed during the OPQ shall be described in detail in the OPQ protocol, which will be approved before execution. The results of the OPQ will ensure that the system name operates and performs according to pre-approved specifications.

8.8 ERES ASSESSMENT (ERES):

An Electronic Records and Electronic Signature Assessment will be performed based on 21 CFR Part 11.

8.9 TRACEABILITY MATRIX (TM):

A traceability matrix shall be prepared for system name. The traceability matrix will cross-reference each requirement defined in the URS documents to the corresponding tests executed in the IQ and OPQ reports.

The traceability matrix will ensure that all qualification testing has challenged the requirements defined in the URS document for the system. The results of the Qualification Tests will ensure that the system will satisfactorily perform the required functions and behave correctly, consistently and reliably.

8.10 VALIDATION SUMMARY REPORT (VSR):

A validation summary report shall be prepared for system name.

The validation summary report will summarize all validation activities as specified in this project validation plan and will be issued for final approval and acceptance that all validation activities have been completed for the system. Approval of the VSR will serve as the milestone, indicating the completion of the validation activities for the system name.

Any discrepancies from the Validation Plan during the Validation Life cycle will be captured in the Validation Summary Report.

8.11 SYSTEM DESCRIPTION:

System description shall be prepared documenting the system brief details, components and responsibilities.

The system shall be maintained further as per defined responsibilities in system description.

8.12 SYSTEM RELEASE CERTIFICATE:

System release certificate shall be prepared to mark completion of validation activity for the system and release the system for intended use.

9.0 VALIDATION RESPONSIBILITIES:

Departments	Responsibilities
M/s ……	
Site Engineer	• To prepare and execute the validation deliverables.
Client Name	
Engineering	• Review and verification of all validation deliverables. • Providing protocol execution support. • Developing SOPs for operation of system. • Ensuring completion of training and existence of training records. • Resolving any deviations encountered during the validation effort.
Production	• Reviewing all validation deliverables. • Providing protocol execution support. • Resolving any deviations encountered during the validation effort.
Quality Assurance	• Monitoring the validation activities. • Ensure Implementation of the validation plan. • Reviewing all validation deliverables. • Providing support as and when required.
Head Operations	• Approval of all validation deliverables.
Head Quality Assurance	• Approval of all validation deliverables.

10. SUPPORTING PROCESS AND CONTROLS:

10.1 STANDARD OPERATING PROCEDURES:

The following SOPs but not limited to provide the end user with approved instructions governing the operation, administration and maintenance of system, should be present. The SOPs may be combined as / if required.

- User Operational Procedures
- Procedure to ensure that operation of the system is conducted in a controlled manner.
- User Management
- Preventive Maintenance
- Disaster Management

The above SOPs will be developed or revised (if required).

10.2 TRAINING:

The Project Team Members, users, and IT Support Personnel (including personnel and contractors) responsible for the validation, use, administration, and/or maintenance of the system shall be required to have the appropriate qualifications and/or receive adequate training prior to performing their roles and responsibilities for the project.

10.3 DISCREPANCIES REPORTING:

For each discrepancy observed and corrective action taken during the execution of the protocol, the test execution team, in consultation with Quality Assurance records the following information on a Protocol Discrepancies Form:

- In Section 1 of the Protocol Discrepancies Form the following is recorded:
  - Discrepancies number (e.g. Discrepancies #01, where 01 is a sequential number, starting with 01)
  - Reference (e.g. Test Number and Page Number)
  - Description of Discrepancies
  - Signature and Date of the Reporter.
- In Section 2 of the Protocol Discrepancies Form, the Discrepancies is further investigated and analyzed for the corrective action taken and to verify if suspension of qualification activity is required, and documented as such. A corrective action comment is included and the performer of the corrective action signs and dates in the provided area.
- If the space provided is not sufficient, additional copies of the Discrepancies protocol form may be used. The Page ___ of ___ on the upper right side of the form should be written including the Discrepancies # and Test Number and Page Number and crossing out those other sections already covered in a previous page.
- In Section 3, after completion of the Discrepancies investigation and conclusion, it should be reviewed and approved by QA for final determination of the closure status of the Discrepancies. The designated person's signature in Section 3 indicates review of documented investigation and conclusions.

All discrepancies should be summarized in the discrepancies report log.

10.4 PROTOCOL DISCREPANCIES FORM:

(This page can be duplicated if necessary) Page__of ____

Discrepancies Number	
Section 1: Reporting	**Reference:**
Description:	
Reported By / Date:	
Section 2: Corrective Action	
Description:	
Discrepancies Requires suspension of qualification? Yes / No:_____	
Assessed By / Date:	
Section 3: Review and Approval	Is the Discrepancies closed? Yes/ No: _____
Description:	
Approved By / Date:	

10.5 DISCREPANCIES REPORT LOG:

(This page can be duplicated if necessary) Page____of ____

Discrepancy Number #	Reference / Description	Reported By (Initials/Date)	Status	Status Updated by (Initials/Date)

10.6 CHANGE CONTROL:

Any changes made to the system after the validation of computerized system shall undergo the change control procedure as per policy of Client name. The need and scope of validation shall be defined in the same.

10.7 MAINTENANCE:

Written Preventive Maintenance Program and calibration of instruments associated in control system should be followed for any validated systems.

10.8 ACCEPTANCE CRITERIA:

System name will be accepted for release/use of the system when the following conditions are met:

- Validation deliverables and Testing deliverables have been developed / executed, reviewed, and approved and demonstrate that the applicable requirements documented in the user requirements specification have been successfully executed and corresponding reports have been duly approved by authorized personnel (s).
- Qualification Tests activities are performed as per the IQ & OPQ in the Production- Environment and other project-specific validation deliverables have been developed / executed, reviewed and approved as identified in this VP.
- Test problems encountered during the qualification / testing are resolved / mitigated / justified.
- Training of the application and its usage with respect to the SOP is imparted successfully to the users of this system and training records are documented.
- Business SOP’s have either been created or updated in the user department.

The Validation Summary Report (VSR) has been approved and issued to notify the Project Team that the system has been successfully validated as per the user requirements as defined in the URS.