**Validation Master Plan (VMP) & Validation Plan (VP)**

**System Name:** Potentiometric Titration System Interfaced with LIMS  
**Version:** 1.0  
**Prepared By:** Durga Prasad K  
**Date:** 20-May-2025

**📁 Document Control**

| **Field** | **Value** |
| --- | --- |
| Document Title | Validation Master Plan (VMP) and Validation Plan (VP) for Potentiometric Titration System Interfaced with LIMS |
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**📝 Approval Table**

| **Name** | **Designation** | **Department** | **Signature** | **Date** |
| --- | --- | --- | --- | --- |
| Venkata Ramana | QC Head | QC | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 20-May-2025 |
| Bhavani | QA Head | QA | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 20-May-2025 |
| Durga Prasad | CSV Analyst | IT Validation | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 20-May-2025 |
| Likitha | RA Executive | RA | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 20-May-2025 |

**📌 1. Objective**

This document serves as both the **Validation Master Plan (VMP)** and the **project-specific Validation Plan (VP)** for the Potentiometric Titration System interfaced with LIMS. It outlines the validation strategy, scope, lifecycle activities, deliverables, and responsibilities required to ensure the system complies with **GAMP 5**, **21 CFR Part 11**, **EU Annex 11**, and **WHO GMP**.

**🧭 2. Scope**

This validation applies to:

* Potentiometric titration instrument hardware and software
* LIMS integration
* Audit trail, access control, backup and restore
* Qualification (IQ, OQ, PQ)
* Functional Risk Assessment (FRA)
* Data integrity (ALCOA+ principles)

This system is classified as **GAMP 5 Category 4 (Configurable System)**.

**🖥️ 3. System Overview**

| **Component** | **Description** |
| --- | --- |
| System Name | Potentiometric Titration System |
| Interface | Laboratory Information Management System (LIMS) |
| Intended Use | Assay, standardization, and endpoint detection in QC |
| Data Flow | Operator input → Instrument analysis → Result → LIMS |
| GAMP Category | Category 4 |

**🛠️ 4. Validation Strategy**

Validation will follow a **risk-based lifecycle approach** as per **GAMP 5**:

**Lifecycle Phases:**

1. **Planning** – VMP/VP, Risk Assessment (FRA), Timeline
2. **Specification** – URS, FRS, TS
3. **Verification** – IQ, OQ, PQ
4. **Traceability & Reporting** – RTM, Validation Summary Report (VSR)

**👥 5. Roles & Responsibilities**

| **Role** | **Responsibility** |
| --- | --- |
| QA Head | Review/approve all validation deliverables |
| \*QC Head | Define user requirements and perform PQ |
| CSV Analyst | Execute validation, maintain documents |
| IT/Engineering | Backup, access control, disaster recovery |
| RA Executive | Provide regulatory input |
| Vendor | Perform installation, configuration, and training |

**📦 6. Validation Deliverables**

| **Phase** | **Deliverables** |
| --- | --- |
| Planning | VMP/VP, FRA, Project Plan |
| Specification | URS, FRS, TS |
| Verification | IQ, OQ, PQ protocols and reports |
| Traceability | RTM |
| Reporting | Validation Summary Report (VSR) |

**⚖️ 7. Risk Assessment Methodology**

Validation risk is assessed using **FMEA**:

* **Severity** (impact on product/data)
* **Probability** (likelihood of failure)
* **Detectability** (likelihood of detection)

A **Functional Risk Assessment (FRA)** will determine which functions require extensive testing and documentation.

**📚 8. Regulatory Compliance**

| **Regulation** | **Applicability** |
| --- | --- |
| **GAMP 5** | System lifecycle and category |
| **ALCOA+** | Data integrity principles |
| **21 CFR Part 11** | Electronic records and signatures |
| **EU Annex 11** | Audit trail, validation, DRP |
| **WHO GMP** | QC process traceability |
| **ICH Q7** | Record retention and traceability |
| **ISO 27001** | Backup, disaster recovery (IT) |

**🔎 9. Qualification Plan**

| **Phase** | **Description** |
| --- | --- |
| **IQ** | Installation Qualification – Hardware, software, LIMS connectivity |
| **OQ** | Operational Qualification – Audit trails, login, method execution, LIMS transfer |
| **PQ** | Performance Qualification – Executed by QC on live samples using approved SOPs |

**🔄 10. Change Control**

Any system changes post-validation must go through **formal change control**. Based on impact, changes will require partial or full revalidation.

**⚠️ 11. Deviations & CAPA**

All deviations encountered during validation will be documented. **Corrective and Preventive Actions (CAPA)** will be closed prior to project finalization.

**📦 12. Archiving & Retention**

All validation-related documents will be archived securely and retained for **at least 10 years**, in accordance with **ICH Q7** and **WHO GMP**.

**🗓️ 13. Timeline**

| **Phase** | **Activity** | **Start Date** | **End Date** | **Owner** |
| --- | --- | --- | --- | --- |
| Planning & Kickoff | VMP, team alignment | 20-May-2025 | 21-May-2025 | CSV, QA |
| URS Finalization | User requirements approval | 22-May-2025 | 23-May-2025 | QC, QA, RA |
| FRS/TS Documentation | Functional/Technical specs | 24-May-2025 | 26-May-2025 | CSV |
| Functional Risk Assessment | FRA document and scoring | 27-May-2025 | 28-May-2025 | CSV, QA |
| RTM Creation | Traceability Matrix | 29-May-2025 | 29-May-2025 | CSV |
| IQ Execution | Installation qualification | 30-May-2025 | 01-Jun-2025 | Vendor, CSV |
| OQ Execution | Operational tests | 02-Jun-2025 | 05-Jun-2025 | CSV, IT, QA |
| PQ Execution | Live environment performance | 06-Jun-2025 | 08-Jun-2025 | QC, QA |
| Deviation/CAPA Closure | Close all issues | 09-Jun-2025 | 10-Jun-2025 | QA, CSV |
| VSR Finalization | Validation Summary Report | 11-Jun-2025 | 12-Jun-2025 | CSV, QA |
| Final Approval | Sign-off | 13-Jun-2025 | 14-Jun-2025 | QA, IT, RA |