**Functional Risk Assessment (FRA)**

**System:** Potentiometric Titration System Interfaced with LIMS  
**Version:** 1.0  
**Prepared By:** Durga Prasad K  
**Date:** 26-May-2025

**Document Control**

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| Document Title | Functional Risk Assessment (FRA) for Potentiometric Titration System |
| Version | 1.0 |
| Prepared By | CSV Team |
| Date | 26-May-2025 |

**Approval Table**

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| --- | --- | --- | --- | --- |
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| Bhavani | QA Head | QA | \_\_\_\_\_\_\_\_\_\_\_ | 26-May-2025 |
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**1. Objective**

The objective of this Functional Risk Assessment (FRA) is to evaluate, identify, and prioritize the potential risks associated with the functionalities of the Potentiometric Titration System interfaced with LIMS. The intent is to determine the extent of testing required based on risk, ensuring regulatory compliance and data integrity.

**2. Scope**

This assessment covers all GxP-relevant functionalities derived from the approved URS and FRS for the potentiometric titration system. It includes system software, audit trail, LIMS interface, electronic signatures, backup/restore mechanisms, and access controls. Non-GxP components like UI styling and report formatting are excluded.

**3. Risk Assessment Methodology**

The risk is assessed based on three parameters:

* **Severity (S)**: Impact of failure on product quality, data integrity, or patient safety
* **Occurrence (O)**: Likelihood of failure
* **Detectability (D)**: Ability to detect failure before it affects the outcome

Risk Priority Number (RPN) = S × O × D  
Risk levels:

* **High**: RPN > 40 → Extensive testing required (IQ/OQ/PQ + negative paths)
* **Medium**: 20 ≤ RPN ≤ 40 → Moderate testing
* **Low**: RPN < 20 → Basic verification

**4. Risk Assessment Table**

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| FRA ID | Function | URS Ref | Potential Risk | S | O | D | RPN | Risk Level | Mitigation/Controls |
| FRA-001 | Automatic titration | UR-001 | Incorrect titration result due to system error | 9 | 5 | 3 | 135 | High | Validated methods, OQ tests, calibration |
| FRA-002 | LIMS integration | UR-004 | Wrong/missing data transferred to LIMS | 9 | 4 | 4 | 144 | High | Interface testing, checksum, alerts |
| FRA-003 | Audit trail | UR-008 | Tampering of data without trace | 10 | 3 | 3 | 90 | High | Secure logs, Part 11 audit testing |
| FRA-004 | E-signature | UR-009 | Unauthorized approvals | 8 | 3 | 4 | 96 | High | Role-based access, Part 11 compliance |
| FRA-005 | Secure login | UR-011 | Unauthorized system access | 8 | 4 | 3 | 96 | High | Password policy, lockout rules |
| FRA-006 | Backup/Restore | UR-012/013 | Data loss due to failed backup | 7 | 3 | 5 | 105 | High | Daily backup logs, DR testing |
| FRA-007 | Export function | UR-014 | Results not exported or accessed securely | 5 | 4 | 4 | 80 | Medium | Folder permissions, test export in OQ |
| FRA-008 | Method configuration | UR-005 | Incorrect titration method applied | 6 | 4 | 4 | 96 | High | Method validation, role-based method assignment |
| FRA-009 | Result retention | UR-016 | Loss of archived records | 9 | 2 | 4 | 72 | High | Archive validation, 10-year retention test |
| FRA-010 | Disaster Recovery | UR-013 | System down with no recovery | 9 | 2 | 5 | 90 | High | Annual DRP testing, logs |

**5. Risk Control Strategy**

* **High Risk:** Requires rigorous testing during IQ/OQ/PQ, negative testing, and traceability in RTM.
* **Medium Risk:** Covered via functional testing and partial negative testing.
* **Low Risk:** Verified by configuration checks and limited test scripts.

**6. Conclusion**

Based on this FMEA-based FRA, the Potentiometric Titration System exhibits multiple high-risk functions due to its direct impact on product quality and regulatory data. All high-risk items shall be subject to complete qualification protocols, audit trail review, and Part 11 compliance testing.

**7. Review & Approval Table**

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| Name | Designation | Department | Signature | Date |
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