**Scenario:**

A new **Potentiometric Titrator** (Metrohm)is being implemented in the **QC lab**, and you are asked to:

* Collect requirements from all relevant stakeholders
* Prepare a **realistic, system-specific URS**
* Plan integration with **LIMS**

**📋 Step 1: Requirement Collection — By Department**

| **Department** | **Collected Requirements for Potentiometry System** |
| --- | --- |
| **QC (Quality Control)** | - Perform automatic titration for assay and standardization (e.g., HCl, NaOH)  - Store test results securely  - pH and conductivity measurement options  - Generate titration report with sample ID  - Transfer results to LIMS automatically  - Multiple methods for different sample types |
| **QA (Quality Assurance)** | - Lock results once reviewed  - Review & approval workflow (electronic or manual)  - Audit trail for data changes  - 21 CFR Part 11 compliant electronic signatures |
| **IT** | - Integration with LIMS server  - Secure login (user/password)  - Daily backup of results  - Disaster recovery plan  - Network folder for exported results |
| **RA (Regulatory Affairs)** | - Data integrity compliance (ALCOA+)  - Retention of results for 5–10 years  - Traceability of test decisions |
| **Validation/CSV Team** | - System must be validated as GAMP 5 Category 4  - IQ/OQ/PQ must be performed  - Audit trail must be testable  - Data mapping document for LIMS interface |