Internal Audit Report – Quality Control Laboratory

Audit Overview

Audit ID: AUD-QC-2025-Q1

Audit Type: Internal – Scheduled

Department Audited: Quality Control Lab (Grain Testing Division)

Audit Period: January 1, 2025 – March 31, 2025

Audit Date: April 5, 2025

Lead Auditor: Anika Rao, Internal Auditor – Compliance Team

Observers: QA Supervisor, Technical Trainer

1. Objective

To assess compliance of laboratory practices with documented SOPs, QC protocols, regulatory standards (ISO 17025, FDA 21 CFR), and internal QMS policies.

2. Scope

This audit covers sample handling, test execution (moisture/protein), ELN documentation, equipment calibration records, and CAPA closure practices.

3. Methodology

- Document review (SOPs, training records, ELN entries)

- Interview with lab technicians and supervisors

- Physical inspection of instruments and reagent storage

- Sampling of test result records and traceability logs

4. Audit Findings

Finding 1: Analytical balance had calibration sticker dated 5 days beyond the defined bi-weekly schedule.

Finding 2: One moisture test record lacked technician signature in ELN.

Finding 3: CAPA CAPA-2025-031 closure entry was delayed by 3 business days.

Finding 4: Sample intake log did not match ELN entries for Batch #C-4483.

Finding 5: All staff were found wearing required PPE and maintaining hygiene standards.

5. Non-Conformance Summary

- NC-01: Calibration lapse (Medium Severity)

- NC-02: Incomplete record entry (Low Severity)

- NC-03: CAPA closure delay (Low Severity)

- NC-04: Intake traceability issue (High Severity)

6. Recommendations

- Implement automated calibration alert system for balances.

- Enforce mandatory digital signature validation on ELN.

- Cross-train intake staff on ELN batch syncing procedure.

- Follow-up audit on traceability scheduled for May 10, 2025.

7. Auditor's Conclusion

While the laboratory demonstrates a strong culture of compliance and clean operational environment, improvements are necessary in calibration scheduling and ELN integration. All findings were acknowledged by management and action plans are under review.

8. Approval

Report Finalized By: Anika Rao

Approved By: Regulatory Compliance Director

Approval Date: April 8, 2025

This audit report must be retained in the QMS repository for a minimum of 5 years.