

# **Compliance and Regulatory Guidelines – Grain Testing Lab**

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## **1. Purpose**

To outline the regulatory and internal compliance framework governing grain testing activities at GPC, including adherence to ISO, FDA, and local food safety regulations.

## **2. Regulatory Standards**

- ISO 17025: General requirements for the competence of testing and calibration laboratories.
- ISO 712: Determination of moisture content in cereals and cereal products.
- AOAC 990.03: Protein (Crude) in Animal Feed and Grains – Kjeldahl Method.
- FDA 21 CFR Part 110: Current Good Manufacturing Practice (cGMP) in Manufacturing, Packing, or Holding Human Food.

## **3. Lab Accreditation**

- GPC Labs are accredited to ISO 17025 by National Accreditation Board.
- Scope includes grain moisture, protein, ash, and pH testing methods.

## **4. Documentation Requirements**

- Maintain all testing SOPs and QC protocols with version control.
- All results to be documented in ELN with digital signature and timestamps.
- Retain all test records and audit trails for a minimum of 5 years.

## **5. Internal Compliance Practices**

- Conduct quarterly internal audits of lab operations and data integrity.
- Perform method validation and equipment calibration as scheduled.
- Address deviations with CAPA documentation and management sign-off.

## **6. Regulatory Audits**

- Labs must be prepared for unannounced regulatory inspections (FDA or state).
- Ensure that the following documents are readily available:
  - \* SOPs and QC protocols
  - \* Equipment logs and calibration certificates
  - \* Staff training records
  - \* Sample retention and traceability logs

## **7. Employee Training**

- All lab personnel must undergo annual compliance training.
- New staff must complete onboarding compliance module within 30 days of hire.
- Records of training and compliance test scores to be archived.

This document is managed under the GPC Quality Management System and is audit protected.