Why Are There So Many Inspections?
Non-GLP

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NAICC 2019
Classification: Public
Agenda

- Types of Inspections
- Focus areas of the Inspections
- Question & Answer
Types of Inspections

- **Quality Management**
  - GMO handling controls in place

- **Regulatory Compliance** (e.g., field trials)
  - Field trial compliance program is being followed

- **Government** (e.g., USDA)
  - Federal regulation and company’s compliance program are being followed

- **GLP**
Quality Management Inspections

- Objective: Determine if GMO handling controls are established and functioning
- Controls are established in order to maintain quality in each phase of the product life cycle
  - Similar standards as Excellence Through Stewardship (ETS)
Quality Management Inspections

- Focus areas for Quality Management inspections include but are not limited to:
  - Training
  - Work flow
  - Work area and equipment cleaning
  - Material Identification
  - Storage
  - Disposal
  - Non-conformities

* The inspector will look for process/SOP are in place.
Regulatory Compliance Inspection

- Objective: Ensure company compliance program requirements are being followed
  - Internal trial locations
  - 3rd party trials
    - The company that is granted the notification/permit is responsible for all compliance activities regarding that trial

- Non-conformities – reestablish compliance
  - Reportable?

- Prepare for government inspection

- Educational opportunity
Regulatory Compliance Inspections

- Focus areas for Regulatory Compliance inspections include but are not limited to:
  - Training
  - Equipment Cleaning
  - Documentation
  - Planting/Harvest Information
  - Material Transport
  - Storage
  - Field Site Identification
  - Reproductive Isolation
  - Volunteer Monitoring
Government Inspections

- USDA Regulations – 7 CFR 340 Performance Standards, Design Protocol and Supplemental Permit Conditions

- USDA inspection
  - USDA In season Focus Areas
    - Reproductive Isolation
    - Equipment Cleaning
    - Documentation
    - Planting information
  - Material Transport
  - Storage
  - Field Site Identification
  - Current Season Monitoring
Government Inspections

- **USDA Post Harvest - Monitoring Evaluation Interview (MEI)**
  - USDA MEI Focus Areas
    - Equipment Cleaning
    - Material Identification
    - Harvest/ Termination information
    - Storage
    - Transport
    - Field Identification
    - Next Season Field Plans
In Summary

● Quality Management Inspection
  - Ensuring GMO handling controls are in place to maintain quality in each phase of the product life cycle

● Regulatory Compliance & Government Inspections
  - Ensuring field trials meet compliance program/government regulations