



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



United States
Department of
Agriculture



Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

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Notice of Compliance

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

