EPA Good Laboratory Practice Program Regulatory Update

Presented to

National Alliance of Independent Crop Consultants

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GLP Program General Update

Quality Assurance

Common compliance observations from FY 2025

GLP Inspection program updates

Preparation for an EPA GLP Inspection

- ✓Notify sponsors of studies to be audited, request for all raw data, including test substance characterization data and study records to be sent to the testing facility
- ✓Notify Test Facility Management, study directors, Quality Assurance Unit, study personnel and archivist
- ✓Assign a contact QA person
- ✓Do a rehearsal (mock inspection)
- ✓Review Facility SOP on hosting a regulatory inspection
- ✓Review final reports, raw data/study records for potential problems
- ✓Do not offer any meals or gifts!

Quality Assurance Unit

I. Report Audits: How much is too much/not enough?

40 CFR 160.35(b)(3):

- Inspect each study at intervals adequate to ensure the integrity of the study
- Maintain written and properly signed records of each periodic inspection showing:
    - Date of inspection
    - Study inspected
    - Phase or segment of the study inspected
    - Person performing the inspection
    - Findings and problems
    - Any action recommended and taken to resolve existing problems
    - Any scheduled date for reinspection
- Any problems which are likely to affect study integrity found during the course of an inspection shall be brought to the attention of the study director and management immediately

Quality Assurance Unit

II. Auditing vs manually generated data

1. Data Retrievability (Legible)
2. Metadata
3. Audit Trails
4. Electronic Signatures
5. Validation

Quality Assurance Unit

III. QA inspections:

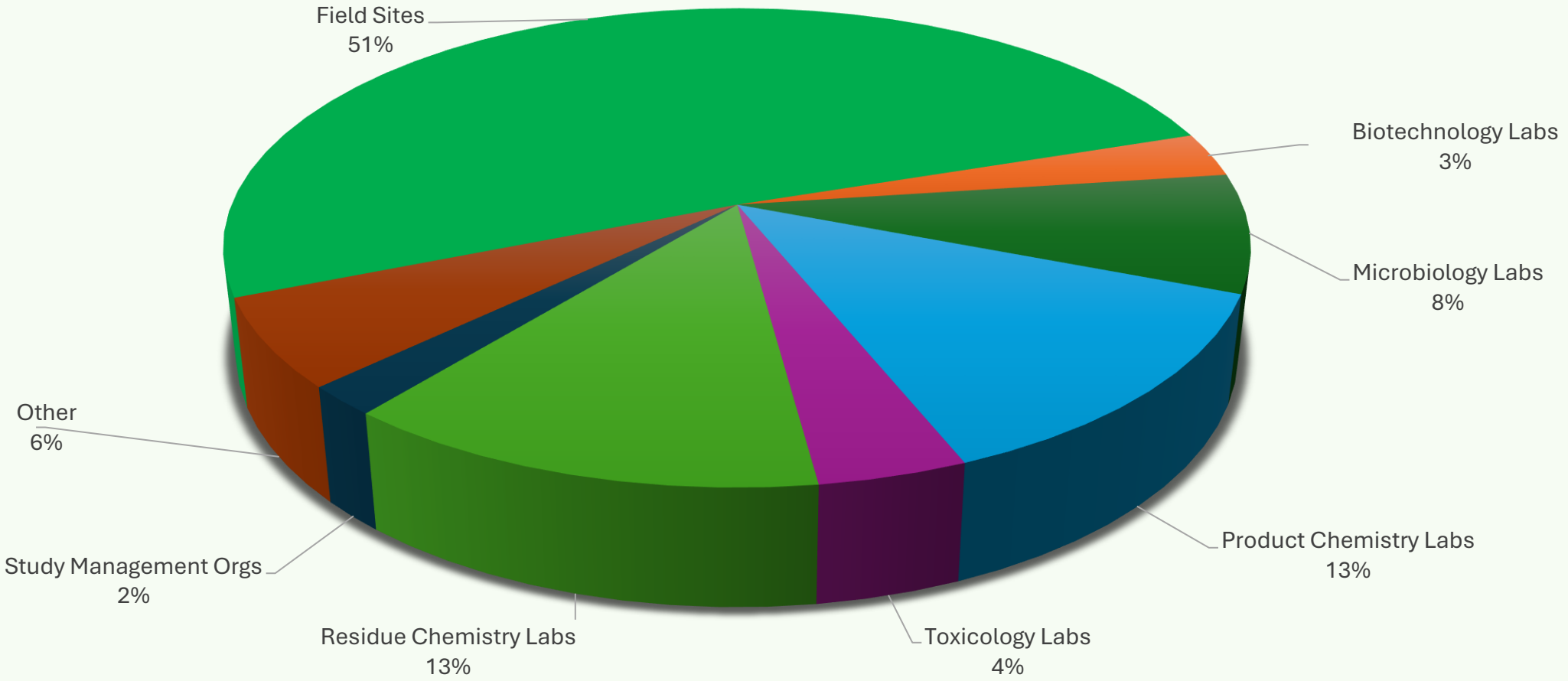
How thoroughly should QA audit studies/data/reports, and best way to document activities?

QA should assure that final report accurately reflects raw data of study

Courtesy of Northern Plaines Ag Research

FY 2025 GLP Inspections by Facility Type

(October 1, 2024 – September 30, 2025)



FY 2025 GLP Inspections

(October 1, 2024 – September 30, 2025)

Total # on-site inspections: **70**

Total # of studies audited: **179**

GLP findings were observed during **25** facility compliance inspections

2025 EPA GLP Inspection Findings

40 CFR 160 Subpart B

1. Lack of QA inspections
2. QA lacks documentation of education, training and experience
3. Protocol deviation was not signed by study director
4. Miscalculation and misreporting
5. QA inspection dates are not matching what's reported
6. Final report does not reflect raw data.
7. Confusion on what constitutes an independent QA

2025 EPA GLP Inspection Findings

40 CFR 160 Subpart D

1. Thermometer was not calibrated against a NSTM thermometer or equivalent

40 CFR 160 Subpart E

1. SOP deviation
2. SOPs not “immediately available” relative to lab or procedure performed
3. Nonexistent SOPs

2025 EPA GLP Inspection Findings

40 CFR 160 Subpart G

1. Protocol falsification
2. Study not conducted following protocol
3. Protocol deviation was not signed by study director
4. Incorrect equation was used in a method
5. Raw data was not initialed at the time of entry
6. Missing raw data
7. Miscalculations
8. Final report does not reflect raw data

2025 EPA GLP Inspection Findings

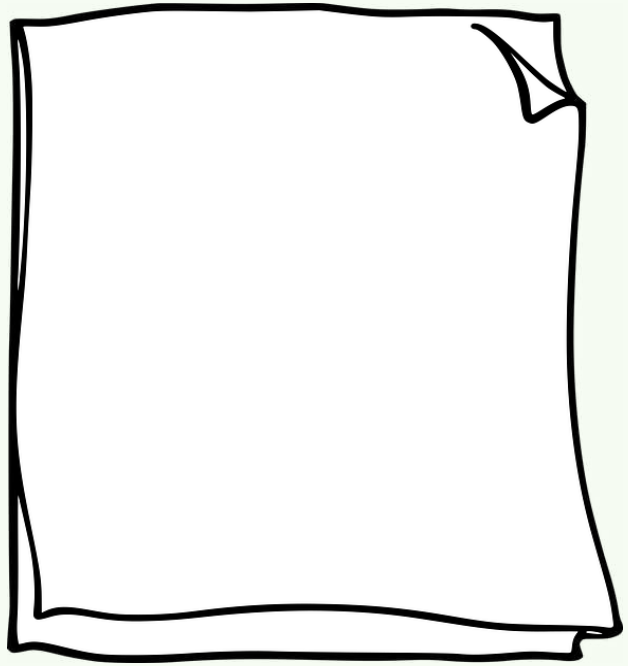
40 CFR 160 Subpart J

1. Lack of names of other scientists and supervisory personnel in the final study report
2. Miscalculation and misreporting
3. Final report does not reflect raw data
4. Unsecured Archives
5. “Expedient retrieval”

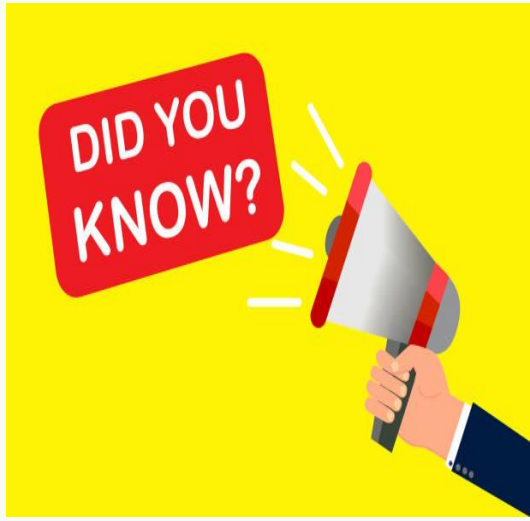
2025 EPA GLP Inspection Findings

40 CFR 169.2(k)

1. Lack/Missing raw data
2. Missing Personnel Records
3. Missing Master Schedule



GLP Reminder 1



Lack of QAU that is independent from study personnel, including study director [40 CFR 160.31(c) and 40 CFR 160.35(a)]

The reason for an independent QAU is to be able to inspect and review any study phases and raw data/records without pressure or influence from QAU superiors.

QAU should be independently inspect and report the findings on real ongoing phases, processes and procedures in addition to data notebooks. Read protocol and SOPs before starting the inspection and audit.

GLP Reminder 2

Final report does not reflect raw data (40 CFR 160.35(b)(5) and (6)

Final report is an important document for a regulatory action. EPA reviewers only see derived data in the final report. Reviewers make their regulatory decision based on the submitted final report.

QA should pay attention to the review and audit of the final report:

- Determine that no deviations from approved protocol or SOPs were made without proper authorization and documentation.
- Review the final study report to assure that such report accurately describes the methods and SOPs, and that the reported results accurately reflect the raw data of the study.

GLP Reminder 3

Each study shall have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study [40 CFR 160.120(a)].

Multiple draft versions of a protocol provided to test facilities prior to approval. Test facilities were not aware of changes from draft protocols to final approved protocol.

Only the final, approved protocol should be distributed. Any changes should be issued as approved protocol amendments.

EPA GLP Program Status for 2026

Reorganization

- Integrated into PWTCB, Ricardo Jones acting branch manager
- 3 GLP inspectors

GLP Program Updates

- New OECD requirements for inspection of Information Technology systems
- Planned updates to GLP inspection website

The only way to do great work is to love what you do

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