National Alliance of Independent Crop Consultants

EPA Regulatory Inspection & Field Site Preparation

Orlando, Florida
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Content

- Targeting
- Pre inspection procedures
- GLP points of interest:
  - Test substance & equipment
  - SOPs
  - Electronic data
LDIB Access to Studies

- Studies received by OPP entered into OPPIN data base
- LDIB accesses OPPIN data base for studies submitted under FIFRA
- LDIB’s data base LISA
Targeting

- Neutral Scheme
  - Most common
  - Random facility selection
- For Cause
  - Requested inspection:
    - OPP/ OCE or foreign source
    - Informant?
Target Selection Criteria

- Last date of inspection
- Compliance history
- OPP, OCE, OECA priority list
  - Type of chemicals
  - Types of studies
- Number of studies submitted
- Date study received at EPA
- Geographical location
First Contact with the EPA Inspection Authority

- EPA sends a letter to the field site and study sponsors which specifies:
  - Studies to be audited
  - The nature and purpose of the inspection
  - The dates of inspection
  - We will choose one or more ongoing study(s)
EPA Letter Requirements

- Suitable space for the auditor
- Have available & in good order, all original data *(certified copies sometimes accepted)*
EPA Letter Requirements

- Copies of the protocol & amendments and any reports to sponsor
- Sponsor correspondence with study personnel including the study director
EPA Letter Requirements

- Study personnel should be available for the inspection
- Relevant SOPs must be available
- Test substance information available
  - Characterization data
  - Purity and lot number information
  - Records of receipt, storage, usage including chain of custody procedures
Call From the Inspector

- Introduce ourselves and inspection team if relevant
- Clarify the “nature” of the inspection
  - neutral scheme or for cause
- Answer any questions from EPA letter
- We’ll ask for:
  - Floor Plan and site map of your facility
  - Organization chart (sponsor down)
Call From the Inspector

- In addition, we’ll ask for:
  - A discussion of your facility, (past, present, and future plans)
  - Quality assurance routing forms
  - Master schedule
  - Personnel C.V.’s and records of training
  - List of current and historical SOPs
Call From the Inspector

- We verify your address and request directions to your site
- We provide you with our phone information, and encourage you to contact us with any questions that may arise prior to inspection
Chemical Handling and Equipment
Chemical Substance Handling

- Procedures established for storage & distribution:
  - Minimize contamination/deterioration
    - Environmental conditions (i.e. light, temperature, humidity, ventilation)
  - Identification throughout study distribution
  - Chain of Custody (COC)
    - Document amount used, when, and by whom
    - “Cradle to Grave” at the individual facility
Substance Container Labeling

- Name
- CAS / code number
- Batch number
- Expiration date
- Storage conditions
- Storage containers assigned to minimize contamination
Test, Control & Reference Substance Characterization

§160.105

- Records typically maintained and sent to audit by the study sponsor
  - Analysis for each batch to determine identity, strength, purity, composition...
  - Determined and documented before its use in the study
Test, Control & Reference
Substance Characterization
§160.105

- Records typically maintained and sent to audit by the study sponsor
  - Solubility when relevant
  - Stability shall be determined before experimental start date or concomitantly
How do we define “Equipment” for a GLP Study?
Equipment Design
§160.61

- Equipment used for the *generation, measurement, or assessment of data* and equipment used for facility environmental control shall be:

  - Appropriate design and capacity to function according to the protocol
  - Suitably located for “proper” operation, inspection, cleaning, and maintenance
Equipment shall be adequately inspected, cleaned and maintained

Equipment used for the generation, measurement, or assessment of data shall be adequately tested, calibrated, and/or standardized
Equipment Standard Operating Procedures
§160.63(b)

- Methods, materials, and schedules used in the routine inspection, cleaning, maintenance, testing, calibration / standardization of equipment should be documented in an SOP.
Equipment Standard Operating Procedures

- Specify remedial action taken in event of failure or malfunction
- Person designated as responsible for performance of above operations
Standard Operating Procedures (additional points)

- Are SOPs current and properly approved?
  - Rubber stamp approval by management?
- Do they reflect current practices?
- Accurate with appropriate detail?
- Are they available at each work area, are they followed?
- Are historical SOPs available?
Written Records
§ 160.63 (c)

- Records shall be maintained for equipment.
  - Inspection
  - Maintenance
  - Testing
  - Calibration / verification
  - Retirement of equipment
Also must include:
- Dates of operations

Type of maintenance operations: routine
- Standard Operating Procedure followed

Repair / maintenance operation: nonroutine
- Describe problem
- How and when problem discovered
- Action to correct the problem
Fundamentals of Electronic Records
Electronic Records

- Must establish the following record keeping requirements:
  - Ability to generate and maintain accurate and complete copies of records for potential review, and protect them against alteration
  - Computer systems (including software and hardware) must be available for agency inspection
Electronic Records

- Protection of electronic signature(s) so that record is not compromised (i.e.) copied, detached, altered
Electronic Signatures

- Individual entering data shall be identified
  - Biometric or user name / password
- Certified letter stating the electronic signatures are legally binding and equivalent to a hand written signature
- Employee training on use and security
Use of computer-generated, time stamped audit trails...provides record of actions *(key element during agency review)*
Electronic Records and the Audit Trail

- When a change is made the audit trail must establish:
  - When change was made (date & time)
  - Who made the change
  - The original data without overwriting
  - The new entry
  - Reason for the change
Electronic Records (Continued)

- Records are retrievable for legal proceedings and data audits
- Electronic records must be archived in such a way to preserve data integrity
Electronic Data Archives

- Data retention should be compliant with the GLP regulations
- Limited access
- Minimize deterioration
- Have evidence of reliability for electronic data transfer to archives