EPA Good Laboratory Practices

- Presented to Pesticide Program Dialogue Committee (PPDC)
- October 28, 2021
- Francisca Liem and Dan Myers
  US Environmental Protection Agency

What is Good Laboratory Practice (GLP)?

- **GLP is an internationally accepted quality management system focused on the process and conditions under which non-clinical studies are planned, performed, monitored, recorded, reported and archived**
- **The purpose of GLP is to assure the quality, validity and integrity of facilities and their scientific studies that support regulatory decisions by government agencies (e.g., EPA FIFRA & TSCA)**
- **Why PPDC should know about GLP**

GLP was instituted in the US following cases of fraud generated by toxicology labs submitting data to both EPA and FDA

Ten Pillars of Good Laboratory Practices

1. Statement of Compliance, Inspection, Effects of Noncompliance
2. Organization and Personnel
3. Facilities
4. Archives
5. Equipment
6. Testing Facility Operation – Standard Operating Procedures
7. Test system care
8. Test, Control and Reference Substances
9. Protocol and Conduct of Study
10. Records and Reports

EPA GLP Program - Basics

- **EPA Headquarters Program**
- **Studies submitted to Office of Pesticide Programs Information Network – OPPIN**
- **A number of pesticide studies submitted to OPP are audited during a facility inspection**

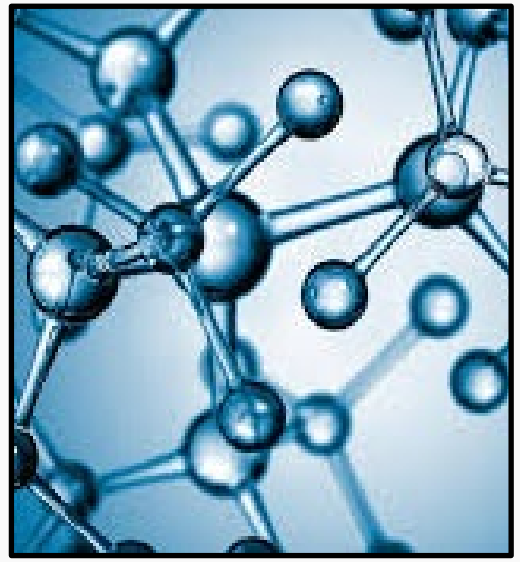
Types of GLP Inspections

I. Neutral Scheme:

- **Random facility selection. Test facilities from OPPIN and Integrated Compliance Information System (ICIS) are randomly selected based on criteria and applied weights:**
  - **Compliance history.**
  - **Last inspection date.**
  - **Type and Number of studies submitted to OPP.**
  - **Geographical location.**

II. Requested / For Cause:

- **EPA (related to OPP registration evaluation and PRIA actions).**
- **Foreign government (compliance concerns).**
- **Tips and complaints**



Responsibilities of the EPA Good Laboratory Practice Program

- To assure the quality, validity and integrity of data submitted to OPP in support of a pesticide registration by conducting inspections and data audits
- To assure that studies submitted to OPP for regulatory decision have been conducted according to the GLP regulations
- To assure that testing facilities conducting the studies are in compliance with the GLP regulations
- To provide compliance assistance to the regulated community
- Participate in OECD Mutual Acceptance of Data program

Non-compliance Response

- **Regulatory actions:**
  - **Study rejection by OPP.**
  - **Suspension or cancellation of a registered pesticide**
  - **Denial of an application for a pesticide approval.**
- **Civil actions:**
  - **Notice of non-compliance**
  - **Notice of warning**
  - **Penalties**
- **Criminal Actions:**
  - **Imprisonment**
  - **Penalties**

EPA GLP and the Organization for Economic Co-operation and Development (OECD)

- Principles of GLP reside within OECD, Chemical Safety and Biosafety, Testing of Chemicals, GLP Working Party. These principles ensure the quality and integrity of test data related to non-clinical safety studies
- OECD, Mutual Acceptance of Data (MAD) allows for results of these studies to be shared across the MAD countries

International Activities

- EPA cooperates with other countries in establishing and harmonizing GLP programs:
  - EPA participates in the OECD's MAD program, which supports international recognition of GLP Compliance Monitoring Programs for the assessment of testing data.

    - 31 member and 7 non-member countries participate in evaluating each others' testing programs against OECD criteria and reducing duplication of testing and trade barriers.

    - EPA routinely receives requests to share inspection information with member countries, give presentations, participate on audit teams and provide training.

Questions?

Contact:

Francisca Liem
Liem.Francisca@epa.gov
202-564-2365

Dan Myers
Myers.Dan@epa.gov
303-462-9392