

## OVERVIEW OF GLP-REQUIRED PERSONNEL AND THEIR RESPONSIBILITIES

A large commitment of personnel, time and materials is necessary in order to successfully complete a Good Laboratory Practices (GLP) study. A large portion of GLP is having full documentation and to be able to recreate a study on paper, making it legally defensible. Many regulatory agencies around the world require data to be generated using GLPs. A GLP residue study generally takes three to four years from writing the protocol, through conducting the field trials and laboratory analysis, and is completed with the writing and submission of the final report. Additional time is also needed for other preliminary steps such as writing and/or reviewing Standard Operating Procedures (SOP), finding field trial sites and acquiring all the equipment and materials needed for the entire project.

There must be a strong commitment to the project from the government. It is important that the decision makers within the institution/organization understand what is involved and are committed to the doing what is necessary to generate GLP residue data in support of establishment of Maximum Residue Levels (MRL). These key decision makers must have the authority to assign the personnel, facilities, and provide support for the duration of the project. Ideally, this commitment will be to the long-term goal of developing a specialized team dedicated to doing GLP residue work. Dedicated personnel are essential, as learning to complete residue studies under GLP is a sharp learning curve, generally at least two (2) years of constant practice. Adequate infrastructure and support are also essential as there must be adequate space to conduct the work in compliance with US EPA GLP or OECD Guidelines. Inadequate personnel, resources or time reduces quality of work and may result in the loss of a study.

It is essential to have a technical committee to oversee the project, liaison with members within the organization, consult on technical matters, help acquire equipment/materials, and ensure that the resources, including personnel, are adequate to do the work.

Personnel are perhaps the most important part of conducting GLP studies. They must be adequately trained in GLP, be committed to the project, understand the whys and how's of the protocol, GLPs, etc., and have the time necessary to complete their responsibilities. Personnel assigned to conduct these studies should receive a reduction in their other duties. GLP studies require five (5) unique and specific positions. They are presented below with their specific responsibilities and rough estimates of the time needed to do them.

### 1. Sponsor (Testing Facility Management):

- a. One person who represents the organization at a level where they can assume the responsibility for ensuring that the study is completed in an adequate and timely manner. Specific responsibilities include:
  - i. Provide resources to ensure proper personnel are trained and able to conduct the research and perform their duties.
    1. Designate a study director (SD) for the study, and be able to replace the study director promptly if it becomes necessary.
    2. Designate a quality assurance unit (QA), and be able to replace the quality assurance personnel promptly if it becomes necessary.
  - ii. Read and sign the Standard Operating Procedures (SOPs) for the other members of the team.
  - iii. Read and sign the protocol.

- iv. Review and sign Quality Assurance (QA) inspection and data audit reports.
- b. Direct involvement in the project helps the functioning of the field and laboratory.
- c. Time commitments will vary depending the activities and their participation in the project. The obligations will be high during the initiation of a GPL residue program, as the research team must be identified, SOPs and protocols developed , reviewed and signed, etc. During the conduct of a study the Sponsor needs to be available to answer questions, resolve problems, and review and sign QA documents and the final report.

## 2. **Study Director (SD):**

- a. The Study Director is the individual responsible for the overall conduct of a study.
- b. This one person serves as the single main point of contact for the study. That means he/she is the ONLY PERSON who can make decisions about the study and make changes to the protocol.
  - i. The SD is a scientist or other professional of appropriate education, training, and experience, or combination thereof, to be able to provide oversight of the entire residue project.
- c. This is a time consuming position; the study director (SD) needs to dedicate approximately 50% of their time to the project during the active writing and research phases. More time is needed if the SD is responsible for multiple studies. Study Director responsibilities include:
  - i. Develop and write the protocol.
  - ii. Work with the other researchers and quality assurance personnel on SOPs for each phase of study.
  - iii. Be available for decisions and protocol changes during conduct of the study.
  - iv. Assess the field and laboratory data as it is generated.
  - v. Read and respond to QA inspections and raw data audits for lab and field.
  - vi. Review Field Data Books (FDB) and work with the Field Investigator for accuracy and completeness, and summarize the data for the final report.
  - vii. Review the Analytical Summary Report.
  - viii. Write the Final Report and work with QA to ensure accuracy and GLP compliance.
  - ix. Communicate study needs to Testing Facility Management (Sponsor).

## 3. **Field Investigator (FI):**

- a. More than one person can act as a field investigator (FI) within a study, but only one FI can be assigned to a single field trial at any one time. Conducting field trials is a full-time job during application of the test substance and field sample harvest. This is especially true if the researcher must travel to the trial sites. It is essential that the researcher have enough time to record the required data at the time of the activity, not a couple days/weeks/months later (data entry MUST be done at the time the activity occurs). FI responsibilities include:
  - i. Write/review SOPs

- ii. Select high quality test site locations where a healthy crop is grown and maintained under good agricultural practices, and is typical of local farming practices, and meets protocol requirements; such as being able to collect test site history and weather data from the farm.
  - iii. Select and train other personnel who will be assisting the FI.
  - iv. Keep data and test substance in secure locations.
  - v. Ensure that necessary equipment is in good working order and the required calibrations/verifications have been completed and recorded.
  - vi. Apply the test substance and record the data in the FDB.
  - vii. Collect samples and ship/deliver to the analytical laboratory.
  - viii. Coordinate timing of sample shipment/delivery with laboratory personnel
  - ix. Work with QA officer to ensure that required inspections and audits are conducted and respond to findings as soon as possible.
  - x. Submit accurate and complete FDB to the Study Director and work with SD and QA to address questions/issues.
- b. It is essential that the Field Investigator understand GLPs, Good Agricultural Practices, pesticide application techniques, and be detail oriented.

#### 4. **Laboratory Investigator (LI):**

- a. One person serves as Laboratory Investigator (LI). The LI acts as the team leader, and should have strong management skills and technical background. The laboratory also must have enough space and equipment to be able to complete activities (sample storage, grinding, extraction and analysis), without cross contamination, and conduct the analysis in a timely manner. LI responsibilities include:
- i. Write/review SOPs
  - ii. Assign and train support personnel for: sample receipt, preparation, extraction, and analysis.
  - iii. Develop analytical working method from reference method and verify recoveries.
  - iv. Coordinate sample receipt with field personnel.
  - v. Ensure that analysis is in compliance with protocol, SOPs and GLPs.
  - vi. Trouble shoot chemistry issues
  - vii. Work with QA officer to ensure that required inspections and audits are conducted and respond to findings as soon as possible.
  - viii. Assess data as it is generated.
  - ix. Write Analytical Summary Report and submit to QA, address all issues, then submit to SD.
- b. GLP sample handling and analysis is a full-time job during those activities. It is helpful if the sample grinding, extraction and analysis are conducted at a different time or in a different space from other samples. Maintaining sample integrity is essential.

## 5. **Quality Assurance Officer (QA):**

- a. QA can be more than one person, although one person must take the leadership role and be responsible for, and sign, the protocol and final report. This is one of the most difficult and time consuming positions. The lead QA must understand all aspects of the study, field and laboratory. Quite often there are at least two QA, one for the field and one for the laboratory. In-Life inspections can take more than a day if travel is involved. Data audits of each FDB take anywhere from a few hours to a couple of days, depending on the quality of the FI's work. The audits of the laboratory raw data and Analytical Summary Report may take more than a week, depending on the size of the study. The Final Report can also take several days to complete. QA responsibilities include:
  - i. Liaison with, and report directly to, Testing Facility Management (Sponsor).
  - ii. Assist SD, FI, LI and other personnel in development of SOPs. It is not the responsibility of the QA to write the SOPs, but rather to review for completeness and adherence to GLPs, and provide guidance.
  - iii. Review the protocol for GLP compliance and make suggestions.
  - iv. Work with the SD, FI and LI to ensure that required inspections and audits are conducted, and track audit responses.
  - v. Conduct facility inspections of the field test sites and analytical laboratory.
  - vi. Conduct In-Life inspections on critical phases of each study (e.g., test substance application; residue sample harvest/shipping; sample receipt and storage; sample grinding; extraction; and sample analysis).
  - vii. Perform audits of all the raw data generated for the each Field Data Books, the laboratory sample receipt and handling logs, analytical standard receipt and handling logs, chromatograms, etc.
  - viii. Review the Analytical Summary Report for accuracy and compliance with GLPs.
  - ix. Review the Final Report of accuracy and compliance with GLPs
  - x. Provide reports to Sponsor, as well as study personnel.
- b. The QAs are not to be directly involved in the conduct of GLP studies. They can make suggestions, but cannot do any of the work or tell the researcher what to do.
- c. The person(s) assigned QA responsibility must be detail oriented, have a complete understanding of GLPs, and have a good technical understanding of what they are reviewing. Personnel with a strong background in quality control generally make good QAs.

For further information about GLPs, please visit:

The USA/Environmental Protection Agency's Volume 40 Code of (US) Federal Regulations Part 160: <https://www.gpo.gov/fdsys/pkg/CFR-1999-title40-vol16/pdf/CFR-1999-title40-vol16-part160.pdf>

The Organisation for Economic Co-operation and Development's Principles on GLPs: <http://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm>

#### Additional Important Definitions:

- Study Completion Date: the date the final report is signed by the study director.
- Study Initiation Date: the date the protocol is signed by the study director.
- Experimental Start Date: the first date the test substance is applied to the test system.
- Experimental Termination (End) Date: the last date on which data are collected directly from the study.
- Test Substance: the pesticide substance or mixture administered or added to a test system in a study.
- Reference Substance: is any chemical substance or mixture, or analytical standard, or material other than a test substance, feed, or water, that is administered to or used in analyzing the test system in the course of a study for the purpose of establishing a basis for comparison with the test substance for known chemical or biological measurements.
- Quality Assurance Unit: any person or organizational element, except the Study Director, designated by Testing Facility management, to perform the duties relating to quality assurance of the studies.