MiChem Dynamics
LEADING CHANGE

# UNDERSTANDING AND IMPLEMENTING **OECD** PRINCIPLES ON GOOD LABORATORY PRACTICE (GLP)

The training course on OECD Principles of Good Laboratory Practice (GLP) is designed to provide participants with a comprehensive understanding of the essential guidelines and standards governing non-clinical laboratory studies. Over the course of the program, participants will delve into key aspects such as laboratory organization and personnel responsibilities, the establishment of a robust quality assurance program, facility requirements, proper handling of test systems and reference items, development and adherence to standard operating procedures, and the effective planning, conduct, and reporting of laboratory studies. The training will emphasize practical applications through interactive workshops and case studies, allowing participants to integrate theoretical knowledge into real-world scenarios. By the end of the course, participants will be equipped with the knowledge and skills necessary for implementing and maintaining Good Laboratory Practice, fostering data integrity, and ensuring compliance with international regulatory standards.

**THE COURSE WILL RUN OVER A PERIOD OF 2 DAYS**

## LEARNING OUTCOMES:

- Understand the underlying structure of the OECD guidelines on GLP and all elements associated with the quality management system.
- Write their own management system documents in compliance with the OECD guidelines on GLP.
- Identify relevant performance monitoring approaches.
- Continually improve data quality and effectiveness.

## WHO SHOULD ATTEND THIS COURSE:

- Technical / Quality managers
- Laboratory technicians
- Anyone involved in the development, maintenance or improvement of a quality management system

## MINIMUM ENTRY REQUIREMENTS:

- Fluency in English writing and reading skills

## TUITION:

- Training material included (English)
- Certificate of attendance or competence (based on outcome of assessment) will be issued on successful completion of training.

## COURSE OVERVIEW:

### DAY 1

- Introduction
- Terms and Definitions
  - Defines key terms and concepts used within the context of the OECD Principles.
- Laboratory Organization and Personnel
  - Laboratory Management's Responsibilities
    - Describes the responsibilities of laboratory management in ensuring the overall compliance with GLP.
  - Study Director's Responsibilities
    - Outlines the specific responsibilities of the study director, who oversees the overall conduct of a particular study.

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## COURSE OVERVIEW:

- Principal Investigator's Responsibilities
  - Specifies the responsibilities of the principal investigator, a key role in the implementation of a laboratory study.
- Study Personnel's Responsibilities
  - Details the responsibilities of various study personnel involved in the conduct of laboratory studies.

- Quality Assurance Program
  - General
    - Describes the overall framework and importance of the quality assurance program in maintaining data integrity and compliance.
  - Responsibilities of the Quality Assurance Personnel
    - Outlines the specific duties and responsibilities of quality assurance personnel in overseeing and ensuring the quality of laboratory studies.
- Facilities
  - General
    - Addresses the general requirements for laboratory facilities.
  - Test System Facilities
    - Specifies requirements for facilities related to the test systems involved in laboratory studies.
  - Facilities for Handling Test and Reference Items
    - Details the facilities needed for the proper handling of test and reference items.
  - Archive Facilities
    - Discusses requirements for facilities dedicated to archiving study-related records and materials.
- Waste Disposal
  - Covers the proper procedures for the disposal of laboratory waste.
  - Apparatus, Material, and Reagents
    - Provides guidelines for the selection and use of apparatus, materials, and reagents in laboratory studies.

### DAY 2

- Test Systems
  - Physical/Chemical
    - Describes considerations for physical and chemical test systems.
  - Biological
    - Addresses considerations for biological test systems.
- Test and Reference Items
  - Receipt, Handling, Sampling, and Storage
    - Details procedures for receiving, handling, sampling, and storing test and reference items.
  - Characterization
    - Discusses the characterization requirements for test and reference items.
- Standard Operating Procedures
  - Covers the development, implementation, and maintenance of standard operating procedures (SOPs) in laboratory studies.
- Performance of the Study
  - Study Plan
    - Discusses the importance of a study plan in outlining the conduct of the laboratory study.
  - Content of the Study Plan
    - Specifies the necessary components that should be included in a study plan.
  - Conduct of the Study
    - o Outlines procedures for the actual execution of the laboratory study.
- Reporting of Study Results
  - General
    - Provides general guidelines for reporting study results.
  - Content of the Final Report
    - Specifies the required content for the final report of a laboratory study.
- Storage and Retention of Records and Materials
  - Describes the procedures and requirements for the storage and retention of records and materials related to laboratory studies.
- Test (assessment)

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