Good Laboratory Practices

- **Definition**: GLP embodies a set of principles that provides a framework within which laboratory studies are planned performed, monitored, reported and archived.
- GLP is sometimes confused with the standards of laboratory safety like wearing safety

HISTORY

- GLP is a formal regulation that was created by the FDA (United states food and drug administration) in 1978.
- Although GLP originated in the United States , it had a world wide impact.
- Non-US companies that wanted to do business with the United states or register their pharmacies in the United States had to comply with the United States GLP regulations.
- They eventually started making GLP regulations in their home countries.
- In 1981 an organization named OECD

WHY WAS GLP CREATED?

- In the early 70’s FDA became aware of cases of poor laboratory practice all over the United States.
- □ FDA decided to do an in-depth investigation on 40 toxicology labs.
- □ They discovered a lot fraudulent activities and a lot of poor lab practices.
  □ Examples of some of these poor lab practices found were
  1. Equipment not been calibrated to standard form , therefore giving wrong measurements.
  2. Incorrect/inaccurate accounts of the actual lab study
  3. Inadequate test systems

OECD Principles of GLP

- **Define and describe a quality system concerned with the organisational processes and conditions under which a non-clinical health and environmental safety study is conducted**
- **□ Non-clinical laboratory study means in vivo or in vitro experiments in which test articles are studied prospectively in test systems under laboratory conditions to determine their safety**

GLP in the OECD Principles

- ‘a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental studies are planned, performed, monitored, recorded, archived and reported.’
- It does not concern with the technical validity of the studies

Fundamental points of GLP

- Good Laboratory Practice applied in whatever industry targeted, stresses the importance of the following main points
- Resources : Organisation, personnel, facilities, equipment
- Rules : Protocols, Standard Operating Procedures, concept of Study Director
- Characterisation : Test items, test systems Documentation : Raw data, final report, archives
- Quality Assurance : Independence from study conduct

OBJECTIVES OF GLP

- GLP makes sure that the data submitted are a true reflection of the results that are obtained during the study.
- GLP also makes sure that data is traceable.
- Promotes international acceptance of tests.

MISSION OF GLP

- Test systems
- Archiving of records and materials.
- Apparatus, material and reagent facilities.
- Quality assurance programs.
- Performance of the study.
- Reporting of study results.
- Standard operating procedures (SOP) Personnel and test facility organization

- **GLP principles**
  1. Organization and Personnel
  2. Quality assurance program
  3. Facilities
  4. Equipment, reagents and Materials
  5. Test systems
  6. Test & Reference items
  7. Standard operating procedures
  8. Performance of Study
  9. Reporting of results
  10. Storage of Records and Rep

Standard Operating Procedures (SOP)

- Written procedures for a laboratories program.
- They define how to carry out protocol specified activities.
- Most often written in a chronological listing of action steps.
- They are written to explain how the procedures are suppose to work
- Routine inspection, cleaning, maintenance, testing and calibration.
- Actions to be taken in response to equipment failure.
- Analytical methods
- Definition of raw data
- Keeping records, reporting, storage, mixing, and retrieval of data

Statistical Procedures for Data Evaluation

- Statistical procedures are not simply chosen from a text book
- Practitioners in a particular field may adopt certain standards which are deemed acceptable within that field.
- Regulatory agencies often describe acceptable statistical procedures.

Instrumentation Validation

- This is a process necessary for any analytical laboratory.
- Data produced by “faulty” instruments may give the appearance of valid data.
- The frequency for calibration, re-validation and testing depends on the instrument and extent of its use in the laboratory.
- Whenever an instrument’s performance is outside the “control limits” reports must be discontinued
- Equipment records should include:
  - Name of the equipment and manufacturer
  - Model or type for identification
  - Serial number
  - Date equipment was received in the laboratory
  - Copy of manufacturers operating instruction (s)

Reagent/ Materials Certification

- This policy is to assure that reagents used are specified in the standard operating procedure.
- Purchasing and testing should be handled by a quality assurance program.
- Requirements:
  - Reagents and solutions shall be labeled
  - Deteriorated or outdated reagents and solutions shall not be used
  - Include Date opened
  - Stored under ambient temperature
  - Expiration date

Analyst Certification

- Some acceptable proof of satisfactory training and/or competence with specific laboratory procedures must be established for each analyst.
- Qualification can come from education, experience or additional trainings, but it should be documented
- Sufficient people
- Requirements of certification vary

Laboratory Certification

- Normally done by an external agency
- Evaluation is concerned with issues such as
  - Adequate space
  - Ventilation
  - Storage
  - Hygiene

Specimen/Sample Tracking

- Vary among laboratories
- Must maintain the unmistakable connection between a set of analytical data and the specimen and/or samples from which they were obtained.
- Original source of specimen/sample (s) must be recorded and unmistakably connected with the set of analytical data.

Documentation and Maintenance of Records

- Maintenance of all records provide documentation which may be required in the event of legal challenges due to repercussions of decisions based on the original analytical results.
- General guidelines followed in regulated laboratories is to maintain records for at least five years
- Length of time over which laboratory records should be maintained will vary with the situation

Important questions to be answered for any analytical instrument

- What is the equipment being used for?
- Is the instrument within specification and is the documentation to prove this available?
- If the instrument is not within specifications, how much does it deviate by?
- If the instrument is not within specifications what

GLP compliance

- OECD Principles of GLP → basic GLP document
- Each country has a national GLP *compliance monitoring authority* → facility claim to be compliant with OECD Principle of GLP must be by NATA/NPCB
- *Registration Authorities* looks for compliance → To principles of GLP