Good Laboratory Practices

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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 goggles.

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 worldwide 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 (organization for economic cooperation and development) produced GLP principles that are international standard.

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 of 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

FAMOUS EXAMPLE

- One of the labs that went under such an investigation made headline news.
- The name of the Lab was Industrial Bio Test. This was a big lab that ran tests for big companies such as Procter and Gamble.
- It was discovered that mice that they had used to test cosmetics such as lotion and deodorants had developed cancer and died.
- Industrial Bio Test lab threw the dead mice and covered results deeming the products good for human consumption.
- Those involved in production, distribution and sales for the lab eventually served jail time.

OECD Principles of GLP

- Define and describe a quality system concerned with the organizational 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
- **Characterization**: Test items, test systems
- **Documentation**: Raw data, final report, archives
- **Quality Assurance**: Independence from study conduct

Resources

- Organisation and personnel
- Facilities and equipment

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

- Organization and Personnel
- Quality assurance program
- Facilities
- Equipment, reagents and Materials
- Test systems
- Test & Reference items
- Standard operating procedures
- Performance of Study
- Reporting of results
- Storage of Records and Reports
**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.

**SOP**
- 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.

**Instrument Validation (cont)**
- 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.
Reagents and Solutions cont
- 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 action has been taken to overcome the defect?
- Can the standards used to test and calibrate the instrument be traced back to national standards?
GLP compliance

- OECD Principles of GLP
- Each country has a national GLP compliance monitoring authority
- Registration Authorities looks for compliance

basic GLP document

facility claim to be compliant with OECD Principle of GLP must be by NATA/ NPCB

To principles of GLP

References

- [http://www.sjsu.edu/faculty/chem55/55glpout.htm](http://www.sjsu.edu/faculty/chem55/55glpout.htm)
- UGA Office of the Vice President for Research
- Wikipedia