GLP: GOOD LABORATORY PRACTICE

- **GLP** is an FDA regulation.
- GLP is a formal regulation that was created by the FDA (United states food and drug administration) in 1978.

Definition of GLP

- GLP embodies a set of principles that provides a frame work within which laboratory studies are planned performed, monitored, and archived and reported.

WHY WAS GLP CREATED?

- In the early 70's FDA became aware of cases of poor laboratory practice all over the United States.
- 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.

Purpose of GLPs:

- GLP is to certify that every step of the analysis is valid or Not.
- Assure the quality & integrity of data submitted to FDA in support of the safety of regulated products.
- GLPs have heavy emphasis on data recording, record & specimen retention.

GOOD LABORATORY PRACTICES PRINCIPLES.

1. Test Facility Organisation and Personnel.
2. Quality Assurance Programme(QAP).
3. Facilities.
4. Apparatus, Material and Reagents.
5. Test systems.
6. Test and Reference Substances.
7. Standard Operating Procedures(SOP).
8. Performance of The Study.
9. Reporting of Study Results.
10. Storage and Retention of Records and materials.

1.Test Facility Organization and Personnel

Study Personnel Responsibilities

- Should have the Knowledge of the GLP principles.
- Access to the study plan and appropriate SOP's.
- Comply with the instructions of the SOP's.
- Record raw data.
- Study personnel are responsible for the quality of their data.
- Exercise health precautions to minimize risk.
- Ensure the integrity of the study.

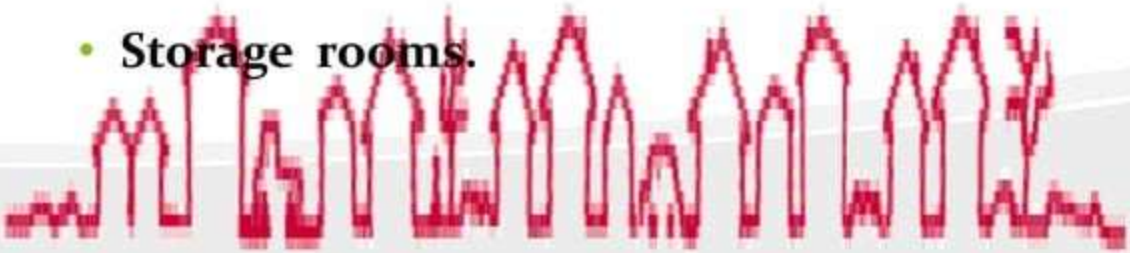
2.Quality Assurance Program

Responsibilities of the QA Personnel

- Access to the updated study plans and SOP's.
- Documented verification of the compliance of study plan to the GLP principles.
- Inspections to determine compliance of the study with GLP principles.
- Three types of inspection.
  - Study-based inspections.
  - Facility-based inspections.
  - Process-based inspections.
- Inspection of the final reports for accurate and full description.
- Report the inspection results to the management.
- Statements.

3. Facilities

- Suitable size, construction and location.
- Adequate degree of separation of the different activities.
- Isolation of test systems and individual projects to protect from biological hazards.
- Suitable rooms for the diagnosis, treatment and control of diseases.
- Storage rooms.



4. Apparatus, Materials and Reagents

- Apparatus of appropriate design and adequate capacity.
- Documented Inspection, cleaning, maintenance and calibration of apparatus.
- Apparatus and materials not to interfere with the test systems.
- Chemicals, reagent and solutions should be labeled to indicate identity, expiry and specific storage instructions.

5. Test Systems

- Physical and chemical test systems.
- Biological test systems.
- Records of source, date of arrival, and arrival conditions of test systems.
- Proper identification of test systems in their container or when removed.
- Cleaning and sanitization of containers.
- Pest control agents to be documented.

6. Test and Reference Items

- Receipt, handling, sampling and storage
- Characterization.
- Known stability of test and reference items.
- Stability of the test item in its vehicle (container).
- Experiments to determine stability in tank mixers used in the field studies.
- Samples for analytical purposes for each batch.

7.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.

7.SOP's

- Routine inspection, cleaning, maintenance, testing and calibration.
- Actions to be taken in response to equipment failure.
- Keeping records, reporting, storage, mixing, and retrieval of data.
- Definition of raw data.
- Analytical methods.

8. Performance of the Study

- Prepare the Study plan.
- Content of the study plan.
  - Identification of the study.
  - Records.
  - Dates.
  - Reference to test methods.
  - Information concerning the sponsor and facility.
- Conduct of the study.

9. Reporting of Study Results

- Information on sponsor and test facility.
- Experimental starting and completion dates.
- A Quality Assurance Program Statement.
- Description of materials and test methods.
- Results.
- Storage (samples, reference items, raw data, final reports) etc.

10. Storage and Retention of Records and Materials

- The study plan, raw data, samples.
- Inspection data and master schedules.
- SOPs.
- Maintenance and calibration data.
- If any study material is disposed of before expiry the reason to be justified and documented.
- Index of materials retained.

What Good Laboratory Must Contain.?

- Area should be free from smoke, smell, dust etc.
- Ensure good ventilation, proper illumination and prefer natural light.
- Air conditioned the lab with humidity control.
- Enough space for measuring and testing instrument.

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- Proper arrangement of testing.
- Take care of all safety points including proper earthing as well as fire safety.
- Avoid uncleanable spots in floors, walls, ceiling.
- Establish proper areas for storage of incoming samples as well as test–completed samples.
- Also provide sample collection place as well as packing and disposal of tested samples.

Do this for GLP

- Keep the things at its location after use.
- Store heavy things at bottom & if possible on Trollies.
- Give name of location to everything.
- Follow "Everything has the place & Everything at its place" principle.
- Prepare location list & display it.
- Put ladders for things stored on top.
- Identify everything with its name/ purpose.
- Follow "FIFO" to prevent old accumulation for laboratory chemicals.

Benefits of good laboratory practices.

- It will give better image of company as a Quality producer in Global market.
- Provide hot tips on analysis of data as well as measure uncertainty and perfect record keeping.
- Provide guideline for doing testing and measurement in detail.
- Provide guidelines and better control for maintenance of instruments, environment control, preservation of test records etc

CONCLUSION

- **Gives better image of company as a Quality producer in Global market Provide hot tips on analysis of data as well as measure uncertainty and perfect record keeping & guideline for doing testing and measurement in detail.**
- **Finally GLP Provide guidelines and better control for maintenance of instruments, environment control, preservation of test records etc.**

References

- Good Laboratory Practice. By European Chemical Industry Ecology and Toxicology Centre (ECETOC), MonographNo. 1,Brussels October 1979.
- Good Laboratory Practice. by G.E. Paget, MTP Press Limited, Lancaster 1979.


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