INTRODUCTION

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected consists with the principles that have their origin in the declaration of Helsinki (ICH GCP guideline

HISTORY

Good Laboratory Practice (GLP) was first introduced in New Zealand and Denmark in 1972. In the early 1970s FDA became aware of cases of poor laboratory practice all over the United States. One of the laboratory that went under such investigation was Industrial Bio Test. It was run by Procter and Gamble. It was discovered that mice that they have used to test for cosmetics such as lotion and deodorants had developed cancer and died. The laboratory threw the mice and covered the results.

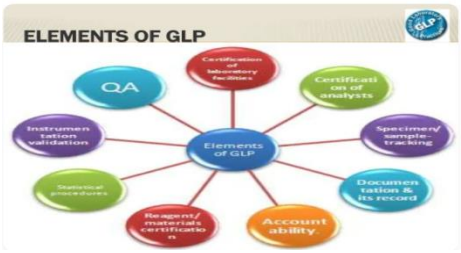
DEFINITION

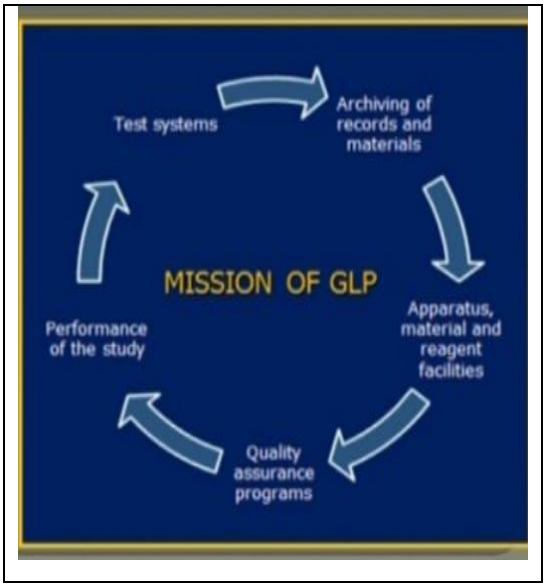
Good Laboratory Practice (GLP) embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived.

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.

- Pramotes international acceptance of tests.





Mission of GLP

Test systems.

- Archieving 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 Standard Operating Procedures (SOP).
- Written procedures for 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 personnel

PRINCIPLE

1.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. Properly designed SOPs will bring the following benefits to the laboratory

1.Test Facility Organization and Search

*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.