Good Laboratory Practice

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GLP ?

Good Laboratory Practice (GLP)

Is the managerial concept of quality system concerned with the organizational process & the conditions under which

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pre-clinical and environmental studies are

↓

Planned

↓

Performed

↓

Monitored

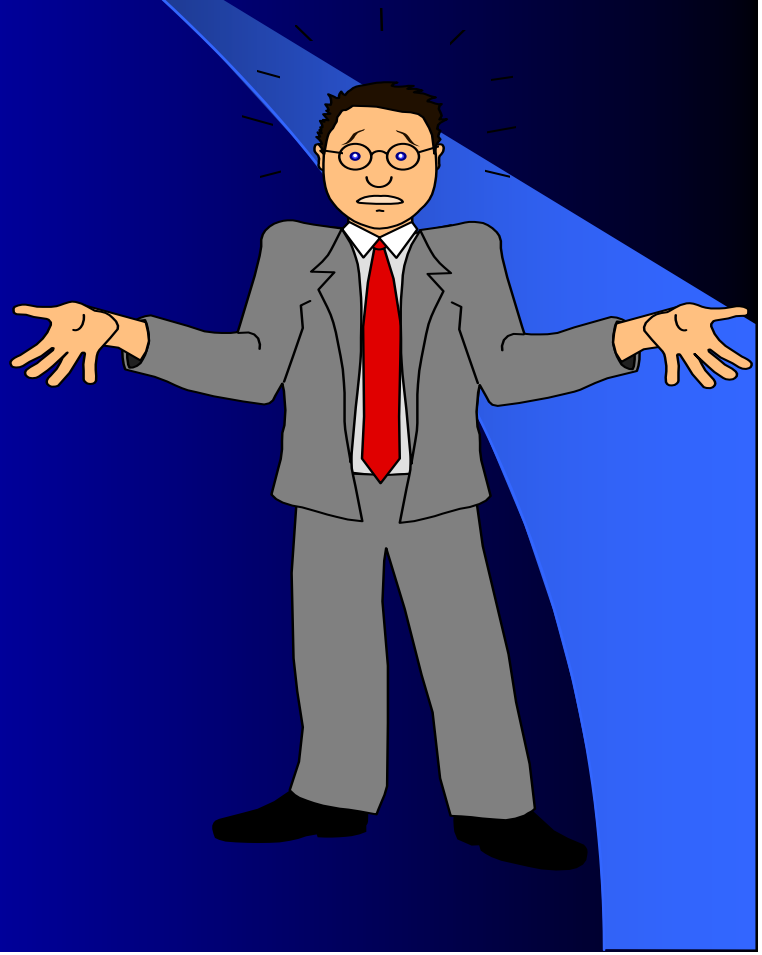
↓

Recorded

↙ ↘

Archived Reported

Why GLP Now?



Data Quality

Has now acquired international dimension

If test data from the lab/org/country can be relied upon

- **A- A**void duplicative testing
- **B- B**reak technical barriers
- **C- C**ost containment

Protection of human beings and environment

Cost of Quality ?

Cost of Lack of Quality ?

Studies to which GLP regulations apply

* Study of products regulated by the drug regulatory bodies

- ✔ Pharmaceutical products
- ✔ Pesticide products
- ✔ Veterinary drugs
- ✔ Food and color additives

*** In vivo and in vitro studies**

* Data reports submitted to regulatory bodies for
  IND(Investigational New Drug)
  NDA (New Drug Application)

Studies to which GLP regulations apply

* Animal studies

* **ADME studies**
* **Acute, subchronic and chronic studies**
* **Carcinogenicity studies**
* **Reproductive studies**
* **Mutagenicity tests**
* **Phototoxicity, ototoxicity,**
* **Eye irritation, dermal irritation**

Studies where the GLP regulations are not mandatory but advisable

- Basic Research
- Developing new methodologies
- Dose range finding studies
- Stability studies

Key activities to implement GLP

1.Preparation and approval of

* Standard operating procedures (SOPs)
* Standard test procedures (STPs)
* Specifications of test and materials

2. Control of documents

* Review
* Distribution
* Preservation

Key activities to implement GLP…..

3. Training of personnel about SOPs & STPs
   - **Analysts**
   - **Pharmacologists and Physiologists**
   - **Microbiologist**
   - **Technicians etc.**

4. Post training evaluation

5. Implementation of SOPs, STPs & Safety precautions

Key activities to implement GLP…..

6. Up keeping of laboratory with required facilities

- **Chemical and instrument laboratory**
- **Microbiological laboratory**
- **Pharmacology and Physiology Laboratory**
- **Clinical laboratory**
- **Animal houses**

7. Standardization

Key activities to implement GLP…..

8. Adequate recording of raw/final data

9. Presentation of the results as per predefined format

10. Rechecking of the data by a second person equally qualified and competent

11. Validation of equipment

* Analytical instruments
* Automated instruments
* Incubation and sterilization equipment.


Organization and personnel
Test and
Reference items
Quality assurance
unit
GLP
Test
system
Facilities
SOPs and performance
of the study
Records and
reports
Apparatus, materials
and reagents

Organization and Personnel

Test facility management's responsibilities

- To ensure

  * Sufficient number of qualified personnel
  * Appropriate facilities
  * Equipments and materials

  for timely & proper conduct of study

  * Maintenance of personnel record of qualifications
    Training & experience
    Job description

Organization and Personnel

Test facility management's responsibilities to ensure....

* Proper training of personnel to assigned functions

* To establish and follow SOP

* Quality assurance program with designated personnel

Organization and Personnel…..

Study director's (SD) responsibilities

- Approval of protocols (SOPs, STPs) & the study plan
- Approval of any revised protocol
- Ensures the follow up of SOPs, STPs
- Documentation of the raw data/observations and unanticipated responses
- Archiving Raw data, and Final report.

Principle Investigator's (PI) responsibilities

- Ensures the study is conducted in accordance with GLP

Study personnel's responsibilities

- Recording of all raw data in compliance with the principles of GLP
- Deviations from the instructions to be reported the PI or SD
- Takes health precautions and personal safety

Quality Assurance Unit

Responsible for monitoring in compliance with GLP principles

- Individual should not be involved in the conduct of the study
- Maintains copies of protocols & SOPs
- Inspects each laboratories and man at work
- Determines that there is no deviations from approved protocol
- Reviews study report
- Prepares the statement

Validation of Analysts

* Variation due to degree of skill, knowledge & analytical mind

* Necessary to validate the analysis in terms of precision & accuracy

* Each sample analyzed by 5 analysts, 5 times

Acceptance Criteria

- Within ±2% of expected value of known sample
- Variation should not be more than ±1 % by different analysts
- Minimum recovery should not be <99%

Personnel Safety

* Wear protective gloves, safety shoes,aprons goggles and proper clothing

* Glassware should not be used for drinking purpose

* Chemicals should not be tasted

* Never pipette using mouth

Animal Facilities

Sufficient number of animal rooms or area

* Separation of species
* Isolation of individual projects
* Quarantine of animals
* Routine or specialized housing of animals
* Separate areas for the diagnosis, treatment and control of laboratory disease

Care and use of laboratory animals

1. Institutional Animal Ethics Committee

2. Investigators responsibility

- **Facilities for handling test and reference items**

Separate rooms/ areas for receipt & storage to preserve

identity
concentration
stability

- **Archive facilities**

- **Waste Disposal**

Apparatus, Materials & Reagents

*** Validated computerized systems used for**

* Generation, storage and retrieval of data

*** Inspected, cleaned, maintained and calibrated according to SOPs**

*** Chemicals, reagents, solutions**

* Labeled to indicate identity, expiry date, storage instructions, source, preparation date and stability

Test and Reference Items

“Receipt, handling, sampling and storage”

* Records for characterization, date of receipt, expiry date, quantities received

* Handling, sampling and storage procedures should be identified to maintain homogeneity and stability

* Storage containers should carry identification information, expiry date etc

SOP

1. Approved by study director and principal investigator

2. SOPs should be available wherever applicable e.g.,

* Test and reference items
* Apparatus, materials and reagents
* Record keeping, reporting, storage and retrieval
* Test system
* Quality assurance procedure

SOP

Components

* Date of approval of protocol
* Descriptive title
* Name and address of the testing facility
* Experimental design and procedure
* Dosage levels
* Type and frequency of test, analysis and measurement
* Record of results
* Number, body weight range, sex, source of supply, species, strains and age of the test animals
* Statistical methods

Performance of the study

Study plan

* Contents of the study plan

  Identification of the study, the test and reference item
  Information concerning the sponsor and the test facility
  Test methods
  Records

* Conduct of the study

  Unique identification
  According to the study plan
  Direct recording of the data

Records and reports

Should include :

* Name and address of laboratories

* Objectives and procedure of protocols

* The test and control article identified by name, chemical, abstract number or code number, strength and purity

* Description of the test system

Records and reports……

* The name of head of laboratory / study director

* The description of transformation, calculation, summary and analysis of the data

* The sign of individual with date

* Minimum retention period is 2 – 5 years

Significance of Signature

“Accepting the responsibility”

How Do I Know It Works ?

How Do I Know the Data is Valid?

Neuropharmacology of GLP