Good Laboratory Practices

Module III
Pharmaceutical Quality Assurance
B. Pharm. VI Sem.

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The Fundamental Points of GLP

The GLP regulations set out the rules for good practice and help researchers perform their work in compliance with their own pre-established plans and standardized procedures.

The regulations are not concerned with the scientific or technical content of the research programmes. Nor do they aim to evaluate the scientific value of the studies.

All GLP texts, irrespective of their origin, stress the importance on the following points five points:

1. Resources: organization, personnel, facilities and equipment
2. Characterization: test items and test systems
3. Rules: study plans (or protocols) and written procedures
4. Results: raw data, final report and archives
5. Quality Assurance

Good Laboratory Practice

A. Good laboratory practice or GLP is a set of principles intended to assure the quality and integrity of non-clinical laboratory studies that are intended to support research or marketing permits for products regulated by government agencies.

B. The term GLP is most commonly associated with the pharmaceutical industry and the required non-clinical animal testing that must be performed prior to approval of new drug products.

C. However, GLP applies to many other non-pharmaceutical agents such as colour additives, food additives, food contamination limits, food packaging, and medical devices.

Good Laboratory Practice (GLP)

D. GLP is a formal regulation created by USFDA as these regulations were proposed on November 19, 1976 and designated as a new part of Chapter 21 of the Code of Federal Regulations (CFR) as 21 CFR Part 58 in 1979.

E. In 1981 an organization named OECD (Organization for Economic Cooperation and Development) produced GLP principles that are international standards.

F. GLP in OECD principles is defined as "a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported".

When and Why GLP was created?

A. GLP was first introduced in New Zealand and Denmark in 1972, and later in the US in 1978 in response to the Industrial Bio Test Labs scandal.

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

C. They discovered a lot fraudulent activities and a lot of poor lab practices.

D. Examples of some of these poor lab practices found were:
Equipment not been calibrated to standard form, therefore giving wrong measurements.
Incorrect/inaccurate accounts of the actual lab study.
Inadequate test systems.

Why GLP was created?

E. GLPs were initially invoked in a reaction to malpractices in the laboratories conducting safety experiments of medicines.

F. In the early 1970s, research laboratories in the USA found doing work in unethical ways, like:

Data generation without conduct of the study.
Falsification of the laboratory work.
Replacement of dead animals and fabrication of test results etc.

Advantages and Disadvantage of GLP

Advantages and Disadvantage of GLP

A. Assures that the data are a true reflection of results obtained from studies.
B. Preclinical safety and residue safety.
C. Generation of high quality and reliable test data.
D. Mutual acceptance of data
E. Increases public confidence.
F. Shortens the time-to-market for new products.

Disadvantages of GLP

A. More man power is required.
B. Expensive process.
C. Time consuming process.

Objectives of GLP

1) GLP makes sure that the data submitted are true reflection of the results obtained from the studies.

2) GLP makes sure that the data is traceable.

3) Promotes international acceptance of tests.

GLP Principles

How to practice GLP?
(The elements of GLP)

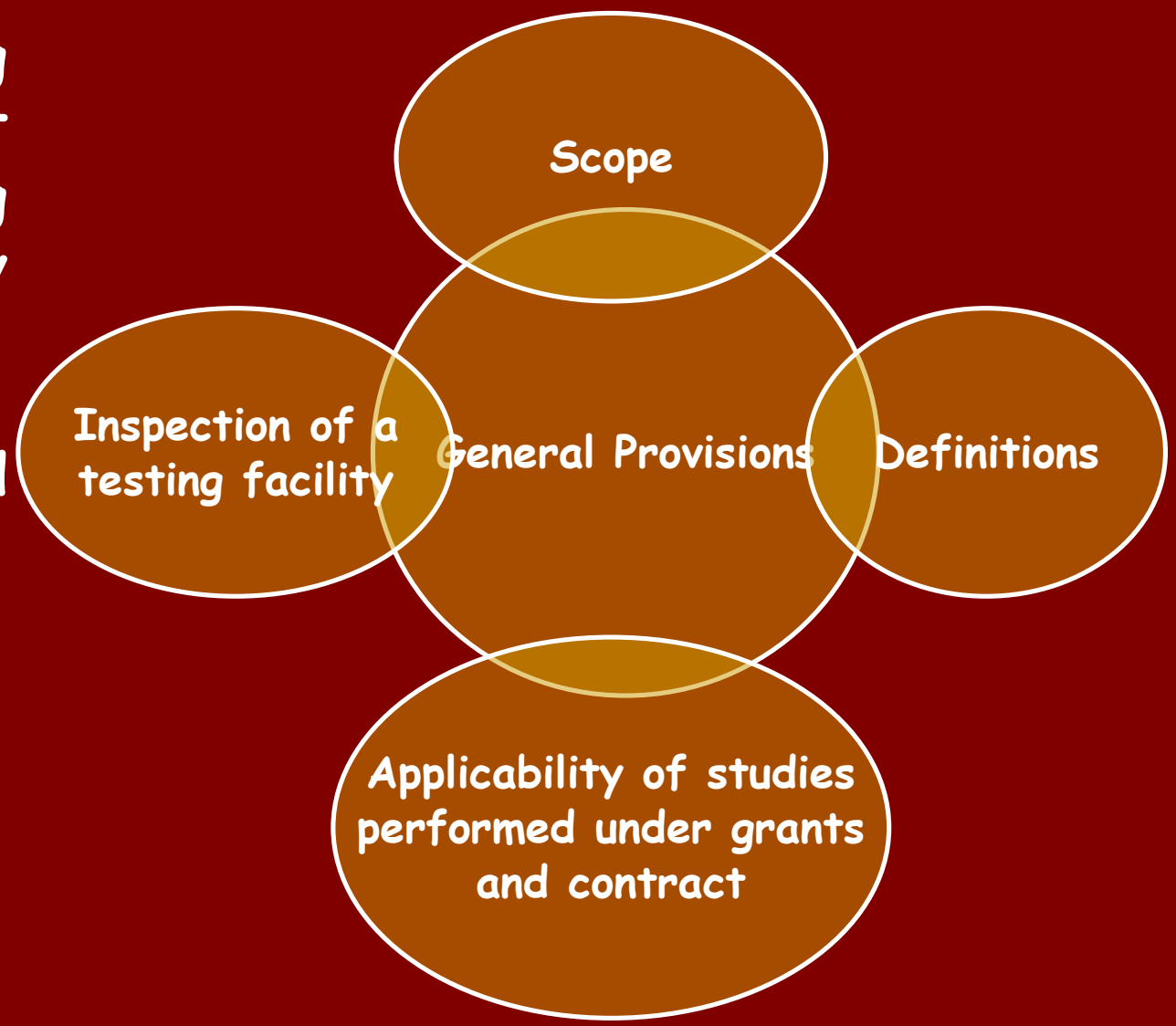
A. General provisions
B. Organization and Personnel
C. Facilities
D. Equipment
E. Testing facilities operation
F. Test and control articles
G. Protocol for and the conduct of the study
H. Records and Reports

A. General Provisions

A. It prescribes GLP for conducting non-clinical laboratory studies that support research and marketing permits of products regulated by FDA.

B. Applicability to studies performed under grants and contracts.

C. Inspection of the testing facility.



B. Organization and Personnel

Organization: Functions

A. Identification of quality activities. Dividing the jobs among the personnel. Define the authority and responsibility of each job and relationship of each job with other jobs. Coordinate the work of internal departments and outside agencies.

B. GLP regulations require that the structure of R&D organizations and the responsibilities of R&D personnel be clearly defined.

C. GLP also stresses that there should be sufficient staff to perform the tasks required. The qualifications and the training of staff must also be defined and documented.

Organization and Personnel

Each individual engaged in the conduct or supervision of non-clinical laboratory study shall have:

A. Education

B. Training: General training and Specific training

C. Experience or combination

D. Personal sanitation and health precautions.

Testing facility management

A. Sufficient number of qualified personnel, appropriate facilities, equipment and materials are available for conductance of the study.

B. Maintenance of records of qualifications, training and experience of personnel and their job description.

C. Appointment of study director.

D. Quality assurance program with designated personnel

Study Director

A Scientist or other professional of appropriate education, training and experience Responsibilities of the study director are:

A. Approval of protocol and study plans including amendments.
B. Technical conduct of the study.
C. Ensure that the QA personnel and study personnel are updated with the study plan and SOPs.
D. Interpretation, analysis, documentation and reporting of the results.
E. Also checks that experimental data is accurately recorded and verified.
F. Sign and date the final report for acceptance of data.

Quality Assurance Unit

A. An individual or a group designated by management to assure that the studies are in compliance with GLP principles.

B. Monitors the study to assure management that the facilities, equipment, personnel, methods, practices, records and controls are in conformance with the regulations.

C. Maintain the copies of master schedule sheet, protocol and SOPs.

D. Access to updated study plans and SOPs.

E. Documented verification of compliance of the study with GLP principles.

Quality Assurance Unit

F. Inspections to determine the compliance of the study with GLP principles and three type of inspections are:

Study based inspections.
Process based inspections.
Facility based inspections.

F. Determines any deviation from the approved protocol and report to SD, PI and management.

G. Prepare statements to be included in the final report containing dates and types of inspection.

C. Facilities

General facilities

Testing system facilities

A. Suitable size, construction and location.
B. Adequate degree of separation of different activities.
C. Laboratories should be well ventilated, free of dust, drafts and extreme temperatures.
D. Minimum 150 sq feet of floor space and minimum 6 linear feet of usable bench space should be provide for each analyst.

Archive facilities

Secure storage and retrieval of study plans, raw data,final report and the specimens to prevent untimely deterioration.

Waste disposal

Appropriate collection, storage and disposal facilities and decontamination procedures.

Animal care facilities

A. Located away form testing laboratories preferably in a separate building.

B. Contamination risk is reduced by "barrier" system ,as well as by providing "clean" and "dirty" corridors.

C. Separate areas for animals of different species and studies.

D. Separate areas for diagnosis, treatmentand control of laboratory animal diseases.

E. Lightening should be proper as light intensity and noise level is sufficient.

F. Maintain room temperature, humidity and air changes in animal quarters.

D. Equipment

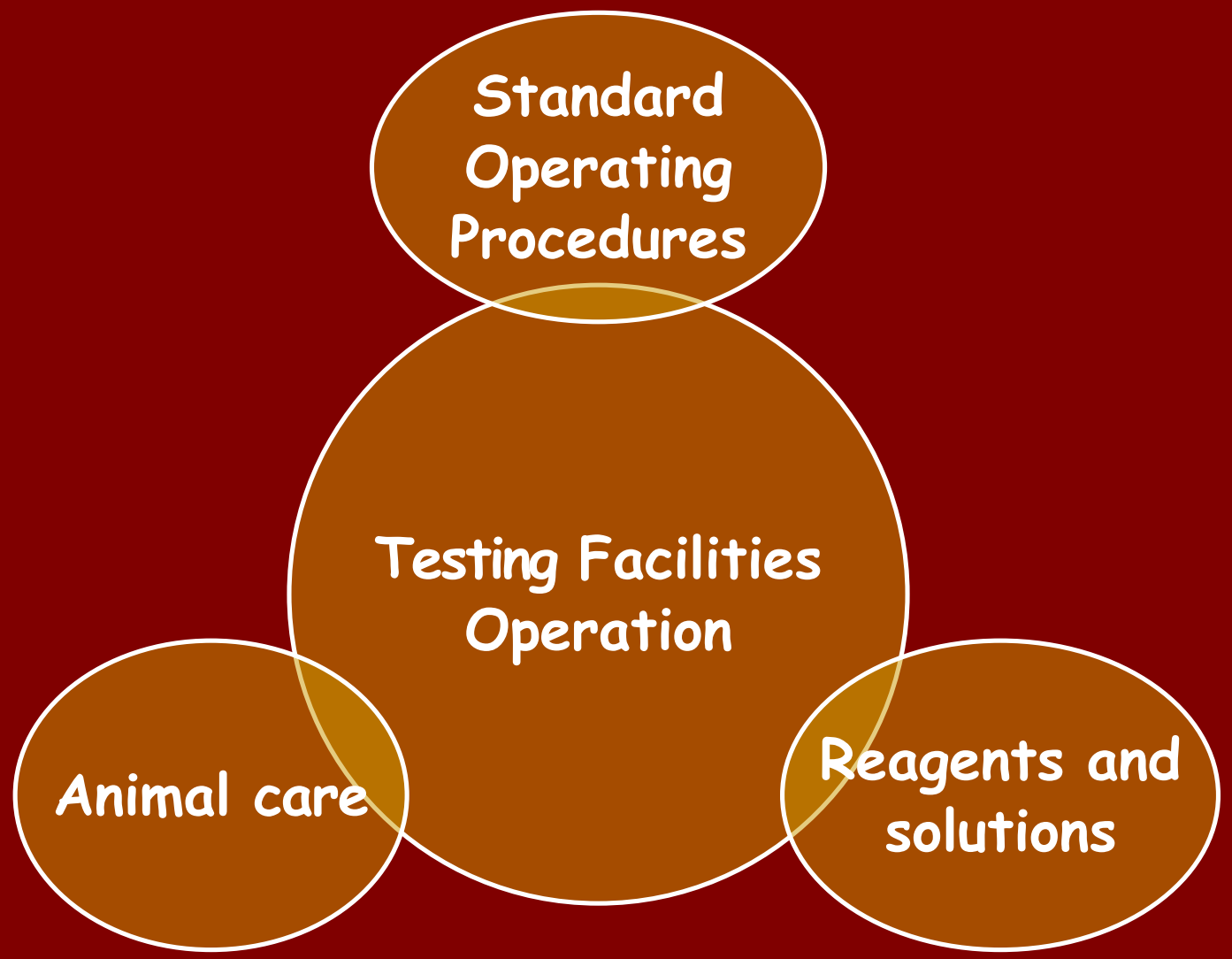
A. Appropriate design and adequate capacity.

B. Equipment shall be adequately inspected, cleaned and maintained.

C. Equipment used for generation, measurement or assessment of data shall be adequately tested, calibrated and standardized.

D. Log books for each equipment should be there.

E. Testing Facilities Operation



Standard Operating Procedures

A. Ensure quality and consistency of service to patients
B. Ensure good practice is achieved at all times
C. Utilise the expertise of the pharmacy team effectively
D. Provide role clarification for all members of the pharmacy team
E. provide staff training
F. Provide assurance of staff understanding of processes to be followed in the pharmacy
G. Provide an opportunity for pharmacists to define and assess their practice
H. Facilitate communication and team work.
I. Any deviation from SOP should be authorized by SD and documented in the raw data.
J. Routine inspection, cleaning, maintenance, testing and calibration.
K. Actions to be taken in response to routine failure.

Reagents and solutions

A. Reagents used in the operation should be specified in the SOPs.

B. Reagents and solutions should be labeled.

C. Deteriorated or outdated reagents and solutions should not be used.

D. Store under ambient temperature

Animal Care

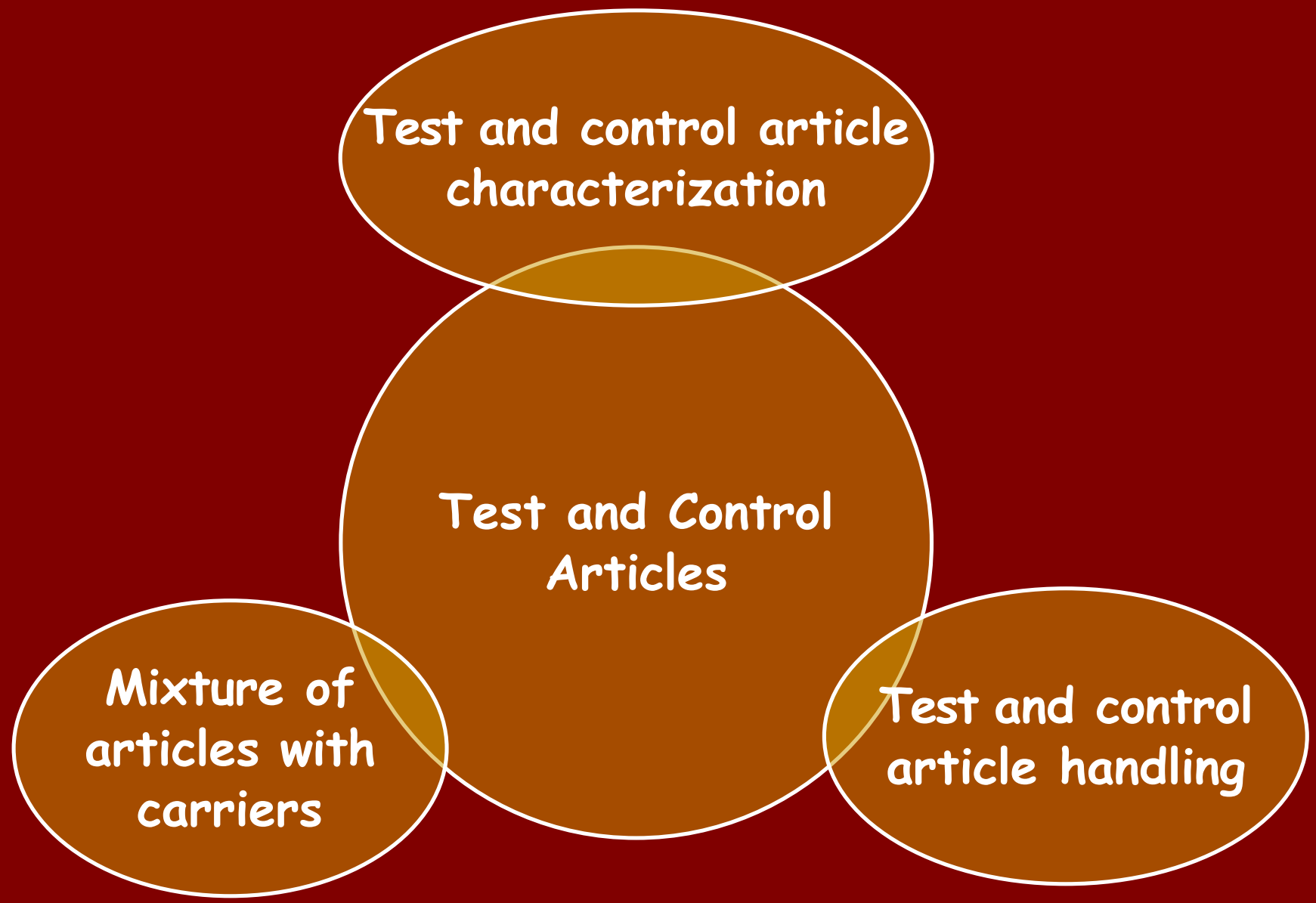
A. SOPs - for housing, feeding, handling and care of animals. Animals should be free of any disease and if, during the course of study, animals contract a disease then the diseased animals shall be isolated.

B. Diagnosis, authorization of treatment, description and date of treatment shall be documented and retained.

C. Animals of different species shall be housed in separated rooms when necessary.

D. The animal cages, racks and accessory equipment shall be cleaned and sanitized at appropriate intervals.

F. Test and Control Articles



Test and control article characterization

A. The identity, strength, purity and composition or other characteristics of test and control article shall be determined and documented for each batch.

B. Methods of synthesis, fabrication or derivation shall be documented by the sponsor or the testing facility.

C. Stability of each test and control article is determined.

D. Storage conditions are maintained and each storage container shall be labeled by name, chemical abstract number or batch number.

Test and control article handling

Handling procedures of test and control articles ensures:

A. Proper storage.

B. Minimum risk of contamination and deterioration or damage.

C. Receipt and distribution of each batch is documented.

D. Documentation include date and quantity of each batch distributed or returned.

Mixture of articles with carriers

A. Appropriate analytical methods shall be conducted for determination of uniformity of mixture and concentration of test or control article in mixture.

B. Stability of mixture is determined.

C. Expiration date should be written on the container.

G. Protocol for and conduct of a nonclinical laboratory study

Protocol for and conduct of a nonclinical laboratory study

- Protocol
- Conduct of a nonclinical study

Protocol

Contents of protocol
1. Identification
2. Title and statement of purpose
3. Identification of test(or control) items
4. Names and address of the sponsor, test facility and test site
5. Name of the study director and other personnel
6. Proposed dates
7. Justification for selection of the test system
8. Description of the test system
9. Experimental design

Conduct of a non-clinical laboratory study

1) Study shall be conducted in accordance with the protocol.

2) Information of the specimens should be present on the container to avoid error in recording and storage of data.

3) All the data generated shall be recorded directly, promptly and legibly by ink.

H. Records and Reports

Reporting of non-clinical laboratory results

Storage, retrieval and retention of records and data

Records and Reports

Reporting of non-clinical laboratory study results

Final report shall contain:

A. Information on sponsor and test facility.

B. Experimental starting and completion dates.

C. Objectives and procedures stated in protocol (including the changes in protocol).

D. Description of materials and test methods.

E. A Quality Assurance Program statement.

F. Storage (specimens, reference items, raw data and final report).

Storage, retrieval and retention of records and data

1) Archives should be there for orderly storage and expedient of all raw data, documentation, protocols, specimens and final reports.

2) Index of materials retained.

3) Master schedule sheet, copies of protocols and records of Quality Assurance inspections shall be maintained by QAU.

4) Wet specimens and samples of test and control articles shall be retained until the quality of preparation affords evaluation.

5) If any study plan is disposed of before expiry the reason to be justified and documented.

Conclusion

A. GLP is a FDA regulation which is accepted and approved as international standards by OECD to avoid fraud activities of the testing laboratories for pharmaceuticals to save human and environmental health.

B. Gives better image of company as a Quality producer in global market.

C. Also it establishes good relationship among the countries.

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Thanks for studying !!!!