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The Constituent College

SHRI B. M. PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPURA

A Report on Workshop

"Good Laboratory Practice"

Organized by

R & D Cell, BLDE (DU) in association with Centre for Advanced Medical Research (CAMR)

Date: 19/4/2024 **Venue: Dept. of Medical Education.**

Participants: Faculty, Postgraduates and Laboratory Technicians.

Resource Person: Dr. Imran Khan, M.V.Sc., Consultant, GReAT Consultancy Services, Mumbai.

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SHRI B. M. PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPURA

Research & Development Cell

In association with

Centre for Advanced Medical Research (CAMR)

RESOURCE PERSONS:

DR. M. IMRAN KHAN, M.V.SC.

Consultant,
GReAT Consultancy Services
(GLP, Regulatory, Animal Facility, Toxicology)

Director Operations,
Zyirn Research Consultancy Services

2024 GLP WORKSHOP

April 19th, 2024
10:00 a.m. - 05:00 p.m.

Medical Education Hall, 2nd Floor, Hospital Building

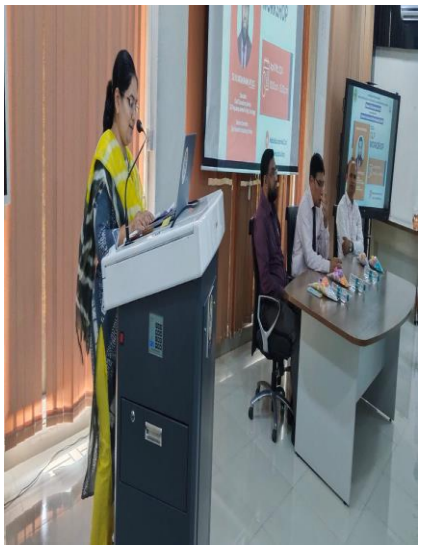
Objectives of the workshop:

- To ensure the safe and smooth running of a laboratory environment
- To understand the the GLPs direct several conditions under which studies are initiated, planned, performed, monitored, recorded, and reported.
- To improving the conceptual knowledge of the participant for Good Laboratory Practice and resolving any dilemmas that a working.

Content covered:

Sessions	Timings	Content covered
9.00am to 10.00am Inauguration of the workshop		
I	**10.00am to 11.00 am**	Introduction to General Principles of GLP covering the ten primary elements of GLP.
11.00am to 11.15 am TEA BREAK		
II	**11.15 am to 1.15pm**	• Responsibilities of Test Facility Management • Roles and Responsibilities of Study Director and Study Personnel
1.15pm to 1.45pm LUNCH BREAK		
III	**1.45pm to 3.45pm**	Quality Assurance Unit and GLP, including the responsibilities of QAU
IV	**4.00pm to 6.00pm**	• The Conduct and Performance of the Study under GLP. • GLP Principles: Primary Elements Apparatus, Materials and Reagent.

The workshop started with the welcoming and introducing to the speaker and the team by Dr. Nirmala G, Co-Ordinator, (R & A), BLDE (DU). Dr.Chandrika, Dy.Director, R & D Cell, BLDE (DU) introduced Resource person for the workshop. Dr.M.B.Patil, Dean Faculty of Medicine, SBMPMC & Dr. Akram A.Naikwadi, Professor & HoD, & Member Secretary, of IEC, BLDE (DU), addressed few words about the important of GLP & Accreditation of Laboratory. He also briefed about the purpose of GLP to avoid duplication of research to improve the protection of human health and environment; to facilitate international acceptance of test data; to prevent the creation of technical trade barriers.



Session-I:

Introduction to General Principles of GLP covering the ten primary elements of GLP.

GLP Regulations (OECD)

The GLP regulations aim to standardize procedures and practices in nonclinical studies to ensure accurate, reliable and traceable data. This background helps highlight the significance of adhering to GLP standards in research and regulatory contexts. GLP was first introduced in New Zealand and Denmark in 1972.

On the international level, the **OECD**, followed suit by assembling an expert group who formulated the first OECD Principles of GLP.

The Objectives were;

1. To avoid non-tariff barriers to trade in chemicals,

2. To promote mutual acceptance of non-clinical safety test data, and
3. To eliminate unnecessary duplication of experiments

The proposals were subsequently adopted by the OECD Council in 1981 through its "Decision Concerning the Mutual Acceptance of Data in the Assessment of Chemicals" **[C(81)30(Final)]**, in which they were included as Annex II. After some 15 years of successful application, the OECD Principles were revised by an international group of experts and were adopted by the OECD Council on **26th November 1997 [C(97)186/Final]** by a formal amendment of Annex II of the 1981 Council Decision.

The Principles of Good Laboratory Practice (GLP) are a managerial quality control system covering the organizational process and the conditions under which non-clinical health and environmental studies are planned, performed, monitored, recorded, reported and retained (or archived).

Good Laboratory Practice (GLP) standards were authored by the United States Food and Drug Administration (FDA) to ensure sound and repeatable non-clinical research. They set the standard by which studies are designed, conducted, and reported to assure reproducibility, accuracy, and consistency.

Importance of the good laboratory practice:

GLP prioritizes safety within the laboratory. Strict guidelines on animal welfare, chemical handling, and waste disposal minimize risks for researchers and the environment. Ignoring these can lead to accidents, environmental contamination, and ethical controversies, ultimately hindering scientific progress.

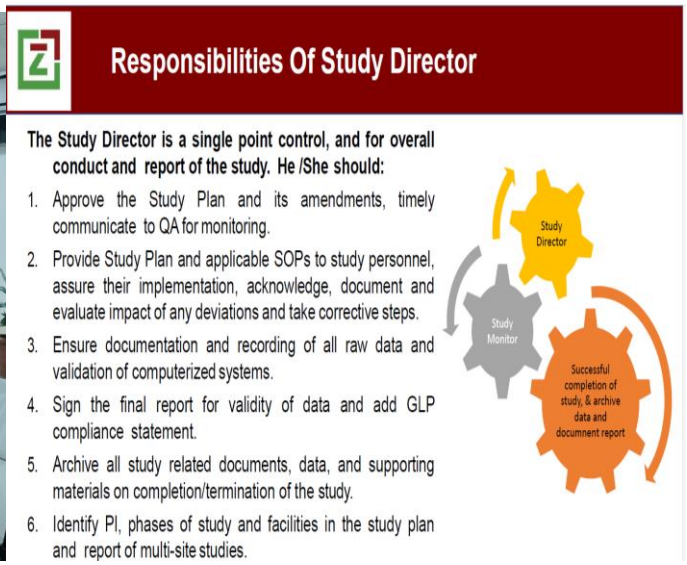
GLP Principles: Primary Elements: Good Laboratory Practice (GLP) is a Quality System concerned with the organizational processes and the conditions under which Non-clinical health and environmental safety studies are:

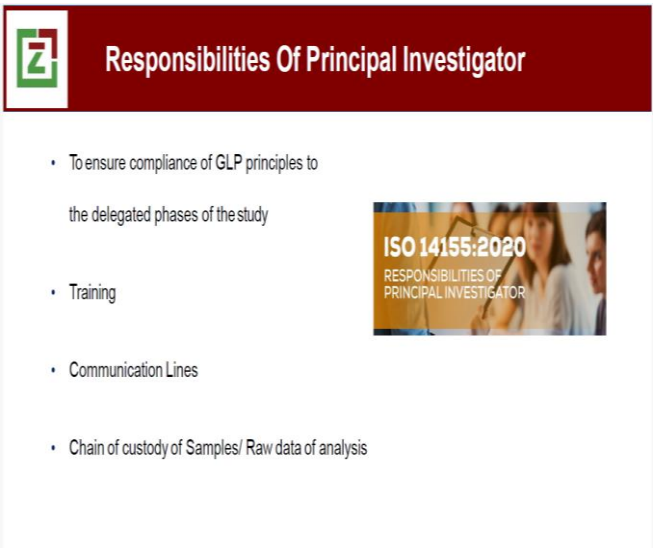
- Organization and Personnel.
- Facilities.
- Budget Operations (University and Grant Expenditures)
- Equipment, Reagents, and Materials (Physical, Chemical, and Biological)
- Reporting of Results.
- Archival.

Session-II:

Responsibilities of Test Facility Management

Roles and Responsibilities of Study Director and Study Personnel

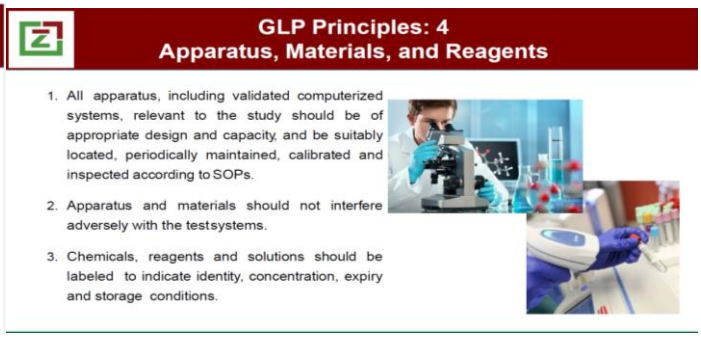




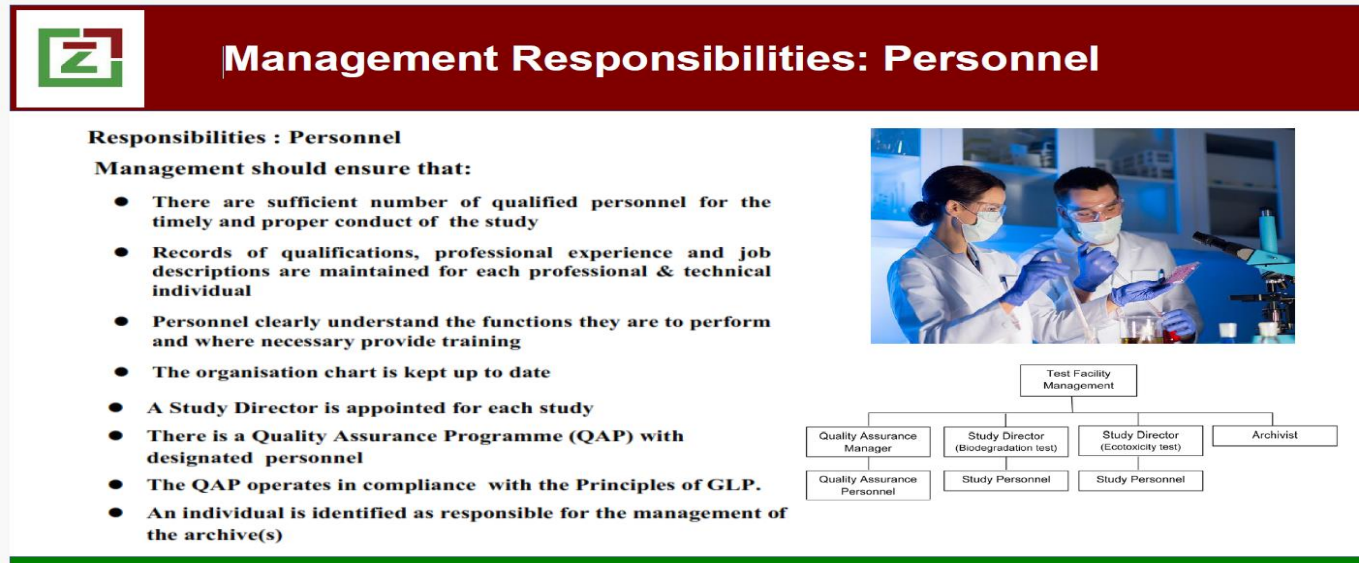
GLP principles: Purpose:

To ensure **safety**
2. To promote the development of **quality test data**

3. To provide basis for **mutual acceptance of data (MAD)** among countries
4. To **avoid duplicative testing**, thereby saving time and resources
5. To **avoid technical barriers to trade**
6. To improve the **protection of human health** and **environment**
7. The 3 R's : **Reliability, Repeatability** & **Reconstructability**



- General
- Personnel
- SOPs
- Study-based
- Facilities
- Equipment
- Computerized systems
- Multi-side studies



SESSION III:
Quality Assurance Unit and GLP, including the responsibilities of QAU

A quality assurance programme is defined as "a defined system, including personnel, which is independent of study conduct and is designed to assure test facility management of compliance with these Principles of Good Laboratory Practice". The responsibilities of the management of a test facility include ensuring "that there is

a Quality Assurance Programme with designated personnel and assure that the quality assurance responsibility is being performed in compliance with these Principles of Good Laboratory Practice".

The responsibilities of the Quality Assurance personnel include, but are not limited to, the following functions. They should:

- Maintain copies of all approved study plans and Standard Operating Procedures in use in the test facility and have access to an up-to-date copy of the master schedule.
- Verify that the study plan contains the information required for compliance with these Principles of Good Laboratory Practice. This verification should be documented.
- Conduct inspections to determine if all studies are conducted in compliance with these Principles of Good Laboratory Practice.
- Inspections should also determine that study plans and Standard Operating Procedures have been

made available to study personnel and are being followed

The QA statements:

- The Principles of GLP require that a signed quality assurance statement be included in the final report, which specifies types of inspections and their dates, including the phase(s) of study inspected, and the dates inspections results were reported to management and the Study Director and the Principal Investigator(s), if applicable.
- Procedures to ensure that this statement reflects QA's acceptance of the Study Director's GLP compliance statement and is relevant to the final study report as issued are the responsibility of management.
- The format of the QA statement will be specific to the nature of the report.
- It is required that the statement include full study identification and the dates and phases of relevant QA monitoring activities.

QA and Non-regulatory or Non-GLP Studies:

1. Compliance with GLP is a regulatory requirement for the acceptance of certain studies.
2. However, some test facilities conduct in the same area studies which are and which are not intended for submission to regulatory authorities.
3. If the non-regulatory studies are not conducted in accordance with standards comparable to GLP, this will usually have a negative impact on the GLP compliance of regulatory studies.
4. Lists of studies kept by QA should identify both regulatory and non-regulatory studies to allow a proper assessment of work load, availability of facilities and possible interferences.
5. QA should have access to an up-to-date copy of the master schedule to assist them in this task.
6. It is not acceptable to claim GLP compliance for a non-GLP study after it has started.
7. If a GLP-designated study is continued as a non-GLP study, this must be clearly documented

Session IV:
The Conduct and Performance of the Study under GLP & GLP Principles: Primary Elements Apparatus, Materials and Reagent.

Content of the Final Report:

The final report should include, but not be limited to, the following information:

1. Identification of the Study, the Test Item and Reference Item

a) A descriptive title;
b) Identification of the test item by code or name (IUPAC, CAS number, biological parameters, etc.);
c) Identification of the reference item by name;
d) Characterisation of the test item including purity, stability and homogeneity.

2. Information Concerning the Sponsor and the Test Facility
a) Name and address of the sponsor;
b) Name and address of any test facilities and test sites involved;
c) Name and address of the Study Director;
d) Name and address of the Principal Investigator(s) and the phase(s) of the study delegated, if applicable;
e) Name and address of scientists having contributed reports to the final report

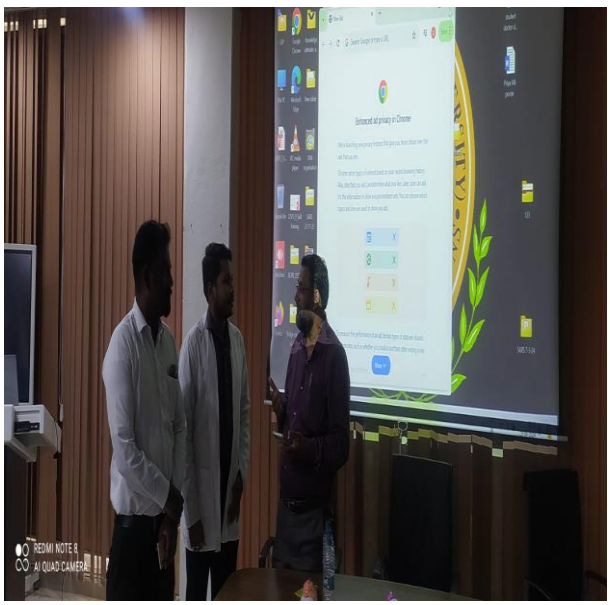
Storage and Retention of Records and Materials:
The following should be retained in the archives for the period specified by the appropriate authorities:

a) The study plan, raw data, samples of test and reference items, specimens, and the final report of each study;
b) Records of all inspections performed by the Quality Assurance Programme, as well as master schedules;
c) Records of qualifications, training, experience and job descriptions of personnel;
d) Records and reports of the maintenance and calibration of apparatus;
e) Validation documentation for computerised systems;
f) The historical file of all Standard Operating Procedures;
g) Environmental monitoring records.

As per the OECD GLP Guidance documents;
1. It is the responsibility of Test Facility Management to ensure that instruments are adequate and functioning according to their intended use.

2. Test Facility Management should also ensure that instruments are inspected and calibrated at prescribed intervals.
3. Calibration should be traceable to national or international standards of measurement as appropriate.
4. If reference standards are kept by the user they should be calibrated by a competent body at prescribed intervals.
5. Every lab should have **Instrument Master List** listing all the Equipment and Instruments with their details.
6. Every instrument used in GLP should be in the **Instrument Master List**.
7. Each instrument should have a **Unique Identification Number**.
8. Every Instrument should have **Instrument label with all the pertinent details** covered in the label.
9. Every instrument should have a **log book** where the usage of the instrument is recorded.
10. The Log book of the instrument should have

I. The Purchase of the instrument
II. Installation Qualification
III. Operational Qualification
IV. Performance Qualification
V. Calibration details (initial and at regular intervals)
VI. Preventive maintenance
VII. Breakdown maintenance
VIII. Annual Maintenance Contract



Conclusion:

Good Laboratory Practice (GLP) is an essential framework for ensuring the quality, integrity and reliability of non-clinical laboratory studies. By adhering to GLP principles and guidelines, laboratories can generate data that is credible, reproducible, and compliant with regulatory requirements.

Feedback:

1. Good Laboratory Practices are defined by the Organization for Economic Cooperation and Development (OECD) as a set of rules and criteria for quality systems concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored.
2. Five fundamental points of GLP
3. Safe Laboratory practices and procedures.
4. The benefit of Good Laboratory Practice.

Reported by:

Dr. Nirmala G.
Co-ordinator, R & A, BLDE (DU).

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Attendance Sheet:

Event: A workshop on "Good Laboratory Practice

Date: 19/4/2024

Venue: Medical Education Department.

Topic: Good Laboratory Practice.

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