
بسم الله الرحمن الرحيم

SUPERVISED CLINICAL LABS PRACTICES

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SUPERVISED CLINICAL LABS PRACTICES

TDR For research on diseases of poverty
UNICEF • UNDP • World Bank • WHO

SUPERVISED CLINICAL LABS PRACTICES

Course Contents

1. INTRODUCTION TO PRINCIPLES OF GOOD LAB PRACTICE

- Introduction
- The fundamental points of good lab practice
- The good lab practice principles

2. RESOURCES

- Management
- Personnel
- Facilities : buildings and equipment

3. CHARACTERIZATION

THE TEST ITEM

- o Date of dispatch
- o Number of containers or items, type of contents and quantity
- o identity of the test item
- o batch numbers
- o identity of the person responsible for the dispatch
- o Name of the transporter and type of carrier.

4. QUALITY ASSURANCE

- o Protocol (or study plan) review
- o Sop review
- o Planning (master schedule, inspection plan)
- o Audits and inspections
- o Quality assurance statement
- o Qa inspections of suppliers and contractors
- o Issuing and archiving of QA files and reports

OECD - GLP - TDR

OECD: Organization for Economic Cooperation and Development
GLP: Good Laboratory Practice
TDR : Tropical Diseases Research

The **World Health Organization** is a specialized agency of the United Nations that is concerned with international public health. It was established on 7 April 1948, and is headquartered in Geneva, Switzerland.

TDR, the Special Programme for Research and Training in Tropical Diseases, is a global programme of scientific collaboration that helps facilitate, support and influence efforts to combat diseases of poverty.

Good Laboratory Practice (GLP)

Good Laboratory Practice (GLP) deals with the **organization, process and conditions** under which laboratory studies are *planned, performed, monitored, recorded* and *reported.* GLP promote the quality and validity of tests.

GLP was first introduced in New Zealand and Denmark in 1972, and later in the US in 1978 in response to the Industrial BioTest Labs scandal. ... The principles of **GLP** aim to ensure and promote safety, consistency, high quality, and reliability of chemicals in the process of non-clinical and laboratory testing.

Good Manufacturing Practice (GMP)

Good Manufacturing Practice (GMP) is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use.

What is the difference between GMP and GLP?

- "**GMP**" is Good Manufacturing Practices, and "**GLP**" is Good Laboratory Practices. Both the **GMP** and the **GLP** are regulations that are governed by the Food and Drug Administration (FDA)
- When comparing the **GLP** and the **GMP**, the former one is considered to be less costly and less onerous.

Introduction to the OECD GLP Principles

Organization for Economic Cooperation and Development

- **Abbreviation:** OECD. *OCDE*
- **Formation:** 16 April 1948 as OEEC and reformed in September 1961 as OECD
- **Type:** Intergovernmental Organisation
- **Headquarters:** Paris, France
- **Membership:** 35 States
- **Official Languages:** English, French
- **General Secretary:** Jose Angel Gurria

Fundamentals of OECD GLP Principles

Introduction

and

Fundamentals of GLP

The History of GLP

- In the early 1970s, the FDA investigated a number of cases of poor practices in toxicological laboratories throughout the USA

- Result of this investigation in about 40 laboratories revealed many cases of poorly managed studies, insufficient training of personals, and some cases of deliberate fraud

WHY WAS GLP CREATED..??

FDA Investigation findings

- Poorly-trained Study Directors and study personals
- Poorly-Designed protocols
- Protocols not followed – procedures not conducted as prescribed
- Raw data badly collected – not correctly identified-without traceability-not verified or approved by responsible persons
- Lack of standardized procedures
- Poor animal husbandry

FDA Investigation findings

- Inadequate characterization of test items and test systems
- Inadequate resources
- Equipment not Properly calibrated or otherwise qualified
- Reports not sufficiently verified, inaccurate account of study or raw data
- Inadequate archives and retrieval processes

FDA Decision

- Introduces a new regulation to cover

  NON-CLINICAL SAFETY STUDIES

- Good Laboratory Practice regulations
  - Draft USA GLP in 1976
  - An enforceable USA regulation in 1979

GLP

promotes

Quality and Validity

of test data

GLP Principles

MAIN GOAL: To help scientists obtain results that are:

- Reliable
- Repeatable
- Auditable
- Recognized by scientist worldwide

GLP Principles

- GLP principles are a set of organized requirements
- The purpose is not to assess the intrinsic scientific value of a study

GLP Aim

To make the incidence of

False Negatives

more obvious

(False negative : Results demonstrate non-toxicity of a toxic substance)

GLP Aim

To make the incidence of

False Positive

more obvious

(False positive: Results demonstrate toxicity of a non-toxic substance)

GLP Aim

To promote mutual recognition of study data across international frontiers

GLP

- ***Limit waste*** of resources
- Ensure ***high quality*** of results
- Ensure ***comparability*** of results
- Promote ***mutual recognition*** of results

(Preamble to European Directive 87/18 EEC)

GLP

Managerial concept for the organization of studies

GLP

Define conditions under which studies are:

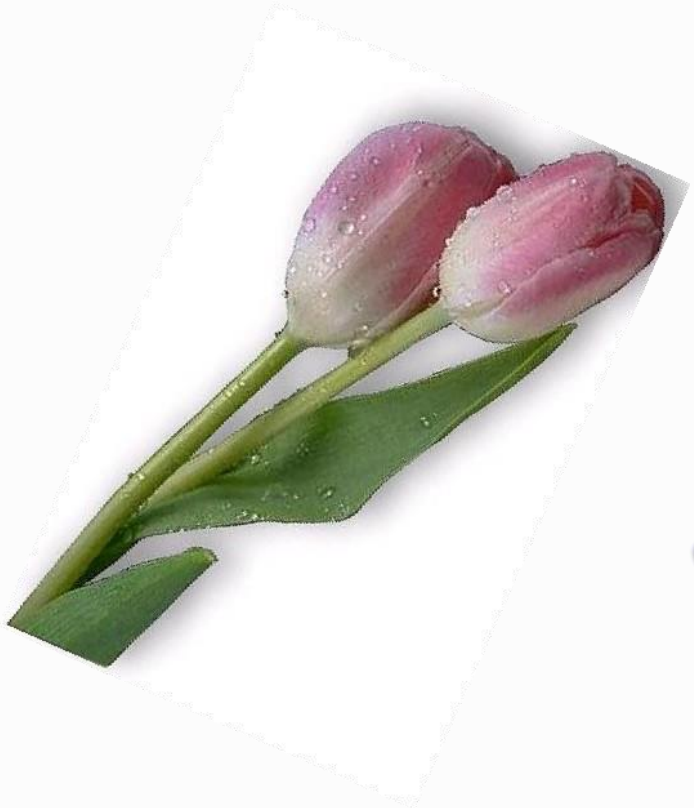
- Planned
- Performed
- Recorded
- Archived
- Monitored

Five Basic Points

1. **RESOURCES:** Management, Personal, Facilities Buildings & Equipment etc
2. **CHARACTERIZATION:**

   Test Article - Identification, Quality…….

   Test System – Identification, Health status…….
3. **RULES:** Protocols/Study Plans, Procedures
4. **RESULTS:** Raw data, Final Report, Archives
5. **QUALITY ASSURANCE:** Audit/Inspection – Training - Advice



Thank You...