IJNRD.ORG ISSN : 2456-4184
INTERNATIONAL JOURNAL OF NOVEL RESEARCH AND DEVELOPMENT (IJNRD) | IJNRD.ORG
An International Open Access, Peer-reviewed, Refereed Journal

Good Laboratory practice

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Abstract

The laboratory practice (GLP) shall play a significant role in assuring consistency, reliability, reproducibility and quality of laboratory tests in the current era of fast expanding technology and evidence based medicine. It offers laboratories a framework for how to organise, carry out, track, document and report their activities additionally it depicts the calibre of laboratory services provided at any evaluation and accreditation procedures. The quality assessment statement is not a statement of GLP compliance.

Laboratory practice found were.

1. Equipment has not been calibrated to standard form therefore giving wrong result.
2. Incorrect and inaccurate account of the actual laboratory studies.
3. Inadequate test system.

Keywords:

GLP , principle , ISO, OECD

Introduction

Good clinical practice (GCP) is a global ethical and scientific quality standard for Planning , carrying out, documenting, and reporting trials involving human subjects Observance of this standards offers public assurance of trial subjects rights, safety and wellbeing are safeguarded by the values that support them .It is originated from the the Helsinki Declaration (ICH GCP guidelines) .The goal of Good laboratory practice (GCP) is to advance the reliability and validity of test result. It is managerial idea that addresses the organisational process and circumstances that which laboratory tests are designed carried out that (OECD GLP recommendation) recorded and reported.

History

In 1972 the first two countries to adopt Good Laboratory Practice (GLP) were New Zealand and Denmark

.Early in the 1970s, the FDA learned about laboratory practices all around the countries. Industrial Laboratories was one of the labs that underwent such an inquiry. it was revealed that the mice used to test lotions and deodorant for cosmetic purpose Had died of cancer.

The organisation for Economic Cooperation and Development (OECD) assisted in spreading GLP to several national a few years later. Standards of laboratory safety should not be confused with GLP, data quality system. Gloves, safety glasses and attire for handling laboratory materials. in 1981 in OECD council formally recommended that members nation adopt GLP principle .they were created because, as stated in council Decision on mutual Acceptance of data in the assessment of chemicals, "data progress in testing in chemicals in nation that is OECD member according to OECD the OECD's Principles of Good Laboratory Practice and test guidelines must be adopted in other member nations for evaluation and other purposes pertaining to the protection of environment and man. The Environment Protection Agency (EPA) completes the OECD's work on chemical safety. Division of health and safety. Free-off is a publication from the Environmental Health and Safety Division.

Definition

The term "Good Laboratory Practice" (GLP) refers to a collection of guidelines that offer a framework for the planning, execution, monitoring, recording, reporting, and analysis of laboratory experiments Archived.

These studies are conducted to produce information that can be used to evaluate the risks and hazards to users, consumers, and other parties, including the environment. Agrochemicals, medicines (limited pre-clinical research), Cosmetics, food, contaminants, and food additives, GLP enables assurance for innovative foods, bio-seeds, detergents, etc. Regulatory agencies that the information provided is accurate A reflection of the findings from the research and can Therefore be trusted for determining risk and safety Assessments.2

Purpose of Good laboratory practice

GLP is necessary because mistakes happen to everyone. Even though the standards are not mandated, it is still a good idea to follow GLP principles. There are some basic guidelines, including: Do as you say (by following the specified standard operating procedures) and say what you do Be able to demonstrate it (with accurate record-keeping) (Jean Cobb, 2007). Good laboratory practices (GLP) are guidelines that enable the creation of The accuracy and reliability of test results used to assess the safety of chemicals and substances (Clasby, 2005) product.

Therefore, GLP tries to reduce the likelihood of errors or confusions by imposing stringent labeling regulations. By showing how the right item was applied to the relevant test in the specified amounts, the recorded information may be given. Systems.

In some circumstances, employers value GLP experience. If you have: Real-world experience working on a study using GLP principles, an employer would find it helpful. Effective planning is the key to success. With the ideal proposal in mind and a well-crafted Is it possible to obtain an evaluable result from a planned and described testing procedure Of a research. GLP heavily relies on designing and carrying out a pre-determined study.

Objective of Good laboratory practice

1. GLP ensures that the data submitted are an accurate representation of the findings of the study.
2. Additionally, GLP ensures that data may be tracked.
3. Encourages test acceptance worldwide.

Mission of Good laboratory practice

- System testing; materials and record archiving.
- Equipment, supplies, and reagent facilities.
- Quality control procedure.
- Execution of the study.
- Reporting of research findings.

- SOPs, or standard operating procedures.
- Organization of personnel and test facilities Standard Operational guidelines (SOP).
- Written protocols for the lab program.
- They specify how to carry out the stated protocol Activities.
- Most frequently presented as a chronological listing of events Steps.
- The purpose of these is to describe how the procedures are Expected to function.

Principle of Good laboratory practice

The fundamentals of proper laboratory conduct The Management, Quality Assurance, Study Director, and National Compliance Monitoring Authority are the four pillars of Good Laboratory Practice. All of them play crucial roles in the coordination of conducting and overseeing safety studies, and it should be remembered that they are all necessary for GLP to produce high-quality data. There are certain overlaps between GLP and other quality systems, such as certification schemes, despite the fact that GLP varies from other quality systems in some key areas that are crucial not only for the traceability of data but also particularly for the complete reconstructability of the study. (1905 Seiler).

The purpose of this chapter is to provide sufficient details about the GLP, including the test facility organization and personnel, facilities for the quality assurance program, test systems, archives, and waste disposal, equipment, materials, and reagents, physical, chemical, and biological test systems, receipt, handling, sampling, storage, and characterization of test and reference items, standard operating procedures, study execution, and study results reporting.

The chapter's issues can be summed up as follows:

1. Test facility management.
2. Quality assurance program
3. Meeting the requirements of the test facility
4. Equipment
5. Receipt , handling , sampling and storage
6. performance of study
7. Reporting of study result
8. storage and retention of the records and materials
9. Standard operating procedure

1. **Test facility administration:**

The term "test facility" refers to the individuals, locations, and operational components required for carrying out the non-clinical health and environmental safety investigation. The term "test facility" refers to a group of "test sites" that may be spread across one or more geographical locations where different phases or aspects of a single overall study are carried out. It also refers to the people who work

there and are responsible for carrying out these studies, in addition to the buildings, rooms, and other premise

2. Quality assurance program:

The technique, rules, and authority utilised to accept or reject all parts, drug product containers,

closures, in-process materials, and packaging material are known as quality control. The power to evaluate production records and the labelling of pharmaceutical items to ensure that no Although mistakes have happened, they have all been thoroughly investigated. The standard and dependability of Test results depend on the status and reliability of the test system that is employed in its manufacturing. This is intended to be the control of several technical aspects and specifications, including Essential to guarantee the system's integrity and the calibre of the data produced. In a research The most crucial elements for GLP compliance can be summed up as "suitability", "integrity" and "capacity" (OECD) 1998.

ISO Members	OECD Member
The same standard for all ISO	Different regulations in different countries
Designed for repetitive study	Designed for single studies
Description of quality system in quality manual.	Description of quality system in SOP's
General statement for responsibility of personnel .	Very specific responsibilities of personnel
No specific requirements for storage of records and reports.	Specific requirements for storage retention & archiving
No study plans required	Study plan required for each study
Written operating procedures without specific format .	SOPs with detailed requirement for format & content
Analysis methods must be verified through inter- laboratory test.	Validation through inter- laboratory tests not required
Documented complaint procedures.	In case of problems only, course of law
Storage of test samples and data until client accepts results.	Storage of test samples according to local regulatory requirements

3. Meeting the requirements of test facility :

The GLP principles only state that an archive should be "of suitable size, construction, and location to meet the specific requirements for its location." Requirements". As a result, each test facility is completely free to specify the to identify the location of its archives and the ideal locations for each type of content (Seiler, 2005) Storing.

4. Equipment:

Equipment used for the generation, storage, and recovery of data, as well as for managing environmental parameters important to the study, should include verified computerised systems.

Be properly situated, appropriate in both design and capacity. Records for equipment Should contain: the equipment's brand, model, and type for identification. Serial number, the day the apparatus arrived in the lab, and a copy of the makers' Functioning guidelines. A study's equipment should be regularly inspected, Sanitised, kept up with, and calibrated in accordance with SOPs. Records Of these pursuits ought to continue.

5. Receipt , handling, sampling and storage:

Laboratory tracking of samples varies. Receiving, handling, sampling, and storing must be done properly. Records describing the characteristics of the test item and reference item, the date of receipt, the date of expiration, and the quantities received and used in research should be kept.

To the extent possible, homogeneity and stability should be guaranteed, and contamination or mixup should be avoided, it is important to identify the handling, sampling, and storage processes (Seiler, 2005). They ought to keep a clear link between a set of analytical results and the samples from which they were gathered.

6. Performance of study:

Carefully monitoring the study's performance is necessary. From the start of the study until the final report's completion, all guidelines provided by the GLP must be adhered to.

Every study should have a written plan in place before it is started (Seiler, 2005). The information listed below ought to be included in the study plan: Identifying the research and the examination Item and reference item, details about the test facility and sponsor, dates, and test .Techniques, problems (if any), and documentation. (OECD, 1998).

The research director's dated signature approving the plan of work and the verification of GLP compliance are required. Any deviations from the study plan should be promptly acknowledged, explained, and dated by the principal or study director. Researchers and kept up to date with the unprocessed study data. Complete audit trails should always be retained by computerized systems in order to demonstrate all data modifications without hiding the original data. All data changes have to be able to be linked to the individuals who made them. Cause of Adjustments ought to be made.

7. Reporting of study result:

Every study produces raw data, which are the initial data acquired while carrying out a method. They are necessary for the reconstruction of research and help make the events of a study traceable. The experiment's outcomes, or raw data, are what The study's results will be predicated. It is possible to use some of the raw data directly, and A portion of them will receive statistical analysis. The findings and the explanations offered by The study report's scientist needs to be a genuine and accurate representation of the unprocessed data.

The following details ought to be included in the final report: A title that is descriptive; the test item's name or code; and a description that highlights its homogeneity, stability, and purity. Details about the sponsor and the testing facility Should indicate the following: the sponsor's name and location, any test sites and facilities involved, the Study director, the designated phase(s) of the study, the Principal Investigator(s), and Scientists who provided reports for the final report, the beginning of the experiment, and Dates of completion.

A statement from the Quality Assurance Program describing the different kinds of inspections that were conducted, when they happened, the phase(s) that were examined, and the dates on which management, the Study Director, and the Principal Investigator(s) should be notified of any inspection results. That Statement should also attest to the fact that the raw data is reflected in the final report. It ought to Include the Test Methods and Material Description. A results summary ought to be Provided. All the data and information needed for the study design; An overview of the findings, Involving computations and statistical significance assessments; An assessment and Analysis of the findings and, if relevant, the conclusions. It must allude to the locations Where the study design, specimens, raw data, test and reference item samples, and the final Reports are due.

8. Storage and retention of records and materials:

Records and materials should be prepared for storage and retention. The study plan, raw data, samples of test and reference items, specimens, and other materials shall be kept in the archives for the time period designated by the relevant authorities.

Every study's final report includes a record of every inspection carried out by the Quality Assurance Program, in addition to master schedules, credentials, experience, training, and Job descriptions for employees; documentation and reports about the upkeep and calibration of Apparatus; computerized system validation documentation. If there's not a required storage time, the last configuration of any research materials have to be recorded.

If specimens and test and reference item samples are discarded for any reason prior to the end of the required retention period, this should be explained and recorded. To make storage easier, any material kept in the archives should be indexed. and neatly retrieving it. It is necessary to offer secure storage for each and every sample, test resources as well as the generated reports.

9. Standard operating procedure:

They are intended to clarify the way in which the standard operating procedures (SOP) for routine inspection, cleaning, maintenance, testing, and calibration, the steps to be taken in the event that equipment fails, analytical techniques, and the definition of raw data, documentation, reporting, data storage, data blending, and data recovery.

Standard Operating test facility management must to have created and approved procedures that are Designed to guarantee the accuracy and consistency of the results produced by that testing facility.

- Regular testing, calibration, cleaning, and maintenance.
- What should be done in the event of equipment failure.
- Analytical procedures.
- Raw data definition.
- Record-keeping, reporting, data storage, blending, and retrieval .

Summary:

- When it comes to non-clinical lab investigations that support research or marketing clearances for FDA-regulated medicines, appropriate practices are outlined in GLP.
- General requirements, facilities, equipment, SOPs, reagents and solutions, test and control articles are all described by GLP.
- GLP provides research execution, standard data collection, a final report of results, study records, and data that has been meticulously archived to enable quick retrieval.
- Records kept for at least five years following data submitted to the FDA to support a marketing application.
- The fundamental components of good laboratory practices are order, cleanliness, hygiene, and common sense.
- In the upcoming year, laboratories will likely choose more based on quality and GLP regulations. This will pave the way for evidence-based laboratory results and a more reliable methodology.

Conclusion:

GLP is an FDA regulation that has been approved by the OECD and accepted as an international standard to prevent fraud in pesticides

pharmaceutical, food additive, and dye testing laboratories, protect human and environmental health, and foster good international trade and relationships between nations.

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