



A Review on Good Laboratory Practice's

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Abstract:

These are mostly focused on research laboratories with Good Practice (GLP) and can therefore help to control human and environmental health concerns and pave the way for a better understanding of the science. We are working to explore the use of GLP standards in other studies around this research, their recognition and potential financial rewards. Follow the rules. GLP can now be used in a wide range of research to meet the needs for objective testing, data quality and reproducible analysis. Given its importance, it is now used in management, business and schools worldwide. GLP is an effective strategy to improve the reliability and reproducibility of analytical data and thereby promote international recognition. Now is the time to articulate and implement a vision of GLP that goes beyond regulatory scrutiny. In today's era of rapid technological advancement and evidence-based therapeutics, Good Manufacturing Practices (GLP) will play a key role in recognition, consistency, reliability, manufacturing and quality control.

Keypoints:

GLP, principle, ISO, OECD

Introduction:

stands for Good Laboratory Practice and is a good practice that includes organizational procedures and condition GLP for planning, conducting, monitoring, reporting and storing non-laboratory research data. GLP ensures the quality and integrity of safety assessment data submitted to the government for the granting of research permits.

A. Audit conducted to obtain GLP certification: Pre-audit, final audit, continuity audit and (if required) actual audit

B. Other audits: GLP Compliance Monitoring (CMA) or OECD Mutual Recognition of Information (MAD) Member State Regulations (RA) or unpublished audits, audits/joint audits upon request of India

History:

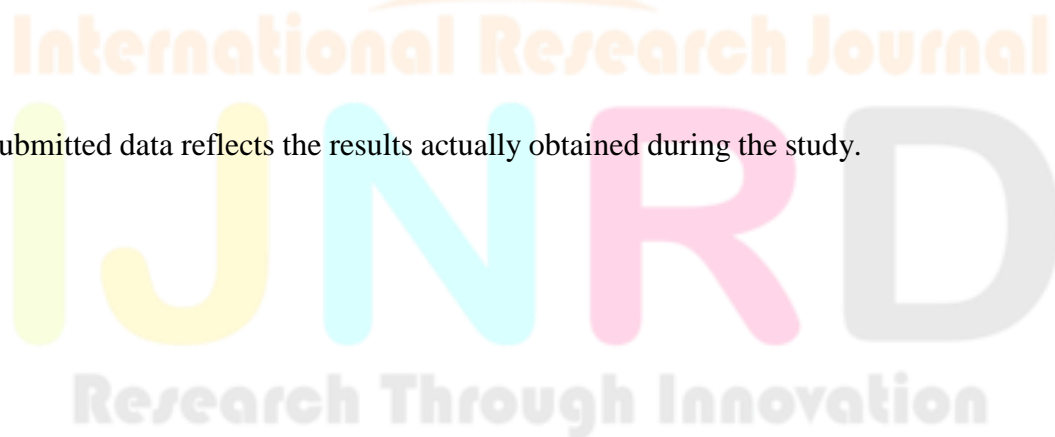
The first two countries to adopt Good Manufacturing Practices (GLP) were New Zealand and Denmark in 1972. In the early 1970s, the FDA worked on international testing. Laboratories were also the subjects of these studies. Mice used to test cosmetics and deodorants were reported to have died of cancer. A few years later, the Organisation for Economic Co-operation and Development (OECD) helped spread GLP to many countries. GLP (quality documentation) should not compromise laboratory safety standards. gloves, safety glasses and clothing for handling laboratory data. In 1981, the OECD Council recommended that member countries adopt GLP standards; data on drug screening in OECD member countries proceeds by country. When trading under OECD regulations, other member countries should adopt the OECD Quality Assessment Principles and Assessment Guidelines for assessment and other purposes related to the protection of the environment and humans. The Environmental Protection Agency (EPA) is completing the OECD's work on chemical safety. Health and Safety Division. Unpaid leave is an announcement from the Ministry of Health and Safety.

Definition:

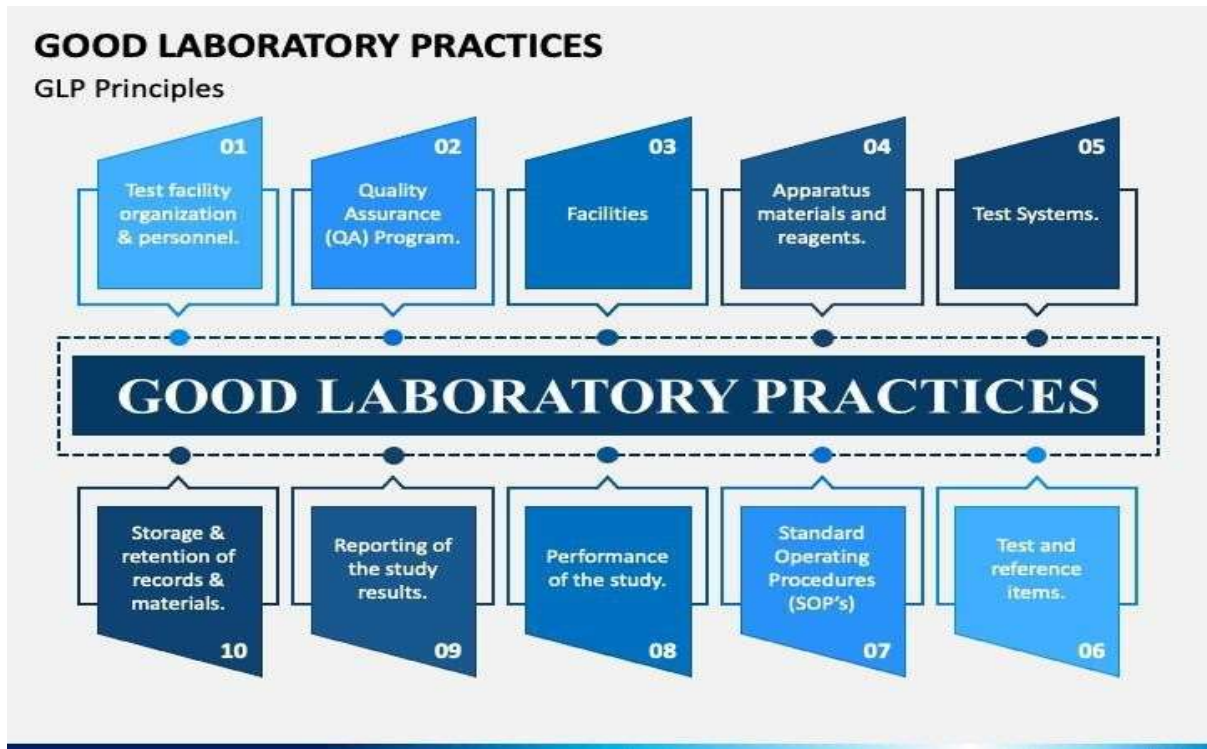
The term “Good Laboratory Practice” (GLP) refers to a collection of guidelines that offer a framework for the planning, execution, monitoring, recording, reporting, and analysis of laboratory experiments Archived.

Objective:

GLP ensures that submitted data reflects the results actually obtained during the study.



Principle of good laboratory practices:



Test facility administration:

The term "test facility" refers to the people, places, and equipment necessary to test the health and safety of the environment. The term "test facility" refers to a group of "test areas" that may be located at one or more locations, at different stages, or in parts of the entire route. This search is performed. It refers to buildings, rooms, and other spaces as well as the people who work there and are responsible for conducting these studies.

Quality assurance program:

ISO Members	OECD Members
The same standard for all ISO	Different regulations in different countries
Designed for repetitive studies	Designed for single studies
Description of Quality System in Quality Manual	Description of Quality System in SOPs

General statements for responsibilities of personnel	Very specific responsibilities of personnel
No specific requirements for storage of records and reports	Specific requirements for storage, retention and archiving
No study plans required (standardized methods should be used)	Study plan required for each study
Written operating procedures without specific format	SOPs with detailed requirements for format and content
Analysis methods must be verified through inter-laboratory test (Proficiency testing)	Validation through inter-laboratory tests not required
Documented complaints 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

Use any location to accept or reject a drug container. Closing, process equipment and packaging are called quality control. The law evaluates the design of the information and labels of pharmaceutical products to ensure that no errors occur and that they are properly examined.

The quality and reliability of the test results depend on the authority and reliability of the test used in production. This is designed to manage the various technical factors and specifications, together with those necessary to ensure the quality of the system and the data generated. The most important elements for compliance with GLP in a study can be assessed as "reasonable", "successful" and "adequate" (OECD) 1998.

Meet the requirements of the test site:

GLP requirements only state that materials must be of a “size, design and location that meets the requirements of the location where they reside.” Therefore, each laboratory is free to determine the location of its own data and the best location for each type of content stored (Seiler, 2005).

Equipment:

Equipment used to generate, store and retrieve data and to manage environmental measures important to the study should include computer systems that can be used.

Suitable location and design and appropriate capacity. Equipment information should include: Make, model and type of equipment for identification. Serial number, date the instrument arrived at the laboratory, and a copy of the manufacturer's operating instructions. Research equipment should be regularly inspected, disinfected, maintained, and measured according to SOPs. Information on these searches should continue.

Receiving, Processing, Sampling, and Storage:

Examination of different samples. Receiving, transporting, testing, and storing should be done properly. Records should be kept that describe the characteristics of test items and materials, the date received, the expiration date, and how much was received and used in the study.

It is important to take into account the standard of handling, testing and storage of the layers, as much as possible to ensure homogeneity and stability and to avoid contamination or mixing (Seiler, 2005). They should establish a clear link between the assessment process and the standards envisaged.

Performance of study:

Attention should be paid to academic performance. All instructions given by the GLP must be followed from the beginning of the study to the completion of the final report. All research should have a plan before it begins (Seiler, 2005). The following information should be included in the study plan: description of the study and investigation activities and activities, details about laboratories and sponsors, dates, times and test papers. (OECD, 1998). Any deviation from the course must be immediately approved, explained, and dated by the Chair or Study Director. Researchers must promptly update incomplete research papers. The computer must be able to complete the audit trail to see all updated data without obscuring the original data. All profile changes must be attributed to the person making the profile change. The reason for the change must be

Reporting of study result:

Priority should be given to training. All instructions given by the GLP must be followed from the beginning of the study to the completion of the final report. The research application should include the following information: description of the research and research activities and events, laboratory and sponsor details, date, time and test results. (OECD, 1998). Any deviation from the course must be immediately approved, explained and dated by the Director or Academic Director. Researchers need to update missing research data. The computer must be able to complete the search to find all new information without affecting old information. All profile changes must be attributed to the person who changed the profile. The reason for the change must be

Storage and Storage of Records and Materials:

Records and materials should be prepared for storage and preservation. Research plans, original documents, test and control samples, samples and other documents should be stored according to the periods determined by the relevant departments.

The final report of each study includes information on each analysis from a well-recognized source, including the employee's mastery time, identification information, experience, information on training and operations, and information on maintenance and repair of computer systems; information. If there is no storage period, the end of the course record must be recorded. All data stored in the database should be indexed to facilitate storage. and reclaim his wisdom. It is necessary to provide secure storage for all models, test resources, and production reports.

Standard operating procedures:

Standard Operating Procedures (SOPs) for routine inspection, cleaning, maintenance, testing and testing, steps to take when equipment is not operating, the review process and returns to raw data, data, media, archived data, hashed data and definition information. The facility manager must establish and approve procedures designed to ensure the accuracy and consistency of results produced by the facility. Failure to do so should be addressed.

Consider the following information when developing an SOP:

The type, quantity and amount of drugs used. Please note that the Safety Data Sheet (SDS) lists important information to identify hazards such as chemical, electrical, electronic, functional warnings and resulting appearance pains, Such as the special office of "particularly harmful products", Purification process.

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.

Reference:

<https://ijarsct.co.in/Paper8307.pdf>

https://www.researchgate.net/publication/221919330_GLP_Good_Laboratory_Practice

<https://ipo.rutgers.edu/rehs/sop>

https://www.researchgate.net/publication/221919330_GLP_Good_Laboratory_Practice

[https://www.oecd.org/en/topics/sub-issues/testing-of-chemicals/good-laboratory-practice-and-compliance-monitoring.html#:~:text=The%20Principles%20of%20Good%20Laboratory,and%20retained%20\(or%20archived\)](https://www.oecd.org/en/topics/sub-issues/testing-of-chemicals/good-laboratory-practice-and-compliance-monitoring.html#:~:text=The%20Principles%20of%20Good%20Laboratory,and%20retained%20(or%20archived))

<https://www.labpeople.com/good-laboratory-practices-to-use-in-2024/>

https://www.researchgate.net/publication/221919330_GLP_Good_Laboratory_Practice

6.ox Arlene (2011). GLP Regulations vs. ISO 17025 Requirements: How do they differ? In Accreditation and Quality

Assurance: Journal for Quality, Comparability, and Reliability in Chemical measurement. Volume 1/1996-

16/2011. DOI: 10.1007/s00769-011-0759-0. Available at:

<https://springerlink3.metapress.com/content/mr20ux0343141g4k/resource-secured>

[target=fulltext.pdf&sid=sbx4al45ojtfu3vvjzteu045&sh=www.springerlink.com](https://springerlink3.metapress.com/content/mr20ux0343141g4k/resource-secured?target=fulltext.pdf&sid=sbx4al45ojtfu3vvjzteu045&sh=www.springerlink.com)