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A systematic review on good laboratory practices

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Abstract
Good Laboratory Practice (GLP) represents a comprehensive quality assurance framework designed to govern the execution of non-clinical laboratory studies. It establishes standardized principles and procedures that uphold the accuracy, reliability, and credibility of data produced across various scientific sectors, including pharmaceuticals, chemicals, agrochemicals, and cosmetics. GLP highlights the critical role of properly implemented Standard Operating Procedures (SOPs), trained laboratory personnel, and well-defined organizational components in ensuring the quality of research outputs. By maintaining laboratories at high operational standards and enforcing appropriate training and safety measures, GLP enhances research efficiency and supports the evaluation of product safety and efficacy. Within this system, Quality Assurance (QA) functions as an independent entity that monitors and verifies adherence to GLP guidelines, approved study protocols, and established SOPs.

Keywords: Quality assurance, standard operating procedure, pharmaceuticals, good laboratory practices

Introduction
The fundamental aim of Good Laboratory Practice (GLP) is to ensure the production of dependable, high-quality scientific data by providing a structured set of principles that guide every stage of laboratory work from study planning and documentation to sample management. GLP applies not only to pharmaceutical research but also to studies involving animal feed additives, biological materials, electronic devices, and a wide range of non-pharmaceutical products. Through non-clinical safety evaluations, including physico-chemical assessments and acute to chronic toxicity studies, GLP establishes a management system that promotes uniformity, consistency, reliability, reproducibility, and overall data integrity in research supporting human and animal health. By enforcing clearly defined standards, GLP ensures that all findings are precise, repeatable, and verifiable, thereby strengthening the scientific credibility of laboratory research. The framework emerged as a response to rising concerns about the safety and effectiveness of market-bound products particularly pharmaceuticals following the discovery of fraudulent practices and poor laboratory operations. These issues included inadequate test systems, inaccurate or misleading study documentation, and the use of uncalibrated or poorly maintained equipment. Although the term "good laboratory practice" had been informally used worldwide for many years, the formal GLP system was first developed in the United States and subsequently shaped regulatory approaches across the globe [1, 2].

Good Laboratory Practice (GLP) encompasses a broad range of elements essential to proper laboratory functioning. These include ensuring that personnel are adequately trained and qualified, following established Standard Operating Procedures (SOPs), and maintaining and calibrating laboratory equipment on a regular basis. GLP also governs the correct handling, storage, and analysis of samples, the validation of analytical methods, the application of quality control processes, and the thorough documentation of all laboratory procedures and outcomes. GLP extends beyond simple regulatory requirements and is recognized as a cornerstone of sound scientific conduct. It promotes transparency, responsibility, and a commitment to high standards in research and development. By reinforcing the reproducibility of experimental findings and enabling reliable comparison of data across different laboratories, GLP assists in identifying and correcting potential inaccuracies or inconsistencies in studies.

To meet GLP expectations, laboratories must be equipped with suitable facilities, including sufficient workspace, proper ventilation, adequate lighting, and controlled environmental conditions such as temperature. Records of employee training and competency evaluations must be properly maintained. Moreover, GLP emphasizes the need for precise and comprehensive documentation of all laboratory-related activities. Raw data, observations, calculations, and final results must be recorded clearly and promptly, adhering to the ALCOA principles meaning they must be attributable, legible, contemporaneous, original, and accurate [3].

Fig 1: Introduction of GLP

History of GLP

Good Laboratory Practice (GLP) refers to a system of principles designed to ensure the quality and integrity of non-clinical laboratory studies conducted across pharmaceutical, chemical, and related industries. The concept of GLP originated in the 1970s as a response to increasing concerns about the accuracy, reliability, and overall credibility of data generated in research laboratories. [4]. During this period, several notable cases revealed poor research practices and deliberate data falsification, which led to unsafe products reaching the market. In response to these concerns, the U.S. Food and Drug Administration (FDA) became one of the first regulatory bodies to take action. In 1978, the FDA introduced the first formal GLP regulations, establishing mandatory requirements for laboratories conducting non-clinical studies submitted in support of research or marketing approvals. The primary objective of these regulations was to create a structured system that ensured laboratory-generated data adhered to sound scientific principles and enhanced its overall reliability and credibility [5].

Over the years, GLP has continued to evolve in response to advancements in science and changes in regulatory requirements. As laboratory technologies and research methods have progressed, updated GLP guidelines have expanded to include new testing approaches and study models, including those involving biotechnology and advanced materials. Today, GLP is recognized internationally, with many countries implementing similar systems to safeguard public health and environmental safety. The core principles of GLP remain essential in modern product development and evaluation, ensuring that all products undergo thorough and reliable assessment before reaching consumers. This continued commitment to quality and transparency strengthens public trust in scientific research and regulatory oversight [6, 7].

By the early 1980s, it became increasingly evident that a globally unified standard was needed. As international trade and collaborative research expanded, inconsistencies in national regulations created challenges for organizations operating across borders. A major milestone in achieving regulatory harmony came in 1997 when the Organization for Economic Cooperation and Development (OECD) introduced its own set of GLP guidelines. This initiative provided member countries with a consistent framework, enabling broader international acceptance of study results. GLP is built upon several fundamental components, including well-designed studies, strong quality assurance systems, qualified personnel, properly maintained equipment, and adherence to standardized operating procedures (SOPs). These elements ensure that laboratory activities are thoroughly documented and reproducible, ultimately enhancing the reliability of generated data. To maintain compliance with GLP requirements, laboratories must undergo routine evaluations and audits that verify adherence to established procedures and protocols [8-10].

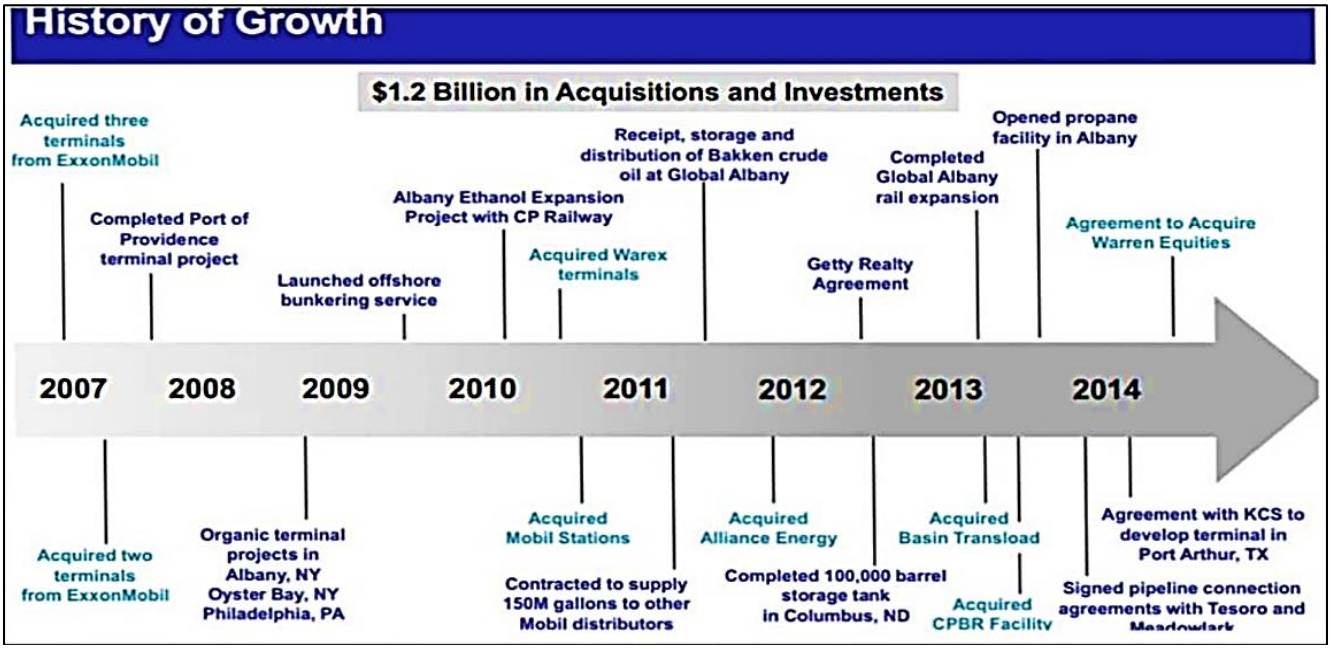

Fig 2: History of GLP

Scope: [11, 12]

- **Data Management:** GLP emphasizes reliable practices for recording, storing, and managing data. Data must remain traceable and protected, ensuring integrity throughout the study.
- **Quality assurance:** A dedicated quality assurance system is required to monitor ongoing studies, conduct audits, and verify that all laboratory operations conform to GLP principles.
- **Reporting and Documentation:** All study results must be documented thoroughly and presented in a clear and transparent manner, enabling accurate review, verification, and reconstruction of the work performed.
- **Study design and planning:** GLP requires that every study be carefully designed in advance, with a written protocol that clearly outlines the study objectives, methodologies to be used, and the anticipated outcomes.
- **Personnel and training:** All laboratory staff must possess the necessary qualifications and receive appropriate training for their assigned duties. Roles and responsibilities must be clearly defined to ensure accountability and efficiency.
- **Facilities and equipment:** Laboratories must maintain appropriate infrastructure and properly functioning equipment to support accurate and reproducible results. This includes routine calibration, maintenance, and validation of instrument.
- **Standard operating processes:** SOPs must be established for all critical laboratory activities to ensure uniformity, consistency, and regulatory compliance across all processes.

Principle

The principles of GLP provide a structured framework that ensures the reliability, integrity, and traceability of non-clinical laboratory studies. These core principles include:

- **Data Handling and record keeping:** All raw data, analyses, and study findings must be recorded accurately and comprehensively. Robust data management systems are essential to maintain data integrity and enable reliable retrieval.
- **Reporting of Study Results:** Study outcomes must be presented clearly, precisely, and transparently, meeting all regulatory expectations to ensure that the findings can be properly evaluated and verified.
- **Compliance:** Regular audits and periodic reviews are necessary to confirm ongoing adherence to GLP requirements, supporting continuous improvement within laboratory operations.
- **Documentation:** Every aspect of the study from raw data and correspondence to final reports must be fully documented. Records should be organized, complete, and easily accessible for inspection or reconstruction of the study [13, 14].
- **Quality Assurance:** An independent quality assurance unit is responsible for overseeing compliance with GLP procedures, verifying that studies are conducted according to established protocols and regulatory standards.
- **Facilities:** Laboratories must be appropriately designed, maintained, and equipped to support safe and reliable research activities. Proper environmental controls and adequate workspace are essential.
- **Equipment's:** All instruments used in the study must be properly calibrated, routinely serviced, and certified to ensure accuracy and reproducibility of results.
- **Test System Management:** Whether chemical, physical, or biological, all test systems must be correctly handled and maintained to ensure the validity of the study. Proper care reduces variability and enhances data reliability.
- **Study Protocol:** Each study must follow a well-defined protocol outlining objectives, methodology, and analytical procedures. Any revisions to the protocol must be documented promptly and clearly to maintain transparency and traceability [15-17].

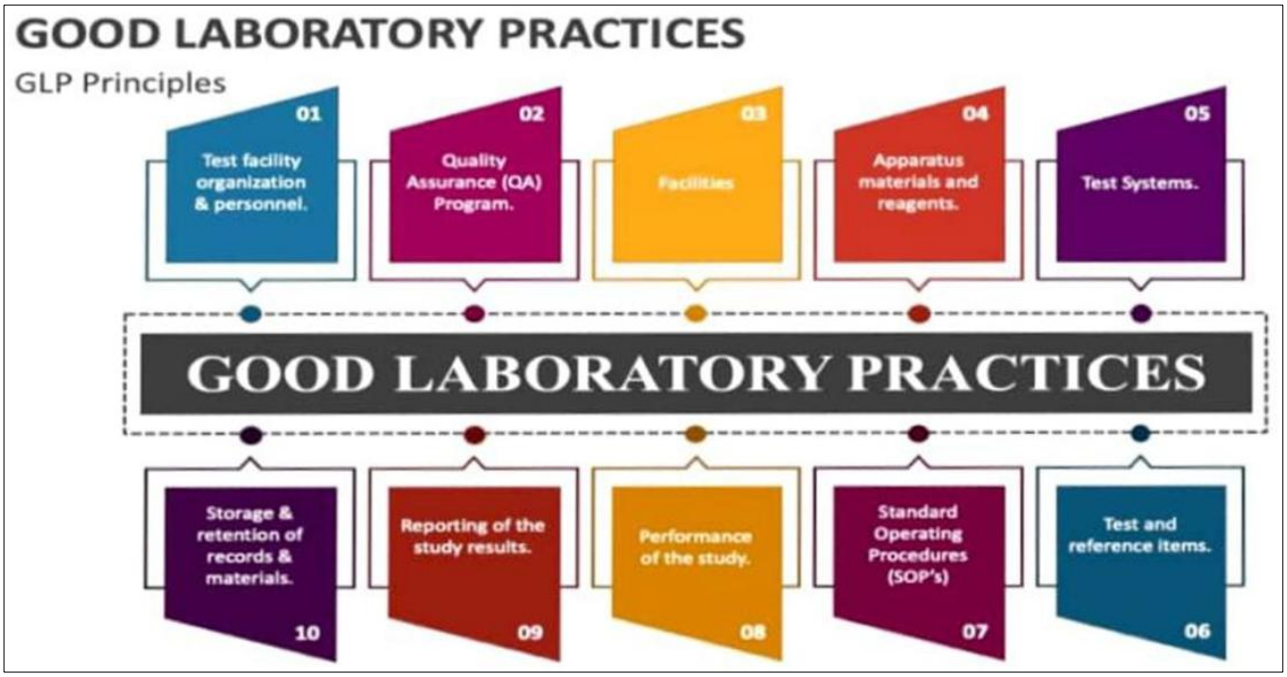

Fig 3: GLP Principal

Components of GLP [18]

1) Personnel

GLP requires that all work in a laboratory is carried out by qualified, trained, and properly supervised personnel. This ensures reliability, traceability, and integrity of the data produced.

2) Protocols.

GLP protocol is the written plan that describes how a non-clinical laboratory study must be carried out.

It ensures uniformity, accuracy, reliability, and reproducibility of the study.

3) Quality method in GLP includes:

- Quality Assurance Unit
- SOPs
- Inspections and audits
- Protocol review
- Raw data verification
- Report review
- Documentation and record keeping
- Equipment calibration and maintenance
- Personnel training
- Handling deviations and corrective actions

4) Control environment buildings

In GLP, the control environment refers to the foundational elements that ensure studies are planned, performed, monitored, recorded, reported, and archived in compliance with GLP principles.

It is the organizational and procedural framework that supports data integrity, traceability, and reproducibility.

5) Handling deviations and corrective actions

In Good Laboratory Practice (GLP), deviations and corrective actions are essential components of the quality system. The goal is to ensure data integrity, reliability, and traceability of all nonclinical study data.

GLP requires that any unplanned or unexpected departure from approved procedures, study plans, or regulatory expectations must be documented, justified, assessed, and controlled.

6) Process equipment's

In Good Laboratory Practice (GLP), process equipment includes any instrument, device, apparatus, or system used during the generation, measurement, handling, storage, or evaluation of study data.

GLP requires equipment to be suitable, calibrated, maintained, qualified, and properly documented to ensure data integrity and study reliability.

This includes equipment such as:

- Analytical instruments (HPLC, GC, LC-MS, spectrophotometers)
- Balances and pipettes
- Environmental chambers, incubators, freezers
- Animal facility equipment
- Sample preparation equipment
- Data acquisition systems
- Environmental monitoring systems

7) Water techniques

Water is a critical reagent in many laboratory studies, especially in toxicology, pharmacology, and analytical studies, so GLP emphasizes its quality and control.

8) Control systems

In GLP (Good Laboratory Practice), a control system refers to the set of mechanisms, procedures, and organizational structures that ensure that laboratory studies are planned, performed, monitored, recorded, and reported reliably and reproducibly. Essentially, it's the "checks and balances" of a GLP-compliant lab.

9) Equipment cleaning

In GLP (Good Laboratory Practice), equipment cleaning is a critical part of maintaining the integrity, reliability, and reproducibility of study data. Contaminated equipment can compromise experiments, introduce errors, or invalidate results. GLP specifies systematic cleaning, documentation, and verification procedures.

10) Experiment

In GLP (Good Laboratory Practice), equipment cleaning is a critical part of maintaining the integrity, reliability, and reproducibility of study data. Contaminated equipment can compromise experiments, introduce errors, or invalidate results. GLP specifies systematic cleaning, documentation, and verification procedures.

11) Release

In GLP (Good Laboratory Practice), equipment cleaning is a critical part of maintaining the integrity, reliability, and reproducibility of study data. Contaminated equipment can compromise experiments, introduce errors, or invalidate results. GLP specifies systematic cleaning, documentation, and verification procedures.

Release is the formal authorization to use, submit, or archive a material, equipment, or study report after confirming that it complies with GLP requirements, is free from contamination, and has passed all necessary quality checks.

12) Testing

In GLP (Good Laboratory Practice), testing is considered a core component of a study. It refers to the systematic evaluation of test substances, products, or materials using predefined procedures to generate reliable, reproducible, and regulatory-compliant data. Testing is central because all GLP studies aim to assess safety, efficacy, or properties of a test item.

13) In technique control

In GLP (Good Laboratory Practice), technique control refers to the systematic monitoring, standardization, and validation of laboratory techniques or methods used in studies to ensure accuracy, reproducibility, and compliance with regulatory requirements. It is essentially about controlling how experiments are performed so that results are reliable and traceable.

14) Stability testing and finished derivatives

Stability testing evaluates how the quality, safety, and efficacy of a drug or chemical derivative change over time

under the influence of environmental factors such as temperature, humidity, and light.
Finished derivatives are the final formulated products derived from the active pharmaceutical ingredient (API) or chemical, ready for use or sale.
These include tablets, capsules, creams, injections, or any chemically modified forms.
Stability Testing for Finished Derivatives under GLP:
Must follow GLP principles, ensuring reproducibility, traceability, and documentation.
Test samples from each batch to verify consistent stability.
Analyze critical parameters like content, purity, and dissolution for drug products.
Store under specified conditions and test at pre-defined time points.

15) Receipt
The act of accepting and documenting incoming test items, reference substances, raw materials, or finished products for laboratory use in a GLP study.

Purpose
- To ensure the identity, quality, and integrity of the received item.
- To maintain traceability from supplier → laboratory → study.
- To prevent use of unverified or damaged materials in studies.

16) Verification
In the context of GLP, verification refers to the process of confirming that a procedure, equipment, method, or data is accurate, reliable, and functioning as intended. It ensures the integrity and reproducibility of laboratory studies. Verification is a core part of quality assurance under GLP.

17) Quality
In GLP, quality is not just a vague concept it is a formalized system that ensures studies are conducted correctly, results are reliable, and regulatory standards are met. The main component responsible for quality is the Quality Assurance Unit (QAU).

18) Efficacy
Efficacy refers to the ability of a test article (drug, chemical, or product) to produce the intended effect under controlled experimental conditions. GLP does not determine efficacy itself, but it ensures that efficacy studies are conducted in a standardized, reproducible, and auditable way.

19) Safety
Safety refers to the evaluation of potential adverse effects of a chemical, drug, or test article on biological systems. GLP provides a framework to ensure that safety studies are conducted reliably, reproducibly, and in compliance with regulatory standards.
Safety studies are usually toxicology studies, conducted to support regulatory submissions before human or environmental exposure.

20) Revalidation
Revalidation is the process of reconfirming that equipment, instruments, analytical methods, or computer systems continue to meet their intended specifications and produce reliable results over time.

In other words
Even if something was validated before, you periodically check again to ensure it still works correctly.
Revalidation is essential in GLP because study results must always be reliable and reproducible, especially when instruments, methods, or systems are used over long periods.

21) Documentation
Documentation is one of the most important written proof of all activities which are regarding with GLP. The maintaining proper documentation is always necessary.

22) Document numeral
Document numeral in GLP", which usually refers to the numbering system for documents in a GLP-compliant laboratory. This is a critical part of GLP documentation because each document must be uniquely identifiable and traceable.

23) Tile
A GLP document is composed of several key components, and Title is one of the mandatory elements. It appears at the top of every document and provides:
- **Identification:** Clearly indicates the purpose and content of the document.
- **Traceability:** Helps QA and regulatory inspectors quickly locate the relevant document.
- **Clarity:** Distinguishes the document from other similar documents.

24) Issue number
The Issue Number in GLP is a key part of document control, ensuring that only the approved version of a document is in use.
It works together with the Document Number, Title, Revision Number, and Approval to maintain traceability, compliance, and reliability.
Proper use of Issue Numbers is critical for GLP audits and regulatory acceptance.

25) Modification date
In GLP, all records whether raw data, protocols, reports, or electronic entries must maintain integrity, traceability, and accountability. The modifications date (also called "date of modification" or "last updated date") is an essential part of this.

26) Review date
In GLP, a review date refers to the date when a document, procedure, or record is formally reviewed for accuracy, completeness, and compliance. This is different from a modification date (which tracks changes).

27) Audits
An audit in GLP is a systematic and independent examination of study processes, data, and records to ensure that they comply with GLP principles, regulatory requirements, and internal quality standards.

28) Internal audits

An internal audit in GLP is a systematic, independent, and documented process for reviewing and evaluating a laboratory's compliance with GLP principles.

Purpose: To ensure that non-clinical laboratory studies are conducted, recorded, and reported according to GLP standards.

Applications of good laboratory practices [19-21]

GLP ensures data integrity, reproducibility, traceability, and regulatory acceptance of laboratory studies. The application of good laboratory practices are as follows:

- **Pharmaceutical Research & Development:** Ensures accuracy and reliability of preclinical safety studies such as toxicity, teratogenicity, carcinogenicity, pharmacokinetics. Facilitates global acceptance of study data by regulatory agencies (FDA, EMA, CDSCO). Supports new drug approval by generating reproducible and auditable data.
- **Chemical, Agrochemical & Pesticide Testing:** Required for safety evaluation of pesticides, herbicides, fertilizers. Ensures environmental safety testing (ecotoxicology, biodegradation, bioaccumulation). It helps in risk assessment and regulatory submission to OECD, EPA etc.
- **Food & Cosmetics Safety Testing:** Ensures safety studies on preservatives, additives, cosmetic ingredients. Minimizes health hazards and ensures compliance with FSSAI, FDA, EU regulations. Supports labeling claims and safety dossiers.
- **In Biotechnology Laboratories:** Ensures quality in molecular biology, cell culture, vaccine development and bioassay labs. Maintains purity, strain identity, contamination control and validated methods.
- **Clinical and Medical Diagnostic Laboratories:** Ensures accuracy in analytical diagnostic techniques (HPLC, ELISA, PCR). Enables traceable test reports and reduces analytical errors. Improves laboratory workflow efficiency and sample integrity.
- **Environmental Monitoring & Toxicology Labs:** Used for water analysis, soil contamination studies, air quality monitoring. Provides reliability in Eco toxicity studies using test organisms (fish, algae, daphnia).
- **Academic & Research Institutions:** Promotes safe, organized, and controlled laboratory environments. Ensures high-quality results in research projects and dissertations. Prevents scientific misconduct and promotes ethical research.
- **Laboratory Management & Quality Assurance:** Ensures systematic documentation, SOP compliance and QA audits. Supports calibration, instrument maintenance and validation of methods.

Elements of GLP

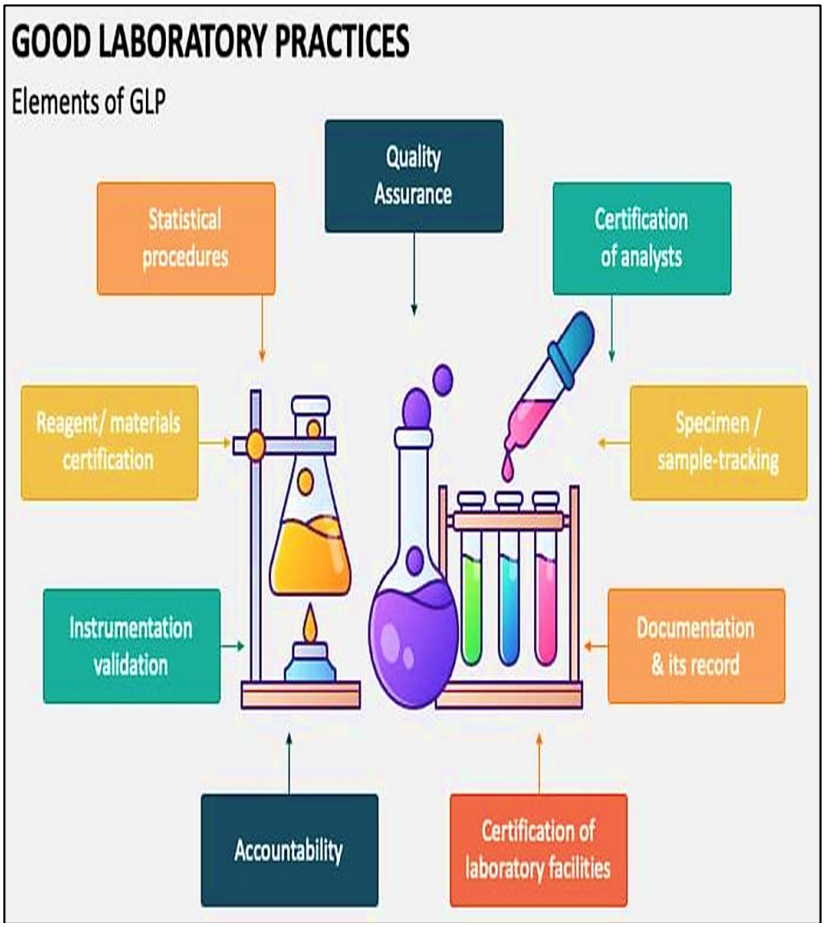

Fig 4: Elements of GLP

Standard Operating Procedures (Sop) [22]

- SOPs provide written instructions that outline how specific tasks and protocol-defined activities should be performed in the laboratory.
- They typically present the required actions in a step-by-step, chronological format to ensure consistency and clarity.

- SOPs describe the correct way each procedure should function, allowing personnel to follow standardized methods.
- They include guidelines for routine activities such as equipment inspection, cleaning, maintenance, testing, and calibration.
- SOPs also specify the steps to follow when equipment malfunctions or fails to operate properly.
- They outline validated analytical methods that must be used during laboratory work.
- SOPs clearly define what constitutes raw data and how it should be handled.
- They provide instructions for proper record keeping, reporting, data storage, sample mixing, and efficient retrieval of information.

Documentation

Documentation is one of the most critical pillars of Good Laboratory Practices (GLP). It ensures that all laboratory activities are recorded, traceable, auditable, accurate, reproducible, and legally acceptable. Proper documentation supports the reliability of non-clinical safety studies and is required by global regulatory agencies such as OECD, FDA, EMA, and CDSCO. Documentation in GLP is a critical element that ensures the reliability, integrity, and traceability of all scientific activities conducted within a non-clinical laboratory setting. It encompasses the systematic recording, retention, and management of all data, observations, procedures, approvals, and study-related information generated throughout the study life cycle. Proper documentation includes study plans, SOPs, instrument logs, calibration records, sample receiving logs, animal husbandry records, environmental monitoring data, analytical data, deviations, amendments, and final reports. Documentation also plays a crucial role in quality assurance, enabling auditors and inspectors to verify that studies are conducted according to established SOPs and regulatory guidelines. GLP places strong emphasis on the principle that any activity not documented is essentially regarded as not having occurred. For this reason, complete and well-organized documentation is essential to protect the scientific credibility of a study, support reproducibility, enable effective audits, and provide a legally sound record of all research activities. GLP also requires the creation, implementation, and regular updating of Standard Operating Procedures (SOPs) for all major laboratory functions. These SOPs outline clear, step-by-step instructions for processes such as sample handling, analytical techniques, equipment calibration, data entry, and reporting, ensuring consistency and allowing deviations to be easily detected and corrected. Before initiating any study, GLP mandates the preparation and formal documentation of the study plan or protocol. Throughout the study, every piece of data including observations, measurements, and calculations must be recorded accurately, clearly, and without delay. This applies to all data sources, such as laboratory notebooks, electronic systems, and automated devices. To maintain data integrity, raw data must follow the ALCOA principles, meaning it must be attributable, legible, contemporaneous, original, and accurate [23].

Training and Safety

Good Laboratory Practice (GLP) encompasses not only the quality assurance elements of laboratory work but also the essential aspects of personnel training and workplace safety. These components are vital for ensuring both the reliability of generated data and the protection of individuals involved in laboratory activities. Laboratories operating under GLP must establish structured training programs that equip all staff with the necessary knowledge of GLP principles, relevant guidelines, and standard procedures. A comprehensive risk assessment is also required to identify potential hazards linked to laboratory tasks, including chemical, biological, physical, and ergonomic risks. These assessments support the implementation of effective safety measures and the development of targeted SOPs to reduce or eliminate identified risks. SOPs should clearly define safety practices, including the proper handling and disposal of hazardous materials, correct use of personal protective equipment (PPE), emergency response actions, and procedures for reporting and investigating incidents. Such measures help maintain a safe working environment while supporting the credibility and integrity of laboratory research [24, 25].

Quality assurance [26, 27]

In GLP, Quality Assurance (QA) is an independent unit responsible for verifying that all studies conducted in the laboratory comply with GLP principles, approved protocols, Standard Operating Procedures (SOPs), and regulatory requirements. QA acts as the internal watchdog that ensures study integrity, data reliability, and traceability.

Objectives of quality assurance in GLP

- Ensure compliance with GLP guidelines and laboratory SOPs.
- Verify study integrity, ensuring results are accurate, traceable, and reproducible.
- Provide independent oversight through audits and inspections.
- Ensure documentation accuracy raw data, reports, and records.
- Monitor facility, equipment, and personnel compliance with GLP.
- Identify deficiencies and recommend corrective actions.

Components of QA in GLP

- Independence QA must be independent of study conduct.
- Documentation all QA activities must be recorded.
- Audits Routine inspections of facilities, processes, and studies.
- Corrective and Preventive Actions (CAPA) address deviations and prevent recurrence.
- Good Documentation Practices (GDP) ensures data integrity, ALCOA+ compliance.
- Quality Assurance Statement Included in each GLP final report.

Laboratory and Personnel

GLP outlines specific principles and requirements that regulate how laboratory personnel and operations are organized to ensure the accuracy and reliability of study outcomes. According to GLP, laboratories must be equipped with appropriate infrastructure, including sufficient workspace, proper ventilation, adequate lighting, and controlled environmental conditions such as temperature and humidity. These factors are essential for maintaining the

stability and integrity of samples, reagents, and laboratory instruments. GLP also emphasizes that all laboratory staff must have the appropriate qualifications, education, training, and experience to perform their duties effectively. Employees should be thoroughly trained in GLP principles, applicable Standard Operating Procedures (SOPs), safety protocols, and ethical standards. Additionally, laboratories are required to maintain detailed records of staff training, outlining each individual's responsibilities, completed training programs, competency evaluations, and ongoing professional development activities. This documentation ensures that personnel remain skilled and compliant with evolving laboratory requirements [28].

Conclusion

Good Laboratory Practices (GLP) are fundamental to ensuring the reliability, credibility, and overall quality of scientific investigations. By adhering to well-structured procedures, laboratories maintain uniformity in experimental execution, data documentation, and analytical methods, thereby strengthening the trust placed in their outcomes. GLP not only improves the precision of research results but also plays a vital role in minimizing risks associated with laboratory activities, safeguarding both personnel and the environment. These practices encompass several essential elements, including proper documentation, qualified and trained staff, and stringent safety measures. Consistent compliance with GLP standards enables laboratories to maintain data integrity, ensure reproducibility, and promptly detect and resolve any errors or inconsistencies. Additionally, Quality Assurance (QA) ensures that studies fully comply with GLP norms and internal SOPs, while also confirming that findings are accurate, traceable, and scientifically sound. Ultimately, GLP is more than a regulatory obligation it represents a commitment to transparency, accountability, and excellence in research. Laboratories that embrace these principles significantly enhance their scientific contributions and uphold their responsibility to the broader scientific community and society.

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