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A REVIEW ARTICLE ON GOOD LABORATORY PRACTICES (GLP)

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Abstract:

Good Laboratory Practice (GLP) refers to a set of principles and procedures designed to ensure the quality, integrity, reliability, and reproducibility of data generated in laboratory studies. GLP provides a framework for planning, performing, monitoring, recording, reporting, and archiving laboratory work.

In GLP, accurate documentation, systematic reporting, and robust quality systems are essential for generating trustworthy data.

While Quality Control ensures the precision of laboratory operations, Quality Assurance provides the confidence that these operations were carried out properly. Good Laboratory Practice (GLP) is based on a set of principles that ensure quality, integrity, and reliability in laboratory studies, particularly those submitted for regulatory purposes.

These principles define how studies should be planned, performed, monitored, recorded, reported, and archived.

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INTRODUCTION:

1 Definition[1]

Good Laboratory Practice (GLP) refers to a set of principles and procedures designed to ensure the quality, integrity, reliability, and reproducibility of data generated in laboratory studies. GLP provides a framework for planning, performing, monitoring, recording, reporting, and archiving laboratory work.

1.2 Origin and Historical Background

- The concept of GLP originated in the 1970s following several incidents of data falsification and poor-quality research data in non-clinical laboratories.
- The U.S. Food and Drug Administration (FDA) first established GLP regulations in 1978 to standardize laboratory studies related to product safety.
- The Organization for Economic Cooperation and Development (OECD) later published the OECD Principles of GLP (1992), which became internationally recognized.

1.3 Objectives of GLP

The major objectives are:

1. To ensure reliability, consistency, and traceability of laboratory data.
2. To promote integrity and transparency in laboratory work.
3. To maintain standardization in experimental procedures.
4. To provide confidence in test results for regulatory submissions.
5. To ensure ethical conduct and proper documentation in all studies.

1.4 Importance of GLP

- Ensures valid and verifiable data for product approval and safety assessments.
- Prevents fraudulent or inaccurate reporting.
- Promotes international acceptance of laboratory data.
- Protects human health and the environment by ensuring reliable toxicological and safety data.

1.5 Scope and Application[2]

GLP applies to all non-clinical health and environmental safety studies that support:

- Pharmaceutical products
- Veterinary drugs
- Pesticides
- Food additives and cosmetics
- Industrial chemicals
- Environmental testing and biotechnological research

1.6 Key Terms in GLP

Term	Meaning
Test Facility	Organization performing the GLP study
Study Director	Person responsible for the overall conduct of the study
Sponsor	Individual or organization commissioning the study
Quality Assurance Unit (QAU)	Independent group ensuring GLP compliance
Standard Operating Procedures (SOPs)	Written instructions defining methods and processes
Test System	Any biological, chemical, or physical system used in the study

1.7 Benefits of Implementing GLP

1. Improves quality and consistency of laboratory operations.
2. Facilitates regulatory approval of research data.
3. Enhances international credibility of test facilities.
4. Encourages systematic documentation and record keeping.
5. Supports ethical research practices and worker safety.

Principles of Good Laboratory Practices (GLP) [3]

Good Laboratory Practice (GLP) is based on a set of principles that ensure quality, integrity, and reliability in laboratory studies, particularly those submitted for regulatory purposes. These principles define how studies should be planned, performed, monitored, recorded, reported, and archived.

Organization and Personnel

- The organizational structure of the test facility must be clearly defined.
- Each staff member must understand their roles, responsibilities, and authority.
- The Study Director has the ultimate responsibility for the conduct and validity of the study.

- Personnel must be adequately qualified and trained for their specific tasks.
- Records of training, experience, and qualifications should be maintained.
- Proper hygiene, discipline, and ethical conduct must be maintained in the laboratory.

Key Points:

- No overlapping responsibilities
- Adequate number of qualified staff
- Continuous training programs

Quality Assurance Program (QAU)

- A Quality Assurance Unit (QAU) is an independent body that ensures the study follows GLP principles.
- QAU conducts inspections, audits, and reviews to verify compliance.
- The QAU should report directly to Test Facility Management, not the Study Director.
- It ensures that the final report accurately reflects raw data.

Responsibilities:

1. Maintain copies of approved study plans and SOPs.
2. Inspect studies periodically to verify GLP compliance.
3. Audit final reports and sign QA statements.

Facilities

- The design and layout of laboratories must prevent contamination, mix-ups, and cross-interference.
- Separate areas must be provided for:
  - Test item storage
  - Sample handling
  - Waste disposal
  - Animal housing (if applicable)
- Environmental conditions such as temperature, humidity, and lighting should be controlled and monitored.

Example:
Microbiological labs should have separate areas for culture preparation and disposal to prevent contamination.

Equipment, Reagents, and Materials

- All instruments, apparatus, and materials used in the study must be calibrated, validated, and maintained regularly.
- Records of calibration dates, maintenance logs, and performance checks should be maintained.
- Reagents and chemicals must be labeled with their identity, concentration, storage conditions, and expiry dates.

Key Practices:

- Use of only approved equipment
- Calibration traceable to national standards
- Preventive maintenance schedule

Test and Reference Items[4]

- Each test and reference item should have a unique identification code.
- Information on composition, stability, storage conditions, and expiry must be available.
- The storage area should be designed to prevent contamination or degradation.
- The handling procedures should ensure homogeneity and traceability throughout the study.

Standard Operating Procedures (SOPs)

- SOPs are written, approved instructions that describe how routine operations are to be performed.
- They ensure consistency and reproducibility in laboratory work.
- SOPs should cover all major operations, such as:
  - Equipment calibration and maintenance
  - Sample collection and analysis
  - Data recording and reporting
  - Safety and waste disposal

Features of SOPs:

- Reviewed and approved by management
- Controlled version numbers and issue dates
- Readily accessible to all staff

Performance of Study

- Each study must have a written and approved study plan (protocol).
- The Study Director ensures that the study plan is followed.
- All raw data must be recorded immediately, accurately, and signed by the responsible person.

- Any deviations from the plan or SOP must be documented, justified, and approved.

Study Phases:

1. Planning
2. Conduct
3. Data recording
4. Review
5. Reporting

Reporting of Results

- The final report must include:
  - Title, objectives, and identification of test items
  - Description of methods and materials
  - Results and statistical analysis
  - Deviations from the study plan
  - Signature of the Study Director and QA statement
- Reports must be reviewed and approved before submission.

Storage and Retention of Records and Materials[5]

- After the study, all materials and records should be archived in a secure, controlled facility.
- This includes:
  - Raw data
  - Reports
  - SOPs
  - Calibration and maintenance records
  - Test samples and specimens (if feasible)
- Retention periods should comply with regulatory requirements.
- Access to archives should be restricted and documented.

Quality, Integrity, and Data Traceability

- Every piece of data generated during a study must be traceable to its origin.
- Data integrity means that information is complete, consistent, and accurate throughout its lifecycle.
- No raw data should be erased; corrections should be dated, signed, and justified.

Data Integrity Principles (ALCOA+):

- Attributable – Who created the data
- Legible – Readable and permanent
- Contemporaneous – Recorded in real-time
- Original – Original or true copy
- Accurate – Correct and truthful (+ Complete, Consistent, Enduring, and Available)

Performance of Study in Good Laboratory Practices (GLP) [6]

The performance of a study is the core activity under GLP. It involves all the steps from planning and execution to data recording, evaluation, and reporting of a non-clinical laboratory study. These steps ensure that the results generated are reliable, reproducible, and scientifically valid.

Study Plan (Protocol)

Definition

A study plan (or protocol) is a document that defines the objectives, design, methodology, statistical considerations, and organization of a study.

It serves as a blueprint for the conduct of the study and must be approved before the study begins.

Contents of the Study Plan

According to GLP principles (OECD, WHO, and FDA), the study plan should include:

1. Title and unique study identification number
2. Name and address of the sponsor and test facility
3. Study objectives and test system description
4. Details of test and reference items (identity, source, batch number, purity, etc.)
5. Experimental design and study schedule
6. Methodology and analytical techniques to be used
7. Data recording and evaluation procedures
8. Quality Assurance (QA) statement and responsibilities
9. Signatures of the Study Director, management, and QA representative
10. Amendments or deviations procedure

Approval of Study Plan

- The study plan must be reviewed and approved by the Test Facility Management and Quality Assurance Unit (QAU) before the study starts.
- Any amendments (changes in design, methodology, or test conditions) must be documented, justified, dated, and approved by the Study Director.

Conduct of the Study

Responsibilities

- The Study Director has overall responsibility for the scientific and technical conduct of the study.
- All study personnel must perform their assigned duties as per Standard Operating Procedures (SOPs).
- The QAU must perform inspections to ensure compliance.

Adherence to SOPs

- All laboratory procedures should follow approved SOPs.
- Any deviations from SOPs must be justified and recorded in the raw data or report.
- Equipment and instruments used must be calibrated and validated before and during use.

Environmental and Operational Controls[7]

- Environmental conditions such as temperature, humidity, light, and cleanliness must be maintained and recorded.
- Proper sample labeling and handling should prevent contamination or mix-ups.
- The use of control samples and blanks ensures result accuracy.

Test System Management

The test system is the biological, chemical, or physical entity used in a study (e.g., animals, cells, microorganisms, or equipment).

Animal or Biological Test Systems

- Must be appropriately housed, fed, and cared for according to ethical and regulatory standards.
- Records must include species, strain, age, sex, source, and health status.
- Proper quarantine, randomization, and identification procedures must be followed.

Chemical or Physical Test Systems

- Chemicals or physical materials should be characterized and tested for stability and homogeneity.
- Storage conditions should prevent degradation.

Data Collection and Recording

Principles of Data Recording

- All data must be recorded promptly, accurately, and legibly.
- Entries must be made in ink or using validated electronic systems.
- Each entry must be signed and dated by the person generating the data.
- Data must be traceable to the individual, equipment, and procedure.

Raw Data

- Defined as any original observation, measurement, or record necessary for the reconstruction and evaluation of a study.
- Raw data include:
  - Instrument printouts
  - Weighing records
  - Animal observation logs
  - Computer-generated data files
  - Photographic evidence

Data Corrections

- If an error is made, the incorrect entry should be crossed out, not erased.
- The correction must be dated, signed, and justified.
- Electronic data corrections must have audit trails showing who made the change and when.

Handling Deviations[8]

Definition

A deviation is any unplanned departure from an approved study plan, SOP, or GLP principle that could affect study quality or data integrity.

Management of Deviations

- Must be immediately reported to the Study Director.
- The impact assessment on study outcome should be documented.
- Corrective and preventive actions (CAPA) should be implemented.
- All deviations should be summarized in the final report.

Computerized Systems and Data Integrity

Use of Computerized Systems

- Increasingly, laboratories use computerized systems for data recording, processing, and reporting.
- Such systems must be validated before use to ensure accuracy, reliability, and security.

Data Integrity Requirements
Electronic data must follow the ALCOA+ principles:

- Attributable – Who generated the data
- Legible – Readable and permanent
- Contemporaneous – Recorded at the time of observation
- Original – Primary record
- Accurate – Reflects the true value
- Plus: Complete, Consistent, Enduring, and Available

Security and Backup

- Access should be limited to authorized personnel.
- Regular data backups should be performed.
- Systems should have audit trails to track changes.

Study Completion and Reporting[9]
Study Completion

- Upon completion, the Study Director must ensure that:
  - All data are collected, reviewed, and verified.
  - Deviations are resolved and documented.
  - The final report is prepared in accordance with GLP.

Final Report
The final report must include:

1. Title and unique study number
2. Study objectives and methods
3. Test and reference item details
4. Results, calculations, and statistical analysis
5. Deviations and their impact
6. Quality Assurance statement
7. Signature and date of Study Director

Archiving

- After study completion, all materials (raw data, samples, SOPs, and reports) must be archived securely.
- Access to archives should be controlled and documented.
- Retention period should comply with regulatory guidelines (usually 5–15 years).

Key Considerations for GLP-Compliant Study Performance

1. Planning: Clear objectives and approved study design
2. Execution: Follow SOPs and maintain traceability
3. Documentation: Record all raw data accurately
4. Verification: Conduct periodic audits and QA inspections
5. Reporting: Prepare transparent and comprehensive final report
6. Archiving: Secure retention of all study-related materials

Summary
The performance of a study under GLP is a systematic, documented process that ensures:

- Scientific validity
- Transparency and reproducibility
- Data traceability
- Ethical compliance

Test Facility Management in Good Laboratory Practices (GLP) [10]
The Test Facility Management (TFM) plays a central and crucial role in ensuring the effective implementation of GLP principles in any laboratory or research organization.
It is responsible for establishing the organizational structure, providing adequate resources, and ensuring that all studies are conducted according to approved standards, SOPs, and regulations.

Definition
A Test Facility is the location(s) where one or more phases of a GLP-compliant study are conducted. It includes all buildings, rooms, equipment, and personnel involved in the testing, recording, and reporting of data.

The Management of the Test Facility refers to the individuals or authorities responsible for ensuring that the facility operates in compliance with the GLP principles, and that studies are properly planned, resourced, and monitored.

Responsibilities of Test Facility Management
The responsibilities of test facility management are broad and essential for maintaining GLP compliance.
They can be divided into organizational, technical, administrative, and ethical categories.

Organizational Responsibilities

- Establish a defined organizational structure with clear lines of authority and communication.
- Appoint qualified and trained personnel for each position.
- Define and document the roles, duties, and reporting hierarchy within the facility.
- Appoint a Study Director for each study who is responsible for its overall conduct.
- Where applicable, designate Principal Investigators for multi-site studies.

Technical Responsibilities

- Ensure that the test facility, equipment, and environment are suitable for the type of studies performed.
- Maintain facilities that minimize the risk of contamination, cross-mixing, or environmental hazards.
- Ensure that equipment calibration, maintenance, and validation schedules are followed.
- Provide adequate Standard Operating Procedures (SOPs) for all operations.

Administrative Responsibilities

- Approve and implement the Quality Assurance Program (QAU).
- Review and approve all study plans before initiation.
- Ensure that resources (personnel, materials, equipment, and time) are sufficient to complete studies effectively.
- Authorize the archiving system for study materials and data.
- Ensure training programs for all personnel and maintain their records.
- Manage communication between the sponsor, study director, and regulatory bodies.

Ethical Responsibilities

- Promote a culture of integrity, transparency, and accountability.
- Ensure the ethical treatment of animals or biological materials according to national and international standards.
- Guarantee that data integrity and confidentiality are maintained.

Design and Maintenance of Test Facility[11]

The test facility must be designed to support efficient and contamination-free studies.

Facility Design

- The layout should allow for logical workflow, separating various functional areas:
  - Test item storage
  - Sample preparation
  - Analytical testing
  - Data processing
  - Waste disposal
  - Animal rooms (if applicable)
- Provide adequate lighting, ventilation, temperature, and humidity control.

Maintenance and Housekeeping

- Routine cleaning and maintenance must be carried out to prevent cross-contamination.
- A preventive maintenance program for all instruments and facility areas must be documented.
- Access to sensitive areas (archives, test storage, animal rooms) should be restricted and logged.

Personnel Management[12]

Recruitment and Training

- All personnel must have appropriate qualifications and experience for their roles.
- A continuous training program should be established to ensure awareness of GLP principles and SOPs.
- Training records should include:
  - Date and type of training
  - Trainer and trainee names
  - Assessment or evaluation results

Delegation of Authority

- Each function within the facility should have a clearly delegated responsibility.
- The Study Director retains ultimate responsibility for scientific and technical conduct, even if tasks are delegated.
- Principal Investigators may be appointed for multi-site studies, but they must operate under the Study Director's supervision.

Test and Reference Item Management[13]

Receipt and Storage

- Upon receipt, each test and reference item should be uniquely identified and labeled.
- Information such as batch number, purity, concentration, and expiry must be recorded.
- Storage conditions (temperature, humidity, protection from light) should be continuously monitored.

Handling and Distribution

- Handling procedures must ensure that the identity, composition, and integrity of test items are preserved.
- Distribution records must show the quantity and recipient of each item used in a study.

Retention and Disposal

- Unused samples should be retained for a defined period or disposed of safely according to environmental regulations.

Equipment and Material Management

Equipment Qualification

All instruments must undergo:

1. Installation Qualification (IQ) – Verifies proper installation.
2. Operational Qualification (OQ) – Confirms that equipment performs as intended.
3. Performance Qualification (PQ) – Demonstrates consistent operation under real study conditions.

Calibration and Maintenance

- Equipment should be regularly calibrated against certified standards.
- Maintenance logs must record the date, nature of maintenance, and responsible personnel.

Reagents and Consumables

- Reagents should be of analytical grade and clearly labeled with name, concentration, preparation date, expiry date, and storage condition.
- Expired or contaminated materials must be discarded safely.

Environmental, Health, and Safety (EHS) Management

Safety Measures

- Establish and implement a laboratory safety program.
- Provide personal protective equipment (PPE) to all personnel.
- Display safety symbols and emergency contact information prominently.

Waste Management

- Segregate biological, chemical, and general waste.
- Maintain waste disposal logs and follow local regulatory requirements.
- Treat or neutralize hazardous waste before disposal.

Emergency Preparedness

- Maintain fire extinguishers, first-aid kits, and spill kits in easily accessible locations.
- Conduct regular mock drills for fire, chemical spills, and medical emergencies.

Quality Assurance Oversight

- Management must ensure the independence and effectiveness of the Quality Assurance Unit (QAU).
- The QAU monitors compliance with GLP, inspects studies, and verifies the accuracy of final reports.
- Management must take corrective and preventive actions (CAPA) for all QAU findings.

Archiving and Record Retention

- A secure archival facility must be established to store study records, reports, raw data, SOPs, calibration logs, and test items.
- The archive should be environmentally controlled (temperature, humidity, pest-free).
- Access to archives must be restricted to authorized personnel and logged.
- Retention periods must comply with national and international regulations (usually 5–15 years).

Multi-Site Test Facilities

In large organizations, studies may be conducted across multiple facilities.

Responsibilities:

- Test Site Management ensures that local facilities and personnel comply with GLP.
- The Study Director remains responsible for the overall integrity of the study.
- Clear communication and documentation between sites are mandatory.

Documentation under Test Facility Management[14]

The management must ensure proper documentation of:

- Organizational charts
- SOPs
- Training and qualification records
- Equipment calibration logs
- Maintenance and cleaning records
- Study plans and QA reports
- Health and safety policies

Importance of Test Facility Management

- Ensures smooth operation of all studies.
- Promotes scientific reliability and data credibility.
- Builds a culture of accountability and integrity.
- Facilitates regulatory compliance and audit readiness.

Documentation and Reporting, Quality Control and Assurance in GLP[15]

Introduction

Good Laboratory Practice (GLP) emphasizes reliability, integrity, and traceability of data generated during non-clinical laboratory studies. The two most critical pillars that ensure these objectives are:

1. Proper Documentation and Reporting, and
2. Effective Quality Control and Quality Assurance Systems.

These elements collectively ensure that studies are scientifically valid, reproducible, and compliant with regulatory requirements.

Documentation and Reporting

Definition

Documentation refers to the process of recording all information related to the conduct of a study, including methods, observations, calculations, and results, in a permanent, traceable, and verifiable form.

Reporting is the preparation of formal summaries and interpretations of the documented data, typically presented in the Final Report of the study.

Together, documentation and reporting form the backbone of data integrity in GLP.

Importance of Documentation in GLP

- Ensures traceability of every action, observation, and decision.
- Provides evidence of compliance with approved procedures and regulations.
- Facilitates reproducibility of experiments.
- Helps identify errors or deviations quickly.
- Forms the basis for audits, inspections, and regulatory submissions.

Types of Documents in GLP

GLP facilities use a wide range of documents, categorized as follows:

Document Type	Purpose / Description
Study Plan / Protocol	Describes the objectives, design, and methodology of the study. Must be approved before initiation.
Standard Operating Procedures (SOPs)	Step-by-step instructions for routine activities to ensure consistency.
Raw Data Records	Original observations and measurements generated during the study.
Instrument Logs	Records of equipment use, calibration, and maintenance.
Test and Reference Item Records	Details about receipt, storage, handling, and disposal of materials.
Training Records	Evidence that staff are qualified and trained for assigned tasks.
Environmental and Safety Logs	Records of temperature, humidity, pest control, and cleaning.
Study Reports	Compiled summaries of results, interpretations, and conclusions.
Archives	Secure storage of all documents, raw data, and materials.

Documentation Practices (Good Documentation Practices – GDP) [16]
To maintain data integrity, the following principles must be followed:

ALCOA+ Principles:

Principle	Meaning
A – **Attributable**	Every entry must identify who performed the action.
L – **Legible**	Information must be clear, readable, and permanent.
C – **Contemporaneous**	Entries must be made at the time of observation.
O – **Original**	Data should be recorded in its first instance.
A – **Accurate**	Entries must reflect the true observation.
+ – **Complete, Consistent, Enduring, Available**	Data must be complete, consistent across sources, durable, and retrievable.

Requirements for Record Keeping

- All records must be dated and signed by the person making the entry.
- Any correction should be made by a single strike-through, not by erasing or overwriting.
- Corrections must be initialed, dated, and justified.
- Records must be kept in bound notebooks, approved electronic systems, or validated databases.
- Data entries should be protected from unauthorized alteration or deletion.

Study Reports
At the end of a study, the Study Director is responsible for preparing the Final Report, which includes:

Contents of the Final Report

1. Title Page – Study title, test facility, study number, dates, sponsor, etc.
2. Study Objectives and Design
3. Test and Reference Items Information
4. Experimental Procedures
5. Results and Data Summaries
6. Statistical Analysis
7. Deviations or Amendments
8. Conclusions
9. Signature and Date of Study Director
10. Quality Assurance Statement

Archiving

- After report submission, all related raw data, samples, records, and materials are archived.
- Archives should be secure, climate-controlled, and access-restricted.
- Retention period is typically at least 5 years after study completion (or longer, as per regulatory requirement).

Quality Control and Assurance[17]
Definition
Quality Control (QC) and Quality Assurance (QA) are two complementary functions that ensure GLP compliance:

- Quality Control (QC): Operational techniques and activities that verify that testing and analytical processes are performed correctly.
- Quality Assurance (QA): An independent monitoring system that ensures all activities are planned, performed, and reported in compliance with GLP principles.

Difference between QC and QA

Aspect	Quality Control (QC)	Quality Assurance (QA)
Nature	Operational function	Independent evaluative function
Objective	Detect and correct errors during testing	Prevent errors and ensure compliance
Responsibility	Laboratory analysts, supervisors	Quality Assurance Unit (QAU)
Timing	During study conduct	Before, during, and after the study

Focus	Technical accuracy	Procedural compliance
Example	Checking calibration accuracy	Auditing calibration records

Quality Control (QC) Activities

- Routine checks of instrument calibration and validation.
- Verification of reagent purity and expiry.
- Replicate testing to ensure precision and reproducibility.
- Internal quality checks and control charts.
- Documentation of non-conformances and implementation of corrective actions.

Quality Assurance (QA) System

Every GLP-compliant facility must have an independent Quality Assurance Unit (QAU).

Responsibilities of the QAU

1. Maintain a master schedule of all ongoing and completed studies.
2. Verify study plans for GLP compliance before initiation.
3. Conduct inspections and audits:
    - Facility-based
    - Process-based
    - Study-based
4. Audit raw data and reports for accuracy and consistency.
5. Report audit findings directly to test facility management and the study director.
6. Verify that corrective actions have been implemented.
7. Sign off on the QA statement in the final report.

Types of QA Inspections

Type	Purpose	Frequency
Facility Inspections	Evaluate the overall compliance of infrastructure and operations.	Periodic (quarterly or annually)
Study-Based Inspections	Assess the conduct and documentation of specific studies.	During study
Process-Based Inspections	Evaluate routine procedures such as sample analysis, data entry, or animal care.	As needed
Report Audits	Ensure accuracy and completeness of final reports.	After study completion

Corrective and Preventive Actions (CAPA)

If deviations or deficiencies are identified:

1. Corrective Actions – Steps to eliminate the cause of existing non-conformities.
2. Preventive Actions – Measures to prevent recurrence.
3. CAPA effectiveness should be verified and documented by QA.

Quality Indicators

QA systems often use quality indicators to assess performance, such as:

- Number of deviations per study
- Frequency of equipment failures
- Timeliness of corrective actions
- Compliance scores during audits

Relationship between Documentation, QC, and QA[18]

These three systems are interconnected:

- Documentation provides the factual record of what occurred.
- Quality Control ensures that procedures and results are technically valid.
- Quality Assurance confirms that the documentation and operations meet GLP standards.

Together, they ensure data integrity, transparency, and regulatory credibility.

Common Non-Compliance Issues

- Missing or unsigned records.
- Outdated or missing SOPs.
- Uncalibrated equipment used in testing.
- Incomplete QA inspections or lack of CAPA.
- Failure to archive raw data properly.

Each of these can lead to regulatory rejection of study data.

CONCLUSION:

In GLP, accurate documentation, systematic reporting, and robust quality systems are essential for generating trustworthy data. While Quality Control ensures the precision of laboratory operations, Quality Assurance provides the confidence that these operations were carried out properly.

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