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A Review: Good Laboratory Practices

Suraj B. Devmare *, Sanjay K. Bais

Fabtech College of Pharmacy, Sangola, Solapur, Maharashtra, India

*Corresponding Author: surajdevmare7000@gmail.com

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Abstract

Good Laboratory Practice (GLP) is a core framework for ensuring the quality, integrity, and reliability of non-clinical laboratory research, particularly in toxicology, environmental safety, and pharmaceuticals. This review paper covers GLP's essential ideas and standards, focusing on its contribution to the improvement of standardized procedures, tight quality control, and ethical research practices. We discuss the benefits of GLP, which include improved data integrity, regulatory compliance, and better inter-laboratory communication. The essay examines the usage of GLP guidelines, the significance of Standard Operating Procedures (SOPs), and the importance of continual staff training. Future trends in laboratory practices and the difficulties encountered in adhering to GLP are also discussed. This study seeks to offer insights for academics, regulatory agencies, and industry stakeholders dedicated to maintaining high standards in laboratory operations by emphasizing the crucial role that GLP plays in guaranteeing scientific legitimacy and public safety.

Keywords - Organization, personnel, facilities, equipment, Quality Assurance.

INTRODUCTION

Animal feed additives, biological products, electronic devices, and other non-pharmaceutical components or goods. Using non-clinical safety tests, such as physiochemical properties or acute to chronic toxicity tests, good laboratory practice (GLP) is a quality system of management controls for research laboratories and organizations to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of products in development for human or animal health (including pharmaceuticals). Responding to the Industrial Bio Test Labs event, GLP was first introduced in New Zealand and Denmark in 1972 and then in the US in 1978. The Organization for Economic Cooperation and Development (OECD) adopted the Principles of GLP in 1992, a few years later, and has since assisted in the expansion of GLP to several additional nations. Non-clinical studies designed to evaluate a product's safety or effectiveness for use in humans, animals, or the environment—including medicines—are referred to as GLP studies. The use of appropriate gloves, eye protection, and clothing when handling lab equipment is a requirement of laboratory safety laws, which are distinct from GLP, a data and operational quality system. The goals of GLP are to guarantee and advance the safety, uniformity, superior quality, and dependability of chemicals during laboratory and non-clinical testing. GLP applies not only to chemicals but also to food additives, medical devices, food packaging, and colorants.The United States Food and Drug Administration (FDA) found instances of subpar laboratory methodology all over the country in the early 1970s. The Food and Drug Administration made the decision to thoroughly audit more than 40 toxicology labs.

They exposed a number of dishonest behaviors and subpar lab procedures. Some of these subpar lab practices included test systems that were insufficient, imprecise or incorrect representations of the actual lab study, and equipment that had not been calibrated to standard form. Though the phrase "good laboratory practice" has been used colloquially in many laboratories across the globe for some time, GLP originated in the US and had a huge influence on the rest of the world. [1]

Pharmaceutical manufacturers are required to adhere to good manufacturing practice (GMP) in order to guarantee the safety, efficacy, and superior quality of their goods. Legislation or regulatory guidance documents may be used to implement the regulations.

Regulators will not allow pharmaceutical items to be placed or remain on the market in their nation unless they can be demonstrated to be manufactured in accordance with GMP. To that goal, they transport conduct inspections of manufacturing plants. Companies that consistently violate GMP regulations have faced significant fines. GMP theory and practice must be taught to all manufacturing professionals at the start and throughout their careers. Everyone who works in a pharmaceutical or biotechnology company's processing, quality control, packaging, or warehouse environment, or one of their contractors, must understand the importance of GMP, how it pertains to them, and how to follow it. This program is an excellent induction and refresher training on the fundamentals of GMP. We start by describing what GMP is and why it is important. We then outlined its main elements. Finally, we cover two components of GMP that affect everyone in the industrial environment: hygiene, cleaning, and sanitation, as well as documentation [2]

The Principles of Good Laboratory Practice (GLP) set norms and requirements for a quality system that governs the organizational processes and conditions under which non-clinical health and environmental safety studies are planned, carried out, monitored, documented, reported, and stored. [3,4,5] These principles apply to non-clinical safety testing of compounds found in various products, ensuring the quality and integrity of safety data given to regulatory bodies worldwide.

History

A set of guidelines known as "Good Laboratory Practice" (GLP) guarantees the caliber and honesty of non-clinical laboratory research, especially in the chemical, pharmaceutical, and other associated sectors. Concerns over the authenticity and dependability of data produced in lab settings grew during the 1970s, which is when GLP first emerged [6]. Inadequate research methods and data manipulation resulted in the introduction of dangerous items into the market in a number of well-known examples during this time. The Food and Drug Administration (FDA) in the United States was one of the first regulatory agencies to address these issues. The first official GLP standards were adopted in 1978, and they set rules that labs had to abide by while doing non-clinical investigations to bolster applications for marketing or research permissions. Developing a structure that would guarantee laboratory data complied with scientific norms and increase its credibility was the main goal.[7]

It became clear that worldwide standards were necessary in the early 1980s. Differences in national laws presented difficulties for businesses doing business abroad as international trade and research cooperation grew. A uniform approach was made available to member nations when the Organization for Economic Cooperation and Development, also known as the OECD, adopted its own GLP principles in 1997. This was a major step in harmonizing rules, which made it possible for study results to be more widely accepted internationally.

Proper study design, quality assurance, staff qualifications, equipment maintenance, & standard operating procedures (SOPs) are some of the essential elements that make up GLP.

These guidelines make ensuring that every facet of laboratory work is recorded and repeatable, which improves the accuracy of the data produced.

In order to ensure that laboratories follow specified protocols, regular assessments and audits are essential to GLP compliance. [8,9,10]

In response to new scientific discoveries and legal constraints, GLP has changed throughout time. New testing techniques and study types, such as those using biotechnology and complex materials, have been included in the revised GLP standards as technology and procedures have progressed. Since many nations have adopted comparable frameworks to protect environmental safety and public health, GLP is now accepted as a worldwide standard. GLP's tenets are still vital to product creation and testing because they guarantee that goods are carefully assessed before being sold to customers, which in turn promotes public confidence in science & regulatory procedures. [11,12]

GMP theory and practice must be taught to all manufacturing staff at the outset and continuously. Each employee of a pharmaceutical or biotechnology company, or one of their contractors, involved in processing, quality control, packing, or warehousing must comprehend the need for GMP, how it affects them personally, and how to adhere to it. This class provides a great overview of the principles of GMP and serves as a great reminder. First, we define GMP and explain why it is necessary. We then went over its main ideas. We wrap up by talking about two aspects of GMP that affect everyone working in a manufacturing setting: documentation and hygiene, cleaning, and sanitation. [13,14]

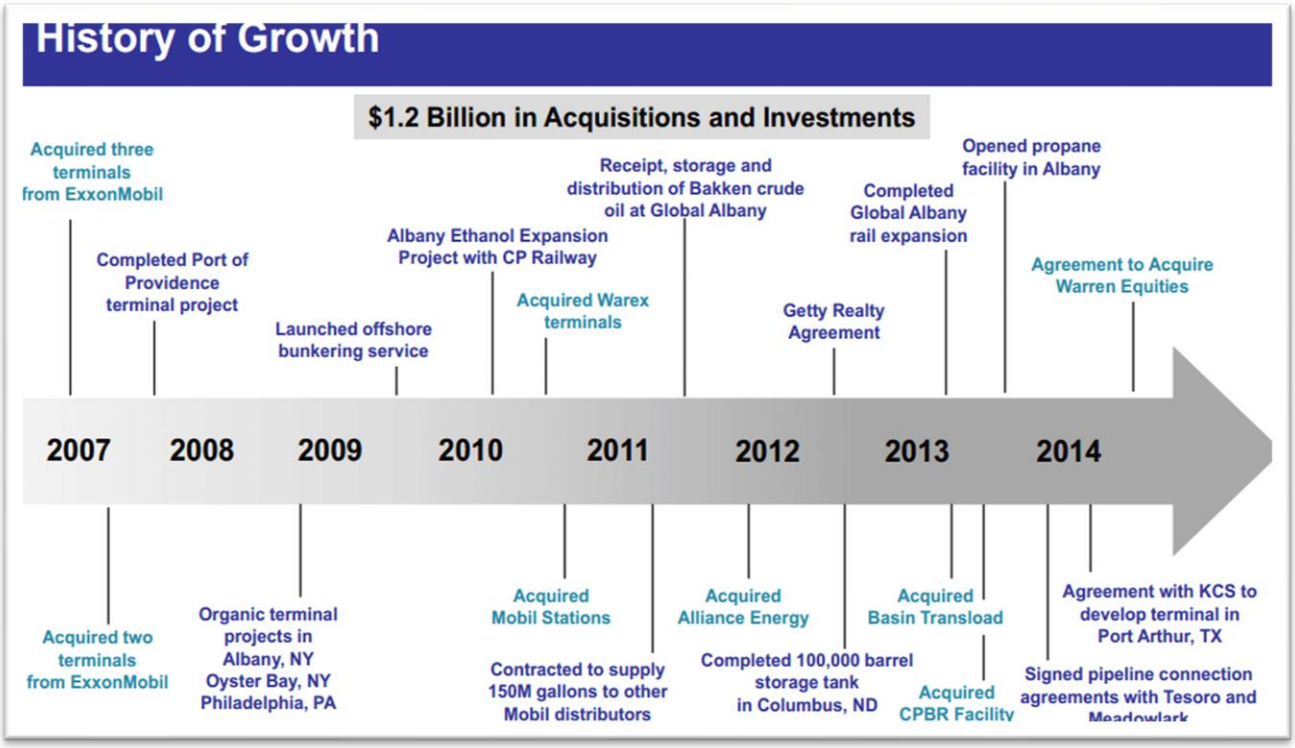

Figure 1*: *History of GLP

Definition

The organizational procedures and circumstances that control the planning, carrying out, monitoring, documenting, archiving, and disclosure of non-clinical wellness and safety-related research are covered by the Good Laboratory Processes (GLP) quality system.

GLP is a set of principles that provide a framework for designing, carrying out, monitoring, reporting, and archiving laboratory experiments. [15]

Scope

Study design and planning

GLP demands that all studies be pre-planned and documented, with protocols outlining objectives, techniques, and expected results.

Personnel and training

Personnel must be qualified and adequately trained for their specific roles in the laboratory. Responsibilities should be clearly defined.

Facilities and equipment

Laboratories must be equipped and maintained in such a way that the results are accurate and reproducible. This includes calibrating and maintaining the instruments.

Standard operating processes

SOPs must be defined for all important procedures in order to assure consistency and regulatory compliance.

Data Management

Accurate data recording, storage, and management techniques are essential. This covers data integrity and traceability. [16,17]

Quality assurance

To ensure compliance with GLP standards, a quality assurance procedure must be created that reviews and audits laboratory practices on a regular basis.

Reporting and Documentation

GLP mandates that all findings from laboratory studies are reported in a clear, concise manner, allowing for easy review and verification.

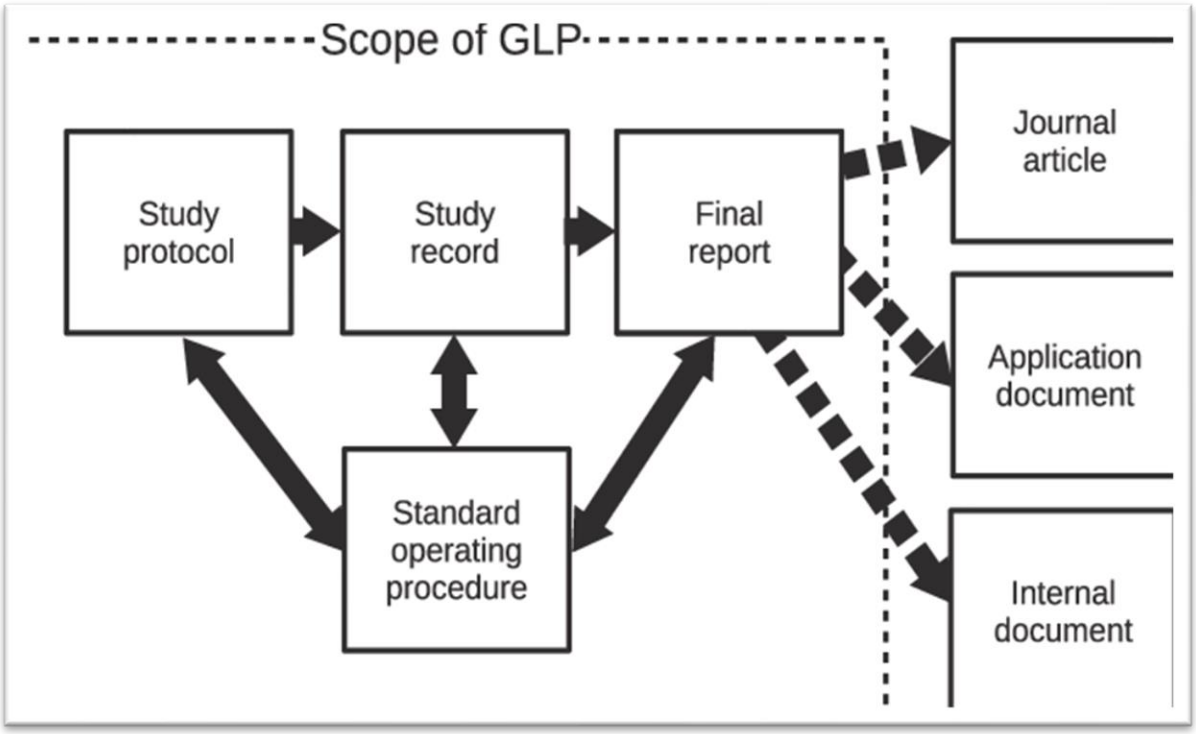

Figure 2*: *Scope of GLP

Good Laboratory Practice" Principles

Organization and personnel

Staff members are qualified and trained for their jobs thanks to a well-defined structure, duties, and responsibilities.

Quality Assurance

To preserve data integrity, an independent quality assurance unit keeps an eye on adherence to GLP guidelines and procedures.

Facilities

To carry out research in a reliable and secure manner, laboratories need to be properly planned, maintained, and furnished.

Equipments

To guarantee precise and repeatable results, every equipment needs to be correctly calibrated, maintained, and certified.

Test System

This covers every chemical or biological system that is used in research. To guarantee validity, proper handling and care are necessary.

Study Protocol

Every study needs a clear protocol that describes its goals, methods, and strategy for analysis. Every modification needs to be recorded. [18,19,20]

Data Handling and Record Keeping

All raw data, analysis, and outcomes must be accurately and thoroughly documented. Appropriate data management systems are part of this.

Reporting of Study Results

In accordance with regulatory requirements, study results should be communicated in a clear, accurate, and transparent manner.

Compliance

Continuous development is made possible by regular audits and reviews, which assist guarantee continued adherence to GLP principles.

Documentation

Every element of the research, including the final reports, correspondence, and raw data, should be recorded. Clear, comprehensive, and retrievable documentation is essential. [21,22]

Figure 3*: *Principles of GLP

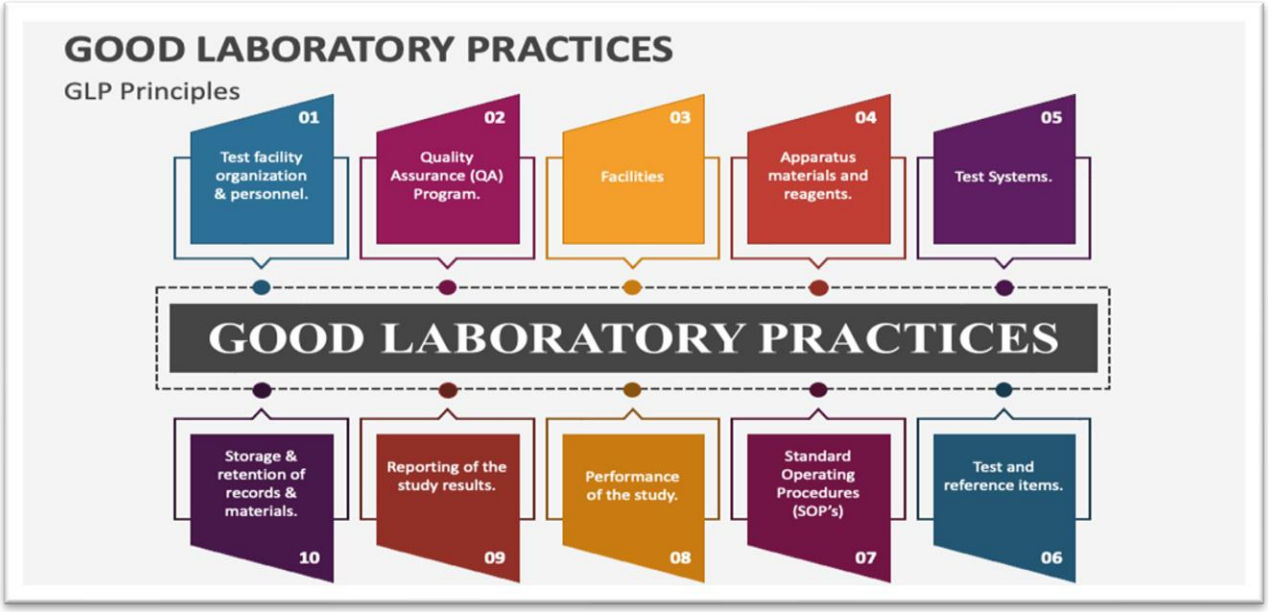

Figure 4*: *Principles of GLP

Benefits of Good Laboratory Practices

Good laboratory practices (GLP) are critical to assuring the accuracy and dependability of laboratory results. Here are several significant advantages.

Data integrity

GLP assures that laboratory data is accurate, reproducible, and credible. This is crucial for regulatory filings and research credibility.

Compliance with regulations

Adhering to GLP helps laboratories comply with local and international rules, which is critical for avoiding legal complications and penalties.

Quality assurance

Implementing GLP encourages systematic quality assurance systems, which improve the overall quality of laboratory work and findings.

Safety

Good laboratory practices improve employee safety by creating suitable protocols and procedures for handling materials and equipment.

Efficient resource use

GLP promotes the optimal use of resources, including time and materials, resulting in cost savings and better workflows.

Training and competence

GLP frameworks encourage ongoing training and competence development for laboratory professionals, ensuring that they are familiar with best practices.

Improved collaboration's

GLP promotes greater communication and collaboration among laboratory workers and between laboratories, which improves teamwork and project results.[28]

Implementing excellent laboratory procedures is critical for the success of scientific research and testing, as it provides a firm foundation for credible and meaningful outcomes.

Simplified Procedures

Reduces duplication of labour and streamlines workflows by standardizing processes. [23,24,25]

Management of Risk

Early risk identification in the research process enables preventative actions to be taken.

Improved Training

Better Training lays out precise training guidelines that raise laboratory staff members' proficiency and abilities.

Effective Communication

Encourages team members to communicate more effectively on procedures, modifications, and outcomes, which promotes cooperation.

Moral Principles

Guarantees that test systems are treated ethically and in accordance with humane standards, particularly in research involving animals.

Long-Term Financial Gains

Causes better planning and execution, which lowers the possibility of expensive rework or research failures.

Assisted with Inspections and Audits

It is simpler to pass regulatory body audits and inspections when processes and documents are well-documented.

Improved Reputation

Establishes the company as an industry leader in quality and dependability, drawing in new customers and business prospects.

Reliable Outcomes

Reproducibility: GLP encourages standardized procedures that improve the ability to replicate study findings in other labs and investigations.

Quicker Regulatory Acceptance

Simplified Submission: Regulatory bodies may evaluate and approve data produced under GLP more quickly if it is of high quality.

Improved Cooperation

Inter-laboratory Comparisons: Because data produced using GLP standards is easier to accept and comprehend, GLP encourages cooperation between institutions.

Higher Morale Among Workers

Clear Expectations Laboratory employees' job satisfaction and morale can be raised in a disciplined and cooperative work environment.

Facilitated Technology Transfer Easier Adoption

Technology transfer is made easier when other firms accept data that complies with GLP.

Better Project Administration

Defined Procedures Improved project management and tracking are facilitated by well-defined procedures and documentation.

Ongoing Enhancement

Feedback Mechanisms Consistent audits and evaluations foster an innovative and ever-improving culture in the lab.

Thorough Record Keeping Detailed Documentation

GLP necessitates thorough record-keeping, which facilitates data retrieval for upcoming research and historical reference.

Improved Evaluation of Risk

Proactive Steps: GLP promotes rigorous risk assessment procedures, which improve the detection and mitigation of possible problems.

Conformity to Best Practices

Global Standards: GLP facilitates worldwide cooperation and data exchange by bringing laboratory procedures into line with best practices from throughout the world.

Market Trust and Customer Trust

Creating data that complies with GLP increases market and customer trust in research findings and goods.

Encouragement of Innovation

Focused Research: GLP enables researchers to concentrate less on administrative duties and more on innovation by standardizing procedures. [26,27]

A decrease in product malfunctions

Early Detection: Time and money can be saved by detecting any product faults sooner thanks to thorough testing and validation.

Figure 5: *Benefits of GLP*

What Qualities a Good Laboratory Must Have?

Adherence to Safety Standards

A good laboratory prioritizes safety by adhering to correct protocols and regulations designed to safeguard staff and the environment.

Effective Communication and Collaboration

A successful laboratory encourages cooperation and open communication in order to improve project outcomes.

Robust Data Management

Effective data gathering, storage, and analysis technologies assist to assure data integrity and accessibility. [28,29] Clarity Well-Defined Procedures: GLP should include precise and comprehensive protocols that cover all laboratory activity, from data reporting to study design

Consistency Standardized Practices

To guarantee the repeatability and dependability of outcomes, GLP must encourage consistent protocols throughout all research.

Accountability Clearly Defined Responsibilities: It is essential to clearly define roles and responsibilities so that all employees are aware of their responsibilities and hold themselves accountable.

Openness: Accessible Documentation: All processes, information, and reports ought to be thoroughly recorded and readily available for examination.

Strict Quality Assurance: Mechanisms for Quality Assurance: To ensure adherence to GLP standards during the course of the study, efficient quality control procedures must be in place.

Moral Aspects: Humane Treatment: To ensure humane and ethical treatment, GLP must include ethical guidelines, particularly in investigations involving animal experimentation.

Adaptability: Adaptability to Changes: GLP should permit modifications to new technologies or approaches as required, all the while upholding standard procedures. Thorough Training and Ongoing Education: In order to keep all staff members up to date on best practices and laws, GLP must place a strong emphasis on ongoing training and professional development.

Sturdy Records: Extensive Record-Keeping: To guarantee that every facet of research is accurately and fully documented, thorough documentation procedures should be put in place.

Integrity of Data: Accurate and Trustworthy Data: GLP must make sure that procedures for gathering, managing, and reporting data are made to preserve the authenticity and integrity of the data.

Controlling Risk: Proactive Identification: Procedures for recognizing, evaluating, and reducing the hazards connected to laboratory research should be part of GLP.

Cooperation: Interdisciplinary Cooperation: To improve the overall calibre of research, GLP must encourage cooperation between various teams and disciplines inside the company. **Standards Compliance**: To guarantee that data is accepted by regulatory bodies, GLP should conform to both national and international regulatory requirements.

General requirements of GLP

Good Laboratory Practice (GLP) is a collection of guidelines designed to ensure the quality and integrity of non-clinical laboratory studies. The following are the general prerequisites for GLP

Organizational and personnel

Employee duties and responsibilities are well defined. Staff that is sufficiently qualified and has received suitable training. An organization structure that promotes quality assurance.

Quality assurance

To supervise compliance, establish an independent quality assurance unit (QAU). Regular audits and inspections of study protocols and data.

Documentation and record keeping

All aspects of a study are comprehensively documented.

To avoid loss or damage, records must be legible, dated, and kept securely maintained.

Facilities and equipment's

Adequate facilities that adhere to safety and quality standards.

Equipment that has been properly maintained and calibrated, with paperwork to prove it.

Test and reference substance

The proper characterization and handling of test and reference compounds. Documentation of origin, identity, purity, and stability.

Data managements

There are systems in place to gather, manage, and store information. Procedures for data integrity, security, and accessibility

Reporting

Final reports must provide a thorough summary of the study's findings. Reports should follow a specific format and contain all important information.

Compliance with regulatory requirements

Complying with applicable national and international norms and recommendations. [30,31,32]

Test Systems

Characterization

Test systems, such as cell lines or animals, need to be appropriately described and maintained.

Ethical Treatment

It is imperative that test subjects be treated in accordance with ethical guidelines.

Standard Operating Procedures (SOPs)

Creation of SOPs

For all important processes and procedures, SOPs should be created.

Review and Revision

To take into account modern procedures and technological advancements, SOPs need to be periodically reviewed and updated.

Training and Competency

Ongoing Training

To guarantee that employees remain current on GLP regulations and procedures, ongoing training programs must be offered.

Training Documentation

All employees should have training records kept up to date.

Safety Procedures

Compliance with Health and Safety requirements

Measures must be taken to guarantee both laboratory safety and adherence to health requirements.

Emergency Procedures

It's important to set up and disseminate clear procedures for handling situations like spills and accidents.

Study Management

Study Director

Each study should have a certified study director in charge of general administration.

Project tracking

Mechanisms should be in place to monitor research developments and make sure deadlines are fulfilled.

Inventory Control

Substance Tracking

It is necessary to accurately track test and reference drugs during the course of their lives.

Monitoring of Expiration

Measures must be taken to keep an eye on and control the dates on which chemicals expire.

Inter-laboratory Comparisons

Collaboration: Opportunities for inter-laboratory comparisons and proficiency testing should be considered to ensure consistency and reliability.

Benchmarking

Regular benchmarking against industry standards can help maintain high-quality practices.

Handling of Non-compliance

Deviation Management

Clearly defined protocols should be put in place to handle non-compliance or departures from GLP.

Corrective Measures

Recurrence prevention and corrective action implementation procedures need to be recorded.

Animal Welfare Considerations

Ethical Evaluation

To guarantee humane treatment, animal research must go through an ethical evaluation.

Monitoring

Throughout the study, ongoing observation of the wellbeing and health of the animals

Environmental Considerations

Trash Management

Methods for appropriately getting rid of hazardous trash produced while conducting research.

Using ecologically friendly methods in laboratory operations is known as sustainability practices.

Data Security

Data Integrity

Putting policies in place to safeguard the privacy and reliability of data.

Backup systems

Consistent data backups to guard against vital information loss.

SOP'S

General Laboratory Practices

Guidelines for emergency protocols, the safe handling of hazardous products, and personal protective equipment (PPE) are all part of general laboratory practices.

Personnel Training Procedures

Documentation and competency evaluations are part of the protocols for staff onboarding and continuing training.

Equipment Operation, Equipment Use, and Equipment Maintenance

Protocols for using, calibrating, and maintaining lab apparatus, together with logs for these tasks.

Test Substance Management

Instructions on how to handle, label, and store test and reference substances correctly.

Preparing the Sample

Sample handling refers to the methods used to get samples ready for testing, including recording the chain of custody and sample integrity.

Study protocol Development

A standard structure for creating study protocols that includes the necessary components and approval procedures is the Study Protocol Development Protocol Template.

Information Gathering and Administration

Data entry and record-keeping: Methods for capturing, organizing, and preserving research data in order to guarantee its accuracy and traceability.

Audits and Quality Assurance

Sops for carrying out internal audits, inspections, and the procedure for handling non-compliance are known as quality control procedures.

Writing Reports

Step-by-step instructions for creating research reports that cover the necessary components, formatting, and review procedures.

Dealing with Deviations

Deviation management refers to the methods used to record and deal with departures from research protocols, including remedial measures.

Chemical Waste Management

Guidelines for the appropriate disposal of hazardous waste, including documenting, labelling, and segregation, are provided by Chemical Waste Management Waste Disposal Procedures.

Control of Inventory

Inventory management refers to the methods used to monitor and control the stock of test chemicals and lab equipment.

Utilization and Care of Animals

Guidelines for Animal Welfare: SOPs for the humane treatment and utilization of lab animals, taking into account moral issues and legal requirements.

Reporting Incidents

Procedures for reporting and recording spills, accidents, and other occurrences that take place in the lab are known as incident management procedures.[33]

Protocols for Communication

Guidelines for efficient internal communication among team members about study updates, modifications, and conclusions.

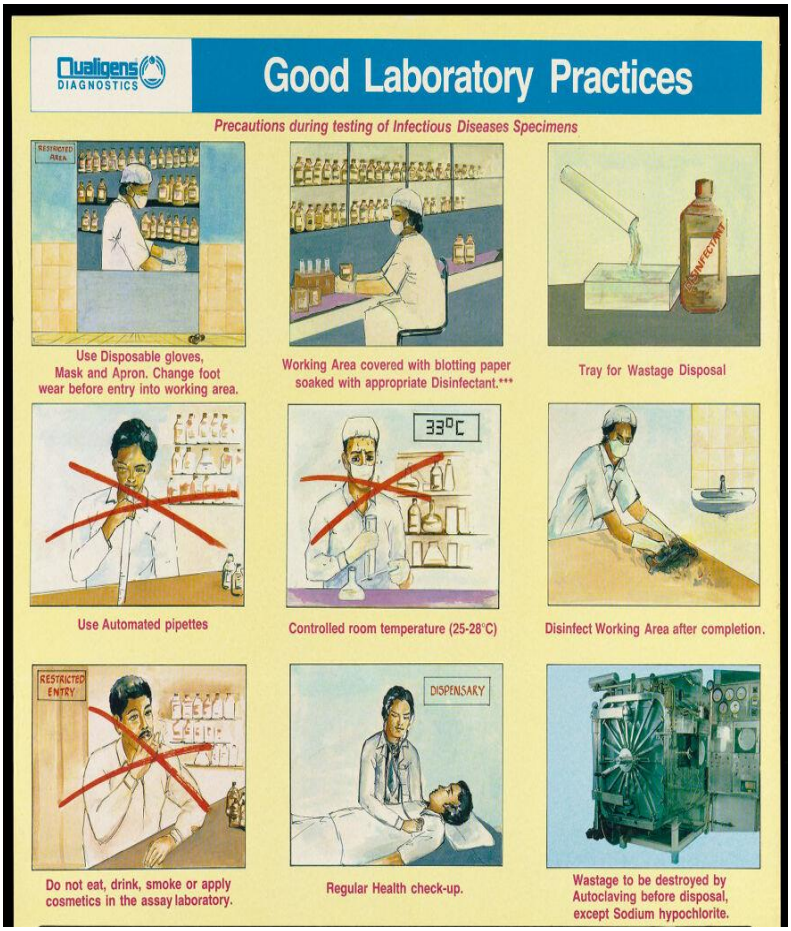

Figure 6*: *Safety Guidelines

Guidelines

Organization and Personnel Structure

Clearly identify positions and duties within your organization. Training: Make certain that all employees are suitably qualified and trained for their positions, and that records are kept up to date.

Assurance of Quality

To monitor adherence to GLP, keep an independent quality assurance unit. Audits: To ensure that GLP principles are being followed, conduct routine audits and inspections.

Facility Design and Maintenance

With the right environmental controls, laboratories should Be built to reduce contamination and guarantee safety.

Accessibility

Facilities must make it simple to obtain the tools and supplies needed to carry out research.

Equipment Validation

To guarantee accuracy, every utilized equipment needs to be tested and calibrated on a regular basis.

Maintenance

Keep thorough records of all calibration and maintenance procedures for your equipment.

Characterization of Test Systems

Adhere to ethical guidelines while characterizing and maintaining test systems, such as plants, animals, and cell lines.

Monitoring

Keep an eye on test systems during the study to make sure they're healthy and happy.

Identification of Test and Reference Substances

Clearly identify and describe each test and reference substance. Storage: To preserve the integrity of the material, follow the right handling and storage protocols.

Research Procedures

Documented Protocols: Prior to beginning any study, draft and approve a documented protocol. Modifications: Throughout the study, record and support any modifications to the protocol. Management of Data.

Data Recording

Make sure that data can be linked back to the original observations by data.

Reporting on Research

Write thorough research papers that cover methodology, findings, and conclusions.

Documentation of Deviations

Keep track of any protocol deviations and describe how they affect the study.

Retention term

To guarantee traceability, establish and adhere to a retention term for every paperwork.

Adherence to Regulations

Standards Adherence

Comply with applicable national and international GLP laws and recommendations, such as those issued by the FDA, WHO, or OECD.

Moral Aspects

Animal Welfare

Make sure that the ethical rules governing the care of study animals are followed. Obtaining informed consent for human studies is necessary, if applicable.

Safety Protocols for Emergency Procedures

Create and disseminate emergency protocols in the event of mishaps or spills of hazardous materials.[34]

CONCLUSION

Good laboratory practices (GLP) are critical for maintaining the integrity, dependability, and quality of scientific research. By following defined protocols, laboratories may ensure consistency in data collection and analysis, boosting the trustworthiness of their findings. GLP not only enhances results accuracy, but it also plays an important role in reducing the dangers connected with laboratory work, assuring people and environmental safety. Furthermore, compliance with GLP rules allows firms to meet legal and regulatory obligations, which can facilitate smoother inspections and audits' places a high value on data integrity. Proper recording of processes, outcomes, and any variations ensures data traceability and reproducibility, which is critical for the scientific community. Furthermore, GLP emphasizes the necessity of continual training and competency for laboratory personnel, promoting a culture of professionalism and accountability. Regular training ensures that personnel are familiar with current procedures and safety protocols, which improves overall laboratory performance. Furthermore, GLP promotes a culture of continual improvement. Organizations can drive innovation and efficiency by examining and updating laboratory processes on a regular basis. To summarize, effective laboratory practices form the foundation of credible scientific research, supporting quality, safety, and regulatory compliance while cultivating an environment of integrity and continual improvement. Adopting these standards is critical for every laboratory that wants to make a significant contribution to the scientific community and society as a whole.

REFERENCES

1. D.M.Morens., G.K. Folkers., A.S. Fauci., The Challenge of Emerging and Re-Emerging Infectious Diseases, Journal of Nature,2004:4(1):249-260.
2. A.K. Feehan., J. Garcia-Diaz., Investigator Responsibilities in Clinical Research, Journal of Ochsner, 2020:20(1):44–49.
3. J. Muhammad., S. Sarwar., T. Khan., S.A. Qasmi., A. Ikram., A Cross-Sectional Surveyto Assess Biorisk Management System in Research and Diagnostic Laboratories in Khyber Pakhtunkhwa, Journal of Public Health, 2021:12(2):76-61.
4. Weise A., Buse J., Schauerte A., Good Laboratory Practice G.L.P. in Analytical Laboratories, Journal of Accred Quality Assurance, 2016:21(3):171-183.
5. J. Cohen., Alarm Over Biosafety Blunders, Second Edition, New York,2014, pp.247–248.
6. F.A. Ali., L.A. Pulido., M.N. Garza., M.H. Amerson., A Professional Development Model for Medical Laboratory Scientists Working in the Core Laboratory, Journal of American Society Clinic Laboratory Science, 2012:25(2):67-73.
7. L. Huang., L. Cheng., Q. Cai, R.O. Kosik., Curriculum Reform at Chinese Medical Schools, First Ed., America,2014, pp.1043–1050
8. A.K. Atek., A. Baguma., P. Okwalinga., Biorisk Management Practicesin Public and Private Laboratories in Uganda A Nationwide Baseline Survey, Journal of Bioterrible and Biodefense,2018:9(2):12-19.
9. Hospital Acquired Infections, Https://Www.Healthline.Com/Health/Hospital-Acquired-Nosocomial-Infections(accessed 01.05.22).

10. D. Gillum., P. Krishnan., K. Byers., Asearchable Laboratory and Acquired Infection Database, Journal of Applied Biosafety,2016:21(3):203–207.
11. I.N. Okeke., Towards A fiercely Urgent Expansion of Laboratory Medicine, Journal of Laboratory Medium,2021:10(1):1785-1790.
12. M. Sahrish., Laboratory Biosafety and Biosecurity Related Education in Pakistan Engaging Students Through the Socratic Method of Learning, Journal of Biosafety Biosecurity,2021: 3(1):22–27.
13. L. Hong., R. Zhang., R. Zhao., H. Shen., Investigation of the Awareness in Laboratory Biosafety Among Teachers and Students of Medical Colleges in Jiangsu Province, Journal of Disease Control Prevention,2010:14(5):447–450.
14. F.A. Ali., L.A. Pulido., M.N. Garza., M.H. Amerson., A Professional Development model for Medical Laboratory Scientists Working in the Core Laboratory, Journal of American Society Clinical Laboratory Science,2012:25(2):67–73.
15. J.M. Deboy., A. J. Beck., M.L. Boulton., D.H. Kim., M.D. Wichman., P.F. Luedtke., Corecourses in Public Health Laboratory Science and Practice Surveys, Journal of Public Health Representative,2013: 128(2):105–114.
16. Stat Pearls Publishing Treasure Island, Https://Search.Worldcat.Org/Title/Statpearls/Oclc/1021256616 (accessed 01.05.22).
17. The Scope of Biosafety and Biosecurity in Uganda A Consensus Study Report, Policy Recommendations for the Control of Associated Risks, Https://Doi.Org/10.1016/J.Bsheal.2022.08.005 (accessed 01.05.22).
18. B. Muriithi., M. Bundi., A. Galata., G. Miringu., Biosafety and Biosecurity Capacity Building Insights from Implementation of the Biosafety Training Model, Journal of Tropical Medicine and Health, 2018:46(2):30.
19. R.H. Hill., Undergraduates Need A Safety Education, Journal of Chemical Education,2016:93(1):1495–1498.
20. T. Ssekamatte., T. Mukama., S.P. Kibira., R. Ndejjo., J.N. Bukenya., Z.P. Kimoga., R. Nuwematsiko., E. Buregyeya., J.C. Ssempebwa., Hepatitis Bscreening and Vaccination Status of Healthcare Providers in Wakiso District, Uganda, Plos One, 2020:15(3):235-470.
21. A. Abu-Siniyeh., S.S. Shehri., Safety in Medical Laboratories Perception and Practice of University Students and Laboratory Workers, Journal for Application of Biosafety,2021:26(4):42-48.
22. A.J. Abhayaratne., Y. Samarasinghe., U.M. Francis., an Assessment of the knowledge, Attitudes Practices Among Medical Laboratory Technicians on biosafety Precautions in Selected Government Healthcare Institutions, International Journal of Science and Healthcare Research,2020:5(2):78–85.
23. E. Hunsperger., B. Juma., C. Onyango., Building Laboratory Capacity to Detectand Characterize Pathogens of Public and Global Health Security Concern in Kenya, Journal for Public Health, 2019:19(1):47-57.
24. F. Lestari., A. Kadir., T. Miswary., C.F. Maharani., A. Bowolaksono., D. Paramitasari., Implementation of Bio-Risk Management System in A National Clinical and Medical Referral Centre Laboratory, International Journal of Environment Research, 2022:18(4):399–405.
25. Sinha S., Vohora D., Drug Discovery and Development Pharmaceutical Medicine and Translational Clinical Research, Second Edition, Boston, 2018, pp. 19–32.

26. J.W Kille., Regulatory Toxicology a Comprehensive Guide to Toxicology in Nonclinical Drug Development, Cambridge, 2017, pp.499–539.
27. S. Saganuwan., Toxicity Studies of Drugs and Chemicals in Animals: An Overview, Journal of Veterinary Medicine, 2017:20(4):291–318.
28. J. Colerangle., Preclinical Development of Non-Oncogenic Drugs a Comprehensive Guide to Toxicology in Nonclinical Drug Development, Second Edition, Cambridge, 2017, pp.659–683.
29. M. Dorato., L. Buckley., Toxicology Testing in Drug Discovery and Development. Journal of Current Protocols in Toxicology,2007:31(1):11–19.
30. C. Russell., A. Rahman., A. Mohammed., Application of Genomics, Proteomics and Metabolomics in Drug Discovery, Journal of Development and Clinic,2013:4(3):395–413
31. Andrade EL., Bento AF., Cavalli J., Oliveira SK., Schwanke RC., Non-Clinical Studies in the Process of New Drug Development Good Laboratory Practice, Metabolism, Pharmacokinetics, Journal of Medical Biology Research, 2016:49(12):46-54.
32. Jawahar N., Lakshmi T., Regulatory Requirements for the Drug Approval Process in US, Journal of Pharmaceutical Science Research,2017:9(10):1943–1952.
33. Turnheim D., Benefits of Good Laboratory Practice As A Tool to Improve Testing, Journal of Human Experimental Toxicology,1993:12(6):528–532.
34. Heinz-Taheny K., Pathology and Glps., Quality Control and Quality Assurance. in: Haschek and Rousseaux's Handbook of Toxicologic Pathology,Second Edition, 2013, pp. 51-56.