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GOOD LABORATORY PRACTICES IN PHARMACEUTICAL RESEARCH: REGULATIONS AND BEST PRACTICES

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ABSTRACT

The term good practice is a set of principles that provides a framework for laboratory studies to be planned, performed, monitored, recorded, reported and archived. GLP governs non clinical studies conducted to evaluate the safety and efficacy of chemicals.

The term "good practice" indicates and established way of doing or performing of an activity in the way that is generally recognised as being the proper one. Good Laboratory Practices (GLP) in general symbolizes the "good practices" which need to be used in the laboratory, the purpose of which is testing the physical, chemical and microbial testing of materials as applicable and to avoid threat or hazardous to humans.

"Good Laboratory Practices "are a quality system, which establishes accurate documentation covering all aspects of a study and it's environment with regard to quality and integrity and reliability of safety data. The GLP have been formulated primarily to promote the quality and validity of test data used for determining the safety of the product.

It also describes the recommended practices in judging for "positive" response and to avoid hazardous substances, which affect the environment, and finally human health.

Keywords: GLP, FDA, OECD, EMA, Data management, Traceability, Documentation practices, Risk Management.

1. INTRODUCTION

Good Laboratory Practices (GLP) is mandatory requirement in all pharmaceutical industries. GLP in general is a quality management system for organization and integrity of non- clinical safety tests. A test facilitates on pharmaceutical must comply with the GLP regulations while carrying out safety tests and submission of safety assessment data to the regulatory authorities to ensure quality and safety of the drug is nothing but GLP compliances.[2] GLP intended to promote the quality and validity of the test data. This were primarily developed to create a uniform standard of laboratory testing across all scientific disciplines that could impact public health.[22] The GLP research data is crucial in risk assessments for users, consumers, and the environment in a variety of industries such as industrial and agrochemicals, pharmaceuticals, veterinary medications, cosmetics, biocides, feed additives, and so on. It is a management concept that includes the organizational process and conditions under which laboratory research is planned, conducted, monitored, recorded and reported.[15]

History of GLP

Good Laboratory Practice (GLP) was first introduced in New Zealand in 1972 to promote fair practices in testing laboratories, and Denmark also implemented GLP in the same year. The USA established GLP in 1978 after the FDA accused US research laboratories of misconduct. Searl scientists designed a GLP document as a guide for evaluating research activities, which led to the FDA implementing GLP regulations in 1979. The OECD Principles of GLP came into force in 1981, and the European Union adopted GLP principles in 1987. India made GLP mandatory in 2010. [4]

GLP is an official regulation created by the FDA in 1978 [4]. The OECD Principles of GLP were developed in 1978 by an Expert Group under the control of chemicals.[13] The regulations serve as international standards for non-clinical laboratory studies and were published by the FDA in 1976 [24] .They were endorsed by the OECD Council in 1981 for use in member countries. These principles are an essential part of data assessment for chemical safety and protection of man and the environment.[5]

The OECD works on chemical safety under the Environmental Health and Safety Division, publishing documents on Good Laboratory Practice and compliance monitoring. The most widely accepted guideline for GLP is set by the OECD, forming the basis for international agreements on data acceptance. GLP principles ensure the quality and validity of test data used for assessing chemical safety, protecting researchers from unfounded allegations and promoting fair practices in laboratories. Following GLP guidelines can benefit institutions and laboratories seeking to ensure the accuracy and reliability of their research activities.[26]

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Good Laboratory Practices

GLP embodies a set of principles that provide a framework within which laboratory studies are planned, monitored, recorded, reported and achieved.[22] GLP preferred in most laboratory settings because of its high durability and resistance. Good Laboratory Practice (GLP) refers to a collection of rules and standards that are designed to guarantee the integrity, uniformity, and dependability of non-clinical lab research, particularly those that are utilized to back up research and regulatory filings in the pharmaceutical sector.[11] The GLP principles emphasize documentation, traceability, and integrity in all study aspects, identifying potential risks and implementing controls to mitigate them, particularly in ensuring safety and efficacy of new medicines before trials[3]

SOP (STANDARD OPERATING PROCEDURE)

According to EPA GLP regulations, "Raw data" includes laboratory worksheets, records, and notes that are necessary for reconstructing and evaluating a study report. Examples of raw data are logbooks, notebooks, and computer printouts. Standard Operating Procedures (SOPs) help ensure all details are documented properly. In FDA, it is emphasized that if something is not documented, it is as if it never happened. While SOPs can't guarantee perfect science or prevent all errors, they are crucial for maintaining good documentation and common sense in laboratory procedures. SOPs outline protocols for test objectives and methods, ensuring data quality and integrity.[5] They need to be approved by test facility management and must be followed for routine activities such as cleaning, maintenance, and testing. SOPs should be clear and detailed, allowing trained personnel to carry out procedures effectively. Deviations from SOPs should be documented and approved by the Study Director.[2] In laboratory operations, it is essential to follow SOPs to maintain quality and integrity in data generation. Room preparations, test system handling, and Quality Assurance inspections are also covered in SOPs. SOPs should be scientifically sound, constantly updated, and written in a clear and concise manner to avoid unnecessary steps or confusion. Study personnel are responsible for following SOPs and taking necessary health precautions.[23] SOPs serve as documented procedures for routine test facility operations, providing detailed instructions for various activities. Test site personnel should follow SOPs unless directed otherwise by the Study Director, with such deviations clearly outlined in the study plan.[5]

- Routine inspection, cleaning, maintenance, testing and calibration.
- Action be taken in response to equipment failure.
- Analytical methods.
- Definition of raw data.
- Keeping records, reporting, storage, mixing and retrieval of data.

Purpose of GLP

Good laboratory practice (GLP) aims to improve the quality and validity of test data for determining chemical safety. It focuses on reducing mistakes through specific labeling requirements and practical experience.[7] GLP guidelines are established by regulatory authorities such as the FDA and EMA to ensure that preclinical data fulfils the quality criteria for drug approval. They protect human health by giving accurate information about the safety and efficacy of new pharmacological products. Adherence to GLP streamlines global drug development and approval processes, eliminates scientific misconduct, and increases the trustworthiness of findings.[23]

GLP regulations

GLP Regulations aimed to provide rules for good practices in the laboratories.[13] The guidelines and regulations helps in the standardization of processes guaranteeing the safety, efficacy and quality of pharmaceutical products. Key Regulations: OECD, EMA and European union directives, FDA .[24]

1.Organization for Economic Co-operation and Development (OECD) : The OECD Principles of Good Laboratory Practice (GLP) set quality standards for test facility organization and safety studies.[26] They cover daily activities like testing layout, equipment cleaning, animal handling, and recording results. These principles ensure studies submitted to regulatory authorities are of sufficient quality and verifiable.

OECD an intergovernmental organisation composed of 29 industrialised countries from North America, Europe, the Pacific, and the European Union[27], has initiated the task of harmonising these standards in the international trade of chemicals, agrochemicals, and pharmaceutical products.[12] These worldwide standards are primarily intended to eliminate duplicate testing and make the best use of monitoring and human resources.[26] The OECD council's expert group on GLP officially published the GLP document in 1981[10], stating that "Data generated in the testing of chemicals in an OECD member country in accordance with OECD test guidelines and principles of Good Laboratory Practice shall be accepted in other member countries for purposes of assessment and other uses relating to the protection of man and the environment." Subsequently,[6]

2.The Food and Drug Administration (FDA) Good Laboratory Practices (GLP) is a quality system created by the FDA in 1978 for non-clinical health and environmental safety research. It deals with problems such as miscalibration of equipment, incorrect calculations, inadequate test systems, substitution of animals and fabrication of test results...[4]

3.The European Medicines Agency (EMA)[11] and the European Union (EU) have both implemented GLP regulations to guarantee the quality and integrity of non-clinical safety testing data for pharmaceuticals, veterinary medicines, and specific food additives.[27]

Best Practices in GLP:

Standards are essential in ensuring the quality reliability and integrity of data generated in laboratories. Here, some of the best practices tv ensure compliance with GLP.

Documentation and records maintenance :

Maintaining all records is crucial in regulated labs to ensure documentation for legal disputes arising from initial analysis decisions. It is recommended to keep records for at least five years, with the duration depending on the specific circumstances. Analytical reports must include a signature and date from the project manager to show responsibility for data accuracy. Adherence to these standards should also be noted. Maintaining records ensures documentation for legal challenges related to initial analysis decisions.[17]

Standard Operating Procedure

Written SOPs outlining research techniques that management deems sufficient to guarantee the accuracy and integrity of data produced during a study must be present in a testing facility." η Program guidelines in writing for a lab.[5] They provide how to perform actions that are described by the protocol. Usually expressed as a sequential list of steps to take. They are meant to provide clarification on how the processes are meant to operate

Calibration of equipment

Equipment calibrations should be conducted with standards that can be traced back to approved standards, if they exist.Records of these calibrations should be kept. The present CALIBRATION state of important equipment must be known and verified

Quality assurance

Quality control involves accepting or rejecting components, drug products, and reviewing production records to prevent errors. Test data quality depends on the test system's condition. Compliance with Good Laboratory Practice (GLP) requires suitability, capacity, and integrity. A documented Quality Assurance Programme is performed by individuals, and effective communication is crucial. Records of test site activities are maintained.[24]

Reporting Data integrity and security :

The degree to which the data is unimpaired

The degree to which the data is "fit for purpose" for the correct operation of the application

The degree to which the details of the data are protected

Receipt, handling, sampling and storage

Sample tracking in laboratories involves proper preparation, handling, sampling, and storage of samples, maintaining records for homogeneity and stability, and identifying handling procedures to prevent contamination, with storage containers carrying specific instructions.

Environmental control

Environmental control in pharmaceutical cleanrooms is crucial for quality product manufacturing, ensuring airborne particulate, microorganisms, temperature, humidity, differential pressure, airflow, velocity, and personnel safety through design, validation, and ongoing monitoring.

2. ADVANTAGES OF GLP

- Assures that the data are a true reflection of results obtained from studies.
- Preclinical safety and residue safety.
- Generation of high quality and reliable test data.
- Mutual acceptance of data
- Increases public confidence.
- Shortens the time-to-market for new products.

3. DISADVANTAGES OF GLP

- Expensive process.

- Time consuming process.
- More man power is required.

Benefits of good laboratory practices.

It will give better image of company as a Quality producer in Global market.

Provide hot tips on analysis of data as well as measure uncertainty and perfect record keeping.

Provide guideline for doing testing and measurement in detail.

Provide guidelines and better control for maintenance of instruments, environment control, preservation of test records etc.

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Provide hot tips on analysis of data as well as measure uncertainty and perfect record keeping.

Provide guideline for doing testing and measurement in detail. Provide guidelines and better control for maintenance of instruments, environment control, preservation of test records etc...[12]

4. CONCLUSION

GLP (Good Laboratory Practice) is a crucial tool in ensuring the quality of data used in laboratories, which is relied upon by regulatory authorities and represents genuine test results. It helps prevent fraud activities and ensures that quality data is submitted to authorities. India, a full member of the Mutual Acceptance of Data (MAD) group in the OECD, can obtain a GLP certificate from the National Good Laboratory Practice Compliance Monitoring Authority (NGCMA) under the Department of Science and Technology (DST). This certification helps manufacturers of drugs and pharmaceuticals better present their company as a quality producer in the global market. GLP also provides guidelines and better control for maintaining and preserving environment control and instruments. Compliance with GLP regulations, established by the OECD and FDA, is essential for meeting regulatory requirements and protecting public health. Implementing GLP practices helps obtain quality and reliable data and minimizes hazardous waste in laboratories. Good Laboratory Practices have become an essential tool for professional scientists.

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