Good Laboratory Practice (Glp) Requirements: An Overview

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Abstract: Organization for Economic Co-Operation and Developments (OECD) member countries have recently passed legislation to control chemical substances and others are about to do so. This legislation usually requires the manufacturer to perform laboratory studies and to submit the results of these studies to a governmental authority for assessment of the potential hazard to human health and the environment. Government and industry are increasingly concerned with the quality of studies upon which hazard assessments are based. As a consequence, several OECD Member countries have, or plan to establish, criteria for the performance of these studies. This article offers an overview on the laboratory practice requirements. [New York Science Journal 2010;3(9):86-90]. (ISSN: 1554-0200).

Keywords: Organization for Economic Co-Operation and Developments (OECD); legislation; hazard assessment; laboratory; practice

BASICS OF GOOD LABORATORY PRACTICE

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The purpose of these Principles of Good Laboratory Practice is to promote the development of quality test data. Comparable quality of test data forms the basis for the mutual acceptance of test data among countries. If individual countries can confidently rely on test data developed in other countries, duplicative testing can be avoided, thereby introducing economics in test costs and time. The application of these Principles should help avoid the creation of technical barriers to trade, and further improve the protection of human health and the environment.

SCOPE OF GOOD LABORATORY PRACTICES:

These Principles of Good Laboratory Practice should be applied to testing of chemicals to obtain data on their properties and/or their safety with respect to human health or the environment. Studies covered by Good Laboratory Practice also include work conducted in field studies. These data would be developed for the purpose of meeting regulatory requirements. Good Laboratory Practice (GLP) is concerned with the organizational process and the conditions under which laboratory studies are planned, performed, monitored, recorded, and reported as well as Test facility of laboratories means the persons, premises, and operational unit(s) that are necessary for conducting the study and Director have the individual responsible for the overall conduct of the study conducted Quality Assurance Programme an internal control system designed to ascertain that the study is in compliance with these Principles of Good Laboratory Practice. Laboratory have Standard Operating Procedures (SOPs) written procedures which describe how to perform certain routine laboratory tests or activities normally not specified in detail in study plans or test guidelines.

Good Laboratory practices have following requirements and responsibility

TEST FACILITY ORGANISATION AND PERSONNEL

Management's Responsibilities

Ensure that qualified personnel, appropriate facilities, equipment, and materials are available maintain a record of the qualifications, training, experience and job description for each professional and technical individual ensure that personnel clearly understand the functions they are to perform and, where necessary, provide training for these functions guidelines for health and safety precautions are applied according to national and international regulations used appropriate Standard Operating Procedures are established and followed ensure that there is a Quality Assurance Programme with designated personnel where appropriate, agree to the study plan in conjunction with the sponsor ensure that amendments to the study plan are agreed upon and documented; maintain copies of all study plans; maintain a historical file of all Standard Operating Procedures; for each study ensure that a sufficient number of personnel is available for its timely and proper conduct; for each study designate an individual with the appropriate qualifications, training, and experience as the Study Director before the study is initiated. If it is necessary to replace a study director during a study, this should be documented ensure that an individual is identified as responsible for the management of the archives.

Study Director's Responsibilitie

The Study Director has the responsibility for the overall conduct of the study and for its report. These responsibilities should include, but not be limited to, the following functions: should agree to the study plan; ensure that the procedures specified in the study plan are followed, and that authorisation for any modification is obtained and documented together with the reasons for them; ensure that all data generated are fully documented and recorded; sign and date the final report to indicate acceptance of responsibility for the validity of the data and to confirm compliance with these Principles of Good Laboratory Practice; ensure that after termination of the study, the study plan, the final report, raw data and supporting material are transferred to the archives.

Personnel Responsibilities of employee

Personnel should exercise safe working practice. Chemicals should be handled with Suitable caution until their hazard(s) has been established. Personnel should exercise health precautions to minimize risk to them and to ensure the integrity of the study. Personnel known to have a health or medicinal condition that is likely to have an adverse effect on the study should be excluded from operations that may affect the study.

QUALITY ASSURANCE PROGRAMME

The test facility should have a documented quality assurance programme to ensure that studies performed are in compliance with these Principles of Good Laboratory Practice. The quality assurance programme should be carried out by an individual or by individual's designated by and directly responsible to management and who are familiar with the test procedures. This individual(s) should not be involved in the conduct of study being assured. This individual(s) should report any findings in writing directly to management and to the Study Director.

Responsibilities of the Quality Assurance Personnel

The responsibilities of the quality assurance personnel should include, but not be limited to, functions ascertain that the study plan and Standard Operating Procedures are available to personnel conducting the study ensure that the study plan and Standard Operating Procedures are followed by periodic inspections of the test facility and/or by auditing the study in progress. Records of such procedures should be retained. promptly report to management and the Study Director unauthorized deviations from the study plan and from Standard Operating Procedures; review the final reports to confirm that the methods, procedures, and observations are accurately described, and that the reported results accurately reflect the raw data of the study; prepare and sign a statement, to be included with the final report, which specifies the dates inspections were made and the dates any findings were reported to management and to the study director.

Minimum required facilities

The test facility should be of suitable size, construction and location to meet the requirements of the study and minimize disturbances that would interfere with the validity of the study. The design of the test facility should provide an adequate degree of separation of the different activities to assure the proper conduct of each study.

Test System Facilities

The test facility should have a sufficient number of rooms or areas to assure the isolation of test systems and the isolation of individual projects, involving substances known or uspected of being biohazardous. Suitable facilities should be available for the diagnosis, treatment and control of diseases, in

order to ensure that there is no unacceptable degree of deterioration of test systems. There should be storage areas as needed for supplies and equipment. Storage areas should be separated from areas housing the test systems and should be adequately protected against infestation and contamination. Refrigeration should be provided for perishable commodities.

Facilities for Handling Test and Reference Substances

Prevent contamination there should be separate areas for receipt and storage of the test and reference substances, and mixing of the test substances with a vehicle. Storage areas for the test substances should be separate from areas housing the test systems and should be adequate to preserve identity, concentration, purity, and stability, and ensure safe storage for hazardous substances.

Waste Disposal and Handling

Handling and disposal of wastes should be carried out in such a way as not to jeopardise the integrity of studies in progress. The handling and disposal of wastes generated during the performance of a study should be carried out in a manner which is consistent with pertinent regulatory requirements. This would include provision for appropriate collection, storage, and disposal facilities, decontamination and transportation procedures, and the maintenance of records related to the preceding activities.

APPARATUS AND REAGENTS

Apparatus.

Apparatus used for the generation of data, and for controlling environmental factors relevant to the study should be suitably located and of appropriate design and adequate capacity. Apparatus used in a study should be periodically inspected, cleaned, maintained, and calibrated according to Standard Operating Procedures. Records of procedures should be maintained.

Reagents

Reagents should be labelled, as appropriate, to indicate source, identity, concentration, and stability information and should include the preparation date, earliest expiration date, specific storage instructions.

TEST SYSTEMS

Apparatus used for the generation of physical/chemical data should be suitably located appropriate design and adequate capacity. Reference substances should be used to assist in ensuring the integrity of the physical/chemical test systems in case of biological samples. Proper conditions should be established and maintained for the housing, handling and care of animals, plants, microbial as well as other cellular and sub-cellular systems, in order to ensure the quality of the data. In addition, conditions should comply with appropriate regulatory requirements for the import, collection, care and use of animals, plants, microbial as well as other cellular and sub-cellular systems. Newly received animal and plant test systems should be isolated until their health status has been evaluated. If any unusual mortality or morbidity occurs, this lot should not be used in studies and, when appropriate, humanely destroyed. Records of source date of arrival, and arrival condition should be maintained. Animal, plant, microbial, and cellular test systems should be acclimatized to the test environment for an adequate period before a study is initiated. All information needed to properly identify the test systems should appear on their housing or containers. The diagnosis and treatment of any disease before or during a study should be recorded.

TEST AND REFERENCE SUBSTANCES

Receipt, Handling, Sampling and Storage

Records including substance characterization, date of receipt, quantities received, and used in studies should be maintained. Handling, sampling, and storage procedures should be identified in order that the homogeneity and stability is assured to the degree possible and contamination or mix-up are precluded. Storage container(s) should carry identification information, earliest expiration date, and specific storage instructions.

Characterization

Each test and reference substance should be appropriately identified (e.g. code, Chemical abstract number (CAS), name), batch number, purity, composition, concentrations, or other characterizations to appropriately define each batch of the test or reference substances should be known. Stability of test and reference under conditions of storage should be known for all studies. If the test substance is administered in a vehicle, Standard Operating Procedures should be established for testing the homogeneity and stability of the test substance in that vehicle sample for analytical purposes from each batch of test substance should be retained for studies in which the test substance is tested longer than four weeks.

STANDARD OPERATING PROCEDURES

A test facility should have written Standard Operating Procedures approved by management that are intended to ensure the quality and integrity of the data generated in the course of the study. Each separate laboratory unit should have immediately

available Standard Operating Procedures relevant to the activities being performed therein. Published text books, articles and manuals may be used as supplements to this Standard Operating Procedure.

PERFORMANCE OF THE STUDY

For each study, a plan should exist in a written form prior to initiation of the study. The study plan should be retained as raw data.All changes, modifications, or revisions of the study plan, as agreed to by the Study Director, including justification(s), should be documented, signed and dated by the Study Director, and maintained with the study plan.

REPORTING OF STUDY RESULTS:

The use of the International System of Units (SI) is recommended and final report should be signed and dated by the Study Director. If reports of principal scientists from co-operating disciplines are included in the final report, they should sign and date them. Corrections and additions to a final report should be in the form of an amendment. Amendment should clearly specify the reason for the corrections or additions and should be signed and dated by the Study Director and by the principal scientist from each discipline involved.

Final Report should cantain fallowing minimum information:

A: Identification of the Study, the Test and Reference Substance

- descriptive title;
- Identification of the test substance by code or name (IUPAC; CAS number, etc.);
- Identification of the reference substance by chemical name;
- Characterization of the test substance including purity, stability and homogeneity.

B: Information Concerning the Test Facility

- Name and address;
- Name of the Study Director;
- Name of other principal personnel having contributed reports to the final report.
- Dates
- Dates on which the study was initiated and completed.

C: Statement

- Quality Assurance statement certifying the date's inspections were made and the dates any findings were reported to management and to the Study Director.

D: Description of Materials and Test Methods

- Description of methods and materials used
- Test Guidelines or other test guidelines

E: Results

- summary of results;
- All information and data required in the study plan;
- A presentation of the results, including calculations and statistical methods;
- An evaluation and discussion of the results and, where appropriate, conclusions.
- Storage location where all samples, specimens, raw data, and the final report are to be stored.

STORAGE AND RETENTION OF RECORDS

Storage and Retrieval

Archives should be designed and equipped for the accommodation and the secure storage of study plans, raw data, final reports, reports of laboratory inspections and study audits performed according to the quality assurance programme samples and specimens. Material retained in the archives should be indexed so as to facilitate orderly storage and rapid retrieval. Only personnel authorized by management should have access to the archives. Movement of material in and out of the archives should be properly recorded.

Retention

Retained for the period specified by the appropriate authorities. The study plan, raw data, samples, specimens, and the final report of each study; Records of all inspections and audits performed by the Quality Assurance Programme Summary of qualifications, training, experience and job descriptions of Personnel Records and reports of the maintenance and calibration of equipment. The historical file of Standard Operating Procedures to be maintained. Samples and specimens should be retained only as long as the quality of the preparation permits evaluation. If a test facility or an archive contracting facility goes out of business and has no legal successor, the archive should be transferred to the archives of the sponsor(s) of the study(s).

Conclusion:

A laboratory that has implemented a quality system has definite advantages when performing testing in compliance with Good Laboratory Practice. Manufacturers exporting their products in the OECD member countries have already complied with OECD requirements of GLP in addition to the country specific requirements. Some manufacturers have complied 21 CFR 58 requirements who are exporting in USA in addition to OECD requirements. There are some manufacturers who have already complied with the requirements of GLP voluntarily. It is expected that rest of the companies will be able to comply with

the requirements of GLP by the target date as notified by Govt. of India vide G.S.R.780 (E) dated 10th November 2008 under schedule "L-1" with effect from the 1st day of November, 2010. Manufacturers of Drugs and Pharmaceuticals may procure GLP Certificate from National Good Laboratory Practice (GLP) Compliance Monitoring Authority under the Department of Science and Technology (DST), Government of India which may give them edge over their competitors as the data generated by the GLP certified laboratories is accepted by the OECD countries.

7/12/2010