GLP the standard

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Abstract

Non-clinical research is the one of the processes of health product development. Typically, this process has to test products in the qualified laboratory on many standards that required from each country. Good Laboratory Practice is a quality system which intends to ensure, through careful and accurate documentation, covering all aspects of a study and environments, the quality, integrity and reliability of safety data.

Key words: good laboratory practice, test facilities, OECD GLP

Objectives:

1. To understand the basic elements of Good Laboratory Practices.
2. To understand the history and principle of OECD Good Laboratory Practices.

Non-clinical research is the one of the processes of health product development. Typically, this process has to test products in the qualified laboratory on many standards required by each country. The basic factor to ensure the quality and safety of products is the result of laboratory testing. In many countries, when the companies want to sell health products, they must compile the requirements of each country such as they must have the testing result of safety and efficacy to regulate products with FDA (Food and Drug Administration). In addition, the developed countries have the law to protect their population from hazards. Normally, the test result of health products is the basic requirement from FDA in many countries. Almost all of the standard for registration of health products requires the testing of pharmaceutical products, pesticide products, cosmetic products, veterinary drugs as well as food additives, feed additives, and industrial chemicals [2]. The concept of non-clinical research is preventing risk by testing and assessing chemicals to determine their potential hazards [2,3].The requirements of safety data will help the FDA to screen out the dangerous drugs or chemicals that affect human-safety. However, when the companies send the data of testing to FDA, it does not mean that the result of studies is reliable and adequate. Consequently, many countries have established particular criteria for the performance of the non-clinical studies.

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A brief history of GLP (Good Laboratory Practice) ,from the 1960s and 1970s, a climate of environmentalism and fear of the negative health effects of chemicals became widespread and raved about it[1,2].In 1972,New Zealand formally introduced GLP as the Testing Laboratory Regulation Act, that covered staffed record and many documents. Later in December 1978, United States of America (USA) FDA published US-GLP and made compliance with their law in June 1979. In addition, the Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice was first developed by an Expert Group on GLP established in 1978 for control of Chemicals.[2]

The OECD GLP principles have the long story. first, OECD GLP experts Group established in 1978 under the Special Program on the Control of Chemicals, this group is a coordinating group of expert which is the part of many Guidelines for the pharmaceutical or chemical companies who want to regulate and sale their products in the member countries. The Guidelines were formally recommended to use by member states of the OECD that have signed an agreement binding them to OECD GLP Principles in 1981, which states that “data generated in the testing of chemicals in an OECD Member countries in accordance with OECD Test Guidelines and OECD 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” [2]

At the present, the most powerful Laboratory ’ s standard for regulations in health products is OECD GLP, the principle of OECD GLP were formally recommended to use for 35 member countries : Australia, Austria, Belgium, Canada, Chile, CZECH republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Luxembourg, Mexico, Netherland, New Zealand, Norway, Poland, Portugal, Slovak republic, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom and United states. The OECD GLP guideline required to be followed by test facilities.

The conditions under the OECD GLP guideline are that Laboratory studies must be planned, performed, monitored, recorded and reported. They are many country members and almost all of them are the developed countries that have the powerful purchases.

Basically, the OECD GLP principles refers to the quality system of management controls for research laboratories and organizations to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of chemical (including pharmaceuticals) non-clinical safety tests; from physio-chemical properties through acute to chronic toxicity tests.[2]

Elements of Good Laboratory Practices in general, basic elements of GLP may be defined as follows [2,4]:

1. Resources

Personnel, Facilities and equipment:

GLP regulations require that the structure of organizations and the responsibilities personnel be clearly defined. It also stresses that there should be sufficient staff to perform the tasks required. The qualifications and the training of staff must also be defined and documented. Moreover, the test facilities should have the sufficient facilities such as rooms or area to ensure the isolation of test systems and the isolation of individual projects and equipment to perform the studies. All equipment must be in working order. To ensure this, a strict programme of qualification, calibration and maintenance must be adopted.

2. Characterization

In order to perform a study correctly, it is essential to know as much as possible about the materials used during the study. The responsibilities of Sponsors in OECD GLP Guideline are that the sponsor should understand the requirements of the Principles of Good Laboratory Practice, in particular those related to the responsibilities of the test facility management and the Study Director/Principal Investigator. Moreover, the Sponsors have to follow the Guidelines by first, identification of the test Items : the sponsors have the responsibility to Characterize the test Items such as giving the details of Structural formula (Molecular formula, Molecular weight, IUPAC name) and Physico-chemical properties of Items ,etc. The data that sponsors give to the test facilities should be confirmed by the creditable laboratory too. Second, study plan of the test items should be approved by the test facility management and the sponsors if required by national regulation or legislation in the country where the study is being performed. Third, the sponsors should contain the important information of the study such as name and address of the sponsors, date of approval of the study plan by signature of the test facility management and sponsors.

3. Performance of the study

Protocols and Standard operating procedures (SOPs)

The main steps of research studies are prescribed in the study plan. Being able to repeat studies and obtain similar results is a sine qua non of mutual acceptance of data and, indeed, a central tenet of the scientific methods, so the details of routine procedures must also be available to scientists involved in the study. These details are found in written standard operating procedures (SOPs). With the protocol and the SOPs it should be possible to repeat the study exactly, if necessary.

4. Results

Raw data

All data generated during the conduct of the study should be recorded directly, promptly, accurately and legibly by the individual entering the data. These entries should be signed or initialed and dated.

Final Report

A final report should be prepared for each study. It contains an account of the way in which the study was performed, incorporates the study results and includes the scientific interpretation of the data and it should be signed and dated by the Study Director to indicate acceptance of responsibility. The report is provided to regulatory authorities as a part of the submission for registration and marketing approval.

Archives

Test facilities have to design area or facility (e.g. cabinet, room, building or computerized system) for the secure storage and retention of records and materials.

5. Quality Assurance

Quality assurance (QA), as defined by GLP, is a team of persons (often called the quality assurance unit – QAU) charged with assuring management that GLP compliance has been attained within the laboratory. The Quality Assurance Program should be carried out by an individual or by individuals designated by and directly responsible to the management and who are familiar with the test procedures. And the Quality assurance personnel has the responsibilities to verify that the study plan, conduct inspections to determine if all studies are conducted in compliance with these Principles of Good Laboratory Practice.[2]

Good Laboratory Practice is a quality system which intends to ensure, through careful and accurate documentation, covering all aspects of a study and environments, the quality, integrity and reliability of safety data. The results of non-clinical studies are significant to ensure the quality and safety of products. The requirement of studies under the conditions of GLP is one way to protect the population from the hazards. In which countries that comply with the GLP standard for the health products will promote the quality and validity of non-clinical studies.

Reference:

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