# GOOD LABORATORY PRACTICES

## ❖ GOOD LABORATORY PRACTICES (GLP)

A number of countries require manufacturers of pharmaceuticals, veterinary drugs, pesticides, cosmetics, processed food products, feed additives, industrial chemicals etc. to establish that use of these products do not pose any hazards to human health and the environment. Non Hazardous nature needs to be established through studies and data, which will be examined by the regulatory authorities of the concerned countries. Good Laboratory Practices (GLP) is a system which has been evolved by Organizations for Economic Co-operation and Development (OECD), used for achieving the above goals. To avoid different schemes of implementation that could impede international trade in chemicals, OECD member countries have pursued international harmonization of test methods and Good Laboratory Practices.

## ❖ DEFINITION AND SCOPE

Good Laboratory Practices (GLP) is a system of controls and management for laboratories and research organizations to ensure the consistency and reliability of results as outlined in the OECD principles of GLP and national regulations. Good laboratory Practice embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. These studies are undertaken to generate data by which the hazards and risks to users, consumers and third parties, including the environment, can be assessed for pharmaceuticals, agrochemicals, cosmetics, food and feed additives and contaminants, novel foods and biocides. GLP helps assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be relied upon when making risk/ safety assessments.

GLP applies to nonclinical studies conducted for the assessment of the safety of chemicals (test items contained in pharmaceutical products, pesticide products, cosmetic products, veterinary drugs as well as food additives, feed additives and industrial chemicals) to man, animals and the environment. These test items can be of synthetic, natural or biological origin and may also be sometimes living organisms. The purpose of these principles of GLP is to promote the development of quality test data and also traceability and integrity of data. Comparable quality of test data forms the basis for the mutual acceptance of data among countries. If individual countries can confidently rely on test data developed in other countries, duplicative testing can be avoided, thereby saving time and resources. The application of these principles should help to avoid the creation of technical barrier to trade,

and further improve the protection of human health and the environment. Non-clinical health and environmental safety studies covered by the Principles of Good Laboratory Practice include work conducted in the laboratory, in greenhouses, and in the field. Unless specifically exempted by national legislation, these Principles of Good Laboratory Practice apply to all non-clinical health and environmental safety studies required by regulations for the purpose of registering or licensing pharmaceuticals, pesticides, food and feed additives, cosmetic products, veterinary drug products and similar products, and for the regulation of industrial chemicals.

## ❖ POWERS AND FUNCTIONS OF GLP AUTHORITY

The main functions of GLP Authority are:

i) Monitor the progress of the programme implementation;
ii) Establish National GLP Compliance/Monitoring system for test facilities on the basis of OECD Principles of Good Laboratory Practice;
iii) Grant GLP certification to the test facilities based on their compliance to the OECD Principles of Good Laboratory Practice and OECD Test Guidelines;
iv) Suspend/withdraw and/or terminate GLP Certification from its certified test facilities/laboratories, and/or may even inform relevant GLP Compliance Monitoring Authorities (belonging to OECD member country) should there be a need;
v) Constitute such other Technical Committees/or the Working Groups which it deems fit, to complete a particular cause or need or activity;
vi) Approve the rules and procedure that may be formulated for the smooth functioning of the programme, Technical Committee and Working Groups;
vii) Ensure that National GLP Compliance Monitoring/Authority operates its system in accordance with current OECD Council norms, maintain its international compatibility and mutual recognition; and
viii) Organize and conduct scheduled/unscheduled inspections for its GLP certified laboratories.

## ❖ NATURE OF THE NATIONAL GLP PROGRAMME

GLP certification is voluntary which undertakes such studies, either for its own purpose or for others, will be eligible to seek GLP certification. It will establish and continually update a network of GLP-certified laboratories. GLP certification is valid for a period of three years. GLP-certified laboratories shall be regularly monitored to ensure for their compliance to OECD Principles of Good Laboratory Practice and Test Guidelines by organizing the surveillance visits, that could be by informing the test facility or otherwise also, if required.

In those cases, where serious deviations which may have affected specific studies are found, the GLP Authority shall consider the need to inform the relevant National GLP Authority in other OECD member countries.

In needy situations, the National GLP Programme would cooperate with a national regulatory authority of a member country in the following ways:

- In organizing a particular study audit and by providing the results to the requesting regulatory authority.
- By facilitating to conduct and witness a study audit/inspection at the request from the Authority(ies) of a member country either for their inspectors or for their representative(s)' Inspectors from the member country.

National GLP programme has in-built feature of taking action against those test facilities which have been granted GLP certificate are not found to have complied with OECD Principles of Good Laboratory Practice and Test Guidelines which might affect the validity of studies conducted in the test facility. Test facilities interested in GLP certification would be required to give an undertaking to National GLP Programme for agreeing to abide by its Terms and Conditions. GLP Authority (Apex Body) has its membership from the concerned Government Departments/Regulatory Authorities to ensure their inputs and to safeguard their interests.

## ❖ GLP INSPECTORS

National GLP Programme has opted in its system, to empanel as its Inspectors, the experts who are currently employed with Government test facilities/ organizations, and whose qualification(s), experience, etc. are meeting those prescribed by the Technical Committee. Function and the power of the inspector are:

Inspectors evaluate the technical competence of the applicant test facility in all respects for its compliance to OECD Principles of Good Laboratory Practice and OECD Test Guidelines. They are trained by National GLP Compliance Monitoring Authority and /or OECD on GLP Principles.

GLP inspectors are responsible for conducting inspection of a test facility based on the study and analysis of application received from the test facility, carrying out opening and closing briefings in the test facility. They are also responsible for preparing inspection reports with his/her recommendations, whether or not the test facility under consideration qualifies for grant of GLP compliance status, to be placed before the technical committee.

Inspectors are monitored by the national GLP office for their performance.

Inspectors have access to confidential and commercially valuable information of the test facility, required for its assessment while conducting inspections and study audits. Inspectors shall not disclose such confidential and commercially valuable information obtained during the course of inspection and study audit of a test facility to anyone except the National GLP Office.

Inspectors will not normally enter a test facility against the will of its management. However, if there is sufficient evidence to prove that the test facility is not adhering to GLP principles and access to data from the test facility is essential to protect the interest of human health and environment. National GLP office may organize unscheduled/ spontaneous inspection/study audit any time. Access to the inspection team shall have to be granted by the test facility at all reasonable times and facilities, data and records for proper inspection shall be made freely available to inspectors. Refusal to comply shall result in suspension of GLP-certificate.

Inspectors are provided with a copy of the application submitted by the test facility and the same is returned to the National GLP office.

Inspectors submit all reports of test facility inspection/study audit only to the National GLP Office. No copies of such reports or related information is to be provided to test facilities other than that covered during opening and closing briefings during the inspection.

## ❖ GOOD MICROBIOLOGY LABORATORY PRACTICES

- A documented procedural (safety) manual must be available for all staff, and its requirements followed; it must be reviewed and updated regularly. This manual should include laboratory spill and emergency procedures.
- Personnel must receive training on the potential hazards associated with the work involved and the necessary precautions to prevent exposure to biological agents and release of contained material; personnel must show evidence that they understood the training provided; training must be documented and signed by both the employee and supervisor; retraining programs should also be implemented.
- Eating, drinking, smoking, storing of either food, personal belongings, or utensils, applying cosmetics, and inserting or removing contact lenses are not permitted in any laboratory; the wearing of contact lenses is permitted only when other forms of corrective eyewear are not suitable; wearing jewellery or having long fingernails is not recommended in the laboratory
- Open wounds, cuts, scratches and grazes should be covered with waterproof dressings.
- Oral pipetting of any substance is prohibited in any laboratory.

- Long hair is to be tied back or restrained so that it cannot come into contact with hands, specimens, containers or equipment.
- Access to laboratory and support areas is limited to authorized personnel.
- Doors to laboratories must not be left open (this does not apply to an open area within a laboratory).
- Open wounds, cuts, scratches and grazes should be covered with waterproof dressings.
- Laboratories are to be kept clean and tidy. Storage of materials that are not pertinent to the work and cannot be easily decontaminated (e.g., journals, books, correspondence) should be minimized; paperwork and report writing should be kept separate from laboratory work areas.
- Ensure engineering controls (e.g., BSC's, eyewash units, sinks, and safety showers) are functional and properly maintained and inspected.
- Personal protective laboratory clothing, properly fastened, must be worn by all personnel, including visitors, trainees and others entering or working in the laboratory; suitable footwear with closed toes and heels must be worn in all laboratory areas.
- Protective laboratory clothing must not be worn in non-laboratory areas; laboratory clothing must not be stored in contact with street clothing.
- If a known or suspected exposure occurs, contaminated clothing must be decontaminated before laundering (unless laundering facilities are within the containment laboratory and have been proven to be effective in decontamination).
- Wear approved safety glasses and/or goggles. Whether during routine operations or under unusual circumstances (e.g., spill clean-up), eye and face protection must be used. Careful consideration should be given to the identification of procedures requiring eye and face protection, and selection should be appropriate to the hazard.
- Basic hand hygiene: hands must be washed after gloves have been removed, before leaving the laboratory and at any time after handling materials known or suspected to be contaminated.
- Gloves (e.g., latex, nitrile) must be worn for all procedures that might involve direct skin contact with biological material. Gloves are to be removed when leaving the laboratory and decontaminated with other laboratory waste before disposal; Hands must be washed after removing gloves.
- The use of needles, syringes and other sharp objects should be strictly limit. It is recommended to use safety-engineered medical sharps whenever possible (Alberta OHS Code, Part 35 section 525.2). Caution should be used when handling needles and syringes to avoid auto-inoculation and the generation of aerosols during use and disposal; where appropriate, procedures should be performed in a BSC; needles should not be bent, sheared, recapped or removed from the syringe; they should be promptly placed in a puncture-resistant sharps container (in accordance with

Canadian Standards Association [CSA] standard Z316.6-07 before disposal. For disposal of sharps consult Risk and Safety Services website.

- Avoid the use of aerosol-generating procedures when working with biohazardous materials. Needle clipping, pipetting, mixing, sonication, and centrifugation can produce substantial aerosols. If you must perform an aerosol generating procedure, utilize proper containment devices and good work practice controls to mitigate potential exposures; tightly cap tubes prior to centrifuging or vortexing; allow aerosols to settle prior to opening tubes, equipment; open tubes or equipment inside a containment device (i.e., biosafety cabinet) whenever feasible; shield instruments or activities that can emit splash or splatter.
- Use disinfectant traps and in-line filters on vacuum lines to protect vacuum lines from potential contamination.
- Work surfaces must be cleaned and decontaminated in accordance with biological material in use at the end of the day and after any spill of potentially biohazardous material; work surfaces that have become permeable (i.e., cracked, chipped, loose) must be replaced or repaired.
- Contaminated materials and equipment leaving the laboratory for servicing or disposal must be appropriately decontaminated and labelled or tagged out as such.
- Autoclaves used for decontamination need to have regular efficacy monitoring with biological indicators (i.e., consider weekly, depending on the frequency of use of the autoclave), and the records of these results and cycle logs (i.e., time, temperature and pressure) must also be kept on file.
- All biological materials (cultures, recombinant DNA), solid or liquid, must be decontaminated before disposal or reuse; the material must be contained in such a way as to prevent the release of the contaminated contents during removal.
- Disinfectants effective against the agents in use must be available at all times within the areas where the biological material is handled or stored.
- Leak-proof containers are to be used for the transport of biological materials within facilities (e.g., between laboratories in the same facility).
- Spills, accidents or exposures to bio-hazardous materials and losses of containment must be reported immediately to the laboratory supervisor and a Campus Accident Incident Report (CAIR) must be submitted; written records of such incidents must be maintained, and the results of incident investigations should be used for continuing education.
- An effective rodent and insect control program must be maintained.