

**DEFINITIONS OF GENERAL TERMS USED IN  
THE NATIONAL GLP PROGRAMME**

**Good Laboratory Practice**

**Good Laboratory Practice (GLP)** is a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded and reported.

**Terms Concerning the Organization of a TF**

**TF:** The persons, premises and operational unit(s) that are necessary for conducting the non-clinical health and environmental safety study. For multi-site studies, those which are conducted at more than one site, the TF comprises the site at which the Study Director is located and all individual test sites, which individually or collectively can be considered to be test facilities.

**Multi-site Study :** Any study that has phases conducted at more than one site. Multi-site studies become necessary if there is a need to use sites that are geographically remote, organizationally distinct or otherwise separated. This could include a department of an organization acting as a test site when another department of the same organization acts as the TF.

A phase is a defined activity or set of activities in the conduct of a study.

**Test Site :** The location(s) at which a phase(s) of a study is conducted.

**TF Management :** The person(s) who has the authority and formal responsibility for the organization and functioning of the TF according to the Principles of Good Laboratory Practice.

**Test Site Management** (if appointed) : The person(s) responsible for ensuring that the phase(s) of the study, for which he is responsible, are conducted according to these Principles of Good Laboratory Practice.

**Sponsor :** An entity which commissions supports and/or submits a non-clinical health and environmental safety study.

**Study Director :** The individual responsible for the overall conduct of the non-clinical health and environmental safety study.

**Principal Investigator :** An individual who, for a multi-site study, acts on behalf of the Study Director and has defined responsibility for delegated phases of the study. The Study Director's responsibility for the overall conduct of the study cannot be delegated to the Principal Investigator(s); this includes approval of the study plan and its amendments, approval of the final report, and ensuring that all applicable Principles of Good Laboratory Practice are followed.

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**Quality Assurance Programme:** A defined system, including personnel, which is independent of study conduct and is designed to assure TF management of compliance with the Principles of Good Laboratory Practice.

**Standard Operating Procedures (SOPs):** Documented procedures, which describe how to perform tests, or activities normally not specified in detail in the study plan or test guidelines.

**Master Schedule:** A compilation of information to assist in the assessment of workload and for the tracking of studies at a TF.

### **Terms Concerning the Non-Clinical Health and Environmental Safety Study**

**Non-Clinical Health and Environmental Safety Study**, henceforth referred to simply as “study” : An experiment or set of experiments in which a test item is assessed under laboratory conditions or in the environment to obtain data on its properties and/or safety, intended for submission to appropriate regulatory authorities.

**Short-Term Study:** A study of short duration with widely used routine techniques.

**Study Plan:** A document, which defines the objectives and experimental design for the conduct of the study, and includes any amendments.

**Study Plan Amendment:** An intended change to the study plan after the study initiation date.

**Study plan deviation:** An unintended departure from the study plan after the study initiation date.

**Test System:** Any biological, chemical or physical system or a combination thereof used in a study.

**Raw Data:** All original TF records and documentation, or verified copies thereof, which are the result of the original observations and activities in a study. Raw data also may include, for example, photographs, microfilm or microfiche copies, computer readable media, dictated observations, recorded data from automated instruments, or any other data storage medium that has been recognized as capable of providing secure storage of information for a time period.

**Specimen:** Any material derived from a test system for examination, analysis or retention.

**Experimental Starting Date:** The date on which the first study specific data are collected.

**Experimental Completion Date:** The last date on which data are collected from the study.

**Study Initiation Date:** The date the Study Director signs the study plan.

**Study Completion Date:** The date the Study Director signs the final report.

### **Terms Concerning the Test Item**

**Test Item:** An article that is the subject of a study.

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**Reference Item (“control item”):** Any article used to provide a basis for comparison with the test item.

**Batch:** A specific quantity or lot of a test item or reference item produced during a defined cycle of manufacture in such a way that it could be expected to be of a uniform character and should be designated as such.

**Vehicle:** Any agent which serves as a carrier used to mix, disperse, or solubilise the test item or reference item to facilitate the administration/application to the test system.

### **Terms Concerning Computerized Systems**

**Acceptance criteria:** The documented criteria that should be met to successfully complete a test phase or to meet delivery requirements.

**Acceptance testing:** Formal testing of a computerized system in its anticipating operating environment to determine whether all acceptance criteria of the test facility have been met and whether the system is acceptable for operational use.

**Back up:** Provisions made for the recovery of data files or software, for the restart of processing or for the use of alternative computer equipment after a system failure or disaster.

**Change control:** Ongoing evaluation and documentation of system operations and changes to determine whether a validation process is necessary following any changes to the computerized system.

**Computerized system:** A group of hardware components and associated software designed and assembled to perform a specific function or group of functions.

**Electronic signature:** The entry in the form of magnetic impulses or computer data compilation of any symbol or series of symbols, executed, adapted or authorized by a person to be equivalent to the person’s handwritten signature.

**Hardware:** The physical components of a computerized system, including the computer unit itself and its peripheral components.

**Peripheral components:** Any interfaced instrumentation, or remote components such as printers, modems and terminals, etc.

**Recognized technical standards:** Standards as promulgated by national or international standard setting bodies (ISO, IEEE, ANSI, etc.)

**Security:** The protection of computer hardware and software from accidental or malicious access, use, modification, destruction or disclosure. Security also pertains to personnel, data, communications and the physical and logical protection of computer installations.

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**Software (application):** A programme required for or developed, adapted or tailored to the facility requirements for the purpose of controlling processes, data collection, data manipulation, data reporting and/or archiving.

**Software (operating system):** A programme or collection of programmes, routine and sub-routines that controls the operation of a computer. An operating system may provide services such as resource allocation, scheduling, input/output control and data management.

**Source code:** An original computer programme expressed in human-readable form (programming language) which must be translated into machine-readable form before it can be executed by the computer.

**Validation of a computerized system:** The demonstration that a computerized system is suitable for its intended purpose.

### **Terms Concerning GLP Compliance Monitoring**

**GLP Compliance Monitoring:** The periodic inspection of test facilities and/or auditing of studies for the purpose of verifying adherence to GLP principles.

**National GLP Programme:** The particular scheme established by Government of India to monitor Good Laboratory Practice compliance by test facilities within its territories, by : of inspections and study audits.

**National GLP Compliance Monitoring Authority (NGCMA):** The Authority set up by Government of India responsible for monitoring the good laboratory practice compliance of TF within its territories and for discharging other functions related to Good Laboratory Practice as may be nationally determined.

**National GLP Office:** The Secretariat of the NGCMA, located in Department of Science and Technology, Government of India.

**GLP Inspector:** A person, having the required qualification and training (as prescribed by the NGCMA), who performs the TF inspections and study audits on behalf of the NGCMA.

All GLP Inspection teams shall be appointed by Head, NGCMA.

### **NGCMA categorizes its Inspectors as:**

**Lead Inspector:** The one who leads the inspection team during the inspection of the TF. He prepares the agenda for the inspection, assigns responsibilities to the inspection team members, leads the opening and the exit meetings and prepares the inspection report .

**Fellow Inspector:** Inspectors other than the lead Inspector are fellow Inspectors. Their tasks during the inspection will be delegated by the lead Inspector and they will provide inputs for preparing the inspection report and sign the inspection report.

**External Technical Experts:** Head,NGCMA may appoint experts from Government departments/ laboratories/ universities for helping inspection teams from time to time in areas

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requiring specialized technical inputs, for making an assessment about GLP compliance. These experts shall have an exposure to GLP Principles. The experts will give duly signed observations to the lead Inspector for incorporation in the inspection report.

**Observers:** Inspectors under training are called observers and their task during each inspection will be identified by the lead inspector,

**GLP Compliance Status:** The level of adherence by a TF to the GLP Principles as assessed by the National GLP Compliance Monitoring Authority.

**Member of National GLP Programme:** A TF which has been granted GLP-compliance certificate by the NGCMA. All test facilities who are the members of the National GLP Programme have to maintain their membership fee which is currently of Rs. 10,000/- or as decided by NGCMA from time to time.

**Regulatory Authority:** Any authority in any country or territory with legal responsibility for according market approval to chemicals and other aspects of the control of chemicals or items which are synthetic, of natural or biological origin and, in some circumstances, may be living organisms.

**Study Audit:** A comparison of raw data and associated records with the interim or final report in order to determine whether the raw data have been accurately reported, to determine whether testing was carried out in accordance with the study plan and Standard Operating Procedures, to obtain additional information not provided in the report, and to establish whether practices were employed in the development of data that would impair their validity.

**Technical Committee:** The Committee set up by the NGCMA to help the National GLP Office in evaluating the competence of test facilities by reviewing the inspection reports and giving recommendations on the grant/refusal of grant of GLP-compliance certification to the test facilities.

**Legislation Committee:** The Committee set up by the NGCMA to formulate legislation on GLP in India.

**TF Inspection:** An on-site examination of the TF's procedures and practices to assess the compliance with GLP Principles. During inspections, the management structures and operational procedures of the TF are examined, key technical personnel are interviewed, and the quality and integrity of data generated by the TF are assessed and reported.

**Pre-Inspection:** A pre-inspection is carried out for new applicants, to establish whether the TF is ready for a final inspection.

**Final Inspection:** A final inspection is an inspection carried out, when ATR for the pre-inspection are satisfactory.

The final inspection is a complete facility inspection including study audits for detailed assessment of the TF, in accordance with OECD Principles of GLP, Document No. 1 and guidelines of the NGCMA, if any.

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**Surveillance Inspection:** An inspection to ascertain on an annual basis whether a GLP certified test facility continues to comply with the OECD Principles of GLP.

**Inspection for Re-certification:** This refers to a GLP-inspection done after every three years, in case the TF continues to apply for re-certification at least six months before the expiry of its existing GLP certificate.

The re-certification inspection is similar to final inspection and includes a complete facility inspection and study audits for detailed assessment of the TF, in accordance with OECD Principles of GLP, Document No. 1 and guidelines of the NGCMA, if any.

**Verification Inspection:** An inspection performed to verify the corrective actions mentioned in the ATR submitted by TF on major deviations observed during all inspections except pre-inspection. Verification inspection would be done more than once, at the discretion of NGCMA.

**Inspection/Study Audit on request of a Regulatory Authority/ Monitoring Authority:**

Inspections/study audits conducted at the request of the Indian Regulatory Authorities or Monitoring Authorities of foreign GLP Authorities.

**Surprise Inspections:** Inspections undertaken without prior intimation to the certified TF under National GLP Programme to evaluate continued compliance to OECD Principles of GLP. These inspections shall be undertaken only with the approval of Chairman, NGCMA.

**Action Taken Report (ATR):** Corrective actions taken by the TF towards the findings of an inspection, indicated by the inspection team during the exit meeting.

**Suspension of TF from National GLP Programme:** Discontinuation of the GLP certification of a TF from the National GLP Programme based on the recommendations of the inspection team, technical committee and approval of Chairman NGCMA.

**Approved for issue by:**



(Signature with date)  
Dr. Vinita Sharma  
Head, NGCMA