TERMS AND CONDITIONS

OF

NATIONAL GOOD LABORATORY PRACTICE (GLP) COMPLIANCE MONITORING AUTHORITY

FOR OBTAINING AND MAINTAINING ITS GLP CERTIFICATION BY A TEST FACILITY

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NATIONAL GLP COMPLIANCE MONITORING AUTHORITY
DEPARTMENT OF SCIENCE AND TECHNOLOGY
GOVERNMENT OF INDIA
TECHNOLOGY BHAWAN NEW MEHRAULI ROAD
NEW DELHI-110016

Terms and Conditions
For
Obtaining and Maintaining GLP Certification
By a Test Facility (TF):

1. A Test Facility (TF) desirous of obtaining a GLP compliance status, called "GLP Certificate" from the National GLP Compliance Monitoring Authority (NGCMA) shall submit an application in a prescribed Application Form (Document No. GLP-102) along with the prescribed non-refundable application fees of Rs.10000/- by way of a demand draft drawn in favour of `Drawing and Disbursing Officer, Department of Science and Technology' and payable at New Delhi to:

   Head, National GLP Programme,
   National GLP Compliance Monitoring Authority,
   Department of Science and Technology,
   Technology Bhawan, New Mehrauli Road, New Delhi-110016
   (Telefax: 26964793)

2. All documents submitted along with the application (e.g., organizational charts, floor plans, master schedule etc.) should be authenticated by the **TF** management.

3. The applicant **TF** shall offer its records and facilities to the inspectors that may be deputed by the NGCMA for inspection/ surveillance/ verification or uninformed inspection that may be organized by the NGCMA.

4. A **TF** can be a contract research organization, part of an industry or a company or government or university or an R & D institution.

5. If the application is found in order, the Authority will organize inspection of the **TF.** A team of inspectors will be appointed by the Authority. Inspection will comprise of a minimum of two stages - Pre-inspection and Final Inspection. All inspectors will be required to keep information received in respect of the **TF** confidential and not to make copies of any document. A **TF** is obliged to offer its records and facilities with respect to the scope of its application for inspection to the inspectors deputed by the Authority.

6. GLP certification awarded to a TF will be valid for a period of three years. The three-year period, subject to continued compliance to GLP principles, shall be termed as a **cycle of GLP compliance status**.

7. A **TF**, wishing to continue its GLP compliance status beyond the existing cycle through a fresh GLP certification, will have to submit a fresh application to the NGCMA in the prescribed Application Form (Document No. GLP-102) along with the application fees at least six months prior to the expiry of the existing GLP certification. The Authority will undertake an inspection for re-certification through a team of inspectors appointed by it before the expiry of existing GLP certification. The inspection can be held any time during this period of six months.

8. No pre-inspection would be conducted in respect of a **TF** which approaches the Authority for the second cycle of GLP compliance status or subsequent cycles.

9. The validity of the existing GLP certificate can be extended by three months provided the **TF** has applied for re-certification at least six months before the expiry of GLP status and that the inspection has taken place before the expiry of existing status. The extension of three months will be given for reasons such as delay in approval process after the inspection.

10. TF, entering into second or subsequent cycles of GLP compliance status, may note that Action Taken Report (ATR) after the inspection for re-certification should be submitted in time to enable the National GLP Office to present it before the Technical Committee for its recommendations and Chairman, National GLP Compliance Monitoring Authority and Secretary, Department of Science and Technology for his approval within three months of the expiry of the earlier GLP certificate. In case the TF does not submit a satisfactory ATR in time, the existing GLP certificate will lapse.

11. The purpose of the pre-inspection is to enable the NGCMA to have an idea about the organizational, infrastructural and operational aspects of the **TF,** including the type of studies being performed with a view to determine the suitability of the **TF** for the final inspection. The duration of the pre-inspection would be between 1 to 3 days depending on size and scope of the **TF** on mutually-convenient dates. The findings of the pre-inspection will be communicated to the **TF** in writing during the exit meeting with the **TF** by the inspectors. The formal report of pre-inspection will be

communicated to the **TF** within 30 days of the inspection. The **TF** must take corrective actions and submit an Action Taken Report (ATR) within 6 months of receiving the pre-inspection report.

12. The Final Inspection of the **TF** will be carried out after the pre-inspection, if the **TF** is found to follow the GLP principles without serious deficiencies, as recommended in the pre-inspection report. In case some observations were made during the pre-inspection, the **TF** must submit an Action Taken Report ATR) as mentioned in paragraph 10 above before the final inspection can be undertaken. Along with the ATR, the **TF** should inform the Authority about its readiness to undergo the final inspection. The purpose of the final inspection is to make a detailed assessment of the **TF**, including compliance with all the points listed in the OECD Principles of GLP, Document No. 1 and guidelines of the NGCMA, if any.

13. The final inspection would be carried out by a team of inspectors appointed by the Authority. The team may consist of inspectors who conducted the pre-inspection or new inspectors. Generally, the inspection would be conducted on dates mutually agreed to between the Authority and the **TF**. The inspection team may wish to see and study all types of documents such as standard operating procedures, master schedule, operating and instruction manuals of instruments and equipments, study plans along with study reports, organizational charts, floor plans, list of equipment, training records of personnel, orders issued by the test facility management from time to time for appointing new staff, study directors etc., records of QA inspections, information supplied by sponsors along with technical aspects contract documents and any other document considered essential by the inspection team to arrive at a proper assessment. The team will physically visit each and every part of the **TF** and may request the **TF** to conduct some spot-checks, such as functioning of smoke detectors, measuring temperature in animal rooms etc. Staff members of the **TF** at all levels may be interviewed by the inspection team. The duration of the final inspection will be 3 to 5 days depending on the size and scope of a **TF**.

14. The inspection team will communicate its findings in writing to the **TF** during the exit meeting with the **TF** after the final inspection is over. If it is found that the **TF** has not been following GLP principles, the team may recommend a verification inspection at a later date after the **TF** has taken corrective actions on the observations made by the inspection team.

15. Final inspection report along with ATR submitted by a **TF** and the report of verification inspection (if conducted) are submitted to the Technical Committee constituted by the National GLP Compliance Monitoring Authority which, in turn, makes a recommendation for the award of GLP certificate to the concerned **TF** or re-inspection of the **TF** or obtaining clarifications from the **TF** or rejection. The recommendation for the award of GLP certificate is approved by the Chairman, National GLP Compliance Monitoring Authority and Secretary, Department of Science and Technology. The **TF** will then be issued the GLP Certificate highlighting name and address of the **TF**, areas of expertise and starting date of the validity of the certificate.

16. After receiving a GLP compliance certificate, a **TF** becomes a member of the National GLP Programme and has to maintain its membership by paying an annual membership of Rs.10000/-.

17. A GLP-compliant **TF** under the National GLP Programme shall manage and operate in accordance with the OECD Principles of Good Laboratory Practice, OECD Test Guidelines, wherever applicable and instructions, rules and guidelines issued by the National GLP Compliance Monitoring Authority, from time to time. Further, the **TF** is required to submit a list of studies completed on an yearly basis along with the most recent master schedule.

18. Surveillance inspection of **TF** shall be undertaken by the Authority once every year during the first cycle of GLP compliance. The surveillance inspection will be for a duration of 2 to 3 days to ascertain compliance to GLP principles. Surveillance inspections will be carried out by a team of inspectors appointed by the Authority. The surveillance inspection will include **TF's** inspection, scrutiny of the functioning of quality assurance unit and **TF** management, study audits, study of SOP, master schedule etc. Special attention will be paid to the points observed during earlier inspections. The **TF s**hall be asked to submit the following documents to the Authority before the surveillance inspection, namely, the recent organogram, list of personnel, lists of SOPs & equipments, master schedule and floor plans. The surveillance inspection reports are placed before the Technical Committee for evaluation and recommendation for continuation of the GLP certificate.

19. In addition to the above-mentioned inspections, the Authority may also conduct an inspection or study audit, at the request of a regulatory authority.

20. The NGCMA reserves the right to conduct surprise inspections, if deemed necessary.

21. A GLP inspection would start with an opening conference and end with a closing conference. The purpose of the opening conference is to inform the management and staff of the **TF** of the reason for inspection or study audit that is about to take place, and identify the **TF** areas, studies selected for audit, documents and personnel likely to be involved. At the opening conference, an agenda or schedule of inspection would be handed over to the **TF** management, and the inspectors would:

- outline the purpose and scope of the visit;
- describe the documentation which will be required for the **TF** inspection, such as lists of on-going and completed studies, study plans, standard operating procedures, study reports, etc. Access to and, if necessary, arrangements for the copying of relevant documents would be agreed upon at this time;
- clarify or request information as to the management structure (organization) and personnel of the **TF**;
- request information as to the conduct of studies not subject to GLP principles in the areas of the **TF** where GLP studies are being conducted;
- make an initial determination as to the parts of the **TF** to be covered during the **TF** inspection;
- describe the documents and specimens that will be needed for on-going or completed study(ies) selected for Study Audit;
- indicate that a closing conference will be held at the completion of the inspection.

The purpose of the closing conference is to inform the **TF** about the findings, including deficiencies observed during the inspection. The management of the **TF** should essentially be present during the opening and closing meetings.

21. Where serious deviations are found, the NGCMA may take appropriate actions which may include the following:

- issuance of a statement giving details of the inadequacies or faults found which might affect the validity of studies conducted in the **TF**;

- issuance of a recommendation to a regulatory authority that a study be rejected;

- suspension of **TF's** GLP certification or study audit and withdrawal of the **TF's** GLP certification from the register of National GLP Programme.

- requiring that a statement detailing the deviations be attached to specific study reports;

22. A **TF** must maintain a master schedule which should contain at least the following information: study number, name of the test item (coded form is acceptable), name of the test system, type of study (acute, repeated dose, inhalation, dermal etc. along with duration of the study), name of the sponsor (coded designation is acceptable), name of the study director, study initiation date, experiment start date, experiment completion date, study completion date and date of archiving the study-related documents/ specimens

23. In case a **TF** is engaged in multi-site studies and tests, the **TF** must provide details about the test site, such as its location and address, its management structure, type of studies being carried out and facilities available. The **TF** must ensure that the test site adheres to the GLP principles and performs studies and tests accordingly and produce evidence to that effect. The **TF** may be asked to facilitate the visit of the inspection team to the site, if required. In case the site is outside India which cannot be inspected conveniently, the **TF** should have an evidence to show that the test site is a GLP compliant. If the site is located in an OECD member country, it must

have the GLP compliance certificate issued by that country. The Authority can request the GLP Authority of that country to inspect the test site for its compliance with the GLP principles, in case the test site is not GLP compliant. In case the test site is in a non-OECD country, the Authority may inspect the test site to ascertain if the test site follows GLP principles or not. In that case, the **TF** would be required to arrange the visit of the inspection team and bear all the expenses.

24. Reliability of studies and test results is important for safety purpose. Therefore, the **TF** must develop standard operating procedures (SOPs) for all the activities being undertaken in the **TF.**

25. Traceability of test results and safety studies is at the heart of GLP certification. Therefore, records of all tests, test samples, studies conducted, raw data generated, equipment calibration and maintenance records, tissues and blocks, study plans etc. must be archived in a manner that these can be accessed even after several years of archiving. The period of archiving will usually be governed by the requirements of the sponsor and/or regulatory authority. It is, however, recommended to maintain records for two cycles of GLP certification. The archive should be suitably designed so that the risks due to fire, fungus, short circuiting, stealing are minimal for the safety of the archived material.

26. A **TF** must read, understand and apply GLP principles as enunciated in OECD Principles of GLP, Document Numbers 1-14 and submit a statement to this effect to the National GLP Compliance Monitoring Authority along with the application.

27. Actual status of each **TF** in regard to its compliance to GLP principles would be shown in the Authority's website www.indiaglp.gov.in.

28. The applicant **TF** shall pay to the NGCMA the following:-

(i) Application fee Rs.10,000/-
(ii) Annual membership fee Rs.10,000/-
(iii) Actual expenditure on account of travel of inspectors of inspection teams visiting the **TF** for carrying out inspection of different types such as pre-inspection, final inspection, verification inspection surveillance inspection and inspection for re-certification. Boarding

and lodging for the inspection team, including local transportation shall be borne by the **TF**.

29. It may be noted that GLP compliance status is awarded to a **TF**. If the **TF** is a division/section/laboratory/department of a larger company/organization, the GLP compliance certificate will be valid only for the TF and not for the whole company. However, in that case, a clear relationship must exist between the TF and the management of the company. This relationship must be shown in the application. The management of the company must declare in the application that it seeks GLP compliance certificate in respect of the TF mentioned in the application and the TF should be clearly identified with suitable description including floor plans and layout.

30. A TF using computer systems for different activities should give the numbers of computers being used and the procedure being followed to maintain the security and integrity of computerized data.

31. A TF can ask for replacement of some members of the inspection team if it considers that the impartiality, integrity and confidentiality against the test facility cannot be assured. The arguments for replacement have to be addressed in writing to the Head, National GLP Programme.

32. A TF can make a complaint to the Authority for any problem faced by it, including difference of opinion between the test facility management and the inspection team during the course of an inspection or a study audit. The complaint shall be processed by the Authority in accordance with its procedures and its views shall be conveyed to the TF. The National GLP Office will examine the complaint from administrative, procedural and technical angles before sending its views to the TF. If the TF is still not satisfied, it can make an appeal to Chairman, National GLP Compliance Monitoring Authority and Secretary, DST, who may appoint an independent expert to look into the problems and advise the Chairman accordingly. The Chairman’s decision shall be final and shall be acceptable to both parties.

GUIDELINES FOR INSPECTION/STUDY AUDIT OF AN INDIAN TEST FACILITY BY A FOREIGN GLP MONITORING AUTHORITY

1. Requests for inspection/study audit of an Indian test facility should be submitted separately by the Indian test facility and the foreign GLP Monitoring Authority undertaking the inspection/study audit to the National GLP Compliance Monitoring Authority.

2. The request from Indian test facility should clearly give justification for undertaking of inspection/study audit by the foreign GLP Monitoring Authority. The foreign GLP Monitoring Authority should also give justification for taking up inspection/study audit of the Indian test facility in their requests.

3. The decision on the request of the foreign GLP Monitoring Authority shall be conveyed by the Head, National GLP Compliance Monitoring Authority. A copy will be endorsed to the Indian test facility. The clearance from the National GLP Compliance Monitoring Authority will also include clearance for the annual surveillance till the renewal of the GLP certification.

4. The scope for seeking GLP certification, in terms of field of testing, areas of expertise and dates of inspection, should be declared in the request.

   (a) The request from the foreign GLP Monitoring Authority should contain at least the following information:

      (i) Name of the GLP Authority

      (ii) Contact address along with telephone, fax and e-mail of the GLP Authority

      (iii) Name and address of the contact person in the GLP Authority

      (iv) Name and address of the Indian test facility proposed to be inspected

      (v) Likely dates of inspection

      (vi) Names of inspectors likely to inspect the test facility

(vii) Field(s) of testing

(viii) Area(s) of expertise

(b) The Indian test facility should indicate at least the following information in its request :

(i) Name of the test facility

(ii) Contact address of the test facility along with telephone, fax and e-mail

(iii) Name and address of the contact person in the test facility

(iv) Name and address of the foreign GLP Authority

(v) Likely dates of inspection

(vi) Field(s) of testing

(vii) Area(s) of expertise

5. A representative of the Indian GLP Monitoring Authority may accompany the inspection team with the foreign GLP Monitoring Authority inspecting the Indian test facility.

6. The Indian GLP Authority should be informed about the grant of GLP certification to the Indian test facility, both by the foreign GLP Monitoring Authority and the Indian test facility.

7. The foreign GLP Monitoring Authority should submit copies of inspection/study audit reports to the Indian GLP Monitoring Authority.

8. The request for renewal of GLP certification will be processed by the National GLP Compliance Monitoring Authority. The procedure to be followed for this purpose would be the same as that for obtaining GLP certification for the first time.

9. Grant of GLP certification by a foreign GLP Monitoring Authority does not necessarily mean that the Indian GLP Monitoring Authority will also give GLP certification to the applicant test facility.