

TERMS AND CONDITIONS
FOR OBTAINING AND MAINTAINING GLP
CERTIFICATION BY A TEST FACILITY (TF):

1. A Test Facility (TF) desirous of obtaining “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: 91-11-26964793)
2. Copies of all documents submitted along with the application (e.g., organizational charts, floor plans, master schedule etc.) should be authenticated with dated signature by the TF management.
3. The applicant TF shall offer its records and facilities under the scope of certification open for inspections by NGCMA.
4. TF eligible for seeking GLP certification can be a Contract Research Organization, R & D institution, University, part of an Industry/Company or a Government organization involved in conduct of non-clinical health and environmental safety studies for submitting to regulatory authorities.
5. If the application is found complete and eligibility criteria are met, NGCMA will organize inspection of the TF. Test Facility Inspection means an on-site examination of the TF’s procedures and practices by inspectors appointed by NGCMA to assess the compliance with GLP Principles.
6. Inspections conducted by NGCMA are categorized as:
 - a. **Inspections for obtaining GLP certification:** Pre-inspection, Final Inspection and Verification inspection (if applicable).
 - b. **Inspections for maintaining GLP certification:** Surveillance inspection, Inspection for Re-certification and Verification inspection (if applicable).

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- c. **Others-** Surprise inspection and Inspection conducted at the request of Regulatory Authority(ies).
All the above mentioned inspections are defined in Document No. GLP-111 “Definitions of General Terms Used in The National GLP Programme”
7. A team of inspectors for all inspections will be appointed by the Head, NGCMA. Scheduling of inspections will be done as per Document No. GLP-109 “Scheduling of GLP Inspections by NGCMA”, however all inspections will be conducted at dates mutually convenient to both the inspection team and the test facility. All information received with respect to the TF will be kept confidential.
8. GLP certification awarded to a TF will be valid for a period of three years. This three-year period, subject to continued compliance to GLP principles, shall be termed as a **GLP certification cycle**.
9. 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 fees of Rs.10,000/-. The TF will be subject to annual surveillance inspections as described in Document No. GLP-104 “Procedures of National GLP Office.”
10. A TF, wishing to continue its GLP compliance status beyond the existing cycle, 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 6 months prior to the expiry of the existing GLP certification. NGCMA will undertake an inspection for re-certification through a team of inspectors before the expiry of existing GLP certification. The inspection will be held any time during this period of 6 months.
11. Pre-inspection would not be conducted for a TF which approaches the NGCMA for the second cycle of GLP compliance status or subsequent cycles.
12. Pre-inspection may be waived off for TFs certified by Monitoring Authorities of other OECD member countries, at the discretion of Head, NGCMA.
13. The validity of the existing GLP certificate can be extended by 3 months provided the TF has applied for re-certification at least 6 months before the expiry of GLP status and that the inspection has taken place before the expiry of existing status. The extension of 3 months will be given for reasons such as delay in approval process after the inspection.
14. 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, NGCMA, for his approval within 3 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. The TF will then have to resubmit an

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application for GLP certification. In such cases also, pre-inspection of the TF will not be conducted.

15. The findings of all types of inspections will be communicated to the TF in writing during the exit meeting with the TF by the inspection team.
16. The formal report of pre-inspection will be communicated to the TF within 45 days of the completion of the pre-inspection. The TF is required to take corrective actions, if any and submit an ATR to the identified deficiencies within 6 months of receiving the pre-inspection report to NGCMA. The TF should ensure that corrective actions have been completed before submission of ATRs. After receiving the ATR from the test facility, National GLP Office will review it in consultation with the Lead inspector/Inspection team. If all the deficiencies have been addressed satisfactorily in the ATR, the National GLP Office will conduct a final inspection. If no ATR is received from the TF within 6 months, the TF will have to make a fresh application along with the prescribed application fees to the NGCMA.
17. The final inspection report will be communicated to the TF within 45 days of completion of the inspection. The TF is required to take corrective actions, if any, and submit an ATR to the deficiencies pointed out to them during the exit meeting of the final inspection within 45 days of completion of the inspection to NGCMA. 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 NGCMA 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, NGCMA. 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.
18. A GLP-certified TF under the National GLP Programme shall comply and operate in accordance with the OECD Principles of Good Laboratory Practice and instructions, rules and guidelines issued by the NGCMA, from time to time. Further, the TF should immediately submit any major change in organogram, floor plans etc. to the NGCMA.
19. Surveillance inspection of TF is undertaken by the NGCMA once every year after the TF has been awarded a GLP-compliance certificate by the NGCMA. Before the surveillance inspection is undertaken the TF would have to submit 5 copies of following documents highlighting the changes since last inspection:
 - Recent Organograms
 - Recent Floor Plans
 - List of SOPs
 - List of Instruments/Equipments
 - Master Schedule since last inspection

The surveillance inspection report is prepared within 45 days of completion of the

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inspection. The TF is required to take corrective actions, if any, and submit an ATR to the deficiencies pointed out to them during the exit meeting of the surveillance inspection within 45 days of completion of the inspection to NGCMA.

The surveillance inspection reports and ATR submitted by the TF(s) are placed before the Technical Committee for evaluation and recommendation for continuation/discontinuation of the GLP certificate. Surveillance inspection reports are communicated to the TFs along with the recommendations of Technical Committee.

20. In addition to the above-mentioned inspections, the Authority may also conduct an inspection or study audit, at the request of a Regulatory Authority. The inspection procedures of the NGCMA will be followed for such inspections. The inspection report will be placed before the Technical Committee for its recommendation and Chairman, NGCMA for his approval. After the approval it will be sent to the Regulatory Authority/GLP Monitoring Authority of the foreign country.
21. The NGCMA reserves the right to conduct surprise inspections, if deemed necessary. Such inspections can be undertaken after the approval of Chairman, NGCMA. The TF will have to submit an ATR to the findings of the surprise inspection within 45 days of completion of the surprise inspection to the NGCMA.
22. The management of the TF/his representative has to be present during the opening and closing meetings.
23. In case serious deviations are found during a certification cycle, NGCMA may take actions which include, but are not limited to, 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.
 - requirement that a statement detailing the deviations be attached to specific study reports;
24. It is mandatory for a TF to 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.
25. 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

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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, the TF should have an evidence to show that the test site is GLP compliant.

26. 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.
27. For traceability of test results and safety studies, 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. 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 archived material is safe from risks due to fire, fungus, electrical short circuit, stealing etc.
28. A TF must read, understand and apply GLP principles as enunciated in OECD Principles of GLP, Document Numbers 1-15 and submit a statement to this effect to the NGCMA along with the application.
29. Status of each TF with regard to its compliance to OECD principles of GLP would be put up on the website of NGCMA www.indiaglp.gov.in.
30. 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. The travel expenses would be restricted to economy class Airfare/ Taxi/Train fare. Boarding and lodging for the inspection team, including local transportation shall be borne by the TF.
31. The GLP compliance certificate may be awarded to a division/section/laboratory/department of a larger company/organization performing GLP studies/tests. Hence GLP certificate is valid only for the above-mentioned component of the company/organization. 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.
32. 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.

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33. During a certification cycle, incase there is a change in the name of the TF along with merger/takeover/restructuring of the organization due to any reason, it shall be communicated to NGCMA along with supporting documents duly authenticated by Management and the implications on the TF compliance to Principles of GLP. The supporting documents shall be reviewed and if found satisfactory, new certificate with same validity as the previous certificate will be issued by NGCMA. A reference of the previous name of the TF will be made in the new certificate.
34. 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.
35. A TF can appeal to the NGCMA for decision given by NGCMA including difference of opinion between the test facility management and the inspection team during the course of an inspection or a study audit. The appeal shall be processed by the NGCMA in accordance with Document No. GLP-108 "Appeal Procedures of National GLP Compliance Monitoring Authority".
36. A TF requesting an inspection/study audit from a foreign GLP Monitoring Authority should inform to Head, NGCMA as per **Annexure – I** before such an inspection can be undertaken.
37. These Terms and Conditions, including the financial obligations, may be amended from time to time and the TF agrees to such amendments.

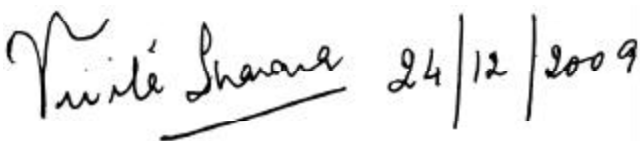
The above terms and conditions are acceptable

Signature of the Applicant : _____

Designation of the Signatory : _____

Name of the Test Facility : _____

Approved for issue by:



(Signature with date)

Dr. Vinita Sharma

Head, NGCMA

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 TF should be submitted separately by the Indian TF and the foreign GLP Monitoring Authority undertaking the inspection/study audit to the NGCMA.
2. The request from Indian TF 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, NGCMA. A copy will be endorsed to the Indian TF. The clearance from the NGCMA 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) Tentative dates of inspection
 - (vi) Names of inspectors proposed to inspect the test facility
 - (vii) Field(s) of testing
 - (viii) Area(s) of expertise

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- (b) The Indian TF should indicate at least the following information in the request:
- (i) Name of the TF
 - (ii) Contact address of the TF along with telephone, fax and e-mail
 - (iii) Name and address of the contact person in the TF
 - (iv) Name and address of the foreign GLP Authority
 - (v) Tentative 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 TF.
6. The Indian GLP Authority should be informed about the grant of GLP certification to the Indian TF, both by the foreign GLP Monitoring Authority and the Indian TF.
7. The foreign GLP Monitoring Authority should submit copies of inspection/study audit reports to the Indian GLP Monitoring Authority.
8. The renewal of GLP certification from foreign GLP Monitoring Authority will be processed by the NGCMA. 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 TF.

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Annexure – I

FORMAT FOR TEST FACILITIES APPLYING FOR INSPECTION/ STUDY AUDIT BY A FOREIGN GLP MONITORING AUTHORITY

Name & Contact Details of Test Facility	
Name & Contact Details of Foreign GLP Monitoring Authority	
Likely dates of Inspection/study audit	
Names & affiliation of Foreign GLP Monitoring Authority Inspectors	
Fields of Testing	
Areas of Expertise	
Justification for undertaking of inspection/ study audit by the foreign GLP Monitoring Authority	
Details of GLP certification granted by National GLP Compliance Monitoring Authority (NGCMA), if obtained/ applied for	
If not applied for GLP certification to NGCMA, reasons thereof	

Undertaking—

1. A representative from NGCMA will be invited to join the inspection team.
2. NGCMA will be informed about the grant of GLP Certification by the Foreign GLP Monitoring Authority and a copy of report and certificate, if applicable, will be submitted to National GLP Office.

Date :

Place :

Signature

Note :

The request for inspection/study audit by a Foreign GLP Monitoring Authority should be submitted to Head, NGCMA **at least 8 weeks** before the likely dates of inspection.