Government of India
Ministry of Science and Technology
Department of Science and Technology
National Good Laboratory Practice (GLP) Compliance Monitoring Authority

TERMS & CONDITIONS OF NGCMA FOR OBTAINING AND MAINTAINING GLP CERTIFICATION BY A TEST FACILITY

Document No.GLP-101
Issue No. 08
Issue Date: October 25, 2019

NATIONAL GLP COMPLIANCE MONITORING AUTHORITY
DEPARTMENT OF SCIENCE AND TECHNOLOGY
TECHNOLOGY BHAVAN, NEW MEHRAULI ROAD
NEW DELHI-110 016
http://www.dst.gov.in/ngcma

TERMS & CONDITIONS OF NGCMA FOR OBTAINING AND MAINTAINING GLP CERTIFICATION BY A TEST FACILITY

1. Test Facilities (TFs) may submit an application for GLP certification/ Re-certification/ Extension in scope of GLP compliance along with prescribed fee through online portal of NGCMA (***ngcma.qci.org.in***).

   After online submission and receipt of an acknowledgement, the TF shall take a print out of the filled Application form and all Annexures (as uploaded), and submit a hard copy of the same to NGCMA Secretariat, DST. This hard copy should be duly signed by the Test Facility Management (TFM) as a token of commitment to ensure that all furnished information is correct and the management of the TF fully understands its responsibilities and commitments to NGCMA. Along with the application form, applicant TFs would be required to submit an undertaking signed on each page for agreeing to abide by Document No. GLP-101 "Terms & Conditions of the National GLP Compliance Monitoring Authority (NGCMA) for obtaining and maintaining GLP certification by a test facility".

   Note: Request for extension in scope of GLP certification during a certification cycle should be submitted atleast 3 months after the grant of GLP certification/ re-certification by NGCMA. This can be also done along with the submission of documents for Surveillance inspection.

2. TF must read, understand and apply GLP principles as enunciated in Organization for Economic Cooperation and Development (OECD) Principles of GLP and submit a statement to this effect to the NGCMA along with the application for GLP certification.

3. In case the application does not fall under the scope of GLP certification, the applicant is informed accordingly and the application file would be closed. The application fee will not be refundable to the TF.

4. Copies of all documents (e.g., organizational charts, floor plans, master schedule, etc.), to be enclosed with the application should be authenticated with dated signatures by the TFM.

5. A TF is eligible for seeking GLP certification, if it is involved in conducting scientific study or research related to non-clinical health or environmental safety studies. Such TFs can be:
   a) Contract Research Organization
   b) R & D Laboratory
   c) University/ Deemed to be University/ Institute of National Importance
   d) Industry/ Company/ Organization
   e) Government organization/ Public Sector Enterprise

6. The GLP compliance certificate is awarded to a division/section/laboratory/department of a larger company/organization, performing GLP studies/tests. Hence, GLP certificate will be valid only for the specified component of the company/organization. In such a case, a clear relationship existing between the TF and the management of the company/ organization must be shown in the relevant documents and application for GLP certification. The management of the company/ organization must declare in the application for GLP certification that it seeks GLP compliance certificate in respect of the TF mentioned in the application form for GLP certification and the TF should be clearly identified with suitable description, including floor plans and layout.

7. The applicant TF shall provide access to its records and facilities, as applicable under the scope of GLP certification, for inspections by NGCMA.

8. It is mandatory for a TF to maintain a Master schedule which should contain details of all studies (GLP and Non-GLP) conducted by it. These details include 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, name of the sponsor (coded name 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.

9. TF using computerized systems for different activities should specify & list the computerized systems being used and the procedure being followed to maintain the security and integrity of computerized data.

10. A GLP compliant TF must have SOPs for all the activities being undertaken in the TF.

11. All study related data, including study plan, raw data, study report, samples of test and reference items and specimens of a GLP study must be archived in a manner that these can be accessed easily at a later date, if required. The period of archiving will usually be governed by the requirements of the sponsor and/or regulatory authority(ies). It is, however, recommended to maintain records for three cycles of GLP certification. The archive should be suitably designed so as to guard against risks due to fire, fungus, electrical short circuiting, theft, etc.

12. In case a TF is engaged in multi-site studies and tests, details about the test site, such as, location and address, management structure, type of studies being carried out and facilities available should be provided. The TF must ensure that the test site adheres to the OECD Principles of GLP, performs studies and tests accordingly & produce evidence to this effect. The TF may be asked to facilitate the visit of the inspection team to the test site, if required. In case the test site is outside India, the TF should have an evidence to show that it is GLP compliant.

13. If the GLP application is found to be complete and eligibility criteria for GLP certification are met, NGCMA will organize TF inspection i.e. an on-site examination of

the TF's procedures and practices to assess compliance with OECD Principles of GLP. It may be noted that ONLY the scope which is mentioned in the GLP application would be included in the scope of GLP inspection. No additional Type of study/ Test item/ Test system would be witnessed by the inspection team during the GLP inspection.

14. Inspections conducted by NGCMA are defined in Document No. GLP-111 "Definitions of General Terms Used in NGCMA" and GLP-104 "Procedures of NGCMA Secretariat".

15. For conducting a TF inspection, a team of inspectors will be appointed by Head, NGCMA. Inspection planning will be carried out as per the procedure specified in 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 TF. A communication of inspection team and dates would be sent to the respective TF by NGCMA. If the TF has reservation on the inspection team or any member, it may indicate the same to NGCMA immediately on the receipt of communication along with valid reasons. If no communication is received from the TF, it shall be assumed that the constitution of the inspection team is acceptable to the TF. All information received with respect to the TF will be kept confidential by the NGCMA and its inspectors.

16. GLP certification awarded to a TF will be valid for a period of three years, unless otherwise revoked in consonance with the Document No. 113 "Policies and procedures of NGCMA for taking adverse and other decisions against test facilities". This three-year period, subject to continued compliance to OECD Principles of GLP, shall be termed as a GLP certification cycle.

17. After receiving a GLP compliance certificate, a TF has to maintain its certification by paying the prescribed annual certification fee. The TF will be subject to surveillance inspection at 18 months (± 3 months) from the date of grant of GLP certification/ Re-certification, as specified in Document No. GLP-104 "Procedures of NGCMA Secretariat."

18. A TF, wishing to continue its GLP compliance status beyond the existing cycle, will have to submit a re-certification application at least 6 months prior to the expiry of the existing GLP certificate. The NGCMA will undertake an inspection for re-certification through a team of inspectors before the expiry of existing GLP certificate.

19. 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 existing GLP certificate and that the re-certification inspection has taken place before the expiry of existing GLP certificate. The extension of three months will be granted for reasons such as delay in approval process after the re-certification inspection or for a verification inspection to be conducted by NGCMA. If a verification inspection is to be conducted for the TF and the validity of existing GLP certificate is going to expire, the TF would be advised not to initiate any new GLP studies during this period. Further, in case the

decision of non-grant of GLP re-certification is taken by the NGCMA, the date of removal of the TF from the National GLP Programme would be the date of re-certification inspection.

20. TF, entering into second or subsequent cycles of GLP certification, may note that Action Taken Report (ATR) after the inspection for re-certification should be submitted in time to enable the NGCMA to follow the approval process. In case the TF does not submit a satisfactory ATR within the stipulated time, the existing GLP certificate will lapse. The TF will then have to apply afresh.

21. Follow-up Actions for Pre-inspection:

a) The TF is required to take corrective actions, if any, and submit an ATR to NGCMA on deficiencies pointed out to them during the closing conference of the pre-inspection within 6 months of the conduct of pre-inspection. The TF should ensure that corrective actions have been completed before submission of ATR.

b) After receiving the ATR from the TF, NGCMA Secretariat will review it in consultation with the lead inspector.

c) If all the deficiencies have been addressed satisfactorily in the ATR, the NGCMA Secretariat will organize & conduct a final inspection.

d) If no ATR is received from the TF within 6 months, action will be taken as per GLP-113 "Policies and procedures of NGCMA for taking adverse and other decisions against test facilities".

e) The formal report of pre-inspection is received by NGCMA from the inspection team within 60 days of conduct of the pre-inspection & is communicated to the TF thereafter.

22. Follow-up Actions for Final inspection:

a) The TF is required to take corrective actions, if any, and submit an ATR to NGCMA for the deficiencies pointed out to them during the closing conference of the final inspection within 45 days of completion of the inspection.

b) The formal report of final inspection is received by NGCMA from the inspection team within 60 days of conduct of the final inspection. Final inspection report, along with ATR submitted by the TF, and the report of verification inspection, if conducted, are submitted to the Technical Committee (TC) on GLP 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 obtain clarifications from the TF or otherwise.

c) The recommendation of the TC on GLP is put up to Chairman, GLP Authority for appropriate decision.

d) If approved for grant of GLP certification, the TF is issued the GLP Certificate highlighting name and address of the TF, area(s) of expertise, test item(s), test system(s) and validity of the certificate.

e) The final inspection report alongwith the recommendations of the TC on GLP and decision on grant of GLP certificate or otherwise is communicated to the TF.

23. A GLP-compliant TF under the National GLP Programme shall comply and operate in accordance with the OECD Principles of GLP and instructions/rules/guidelines issued by the NGCMA, if any. Further, the TF should immediately inform any changes in scope of GLP compliance, major change in organization, change in name/legal status etc. to NGCMA.

24. Surveillance inspection of TF is undertaken by the NGCMA usually midway through the period of validity of GLP certificate {18 months (± 3 months) from the date of grant of GLP certificate}. A GLP certified TF is required to submit all applicable documents through online portal (***ngcma.qci.org.in***) atleast 2 months before the completion of 18 months from the date of grant of GLP certification/ re-certification or as and when intimated by NGCMA.

The findings of Surveillance inspection are communicated to the TF during the closing conference. The TF is required to take corrective actions, if any and submit an ATR to the deficiencies pointed out to them within 45 days of conduct of the inspection to NGCMA. Report of Surveillance inspection is communicated to the TF along with the recommendations of TC on GLP.

25. In addition to the above-mentioned inspections, NGCMA may also conduct inspection(s) or Study Audit(s), at the request of a Regulatory Authority (RA)/ GLP Compliance Monitoring Authority (CMA) of OECD Mutual Acceptance of Data (MAD) adherent country(ies) or Joint GLP Inspections/ Study Audits with RA/CMA of OECD MAD adherent countries(ies). The inspection procedures of the NGCMA will be followed for such inspections. The inspection report will be forwarded to the concerned RA/ GLP CMA who sought such inspection or study audit(s), with a copy to the concerned TF.

26. The NGCMA reserves the right to conduct surprise inspections, if deemed necessary. Such inspections can be undertaken after the approval of Chairman, GLP Authority. The surprise inspection report will be forwarded to the TF along with the decision of Chairman, GLP Authority on its GLP compliance status.

27. The TFM or its representative(s) have to be present during the opening and closing conferences. The list of observations of the GLP inspection will have to be signed by the TFM or its representative(s) and the inspection team.

28. In case serious deviations are found during a certification cycle, NGCMA may take appropriate 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 by the TF;
- Issuance of a recommendation to a RA that a study be rejected
- Suspension of TF's GLP certification or study audit and/or withdrawal of the TF's GLP certification
- Informing the National RA or/and GLP CMA in other MAD adherent country(ies) about the inadequacies found & Action taken by NGCMA
- Requiring that a statement detailing the deviations be attached to specific study reports;
- Action through the courts, where warranted by circumstances and where legal/administrative procedures so permit.

29. Status of each TF with regard to its compliance to OECD principles of GLP would be published on the website of NGCMA (*http://www.dst.gov.in/ngcma*).

30. The applicant TF shall be liable to pay the following:

Application Fee	Rs. 30,000/-***** per each area of expertise for which GLP certification is being sought. (Non-refundable and to be paid along with application)
Annual Certification Fee (Applicable to GLP-certified TFs only)	Rs. 30,000/-***** (Non-refundable)
Travel expenditure on account of inspectors' visit to TF for GLP inspections of NGCMA	a) Economy class Airfare/ AC-2 Tier Train fare and local transportation b) Boarding & lodging facility to Inspection Team

*** Note:**

i) Applicable taxes need to be added to the application and annual certification fee

ii) NGCMA has entered into a Memorandum of Understanding (MoU) with Quality Council of India (QCI). As per the MoU, all arrangements for travel and stay (Booking of tickets and accommodation) of the inspection team shall be made by QCI in consultation with the TF and inspection team, on behalf of NGCMA. However, the TF would be required to arrange local travel of the inspection team in the city of the TF. After the inspection is over, QCI shall raise an invoice to the TF for the arrangements made for the inspection for reimbursement. There shall be no monetary exchange between TF and any member of the inspection team.

31. **Modifications in GLP Certificate during a GLP Certification Cycle**

a) Change in name of the TF

During a certification cycle, any modification in the GLP certificate regarding change in name of the TF, along with merger/takeover/restructuring of the organization for any reason can be done by submitting a request to Head, NGCMA along with duly authenticated supporting documents, and the implications on the TF's compliance to OECD Principles of GLP. A non-refundable fee of Rs. 15,000/- would be applicable for such requests. The request of the TF shall be reviewed and if found satisfactory, new certificate with same validity as the previous certificate will be issued by NGCMA.

b) Extension in Scope

A TF wishing to extend the scope of GLP certification (for any additional area/ study/test item/ test system) during a GLP certification cycle may do so by submitting an application (with requisite fee) for the same through online portal. A non-refundable application fee of Rs. 30,000/- would be applicable for each additional area of expertise of GLP certification whereas in case the TF requests for any modification in the scope of GLP certification w.r.t type of study under the existing certified areas of expertise, test system or test item, a lump sum fee of Rs.15,000/- would be applicable. However, such requests can only be made after atleast 3 months of grant of a GLP certificate or alongwith the documents for surveillance inspection. NGCMA would conduct an Extension in Scope inspection or a Surveillance-cum-extension in scope inspection respectively (as deemed necessary) for the above two cases.

The follow up actions on such inspections and approval process for extension of scope of GLP certification would be the same as for the process of grant of GLP certificate.

c) Reduction in Scope

Voluntary Reduction: A TF wishing to reduce its scope of activities covered in its GLP certificate may do so by voluntarily withdrawing the respective areas. A communication to this effect, stating the reasons for withdrawal of an area or reduced scope be submitted to Head, NGCMA by the TF. A list of GLP studies done by the TF in the respective area(s) which are to be withdrawn from GLP certification should also be submitted, clearly stating the GLP status of studies conducted by the TF in that area.

The information given by the TF would be examined by NGCMA Secretariat and put up for approval of Chairman, GLP Authority. After approval a new GLP certificate would be issued by NGCMA, omitting the respective area(s) of expertise.

Forced Reduction: A TF will have to demonstrate its competence to conduct GLP studies in a particular area of expertise wherein they have not conducted GLP studies for more than 1 year during surveillance inspection. In case the TF fails to do so, the inspection report should mention the same. Thereafter, the case is considered by the TC on GLP, whose recommendations are further referred to Chairman, GLP Authority for a final decision on the reduction in scope of GLP for the TF.

For conditions mentioned at a, b and c above, the validity of the revised GLP certificate, if applicable would be from the date of approval by the Competent Authority till the validity of the existing GLP certificate. The revised GLP certificate will supercede the earlier GLP certificate w.e.f. the date of issue of the revised GLP certificate. The number of revised GLP certificate will have suffix "A", "B", "C" …. , as applicable, to the earlier certificate number and the year of issuance of the revised GLP certificate, such as

Earlier GLP certificate number: GLP-XXX/YYYY

Revised GLP certificate number: GLP-XXXA/YYYY

Any information pertaining to change in scope of GLP compliance of a TF would be published on the website of the NGCMA.

32. **Voluntary Withdrawal**: A TF wishing to voluntary withdraw from the National GLP Programme may do so by a written communication to Head, NGCMA, stating the reasons for the same. A Master Schedule of all studies done by the TF since last GLP Inspection should also be submitted, clearly stating the GLP status of studies conducted by the TF in that area. In addition to this, the location of archives of the TF after voluntary withdrawal should be informed.

The information given by the TF would be examined by NGCMA Secretariat and put up for approval of Head, NGCMA, whose decision would be informed to the TF. Information regarding the same would be sent to OECD Secretariat for further circulation among the OECD MAD adherent countries. The date of voluntary withdrawal of the said GLP certificate would be the date on which the TF had communicated the voluntary withdrawal.

NGCMA or any GLP MA of OECD-MAD adherent country reserves the right to conduct inspection of all GLP data generated at the TF, if deemed necessary.

33. TF can file a complaint/ grievance/ appeal against any adverse decision of NGCMA. The same shall be processed by the NGCMA in accordance with GLP-108 "Procedures for handling of Complaints, Grievances and Appeals".

34. All disputes, if any, arising out of NGCMA decisions that remain unresolved through mechanisms provided by NGCMA are subject to exclusive jurisdiction of the Courts at New Delhi and none other.

These Terms and Conditions should be submitted by the applicant TF along with the Application for GLP Certification/ re-certification, with the clause to be read as:

"I have read, understood and agree to abide to the above Terms & Conditions of NGCMA for obtaining and maintaining GLP certification by a test facility (GLP-101).

Signatures of TFM
Name:
Designation:
Date: