
**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. 09*
*Issue Date: May 09, 2022*

**NATIONAL GLP COMPLIANCE MONITORING AUTHORITY**
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***https://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 only through online portal of NGCMA (*https://dst.gov.in/ngcma*).

   **Note:**
   a) The TF is required to regularly visit /check the portal for any update(s) on the GLP Application or GLP Inspection-related activities. It may be ensured that the TF takes requisite action(s) for these procedures in a time-bound manner, as per the procedures of NGCMA.
   b) 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 application 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 NGCMA along with the application for GLP certification/ re-certification.

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

4. 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) Academic institutions-University/ Deemed to be University/ Institute of National Importance
   d) Industry/ Company/ Organization
   e) Government organization/ Public Sector Enterprise

5. The GLP compliance certificate is awarded to a division/section/laboratory/department of a larger company/organization, performing GLP studies/tests as per OECD Principles of GLP. 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.

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

7. 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 should include study number, whether the study is Unisite or Multisite, Name (*Short Title- to include Test System/ Method or Description of Study*) and type (*acute, repeated dose, method validation etc*.) of study along with duration, category of the test item {e.g. Agrochemicals, Cell Lines, Cosmetics Products, Feed Additives, Food Additives, Industrial chemicals, Medical devices (*Applicable only for Bio-compatibility, not applicable for batch release parameters*), Pharmaceuticals (Human), Pharmaceuticals (Veterinary) and Viruses}, name of the test item (coded form is acceptable), name of the test system, 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.

8. 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 in accordance with the OECD Principles of GLP.

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

10. 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 in accordance with the OECD Principles of GLP.

11. In case a TF is engaged in multi-site studies and tests, details about the same should be provided in the Master Schedule. Details of test site, such as, location and address, management structure, type of studies being carried out and facilities available should be mentioned in the Application form under relevant section. The TF must ensure that the test site adheres to the OECD Principles of GLP, performs studies and tests accordingly & is able to 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.

12. 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 processed by NGCMA/witnessed by the inspection team during the GLP inspection(s).

13. The TF should ensure that atleast ONE study of each type, conducted on a type of test system or using a type of test item, as claimed by it in the GLP application should have been completed and archived before the submission of the application. Such studies may be audited during GLP inspections, which would aim at ascertaining the TF's competency to conduct the said studies in compliance with OECD Principles of GLP.

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 and the same will be agreed upon through the portal. If the TF has reservation on the inspection team or any member, it may indicate the same to NGCMA immediately along with valid reasons. The TF is required to revert on the inspection team/dates, as indicated on the portal within 7 days, else, the inspection will be postponed till further processing by NGCMA. Any information received from the TF with respect to reservation of the TF w.r.t. any member of the inspection team will be kept confidential by the NGCMA.

16. The TF should ensure that during any planned GLP inspection conducted by NGCMA, there would be atleast ONE ongoing GLP study with a live phase to be demonstrated before the inspection team. This would ensure evaluation of the competence and skill of the TF personnel to conduct the GLP studies/ activities and adherence to the Study Plan, TF SOPs & OECD Principles of GLP.

17. Follow-up Actions for GLP inspections:

    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 each inspection conducted by NGCMA within the stipulated time period and as mentioned in Document No. GLP-110 "Evaluation Procedures of Inspection Results". Further, it should be ensured that corrective/ preventive actions should have been completed before submission of ATR and evidences (in the form of relevant documents/ photographs, etc.) for the same should be submitted along with.

18. 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/advisories issued by the NGCMA, if any.

19. The TF should promptly inform any changes in scope of GLP compliance, major change in organization, change in name/ legal status or change in physical location (address), etc. to NGCMA.

20. 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.

21. After receiving a GLP certificate, a TF has to maintain its certification by paying the prescribed Annual Certification Fee (ACF) i.e. Rs. 30,000/- through NGCMA portal.

22. 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." TF is required to submit the application for Surveillance inspection through portal (*https://dst.gov.in/ngcma*) atleast 2 months before the completion of 18 months from the date of grant of GLP certification/ re-certification.

23. A TF, wishing to continue its GLP certified status beyond the existing cycle, will have to submit a re-certification application at least 3 months prior to the expiry of the existing GLP certificate. NGCMA will undertake an inspection for re-certification through a team of inspectors before the expiry of existing GLP certificate.

24. The validity of the existing GLP certificate can be extended by 3 months provided the TF has applied for re-certification at least 3 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.

25. TF, entering into second or subsequent cycles of GLP certification, may note that ATR after the inspection for re-certification should be submitted in time to enable the NGCMA to follow the approval process, failing which action will be taken as per Document No. GLP-113 "Policies and procedures of NGCMA for taking adverse and other decisions against test facilities".

26. Since the GLP certificate is location specific, in case of change in Physical location/ address of the TF within India during a certification cycle, the GLP certificate shall not be

valid at the new location/ address. Therefore, in this case, the TF would have to apply afresh for GLP certification for the new location/address. The TF will also be required to inform the date on which all GLP activities and GLP studies at the earlier location (for which GLP certificate was granted) stand closed, as this date would be considered as the end of validity of the existing GLP certificate.

Further, NGCMA may consider to waive off the pre-inspection for the TF at the new location in case the TF's procedures, key personnel and the legal entity remain the same.

27. 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-member or non-member Mutual Acceptance of Data (MAD) adherent country(ies) or Joint GLP Inspections/ Study Audits with RA/CMA of OECD-member or non-member MAD adherent country(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.

28. 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 communicated to the TF along with the decision of Chairman, GLP Authority on its GLP compliance status.

29. The TFM or its representative(s) have to be present during the opening and closing conferences. The list of observation(s), if any of the GLP inspection will be discussed during the closing conference, wherein the TFM or its representative(s) will be required to indicate its acceptance/reservations to the observation(s) through the portal.

30. 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 GLP 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 of OECD-member or non-member 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.

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

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

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|---|---|
| **Application Fee** | Rs. 30,000/- per each area of expertise for which GLP certification is being sought.<br>(Non-refundable and to be paid along with application) |
| **Annual Certification Fee**<br>(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<br>b) Boarding & lodging facility to Inspection Team |

**Note:**

i) 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. 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 the TF and any member of the inspection team.

33. **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 an undertaking that the TF's procedures, key personnel, scope of GLP activities, floor plans etc. would remain unchanged on merger/takeover/restructuring, so that there are no 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 by NGCMA, the same would be

placed before the TC on GLP. If recommended by the TC and approved by Chairman, GLP Authority, a 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 the portal only. 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 or 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 surveillance application. 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 in 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 is/ 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 submitted 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/ type of study(ies).

**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.

34. **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 addition to this, the location of archives of the TF after voluntary withdrawal should be informed.

The information submitted 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-member or non-member MAD adherent country(ies). The date of voluntary withdrawal of the said GLP certificate would be the date on which the TF had communicated the voluntary withdrawal or the date on which all GLP activities at the TF were closed, as mentioned in the communication by the TF, whichever is earlier.

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

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

36. 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: