

### PROCEDURE(S) OF THE NATIONAL GLP OFFICE

National GLP Office implements the National GLP Programme under the direct control of the National GLP Compliance Monitoring Authority (NGCMA), Department of Science and Technology (DST), Ministry of Science and Technology, Government of India. The Head, NGCMA carries out his/her responsibilities with the approval of Chairman, NGCMA.

#### **Role and Responsibilities of National GLP Office**

1. To implement the National GLP Programme.
2. To lay down policies and procedures for the National GLP programme as per current international norms.
3. To coordinate with Test Facilities (TFs) associated with the programme.
4. To maintain links with OECD's Working Group on GLP, to ensure the functioning of the National GLP Programme as per current international norms and take required measures to establish and maintain international recognition based on OECD Principles of GLP.
5. To process the applications received for grant of GLP certification, organize and conduct GLP inspections and study audits in India and abroad.
6. To train and appoint GLP Inspectors for inspecting TF(s) for compliance with GLP Principles.
7. To inform the TFs the results of the inspection(s) or study audit(s) and ensure the response or corrective action within the specified timeframe.
8. To issue a GLP compliance certificate to a TF.
9. To maintain all inspection/study audit records and GLP compliance status of TF(s) associated with the programme.
10. To constitute working groups or committees to help the NGCMA in discharging its functions.
11. To take appropriate actions if serious deviations are found during the course of an inspection/study audit.
12. To create awareness on GLP in the country by organizing and supporting workshops, symposia, seminars and training programmes for the TF(s) etc.

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### Dealing with a new Application for GLP Certification

The NGCMA receives applications for GLP certification from TFs across the country throughout the year.

1. Applications are received through mail or by hand along with the application fee in the form of a Demand Draft as prescribed in the Application Form of the NGCMA (Document No. GLP-102).
2. The date of receipt of the application is documented and is forwarded to the concerned officer designated by Head, NGCMA.
3. The concerned officer opens a new file for each application received and assigns a unique number to each file. The unique identification number denotes the Application File Number and is in the format – DST/GLP (App)/ab/cd.

Where “ab” = the S.No. of the application received

“cd” = the year in which the application is received

This application file number is used for all correspondence with the TF. All documents/ letters received or communications sent in future by the NGCMA for this application are stored in this file.

An acknowledgement is sent to the applicant on receipt of the application and the application fee.

The application file remains in use for a period of three years after GLP certification of the TF or till the time of rejection of application/ suspension of GLP certification (whichever is earlier), following which it will be maintained for 10 years. The file can be retained beyond 10 years at the discretion of Head, NGCMA.

4. **Conducting GLP Application Review:** The application for GLP certification is reviewed and examined by the concerned officer for its correctness and completeness. Following points are noted:
  - a. Date of application for GLP certification.
  - b. Legal status of the TF (Contract Research Organization, R & D institutions, university, Government Organization, part of industry/company).
  - c. Scope of activities of the TF, including

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- i. Categories of chemicals, on which the TF conducts non-clinical safety studies or carries out tests required for safety studies.
    - ii. Area(s) of expertise for which GLP compliance has been claimed.
  - d. Any other test site, sub contractor and/or external scientist being involved in the conduct of GLP studies by the TF with a mention of their names.
  - e. Names of the regulatory authority(ies) (national and International), where the TF has submitted studies along with the details of studies.
  - f. Type of GLP studies conducted by the TF.
  - g. Type of non-GLP work conducted by the TF.
  - h. Details of any previous GLP inspections/study audits conducted by any other GLP Monitoring Authority, results of such GLP inspections and details of GLP compliance status (if any), including the date(s) of validity of the same.
  - i. Organization charts (signed and dated by Management).
  - j. List of personnel with their qualifications and training.
  - k. Floor plans/layouts with GLP marked area (signed and dated by Management).
  - l. List of instruments/equipments.
  - m. Details of test systems used in the TF.
  - n. List of approved SOPs effective in the TF.
  - o. SOP on preparation and management of SOPs in the TF.
  - p. Description of the working of QAU with list of SOPs for this purpose.
  - q. Master schedule for last one year till the date of application.
5. The TF is informed about any shortcoming in the documents submitted along with the application and is asked to provide the requisite information.
  6. If the application is found to be complete and meets the eligibility criteria, an inspection team is constituted by Head, NGCMA. Information to this effect and dates of pre-inspection/inspection are intimated to the TF. In case the dates are not convenient to the applicant, mutually-agreeable dates are fixed.

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7. In case the application does not meet the eligibility criteria for GLP certification, the applicant is informed accordingly.

### **Maintaining links with OECD Working Group on GLP**

Head, NGCMA has been nominated as an Observer to the OECD's Working Group on GLP. The Head, NGCMA would attend all meetings of the Working Group and present the progress of Indian GLP Programme on annual basis to the Working Group. An Annual Overview of the applications received by the National GLP Office, inspections conducted, GLP certificates awarded and the compliance status of all the applicant test facilities is sent to OECD Secretariat for circulation amongst all the OECD member countries.

Information regarding Annual Overviews of test facilities, details of facilities declared not in compliance with GLP Principles in other OECD member countries received from OECD Secretariat are maintained as hard copies in separate files year-wise.

### **Training and Appointing of GLP Inspectors**

NGCMA empanels inspectors and maintains their training records as per Document No: GLP-107, "Training and Evaluation of GLP Inspector(s)"

To ensure the confidentiality of commercially valuable information while conducting inspections and study audits, a confidentiality agreement as per Document No. 106 "Confidentiality and Non-Disclosure Undertaking" is signed by all the inspectors. These copies are maintained in the concerned TF file. Inspectors submit all reports of TF inspection/study audit only to NGCMA.

### **Appointing External Experts for GLP Inspections/Study Audits**

The Head, NGCMA may appoint external experts from Government Departments/ Laboratories/ Universities for helping inspection teams from time to time for areas that require specialized technical inputs in order to make a complete assessment of GLP compliance. Selection Criteria for External Experts: Qualification, Experience, Training (GLP) shall be as per "Inspection Manual: NGCMA, India" (GLP-103)

### **Creating Awareness on GLP**

NGCMA sponsors conferences, seminars, workshops, etc. at various locations in the country to create awareness about the programme and the OECD Principles of GLP. NGCMA provides financial support for conducting of conferences, seminars, workshops, training courses to interested organizations. The application for funding of conferences, seminars, workshops, training courses is processed as per rules and regulations of the Government of India.

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Requests from various individuals, organizations, professional bodies are received by the NGCMA. A new file with a unique number is created for each awareness programme being organized. The proposal submitted by the organizers is studied along with the tentative programme and the budget details and processed for funding etc. Approvals of Chairman-NGCMA and Integrated Finance Division are obtained and funds released to the organizers. After the event is over, the organizers submit a detailed report on the event and a consolidated audited Statement of Expenditure and Utilization.

### **Organizing GLP inspections**

NGCMA organizes and conducts the different types of inspections as per the procedures described below:

#### **Pre-Inspection**

A pre-inspection is carried out for new applicants, to establish whether the TF is ready for a final inspection. In case a TF has been inspected by Monitoring Authority of a country having full member status in OECD's working group on GLP, pre-inspection may be waived off based on the decision of Head, NGCMA.

The purpose of a pre-inspection is to assess the competency of the TF to adhere to OECD Principles of Good Laboratory Practice, to have an idea about the organizational, infrastructural and operational aspects of the TF, including the type of studies being performed. The duration of the pre-inspection is 1 to 2 days depending on the size of a TF and scope of GLP activities conducted by TF.

The inspection team communicates its findings in writing to the TF during the exit meeting with the TF after the pre-inspection is over.

#### **Final Inspection**

The pre-inspection report may or may not recommend the TF for final inspection, depending on the nature of the deficiencies found during the pre-inspection. Final inspection will be conducted only when the Action Taken Report (ATR) for the pre-inspection is satisfactory.

In case no deficiencies are found during the pre-inspection, the final inspection is conducted for the TF.

In case of minor or major deficiencies, the TF is required to take corrective actions and submit an ATR for those deficiencies within 6 months of receiving the pre-inspection report to NGCMA. After receiving the ATR from the TF, National GLP Office reviews the ATR in consultation with the lead Inspector. If all the deficiencies have been addressed satisfactorily in the ATR, the final inspection will be conducted for the TF.

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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.

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 TF 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 physically visits different parts of the TF and may 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 is 3 to 5 days depending on the size and scope of GLP activities conducted by TF.

The inspection team communicates its findings in writing to the TF during the exit meeting with the TF.

### **Surveillance Inspection**

GLP-compliance certification given by NGCMA is valid for a period of three years. The purpose of a surveillance inspection is to ascertain on a regular basis (yearly) whether a GLP compliant facility is following the Principles of GLP or not. The surveillance inspection is for duration of 2 to 3 days depending on the size and scope of GLP activities conducted by TF.

The TF shall be asked to submit the following documents to the NGCMA before the surveillance inspection, namely, the recent organogram, list of personnel, lists of SOPs & equipments, master schedule and floor plans. Head, NGCMA may indicate the areas to be focused on by the inspection team before a surveillance inspection. Special attention is also paid to the points observed during earlier inspections vis a vis ATR submitted.

Observations communicated to the TF by the inspection team during the exit meeting will have to be addressed within a period of 45 days of the completion of the inspection.

In case serious deviations are found during a surveillance inspection, which may compromise the integrity of the studies conducted there in, NGCMA will follow the suspension procedure spelt out in Document No 113 "Suspension of a Test Facility from the National GLP Programme".

### **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.

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The purpose of the inspection for re-certification 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. The procedures followed are the same as those for the final inspection. The duration of the inspection for re-certification is 3 to 5 days depending on the size and scope of a TF.

The inspection team communicates its findings in writing to the TF during the exit meeting with the TF.

### **Verification Inspection**

During the final inspection, surveillance inspection or inspection for re-certification, it may happen that some major deviations from the principles of GLP are observed, which would require immediate action by the TF management/ staff. In such cases, the inspection 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.

The verification inspection is undertaken exclusively for on-site verification of the corrective actions mentioned in the ATR submitted to NGCMA.

### **Inspections conducted at the request of GLP Monitoring Authority of foreign countries or the Indian Regulatory Authorities**

If the NGCMA receives a request to conduct a GLP inspection or study audit (SA) from the GLP Monitoring Authority of foreign countries or the Indian Regulatory Authorities, the following procedure is followed:

1. The Regulatory Authority/ Monitoring Authority requesting for conduct of a GLP inspection/Study Audit(SA) should submit evidence of having received a study / some data related to a study submitted either by the TF directly or a sponsor who had got the data generated at the TF.
2. The Regulatory Authority/ Monitoring Authority of OECD member countries should clearly mention the purpose and scope of the proposed inspection.
3. The request for inspection/SA shall be forwarded to the Chairman, NGCMA for a decision and approval on conduct of the inspection.
4. Chairman's, decision will be conveyed to the requesting Regulatory Authority/ Monitoring Authority of foreign country.
5. NGCMA requires the Regulatory Authority to provide necessary information (i.e. the details of study conducted by the TF, reference to the study number, name of study director, list of study personnel, and any other study related information) to conduct inspection or study audit.
6. NGCMA informs the proposed dates of inspection to the Regulatory Authority.

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7. The inspection procedures of NGCMA will be followed.
8. The inspection report will be submitted to the Technical Committee for its recommendation and Chairman, NGCMA for his approval. After the approval it will be sent to the regulatory authority/ GLP Compliance Monitoring Authority of the foreign country.

**Surprise Inspections:** The NGCMA reserves the right to conduct surprise inspections, if deemed necessary.

The surprise inspections may be conducted in the following cases:

1. Upon receiving negative feed back on particular study report(s) from the regulatory authorities of India and/or monitoring authorities of other countries. The negative feedback could be suspicion of falsification of the data or serious non-compliance observed in the study report or raw data.
2. Upon receiving feed back on the mal-practices or fraudulent practices after duly evaluating the authenticity of these complaints.
3. Major modifications in organogram or floor plans have been undertaken in the test facility without information to NGCMA.
4. After verification of the ATR, if the inspector(s) raise doubts on satisfactory compliance to OECD Principles of GLP to the NGCMA.

Such inspections would be proposed by the National GLP Office and would be undertaken after the approval of Chairman, NGCMA.

The team for the inspection and duration would be decided by Head, NGCMA. A member from National GLP office would always be present during such inspections as a part of the inspection team.

**Note:**

- 1) Surprise inspections will not appear in the tentative schedule for inspections.
- 2) All expenses pertaining to such inspections shall be borne by the NGCMA as per Government of India rules.

The list of observations/deficiencies/non-compliance(s) observed during the surprise inspection will be duly signed by the inspection team and test facility management during the exit meeting.

The inspection report of surprise inspections will be submitted to the Chairman, NGCMA for perusal and final decision.

In case the inspection is conducted at the request of the regulatory authorities of India and/or monitoring authorities of other countries, the outcome of the inspection would be communicated to them.

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A GLP inspection starts with an opening conference and ends with a closing conference. The purpose of the opening conference is to inform the management and staff of the TF about the scope 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 is handed over to the TF management. The lead inspector describes 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. The TF is informed about the timings of the closing meeting.

At the end of the TF inspection and study audit, closing conference is organized. The purpose of the closing conference/exit meeting is to inform the TF about the findings, including deficiencies/deviations observed during the inspection. The inspection team communicates findings in writing to the TF during the closing conference. The management of the TF or his representative has to be present during the opening and closing meetings.

The TF submits an ATR to the NGCMA within 45 days of the date of completion of inspection except the pre-inspection (6 months).

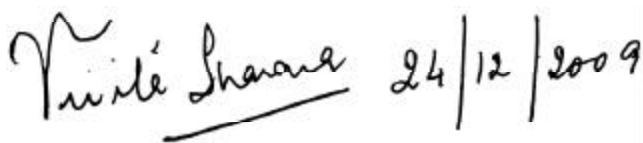
**Note:** For detailed procedure, please refer Document No. GLP -110 "Evaluation of Inspection Results".

### **Issuance of GLP Certificate:**

If the Technical Committee recommends and Chairman, NGCMA approves the grant of GLP certificate for the TF, Head, NGCMA issues the GLP certificate to the TF. The certificate includes name and address of the TF, area(s) of expertise and validity period of the certificate.

**Note:** In case any of the procedures of NGCMA pertaining to test facility inspections/communication of inspection report, submission of ATR by TF, organization of Committee meetings, organization of inspections etc. are deviated for any reason, the same would be placed before Head, NGCMA for acknowledgement. Thereafter, it will be placed for approval of Chairman, NGCMA after providing due justification.

### **Approved for issue by:**

A handwritten signature in black ink that reads "Vinita Sharma" followed by the date "24/12/2009". The signature is written in a cursive style.

(Signature with date)

Dr. Vinita Sharma  
Head, NGCMA

