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PROCEDURES OF NGCMA SECRETARIAT

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PROCEDURES OF NGCMA SECRETARIAT

National GLP Compliance Monitoring Authority (NGCMA) Secretariat implements the National GLP Programme under the administrative control of the 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, GLP Authority.

Responsibilities of NGCMA Secretariat

1. To implement the National GLP Programme.

2. To lay down policies and procedures for the National GLP Programme as per current OECD norms.

3. To maintain links with OECD's Working Group on GLP, to ensure the functioning of the National Programme as per current international norms and take required measures to establish and maintain international recognition based on OECD Principles of GLP.

4. To process the applications received for grant of GLP certification, organize and conduct GLP inspections and study audits in India and abroad.

5. To coordinate with Test Facilities (TFs) associated with the Programme.

6. To train and appoint GLP Inspectors for inspecting TF(s) for compliance with GLP Principles.

7. To inform the TFs of the results of the inspection(s) or study audit(s) and ensure submission of satisfactory response or take corrective action within the specified timeframe.

8. To issue a GLP compliance certificate to a TF.

9. To maintain records of all inspection(s)/ study(s) conducted by NGCMA 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 programs for the TF(s) etc.

Dealing with a new application for GLP Certification

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

1. Applications are received at GLP Cell, Quality Council of India (QCI) through mail or by hand along with the prescribed 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 NGCMA Secretariat by the GLP Cell, QCI. At NGCMA Secretariat, the application is dealt by the concerned officer designated by Head, NGCMA.

3. An acknowledgement is sent to the applicant by GLP Cell, QCI on receipt of the application and the application fee.

4. 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)-abc/de.

   Where "abc" = The Serial No. of the application received
   "de" = 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.

5. **Conducting GLP application review:** The application for GLP certification is reviewed and examined by the concerned officer for its correctness and completeness. The points noted during application review include, but are not limited to the following:

   a. Details of the TF (Type, Legal status, Contact details, etc.)
   b. Date of implementation of OECD Principles of GLP.
   c. Scope of activities of the TF, including

      1) Categories of chemicals, on which the TF conducts non-clinical safety studies or carries out tests required for safety studies.
      2) Area(s) of expertise for which GLP-compliance status is claimed.

   d. Type of non-GLP work conducted by the TF, if applicable
   e. Name of any other test site, sub contractor and/or external scientist being involved in the conduct of GLP studies by the TF.
   f. Organization charts approved by Test Facility Management (TFM).
   g. List of personnel with their qualifications and details of GLP training.
   h. Legible Floor plans/ layouts with GLP marked area(s) approved by TFM
   i. Details of approval status of the TF by Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), Ministry of Environment, Forest and Climate Change, Government of India, if applicable.

j. List of instruments/ equipments including computerized systems.
k. Adequacy of List of approved Standard Operating Procedures (SOPs) effective in the TF including SOPs to maintain security & integrity of computerized data and records.
l. Details of test systems used in the TF.
m. Adequacy of SOP on general procedures for drafting, authorizing, modifying, distributing and archiving SOPs
n. Description of the working of QAU.
o. Location of Archives with details.
p. Master schedule for last one year, as prescribed in the application form.
q. Names of the regulatory authority(ies), (National and International) where the TF has submitted studies along with the details of studies.
r. 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.
s. Signed and dated declaration by the TFM, as per the application form.

6. The TF will be informed about shortcoming(s), if any in the documents submitted along with the application and asked to provide the requisite information.

7. If the application is found complete and meets the criteria, an inspection team is constituted by Head, NGCMA. Information to this effect and mutually agreeable dates of pre-inspection are intimated to the TF.

8. 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 is nominated as a member of the OECD's Working Group on GLP. He/ She or representative of NGCMA attends all the meetings of the Working Group and contributes to its activities as per the requirement. An Annual Overview of the applications received by the NGCMA Secretariat, inspections conducted, GLP certificates awarded and the compliance status (i.e. in-compliance/not in-compliance) of all the applicant test facilities is sent to OECD Secretariat for circulation amongst all the OECD Mutual Acceptance of Data (MAD) adherent countries.

Information of details of TFs/ Studies declared "Not in Compliance" with OECD Principles of GLP by NGCMA is sent to OECD Secretariat for information and necessary action at their end. Similar information received from OECD Secretariat regarding non-compliant TFs/ Studies in other OECD MAD adherent countries is noted and communicated to Indian regulatory authorities.

Training and empanelment of GLP Inspectors

NGCMA empanels GLP inspectors and maintains their training records as per Document No: GLP- 107 "Training and Evaluation of GLP Inspectors".

To ensure the confidentiality of commercially valuable information while conducting inspections and study audits, a confidentiality agreement as per Document No. GLP-106 "Declaration of Impartiality and Confidentiality" is signed by all the members of inspection team. These copies are maintained in the concerned TF file. Inspectors submit all reports of TF inspection(s)/ Study Audit(s) only to NGCMA.

Appointing Technical Experts for GLP Inspections/ Study Audits

The Head, NGCMA may appoint technical experts (serving/ retired) from Government Departments/Laboratories/Universities, Public funded institutes, etc. for helping inspection teams from time to time for areas that require specialized inputs in order to make a complete assessment of GLP compliance. Selection Criteria for Technical Experts: (Qualification, Training in GLP) shall be as per Document No. GLP-103 "Inspection Manual".

Creating awareness on GLP

NGCMA conducts conferences, seminars, workshops etc. at various locations in the country to create awareness about the GLP Programme and the OECD Principles of GLP. Such capacity building programs of NGCMA are conducted with the support of Quality Council of India (QCI) as per the Memorandum of Understanding (MOU) signed between NGCMA and QCI. NGCMA provides financial support to interested organizations for conducting these capacity building programs. The application for their funding is processed as per rules and regulations of the Government of India.

Requests for conducting conferences, Seminars, Workshops, etc. on GLP from various individuals, organizations, professional bodies are also 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 reviewed along with the tentative Programme/ Agenda/ Schedule and budget details and processed for approval of funding by Chairman, GLP Authority and Integrated Finance Division (IFD). Thereafter, the funds are released to the organizers, who submit a detailed report on the event and a consolidated audited Statement of Expenditure and utilization certificate after the event is over.

Organizing GLP inspections

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

Pre-Inspection

The purpose of a pre-inspection is to:

- Assess the competency of the TF w.r.t. OECD Principles of GLP
- 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 the scope of GLP activities conducted by TF.

After the pre-inspection is over, the inspection team communicates its findings in writing to the TF during the closing conference.

The TF is required to take corrective actions to the deficiencies observed, if any, during the pre-inspection and submit an Action Taken Report (ATR) to NGCMA within 6 months of conduct of pre-inspection. After receiving the ATR from the TF, NGCMA Secretariat reviews the same in consultation with the lead Inspector.

Final Inspection

The pre-inspection report may or may not recommend the TF for final inspection. Final inspection will be conducted only when satisfactory ATR for the pre-inspection has been received from the concerned TF within the stipulated time period or in case no deficiencies are found during the pre-inspection.

The purpose of the final inspection is to make a detailed assessment of the TF, including compliance with OECD Principles of GLP and guidelines of the NGCMA.

The inspection team may wish to see and review all types of documents such as SOPs, master schedule, operating and instruction manuals of instruments and equipments, study plans, raw data, 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, 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 2 to 5 days depending on the size and scope of GLP activities conducted by TF.

During the closing conference with the TF, the inspection team communicates its observations in writing to the TF.

Observations communicated to the TF by the inspection team will have to be addressed by the TF within a period of 45 days from conduct of the final inspection.

Surveillance Inspection

GLP- compliance certification given by NGCMA is valid for a period of three years. The surveillance inspection is conducted for GLP certified TF at 18 months (± 3 months) from the date of grant of GLP certification/ re-certification. The purpose of a surveillance inspection is to ascertain whether a GLP compliant facility is following the OECD 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 submit the following documents to the NGCMA 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:

- Recent organogram
- Recent floor plans
- List of SOPs
- List of instruments/ equipments including computerized systems
- Master schedule (from the date of grant of GLP certification/ re-certification)

Before a surveillance inspection, NGCMA may indicate the areas to be focused on by the inspection team. Special attention is also paid to the points observed during earlier inspections vis a vis ATR submitted and recommendations of the TC on GLP, if any.

During the closing conference with the TF, the inspection team communicates its observations in writing to the TF which have to be addressed by the TF within a period of 45 days of the conduct of the surveillance inspection.

In case serious deviations compromising the integrity of studies conducted are found during a surveillance inspection, NGCMA will take an adverse decision as per Document No. GLP-113 "Policies and procedures of NGCMA for taking adverse and other decisions against test facilities".

Re-certification inspection

This refers to a GLP inspection done after every three years. The TF should apply for re-certification at least six months before the expiry of its existing GLP certificate.

The purpose of the re-certification inspection is to make a detailed assessment of the TF, including compliance with OECD Principles of GLP 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 2 to 5 days depending on the size and scope of a TF.

The inspection team communicates its observations in writing to the TF during the closing conference with the TF.

Observations communicated to the TF by the inspection team will have to be addressed by the TF within a period of 45 days of the completion of the re-certification inspection.

Inspection for extension in scope of GLP certification

A TF wishing to extend the scope of its GLP certification during a GLP certification cycle do so by submitting a request for the same after atleast 3 months of grant of a GLP certificate or along with the documents submitted for a surveillance inspection. In the former case, an inspection for extension in scope for the TF is conducted, to include but not limited to inspection of the requested area(s) and Study Audits of studies completed & archived by the TF in those area(s)

During the closing conference with the TF, the inspection team communicates its observations, if any in writing to the TF which have to be addressed by the TF within a period of 45 days of the conduct of the inspection.

Verification Inspection

Immediate action by the TF is required in case major deviations from OECD Principles of GLP are observed during any type of GLP inspection except pre-inspection. The inspection team/ TC on GLP may recommend an on-site verification inspection after the TF has taken corrective actions on the observations made by the inspection team.

The verification inspection would include but not limited to the on-site verification of the corrective actions mentioned in the ATR submitted by the TF to NGCMA.

Inspection team communicates its observations, if any to the TF during the closing conference. These observations will have to be addressed by the TF within a period of 45 days of the conduct of the verification inspection.

Inspection conducted at the request of GLP Compliance Monitoring Authorities or Regulatory Authorities of OECD MAD adherent countries or Indian regulatory authorities

If the NGCMA receives a request to conduct a GLP inspection/ Joint inspection/ Study Audit (SA) from the GLP Compliance Monitoring Authority (CMA) of foreign country (ies) or the foreign/ Indian Regulatory Authorities (RAs), the following procedure will be followed:

a) The RA/ GLP CMA of OECD Mutual Acceptance of Data (MAD) adherent countries should clearly mention the purpose and scope of the proposed inspection.
b) The RA/ GLP CMA requesting for conduct of a GLP inspection/ SA should have 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.
c) The request for inspection/ Joint Inspection/ SA shall be forwarded to the Head, NGCMA for a decision and approval.
d) The decision of NGCMA will be conveyed to the requesting RA/ GLP CMA of the foreign country.

e) NGCMA requires the RA/ GLP CMA of the foreign country 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 GLP inspection or SA.
f) NGCMA informs the proposed dates of inspection to the RA/ GLP CMA of the foreign country.
g) The inspection procedures of the NGCMA will be followed.
h) The inspection report will be sent to the RA/ GLP CMA of the foreign country by NGCMA as per the procedures mentioned in Document No. GLP-114 "Sharing of information with other Compliance Monitoring Authorities" and the case would be placed before the Technical Committee on GLP in its next meeting for information and necessary action as appropriate.

Surprise Inspection

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 feedback on particular study report(s) from the Indian/ Foreign RA and/or GLP CMA of foreign 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 feedback on the mal-practices or fraudulent practices by a particular TF and duly evaluating the authenticity of these complaints.
3. Major modifications in organogram or floor plans have been undertaken in the TF without any information to NGCMA.
4. If doubts arise on satisfactory compliance to GLP Principles after verification of the ATR of the inspections.

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

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

Note:

1) Surprise inspection(s) 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), if any, observed during the surprise inspection will be duly signed by the inspection team and TFM (or his/her representative) during

the closing conference. The TF will have to submit an ATR to these observations within 45 days of the conduct of the surprise inspection.

The outcome of the inspection would be communicated to the RA of India and/or GLP CMA of other OECD MAD adherent countries; at whose request the surprise inspection is conducted, if applicable.

Conduct of a GLP Inspection

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 and/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 TFM. The inspection team describes the documentation which will be required for the TF inspection, such as lists of on-going and completed studies, study plans, SOPs, study reports, etc. The TF is informed about the timings of the closing conference.

At the end of the TF inspection and study audit(s), closing conference is organized. The purpose of the closing conference is to inform the TF about the observations including deficiencies/ deviations observed from OECD Principles of GLP during the inspection. The inspection team communicates findings in writing to the TF during the closing conference of all inspections, except those surprise and verification inspections where no new observations have been noticed during the inspection. The management of the TF or his/her representative has to be present during the opening and closing conferences.

The TF submits an ATR to the NGCMA within 45 days of conduct of inspection except the pre-inspection, where the ATR can be submitted within 6 months.

Note: For detailed procedure of evaluation of a GLP inspection and the ATR submitted by the TF, please refer Document No. GLP-110 "Evaluation Procedures of Inspection Results".

Issuance of GLP Certificate:

Head, NGCMA issues the GLP certificate to the TF after the Technical Committee on GLP recommends and Chairman, GLP Authority approves the grant of GLP certificate to the TF. The certificate is bilingual (Hindi and English) and includes name and address of the TF, area(s) of expertise and validity period of the certificate.

In addition to this, the annexure to the GLP certificate includes the categories of chemical(s) and the biological test system(s), where applicable on which GLP studies are conducted by the TF.

Note: In case any of the procedures of NGCMA pertaining to TF inspections/ communication of inspection report, submission of ATR by TF, organization of Committee meetings, etc. are deviated for any reason, the deviation would be reported to Head, NGCMA for approval.

Approved for issue by:

(Signature with date) 23/6/16.
Head, NGCMA