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

***PROCEDURE(S) FOR HANDLING OF
COMPLAINTS, GRIEVANCES AND
APPEALS***

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NATIONAL GLP COMPLIANCE MONITORING AUTHORITY
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PROCEDURES FOR HANDLING OF COMPLAINTS, GRIEVANCES AND APPEALS

1. Definitions

Complaint: Expression of dissatisfaction, other than an appeal, by any person or organization, against National GLP Compliance Monitoring Authority (NGCMA) or a Good Laboratory Practice (GLP) certified or applicant Test Facility (TF).

Complainant: Any individual/ organization/ body that is making a complaint.

Grievance: Expression of a real or imagined cause for complaint.

Appeal: A formal written request by a GLP certified or applicant TF for reconsideration of any adverse decision made by NGCMA related to the TF's certification status.

Appellant: A GLP certified or applicant TF filing an appeal.

Complaints, Grievances and Appeals (CGA) Committee: A committee constituted for the purpose of resolving complaints, grievances and appeals.

Complaints, Grievances and Appeals (CGA) Officer: An officer designated by Head, NGCMA, who is responsible for handling and processing of Complaints/ Grievances/ Appeals.

Hearing: The process where the CGA Committee hears oral arguments on an appeal presented by an appellant.

Test Facility: Test Facility means the persons, premises and operational unit(s) that are necessary for conducting the non-clinical health and environmental safety study. For multi-site studies, those which are conducted at more than one site, the Test Facility (TF) comprises the site at which the Study Director is located and all individual test sites, which individually or collectively can also be considered to be test facilities.

2. Objective

This document describes the procedures for dealing with:

- a) Complaints/ Grievances from various sources.
- b) Appeals from GLP certified/ applicant TFs for reconsideration of decisions taken by NGCMA.

3. Scope

The procedure described in this document is to be followed in NGCMA for dealing with complaints/ grievances/ appeals.

National Good Laboratory Practice Compliance Monitoring Authority		
Document No: GLP-108	Procedures for handling of Complaints, Grievances and Appeals	
Issue No: 04	Issue Date: 19.07.2016	Page 2 of 7

Complaint/ grievance can be against:

- a) Applicant/ GLP certified TF(s).
- b) Member(s) of inspection team/ Committee members.
- c) NGCMA or any of its staff.

Appeal can be made by TF against a decision taken by NGCMA in respect of:

- a) Refusal to accept an GLP application
- b) Refusal to conduct an inspection
- c) Denial of grant of GLP certification/ re-certification
- d) Refusal to grant GLP certification for extension in scope
- e) Suspension of GLP certification
- f) Withdrawal of GLP certification or
- g) Any other action that impedes the attainment of GLP certification.

4. Responsibility

Responsibility of handling of complaints/ grievances/ appeals rests with the CGA Officer. However, Head, NGCMA is responsible for monitoring of complaints/ grievances/ appeals and decision on them.

5. Terms of Reference of CGA Committee:

Structure and constitution of committee

A panel composed of a minimum of 3 individuals and a maximum of 5 individuals, independent of NGCMA and knowledgeable in matters of GLP certification appointed by the Chairman, GLP Authority in consultation with the Head, NGCMA to deal with complaints/ Grievances/ appeal(s). This panel may be augmented by inviting additional subject experts as deemed appropriate, by the Chairman, CGA Committee and Head, NGCMA in consultation with each other.

The tenure of the committee is for three years. The tenure may be increased or decreased after approval of Chairman, GLP Authority.

CGA Committee members, including the Chair, must fulfil these criteria:

- a) They must not have participated in decision making earlier on the present appeal either as a member of Technical Committee (TC) on GLP or in any other capacity.
- b) They must be free from any conflict of interest concerning the appellant or matter under appeal.
- c) They must be conversant with the GLP certification process and NGCMA functioning.

National Good Laboratory Practice Compliance Monitoring Authority		
Document No: GLP-108	Procedures for handling of Complaints, Grievances and Appeals	
Issue No: 04	Issue Date: 19.07.2016	Page 3 of 7

- d) Before progressing to consider any appeal, all members of the CGA committee must satisfy the above criteria and sign a disclaimer to officially record that they detected no conflict(s) of interest with regard to the matters at hand. In the event of not being sure of disclaimer such member may recuse himself/ herself from consideration of the particular appeal. In such cases, Chairman, CGA Committee must appoint a substitute member(s) with no such conflict(s) of interest.
- e) The committee shall have the necessary expertise to hear the subject of the appeal.
- f) The committee members may co-opt expertise if the need arises. A co-opted person will not have right to vote but will have the prerogative of recording his/her opinion in light of the reason for invite.
- g) Decision is made on a majority voting basis; the Chairman, CGA committee has a dual voting power, one as a member of the committee in all cases and secondly in case of a tied result, will cast his vote so that committee may arrive at a decision.

Function of the committee

The CGA Committee will consider complaints/ grievances/appeals received by NGCMA, deal with them appropriately and make decision on them.

6. PROCEDURE FOR HANDLING OF COMPLAINTS AND GRIEVANCES

- a) The complaint/ grievance must be made in writing to Head, NGCMA with complete details of complainant (Name, Address, Organization, etc.). If the complaint/ grievance has no details of the complainant or the description is not adequate, NGCMA will reserve the right of dealing with the complaint/ grievance as deemed fit. NGCMA can suo moto investigate the reports appearing in media or information received from Organization of Economic Cooperation and Development (OECD) Mutual Acceptance of Data (MAD) Adherent country(ies), if relevant.

The complaint/ grievance against Head, NGCMA will be addressed to Chairman, GLP Authority.

- b) Once the complaint/ grievance is received at NGCMA, Head, NGCMA shall mark it to the CGA officer. The same shall be acknowledged within 15 days of receipt.
- c) The CGA Officer shall maintain a record for the complaints/ grievances, will assign a unique registration number to them and maintain other details (as given in the Annexure I).
- d) Initial scrutiny of the complaint/ grievance is done by the CGA Officer. This is to determine that the complaint/ grievance falls within the ambit of NGCMA activities and whether the complaint/ grievance prima facie holds ground.

National Good Laboratory Practice Compliance Monitoring Authority		
Document No: GLP-108	Procedures for handling of Complaints, Grievances and Appeals	
Issue No: 04	Issue Date: 19.07.2016	Page 4 of 7

- e) If it is found that the complaint/ grievance does not fall within the ambit of NGCMA, the complaint/ grievance is considered closed after approval of Head, NGCMA and the complainant is informed accordingly.
- f) If the complaint/ grievance falls within the ambit of NGCMA and the initial information provided in the complaint/ grievance is sufficient then the complaint/ grievance is investigated further. CGA officer will discuss the same with Head, NGCMA.
- g) As per the approval of Head, NGCMA, an opportunity may be given to the TF or individual(s) (against whom the complaint/grievance is made) to address the complaint, where appropriate. Head, NGCMA may depute a representative/ GLP Inspector/ Technical Expert to investigate the matter, if required.
- h) All expenses relating to the investigation shall be borne by NGCMA.
- i) The CGA Officer shall compile the findings of the preliminary investigation as above & place them before the CGA Committee for its decision.
- j) If required, a hearing with the complainant or clarification/ additional information from the concerned may be taken by the CGA Committee.
- k) The CGA committee will take a decision on the complaint/grievance and convey the same to NGCMA. Accordingly, NGCMA will execute the decision of the committee.
- l) The decision of CGA Committee will be final and binding.
- m) The complainant shall be informed about the decision of the CGA committee and/or action taken by NGCMA.
- n) The complaint/ grievance shall be disposed within three months of receipt.
- o) The entire handling process of the complaint shall respect and maintain confidentiality, avoid conflict of interest and maintain complete impartiality.

7. PROCEDURE FOR HANDLING OF APPEALS

- a) The appeal process is an independent review and evaluation of a decision made by NGCMA that affects the certification status of the GLP certified or applicant TF.
- b) The appeals are addressed to the Head, NGCMA. In case the appeal is against Head, NGCMA, it would be addressed to Chairman, GLP Authority.
- c) Appeal should be submitted in writing within 30 days of the NGCMA decision against which the appeal is made.
- d) Appeal should be sent in the prescribed format (Annexure II) along with grounds for the appeal and relevant supporting documents and should be signed by Test Facility Management (TFM).
- e) Once the appeal is received at NGCMA, Head, NGCMA shall mark it to the CGA Officer. The same shall be acknowledged by NGCMA within 15 days of receipt giving an opportunity to the appellant for personal presence to represent the appeal.
- f) The CGA Officer shall assign a unique registration number and maintain a record for the appeals, along with other details in the Appeals Register (Annexure III).

National Good Laboratory Practice Compliance Monitoring Authority		
Document No: GLP-108	Procedures for handling of Complaints, Grievances and Appeals	
Issue No: 04	Issue Date: 19.07.2016	Page 5 of 7

- g) CGA Officer of NGCMA shall review the appeal for completeness of the supporting documents and if required, shall ask the appellant for submission of missing document, with approval of Head, NGCMA.
- h) After ensuring that the information relevant to the appeal is complete, the CGA Officer will prepare a "Case History" and place before the CGA Committee.
- i) If a TF faces some difficulty with one or more members of the inspection team during the inspection/study audit, including difference of opinion between the TFM and the inspection team, it should submit the appeal to include name(s) of the inspector, dates of inspection and grounds for the appeal with necessary evidence and specific instances leading to the appeal.
- j) If a TF does not agree to the findings and conclusions of an inspection which may form the basis for taking any adverse decision for the TF by NGCMA, it should submit the appeal.
- k) When an appeal is made against NGCMA's decision on suspension/ forced withdrawal/ denial/ non-grant of GLP re-certification, the GLP compliance of data generated shall be put on hold until the appeal process is completed and a final decision has been rendered.
- l) If the decision for suspension/ forced withdrawal/ non-grant of GLP re-certification is upheld, the date of respective inspection which led to such decision should be considered as the date of suspension/ forced withdrawal/ non-grant of GLP re-certification.

Deliberation of CGA Committee and Decision on Appeal

- a) CGA Committee may meet as and when needed.
- b) After examination of the appeal, the Committee shall seek clarification/ documents from all appropriate sources. The Committee, can depute NGCMA official/ GLP inspector/ Technical Expert or an expert to investigate the matter, including an on-site visit, if necessary.
- c) CGA Committee will hear the appellant personally.
- d) Any delay or lapse in submission of clarification or relevant documents or non-cooperation during appeal process by the appellant, the responsibility/onus of delay will be considered on the appellant himself.
- e) If the CGA Committee recommends an on-site visit/inspection, the constitution of inspection team, scope of inspection, duration of inspection and terms of reference of the inspection team shall be decided by the CGA Committee. The report of the inspection is placed before the Committee for a decision on the appeal.
- f) The decision of the committee will be conveyed to NGCMA, which will execute the same.
- g) The decision of the CGA committee is final and binding.


National Good Laboratory Practice Compliance Monitoring Authority		
Document No: GLP-108	Procedures for handling of Complaints, Grievances and Appeals	
Issue No: 04	Issue Date: 19.07.2016	Page 6 of 7

- h) The appeal should be disposed off within 90 days from the date of receipt of complete information for appeal from the appellant.

Costs for the Complaint/ Grievance and Appeal Process

- a) All expenses relating to the investigation done for resolution of complaints/ grievances shall be borne by NGCMA.
- b) In case of appeals, if the resolution is done without undertaking any travel or additional inspection, no financing will be needed. However, if the resolution calls for undertaking travel and an on-site inspection, then the cost will be borne by the appellant.
- c) All the records, correspondences, investigation reports and decisions etc. generated during complaints/ grievances/ appeals are maintained by CGA officer as records of NGCMA.

Approved for issue by:

 19/7/2016

(Signature with date)
Head, NGCMA

National Good Laboratory Practice Compliance Monitoring Authority		
Document No: GLP-108	Procedures for handling of Complaints, Grievances and Appeals	
Issue No: 04	Issue Date: 19.07.2016	Page 7 of 7



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National Good Laboratory Practice (GLP) Compliance Monitoring Authority

COMPLAINTS/ GRIEVANCES REGISTER

Sl.	Date of Receipt	Name and address of Complainant	Details of Complaint/ Grievance	Date of Acknowledgement	Outcome	Date of closure



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Name of the Appellant	
Contact Details of the Appellant	
Subject of Appeal (NGCMA Decision against which appeal is made)	
Summary of Appeal	
Details of Supporting Documents Attached	
Signature of Test Facility Management	
Date of appeal	



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National Good Laboratory Practice (GLP) Compliance Monitoring Authority

APPEALS REGISTER

Sl.	Date of Receipt	Name and address of Appellant (Test Facility)	Details of Appeal	Date of Acknowledgement	Outcome of Appeal	Date Signed off



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**DISCLAIMER FOR MEMBERS OF COMPLIANTS, GRIEVANCES AND APPEALS
COMMITTEE OF NGCMA**

I..... (Full name) here by accept that:

- a) In case I will have any financial dealing or I will be related in any way with the Test Facilities (TFs) whose case(s) will be considered by the Complaints, Grievances and Appeals (CGA) Committee of National GLP Compliance Monitoring Authority (NGCMA), I shall declare this in writing to the Head, NGCMA and will not participate during the discussions regarding the concerned TF(s).
- b) I will maintain confidentiality of all the information provided by NGCMA. The information would include inspection reports, Action Taken Reports (ATRs) of TFs and/or any other related documents.
- c) I will abide by the Terms of Reference of CGA Committee and follow the documents covering policies and procedures of NGCMA.

(Dated Signature of Member of CGA Committee of NGCMA)