

**APPEAL PROCEDURES OF NATIONAL GLP COMPLIANCE
MONITORING AUTHORITY**

All types of appeals should be addressed to Head, NGCMA (except if the Appeal is against the Head, NGCMA, where it should be addressed to Chairman, NGCMA).

All appeals shall be submitted in the format provided as Annexure- I to this document.

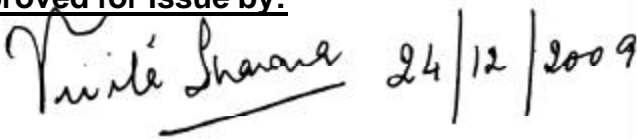
For all types of appeals, the decision of the National GLP Office would be placed before the Chairman, NGCMA for endorsement.

1. If a TF has some reservations on the choice of Inspectors by the NGCMA, it may appeal for replacement of some members of the inspection team if it considers that the impartiality, integrity and confidentiality against the test TF cannot be assured.
2. If a TF faces difficulty with one or more members of the inspection team during the inspection/study audit, including difference of opinion between the test facility management and the inspection team, it should submit the appeal within 10 working days after the date of completion of the inspection/study audit. The appeal should include name of the Inspector, dates of inspection and grounds for the appeal with necessary evidence and specific instances leading to the appeal. The appeal should be signed by the management of the TF as defined in the organogram.
3. If a TF does not agree to the findings and conclusions of an inspection which may form the basis for suspending the TF from the GLP Programme or denial of its entry into the GLP Programme, it should submit the appeal within one month from the date of communication for suspension/denial of GLP certification. The appeal should include dates of inspection, grounds for the appeal and necessary documents to establish clear evidence of GLP compliance. The appeal should be signed by the management of the TF as defined in the organogram.
4. National GLP Office would maintain a register for the appeals made by various TFs. Each appeal will be registered and assigned a unique sequential number. The TF should be informed about the receipt of the appeal and unique sequential number assigned within 10 working days from the date of receipt of the appeal.
5. If the appeal is against an Inspector, it will be examined by the Head, NGCMA for correctness of facts and completeness of the appeal. Evidence submitted by the TF will be thoroughly evaluated. While arriving at a decision the Head, NGCMA, will discuss the matter with the concerned Inspector. The views of the NGCMA will be communicated to the TF. Corrective actions, if required, will be taken which may include re-inspection of the portion of the inspection done by the concerned inspector by another Inspector appointed by the NGCMA. As per the rules and the procedures of NGCMA, the TF shall bear the expenses for the travel and stay of the Inspector(s) nominated by the NGCMA. The status quo with respect to GLP compliance will be maintained till a final decision is taken by the Chairman, NGCMA.

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6. The appeal with respect to non-grant of GLP status or suspension of a TF from NGCMA will be dealt by the Head, NGCMA and the case would be put up to the Chairman, NGCMA with all the background papers which include inspection reports, decision of the Technical Committee and any other documents considered essential. The decision of the Chairman, NGCMA would be final and binding. If the decision to suspend the TF is upheld, the date of inspection should be considered as the date of suspension.
7. In case the appeal is against Head, NGCMA (when member of inspection team), the appeal should be addressed to Chairman, NGCMA. The Chairman will examine the appeal and take appropriate action and inform the TF accordingly. The appeal should have all the reasons & justification appended to it. The appeal should be signed by the management of the TF as defined in the organogram. The Chairman's decision will be final.
8. The appeal against any other decision of National GLP Office shall be addressed to Head, NGCMA. The appeal would be dealt with by Head, NGCMA and would be put up to the Chairman, NGCMA for final decision.
9. The decision on all type of appeals will be taken within 8 weeks from the date of receiving the appeal at National GLP office.

Approved for issue by:

Handwritten signature of Vinita Sharma and date 24/12/2009.

(Signature with date)
Dr. Vinita Sharma
Head, NGCMA

National GLP Compliance Monitoring Authority (INDIA)

Annexure - I

Appeal No.:

(To be filled by National GLP Office)

Format for Appeal to NGCMA

To*:
The _____
NGCMA

From:
Test Facility

Name and Address	Certified by NGCMA	Last Inspection (Date and Type)
	Yes <input type="checkbox"/> No <input type="checkbox"/>	

Appeal Against/for:

- 1) Replacement of Inspector(s)
- 2) Member(s) of inspection Team/ Head, NGCMA (when a member)
- 3) Suspension of TF
- 4) Denial of its entry into the GLP Programme
- 5) Findings of Inspection
- 6) Any other decision of National GLP Office

Name of Inspector(s) (Applicable for 1 and 2 only)	
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Reason for Appeal

S. No.	Documents Enclosed	S. No.	Documents Enclosed

Test Facility Management	Name	Sign and Date

For Use by National GLP Office

Acknowledgement

Received by	Name	Sign and Date

Note:

Tick the appropriate box where applicable. Fields not applicable should be specified as 'NA'.

*Specify Head, NGCMA for all and Chairman, NGCMA, in case appeal is against Head, NGCMA (Point No.:2)

Document No. GLP-108

Number of pages enclosed: