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

OFFICE BASED INSPECTION

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NATIONAL GLP COMPLIANCE MONITORING AUTHORITY
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Office Based Inspection for oversight of GLP Test Facilities under National GLP Programme

The purpose of this document is to describe an approach to conduct Office Based Inspection (OBI) for reviewing the compliance of the Test Facility (TF) with OECD Principles of GLP during times of travel restrictions such as COVID-19 pandemic. The OBI may be followed by the physical visit to inspect the TF and the study data, if required, as and when travel restrictions allow.

Office Based Inspection can be conducted in the following situations:

1. Surveillance inspections of TFs which require only continuation of GLP certification in the previously identified areas of expertise. There should not be any significant changes in floor plans/ TF organization and personnel specially TFM and Quality Assurance (QA) Unit from the previous inspection.

2. Re-certification of TFs which do not require any extension in scope (studies/ test items/ test systems) from their earlier certified scope of GLP certification. There should not be any significant changes in floor plans/ TF organization and personnel specially TFM and QAU from the previous inspection.

Procedure to be followed for conduct of Office Based Inspection

1. A communication would be sent by NGCMA to the TF to submit the following information:

Sl. No.	Name of Document	File Format
I	Updates, if any, on the submitted GLP application	PDF or JPEG
II	Master Schedule for on-going studies, and studies completed since the last inspection (including both GLP and Non-GLP studies)	Excel format
III	Floor plan of the GLP TF, alongwith GLP areas marked therein	PDF or JPEG
IV	Organization Chart of the GLP TF	PDF or JPEG
V	An index of SOPs used within the TF including version numbers and issue dates	Excel or word
VI	Copies of SOPs relating to QA inspections, Archives, Document control, Training of TF Personnel, Test Item Control and Vendor management	Word or PDF
VII	QA Inspection schedules as well as any tracking documents used to demonstrate adherence to the schedule since the previous inspection (this should include planned and completed dates)	Excel
VIII	A list of computer systems used within the GLP TF	Excel
IX	Details of significant changes since the last inspection	Word or PDF
X	A list of key equipment to support GLP studies with calibration status	Excel
XI	Details of all key sub-contractors and vendors that supply GLP critical services	Excel
XII	A list of Study Directors & QA Personnel, highlighting any changes since the previous inspection and details of the training undertaken by the individuals	Word

2. NGCMA would constitute an inspection team for the conduct of the OBI as per its procedure and a mutual convenient date for the same would be finalized in consultation with the TF & inspection team. A representative from NGCMA will necessarily be a part of the OBI.

3. The TF would be informed about the details of studies to be audited during the OBI by the Lead Inspector a day before the inspection commences. Accordingly, the TF would be required to submit the following documents for each study:
   - Study plan, Raw data, Test Item Control Office (TICO) data, CVs & JDs of personnel, calibration records of equipment used, log books, etc.
   - Any other document related to the study

4. **Conduct of OBI**

   a. The inspection procedures of NGCMA would be followed which are in compliance with the OECD Principles of GLP.

   b. On the date of OBI, an Opening Conference would be held via video conferencing. This would be Chaired by the Lead Inspector.

   c. The inspection team would review documents/ Study Reports and interview any TF Personnel (using telephone /video conferencing /screen sharing).

   d. The inspectors would use the OBI checklist (Annexure- I) for the remote review of the information, however, the inspectors would be flexible to investigate issues further in accordance with OECD Principles of GLP.

   e. Any observations regarding shortcomings in the TF's GLP systems would be intimated by the inspection team and discussed with the concerned personnel/ QAU/ TFM during the inspection.

   f. After completion of the inspection, the inspection team would share a list of observations with the TF during a Closing Conference held via video conferencing.

   g. The TF would need to take necessary action on the observations of the OBI and submit an Action Taken Report (ATR) for the same, as applicable.

   h. Based on the OBI and the ATR provided by the TF, the inspection team would prepare an inspection report. The OBI report would record that the inspection was conducted remotely.

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Office Based Inspection Checklist

Name of the Test Facility (TF)			
Address of the TF			
Name of TFM/ Representative			
Date(s) of Inspection			
Name of the Inspector(s)			
Name of NGCMA Representative			

Sl. No.	Document	Rationale for Document	Documents received	Documents reviewed
1	Updates on Current Application	To ensure that any changes are GLP compliant.		
2	Master Schedule for on-going studies, and studies completed since the last inspection	To assess the workload historically and currently (to be used to assist assessment of workload and suitability of facility)		
3	Floor plan of the GLP TF alongwith GLP areas marked therein	To understand where the work takes place in the facility (to be used to assist assessment of workload and suitability of facility)		
4	Organization Chart of the GLP TF	To understand the job responsibilities of TF personnel (to be used to assist assessment of workload and suitability of facility)		

5	An index of SOPs used within the facility including version numbers and issue dates	To ensure timely review of documentation and key procedures		
6	Copies of SOPs relating to QA inspections, Archives, document control, Training of TF Personnel, Test Item Control and vendor management	To assess key quality system procedures		
7	QA inspection schedules as well as any tracking documents used to demonstrate adherence to the schedule since the previous inspection (this should include planned and completed dates)	To ensure QA is functional and adhering to procedures		
8	A list of computer systems used within the GLP test facility	To understand how much electronic data is being produced by the facility		
9	Details of significant changes since the last inspection	This may lead to further document requests		
10	A list of key equipment with calibration status	To assess maintenance of data generating instruments. This should be limited to complex equipment. Some examples of balances/ pipettes etc may be requested but these lists should not be extensive.		
11	Details of all key sub-contractors and vendors that supply GLP critical services	To assess whether there is any potential impact upon compliance through isolation measures		
12	A list of Study Directors and QA Personnel, highlighting any changes since the previous inspection and details of the training undertaken by the individuals	To ensure that all appointments have an appropriate level of role specific training.		
13	A summary of Actions Taken towards the previous inspection	To ensure that all Observations of the previous inspection have been complied with and are closed by the TF		
14	**Study Audits**: Documents required for Study audits of	To ensure smooth conduct of Study Audits		

	completed and archived studies viz. study plans & raw data, Test Item Control Office (TICO) data, CVs & JDs of personnel, calibration records of equipment used, log books, Archival records etc.	as a part of the inspection.		
Further Requests	*Lead inspector to add details of any other requests (if) made and rationale for these.*			

Comments of Lead Inspector, if any:

Dated Signature of Lead Inspector: