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National Good Laboratory Practice (GLP) Compliance Monitoring Authority

EVALUATION PROCEDURES OF INSPECTION RESULTS

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EVALUATION PROCEDURES OF INSPECTION RESULTS

The GLP Inspections conducted by National GLP Compliance Monitoring Authority (NGCMA) are of various types as detailed in Document No. 104 “Procedures of NGCMA Secretariat”.

The procedures followed by NGCMA for evaluating the results of each type of GLP inspection are detailed as under:

Pre-Inspection:

The observations/ findings/ deficiencies (if any) of the pre-inspection are communicated to the Test Facility (TF) in writing during the closing conference.

- a) In case no observations are found during the pre-inspection, the final inspection will be scheduled for the TF.
- b) In case observations are observed during the pre-inspection, the TF shall be required to take corrective actions and submit Action Taken Report (ATR) to these observations on the portal, within 6 months of conduct of the pre-inspection.

After receiving the ATR from the TF, the same is reviewed by the inspection team.

The formal report of pre-inspection would be finalized by the inspection team within 15 days of receiving the ATR.

If all the observations have been addressed satisfactorily in the ATR, the NGCMA Secretariat will organize a final inspection, as per recommendations of the inspection team in the inspection report.

In case the ATR is not found satisfactory, the pre-inspection report, along with ATR submitted by the TF, are placed before the Technical Committee (TC) on GLP, which, in turn, may recommend for conduct of final inspection of the concerned TF or obtain clarifications from the TF or otherwise.

In case ATR is not received within 6 months of conduct of pre-inspection, the inspection team will submit the inspection report within 195 days of conduct of the pre-inspection and NGCMA will follow the procedure as mentioned in Document No. GLP-113 “NGCMA Policies and Procedures for taking adverse and other decisions against test facilities”.

The formal report of pre-inspection and the decision of NGCMA on the same is made available on the portal.

Final Inspection:

The inspection team communicates its observations (if any) in writing to the TF during the closing conference of the final inspection.

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Depending on the observations of the final inspection, the case of final inspection for the TF would be processed, as given below:

1. In case no observations are found during the final inspection, the final inspection report will recommend grant of GLP-compliance certificate to the TF. Accordingly, the final inspection report will be placed before the TC on GLP.
2. In case observations are found during the final inspection, the TF shall be required to take corrective actions and submit ATR to these observations on the portal, within 45 days of conduct of the final inspection.

The ATR received from the TF will be reviewed by the inspection team. The formal report of final inspection would be finalized by the inspection team after assessment of the ATR within 15 days of receiving the ATR. In case the TF fails to submit an ATR within 45 days of conduct of final inspection, the inspection team will submit the inspection report within 60 days of conduct of the final inspection.

Final inspection report, along with ATR submitted by the TF and comments of NGCMA on the ATR are placed before the TC on GLP, which, in turn, makes a recommendation for the grant/ award of GLP certificate to the concerned TF or conduct of verification inspection of the TF or obtain clarifications from the TF or otherwise.

In case the TF does not submit a satisfactory ATR to the observations of final inspection within 45 days, NGCMA will follow procedure as per Document No. 113 “NGCMA Policies and Procedures for taking adverse and other decisions against test facilities”.

3. In case the ATR submitted by the TF requires an on-site verification, the lead inspector may recommend a verification inspection to be conducted for the TF. The final inspection report and the ATR submitted by the TF are placed before the TC on GLP for its recommendation. The TC on GLP may also recommend an on-site verification of the ATR if deemed necessary, even in the absence of a recommendation of verification inspection by the Lead inspector. After a verification inspection is conducted, the final inspection report, ATR to the final inspection and the verification inspection report will be placed before the TC on GLP.

For the above cases 1, 2 and 3, if TC on GLP is satisfied with the final inspection report, the ATR (if applicable) and verification inspection report, (if applicable), it would recommend grant of GLP certificate to the TF. This recommendation would be put forth to the Chairman, GLP Authority for his approval. After the Chairman’s approval, a GLP certificate will be issued to the TF.

If the TC on GLP is not satisfied with the final inspection report, the ATR and verification Inspection report (if applicable), it can either recommend non-grant of GLP certificate. In case TC on GLP recommends non-grant, the matter will be put forth to the Chairman, GLP Authority for approval. The decision of non-grant will be communicated to the TF.

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In case of non-grant of GLP certificate, NGCMA would follow procedures as per Document No. GLP-113 “NGCMA Policies and Procedures for taking adverse and other decisions against test facilities” and Document No. GLP-101 “Terms & Conditions of NGCMA for obtaining and maintaining GLP Certification”.

The formal report of final inspection and the decision of NGCMA on the same is made available on the portal.

Surveillance Inspection:

The inspection team communicates its observations (if any) in writing to the TF during the closing conference of surveillance inspection.

Depending on the observations of the surveillance inspection, the case of surveillance inspection for the TF would be processed, as given below:

1. In case no observations are found during the surveillance inspection, the surveillance inspection report will recommend continuation of GLP certification to the TF till the validity of existing GLP certificate. The surveillance inspection report will be placed before the TC on GLP.
2. In case observations are found during the surveillance inspection, the TF shall be required to take corrective actions and submit ATR to these observations on the portal, within 45 days of conduct of the surveillance inspection.

The ATR received from the TF will be reviewed by the inspection team. The formal report of surveillance inspection would be finalized by the inspection team after assessment of the ATR within 15 days of receiving the ATR. In case the TF fails to submit an ATR within 45 days, the inspection team will submit the inspection report within 60 days of conduct of the surveillance inspection.

Surveillance inspection report, along with ATR submitted by the TF and comments of NGCMA on the ATR are placed before the TC on GLP.

In case the TF does not submit a satisfactory ATR to the observations of surveillance inspection within 45 days, NGCMA will follow procedure as per Document No. 113 “NGCMA Policies and Procedures for taking adverse and other decisions against test facilities”.

3. In case the ATR submitted by the TF requires an on-site verification, the lead inspector may recommend a verification inspection to be conducted for the TF. The surveillance inspection report and the ATR submitted by the TF are placed before the TC on GLP for its recommendation. The TC on GLP may also recommend an on-site verification of the ATR if deemed necessary, even in the absence of a recommendation of verification inspection by the Lead inspector. After a verification inspection is conducted, the

surveillance inspection report, ATR to the final inspection and the verification inspection report will be placed before the TC on GLP.

For all the above cases 1,2 and 3, if TC on GLP is satisfied with the surveillance inspection report, the ATR and verification inspection report, (if applicable), it would recommend continuation of GLP certification of the TF in its previously-identified area(s) of expertise till the validity of the existing GLP certificate to the concerned TF.

If the TC on GLP is not satisfied with the surveillance inspection report, the ATR and verification Inspection report (if applicable), it may recommend withdrawal of GLP certificate (partial/ full) or obtain clarifications from the TF or otherwise.

In case of withdrawal of GLP certificate, the recommendations of TC on GLP would be put forth to the Chairman, GLP Authority for approval.

In case of withdrawal of GLP certificate, NGCMA would follow procedures as per Document No. GLP-113 “NGCMA Policies and Procedures for taking adverse and other decisions against test facilities” and Document No. GLP-101 “Terms & Conditions of NGCMA for obtaining and maintaining GLP Certification”.

The formal report of surveillance inspection and the decision of NGCMA on the same is made available on the portal.

Extension in scope Inspection:

The inspection team communicates its observations (if any) in writing to the TF during the closing conference of the extension in scope inspection.

Depending on the observations of the extension in scope inspection, the case of extension in scope inspection for the TF would be processed, as given below:

1. In case no observations are found during the extension in scope inspection, the extension in scope inspection report will recommend grant of GLP certification for the additional scope to the TF. The extension in scope inspection report will be placed before the TC on GLP.
2. In case observations are observed during the extension in scope inspection, the TF will be required to take corrective actions and submit ATR with respect to these observations within 45 days of conduct of the inspection. The ATR will be reviewed by the inspection team. If all the observations have been addressed satisfactorily in the ATR, the extension in scope inspection report, along with the ATR and comments of NGCMA on the ATR will be placed before the TC on GLP.

For the above cases 1 and 2, if TC on GLP is satisfied with the extension in scope inspection report and the ATR (if applicable), it would recommend grant of GLP certification for the additional scope (areas of expertise/ test items/ test systems, as applicable). The recommendations of the TC on GLP would be put up to Chairman, GLP Authority for approval.

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A fresh GLP certificate will be issued to the TF with the complete scope of certification {both existing scope and extended scope (including additional areas of expertise, test items and test systems)} with the same validity as the existing GLP certificate.

If the TC on GLP is not satisfied with the extension in scope inspection report and the ATR, it can recommend non-grant of GLP certificate. In case TC on GLP recommends non-grant, the matter will be put forth to the Chairman, GLP Authority for approval.

In case of non-grant of GLP certificate, NGCMA would follow procedures as per Document No. GLP-113 “NGCMA Policies and Procedures for taking adverse and other decisions against test facilities” and Document No. GLP-101 “Terms & Conditions of NGCMA for obtaining and maintaining GLP Certification”.

The formal report of extension in scope inspection and the decision of NGCMA on the same is made available on the portal.

Re-certification inspection:

The inspection team communicates its observations (if any) in writing to the TF during the closing conference of the re-certification inspection.

Depending on the observations of the re-certification inspection, the case of re-certification inspection for the TF would be processed, as given below:

1. In case no observations are found during the re-certification inspection, the re-certification inspection report will recommend grant of GLP certification to the TF. Accordingly, the re-certification inspection report will be placed before the TC on GLP.
2. In case observations are found during the re-certification inspection, the TF shall be required to take corrective actions and submit ATR to these observations to NGCMA, within 45 days of conduct of the re-certification inspection.

The ATR received from the TF will be reviewed by the inspection team. The formal report of re-certification inspection would be finalized by the inspection team after assessment of the ATR submitted by it within 60 days of conduct of the re-certification inspection. Re-certification inspection report, along with ATR submitted by the TF and comments of NGCMA on the ATR are placed before the TC on GLP, which, in turn, makes a recommendation for the award of GLP certificate to the concerned TF or conduct of verification inspection of the TF or obtain clarifications from the TF or otherwise.

In case the TF does not submit a satisfactory ATR to the observations of re-certification inspection within 45 days, NGCMA will follow procedure as per Document No. 113 “NGCMA Policies and Procedures for taking adverse and other decisions against test facilities”.

3. In case the ATR submitted by the TF requires an on-site verification, the lead inspector may recommend a verification inspection to be conducted for the TF. The re-certification

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inspection report and the ATR submitted by the TF are placed before the TC on GLP for its recommendation. The TC on GLP may also recommend an on-site verification of the ATR, if deemed necessary, even in the absence of a recommendation of verification inspection by the Lead inspector. After a verification inspection is conducted, the re-certification inspection report, ATR to the re-certification inspection and the verification inspection report will be placed before the TC on GLP.

For the above cases 1, 2 and 3, if TC on GLP is satisfied with the re-certification inspection report, the ATR and verification inspection report, (if applicable), it would recommend grant of GLP certificate to the TF. The recommendations of TC on GLP would be put forth to the Chairman, GLP Authority for approval. After the Chairman's approval, a GLP certificate will be issued to the TF, if applicable.

If the TC on GLP is not satisfied with the re-certification inspection report, the ATR and verification inspection report (if applicable), it may recommend non-grant of GLP certificate. In case TC on GLP recommends non-grant, the matter will be put forth to the Chairman, GLP Authority for approval.

In case of non-grant of GLP certificate, NGCMA would follow procedures as per Document No. GLP-113 "NGCMA Policies and Procedures for taking adverse and other decisions against test facilities" and Document No. GLP-101 "Terms & Conditions of NGCMA for obtaining and maintaining GLP Certification".

The formal report of re-certification inspection and the decision of NGCMA on the same is made available on the portal.

Surprise Inspection:

The inspection team communicates its observations (if any) in writing to the TF during the closing conference of the surprise inspection.

The surprise inspection report is submitted to NGCMA by the inspection team within 10 days of conduct of the inspection and the same will be communicated to the TF thereafter. The report of surprise inspection will be placed before the TC on GLP.

The TC on GLP may recommend continuation of GLP certification of the TF or any other recommendation, as deemed fit. The recommendations of the TC on GLP will be submitted to the Chairman, GLP Authority for perusal and approval.

In case any adverse decision is to be taken against the TF, procedures as mentioned in Document No. GLP-113 "NGCMA Policies and Procedures for taking adverse and other decisions against test facilities" and Document No. GLP-101 "Terms & Conditions of NGCMA for obtaining and maintaining GLP Certification" will be followed.

Note:

- 1) The inspection report is communicated to the TF through the NGCMA portal.

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- 2) It should be ensured that corrective/preventive actions should have been completed before submission of ATR and the ATR should be accompanied with documentary/ photographic evidence against each corrective action.
- 3) If a TF does not agree to any decision of NGCMA, it can make an appeal as per Document No. GLP-108 “Procedures for handling of Complaints, Grievances and Appeals”.

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