## 1. Introduction

Government of India established the National GLP Compliance Monitoring Authority (NGCMA) under the under Ministry of Science and Technology, Department of Science and Technology, New Delhi in April 2002 with the approval of the Union Cabinet. The formation of the NGCMA was notified in the Gazette of India Part 1, Section 1 on August 31, 2002. This document provides information on the functioning of the NGCMA and the procedures followed in awarding GLP certification to test facilities.

## 2. Background

GLP is a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental studies are planned, performed, monitored, recorded, archived and reported. GLP applies to the non-clinical safety testing of test items contained in pharmaceutical products, pesticide products, cosmetic products, veterinary drugs as well as food additives, feed additives, and industrial chemicals. These test items are frequently synthetic chemicals, but may be of natural or biological origin and, in some circumstances, may be living organisms. The application of GLP principles assures the quality and integrity of data generated in the test facility and allows this data to be used by regulatory authorities in hazard and risk assessment of chemicals. In fact, GLP system provides adequate confidence to regulatory authorities like the Drug Controller General of India that, test results and safety studies emanating from a GLP certified test facility in a pre-clinical environment may be relied upon for undertaking advanced level trials such as clinical trials.

The Indian drugs and chemicals industries are large in terms of research and development, production and export of chemicals and drugs. The industries have been engaged in pre-clinical studies for many years. However, in order to reach out to foreign market the industries have been getting studies and other data generated in foreign test facilities which are compliant with GLP principles. This whole process is very expensive. India is becoming an active player in the area of contract research and many R&D laboratories stand to gain if the country has a formal system for granting GLP compliance status to such test facilities engaged in per-clinical studies which is in line with internationally accepted principles and norms. The Indian test facilities, involved in pre-clinical safety studies, had also been impressing upon the government the need of having a system of GLP certification. Some of the Indian test facilities have even obtained GLP-compliance certification based on OECD Principles of Good Laboratory Practice from OECD member countries to meet their pressing needs. Based on the above needs, the Government of India, through a decision of the Union Cabinet, set up a National GLP Compliance Monitoring Authority in 2002. The Cabinet decided the following:-

a) Start the programme "National GLP-Compliance Monitoring Authority" for test facilities under the administrative control of the Department of Science and Technology/Ministry of Science & Technology.

b) Constitute the Apex Body with following membership:

- Secretary, DST - Chairman
- Secretary, Ministry of Chemicals & Fertilizers (Department. of Chemicals & Petro-

Chemicals)

- ♦ Secretary, Ministry of Agriculture (Department. of Agriculture & Cooperation)
- ♦ Secretary, Ministry of Health (Department. of Health)
- ♦ Drugs Controller General (India)
- ♦ Secretary, Ministry of Commerce & Industry (Department. of Commerce)
- ♦ Secretary, Ministry. of Environment & Forests
- ♦ Secretary, Ministry of Chemicals & Fertilizers (Department. of Fertilizers)
- ♦ Director-General, CSIR
- Head, GLP-Programme

c) Adopt OECD Principles of Good Laboratory Practice and Compliance Monitoring to maintain international harmony. )

d) Concerned Regulatory authorities should be members of the Apex Body.

**3. Constitution of National GLP Compliance Monitoring Authority**

The Government of India, recognizing the need to have the national system of GLP Compliance Monitoring, for giving recognition/certification to the test facilities/laboratories engaged in conducting safety studies, with respect to human health and environment, on chemicals or their products, on the basis of Organisation for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practices and OECD norms, resolves to constitute with effect from the date of publication of this Resolution, the GLP Authority consisting of following members, namely :-

Chairman

1. Secretary, Department of Science and Technology, Ministry of Science and Technology

Members

2. Secretary, Department of Chemicals & Petrochemicals, Ministry of Chemicals and Fertilizers

3. Secretary, Department of Agriculture and Cooperation, Ministry of Agriculture

4. Secretary, Department of Health, Ministry of Health & Family Welfare

5. Drugs Controller General (India) Directorate General of Health Services

6. Secretary, Department of Commerce

Ministry of Commerce & Industry

7. Secretary, Ministry of Environment & Forests

8. Secretary, Department of Fertilizers
Ministry of Chemicals & Fertilizers

9. Secretary, Department of Consumer Affairs
Ministry of Consumer Affairs, Food & Public Distribution

10. Director General, CSIR & Secretary-DSIR

Member-Secretary

11. Head – National GLP Programme
Department. of Science & Technology

2. The GLP Authority shall exercise the following powers & functions:

i. monitor the progress of the programme implementation against targets;

ii. establish National GLP Compliance/Monitoring system for test facilities on the basis of OECD Principles of Good Laboratory Practice;

iii. grant GLP certification to the test facilities based on their compliance to the OECD Principles of Good Laboratory Practice & OECD Test Guidelines;

iv. suspend/withdraw and/or terminate GLP Certification from its certified test facilities/laboratories, and/or may even inform relevant GLP Compliance Monitoring Authorities (belonging to OECD member country) should there be a need;

v. constitute such other Technical Committees/or the Working Groups which it deems fit, to complete a particular cause or need or activity;

vi. approve the rules and procedure that may be formulated for the smooth functioning of the programme, Technical Committee and Working Groups;

vii. ensure that National GLP Compliance Monitoring/Authority operates its system in accordance with current OECD Council norms, maintain its international compatibility and mutual recognition; and

viii. organize and conduct scheduled/unscheduled inspections for its GLP-certified laboratories.

3. The Programme would inter alia envisage

(i) Indian Regulatory Authorities, for the purpose of the assessment of chemicals, would start accepting only that test data which is from the test facilities/laboratories having the GLP-Certification from National GLP Compliance Monitoring Authority.

(ii) Indian Regulatory Authorities would start giving the recognition to the test studies from OECD member countries and GLP-Compliance laboratories/test facilities.

(iii) Indian Regulatory Authorities would accept, the assurance from other member country that test data have been generated in accordance with OECD Principles of Good Laboratory Practice and OECD Test Guidelines.

(iv) Enacting a law, involving all the interests and the concerned agencies, both governmental and non-governmental for entertaining their interests as well as obligations, as an integrated scheme of the Government of India, for constituting the National GLP Compliance Monitoring Authority, as a constitutional entity.

4. The Authority may appoint experts for facilitating the work assigned to it.

5. The National GLP Compliance Monitoring Authority shall have a Cell, which will function under the administrative control of Department of Science and Technology. Head, National GLP Compliance Monitoring Authority would implement the decisions of the GLP Authority, conduct day-to-day activities of the Programme in accordance with the prescribed procedures, exchange with other member countries relevant information concerning their procedures for monitoring compliances as per OECD norms and to maintain international liaison and discharge other functions relevant to recognition and implementing the OECD series on Principles of Good Laboratory Practice and Compliance Monitoring. (True copy of the Notification published in the Gazette of India, Part I, Section 1, on August 31, 2002 may be seen at Annexure 1.)

## 4. OECD programme on GLP

In 1978, member countries of the Organization for Economic Cooperation and Development (OECD) developed *OECD Principles of Good Laboratory Practice and Compliance Monitoring. OECD formally recommended Principles of Good Laboratory Practice for use in member countries in 1981. The programme on GLP Principles is being governed by the OECD Council Acts, namely:

1. Decision of the Council concerning the Adherence of non-Member Countries to the Council Acts related to the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final) and C(89)87(Final)] 26 November 1997 - C(97)114/FINAL
2. Decision-Recommendation of the Council on Compliance with Principles of Good Laboratory Practice 2 October 1989 - C(89)87/Final amended on 9 March 1995 - C(95)8/Final
3. Decision of the Council concerning the Mutual Acceptance of Data in the Assessment of Chemicals 12 May 1981 - C(81)30/Final amended on 26 November 1997 - C(97)186/FINAL.

This system has been in operation since then and was reviewed after 15 years of its implementation and now the revised OECD Principles of Good Laboratory Practice (1997) and Compliance Monitoring are being followed.

OECD has set up a Working Group on GLP, which is comprised of representatives of the governments which have entered into the multilateral agreement on **Mutual Acceptance of Data (MAD)**. The member countries of the Working Group on GLP include: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Israel, Italy, Japan, Korea, The Netherlands, New Zealand, Norway,

Poland, Portugal, Slovak Republic, Slovenia, South Africa, Spain, Sweden, Switzerland, United Kingdom, United States of America, European Commission.

National GLP Compliance Monitoring Authority has adopted the OECD series on Principles of GLP and Compliance Monitoring for operation of its system and for giving recognition to those facilities which would demonstrate their compliance with the OECD Principles of GLP and OECD Test Guidelines. Head, National GLP Programme has been nominated as an Observer in the Working Group of GLP by the Government of India.

## 5 Organizational Structure

**Functional Organs :**

### 5.1 **GLP Authority**

GLP Authority is the Apex Body of the National GLP programme. Its members are Secretaries from the concerned government ministries/departments / agencies with Secretary, Department of Science and Technology its Chairman. The constitution of the said body and its responsibilities have been explained earlier.

### 5.2 **National GLP Office:**

The National GLP Programme is being implemented through the National GLP Office which is under the direct control of the Head, National GLP Programme, who acts under the superintendence and direction of the Government of India (Department of Science and Technology, Ministry of Science and Technology) for carrying out its responsibilities.

**Responsibilities of National GLP Office:**

(i) To implement the National GLP programme and develop effective coordination with individuals/organizations associated with the same.

(ii) To maintain links with **Working Group on OECD** and participate in its meetings, so as to be able to operate the National GLP Programme as per current international norms and take all those measures, which may be required to establish and maintain international recognition, based on OECD Principles of GLP.

(iii) To appoint GLP inspectors having requisite qualifications, experience and training for inspecting test facilities for their compliance with GLP Principles.

(iv) To process the applications received for grant of GLP Compliance status and organize and conduct GLP inspections and study audits for applicant test facilities in India and abroad.

(v) To inform the test facility of the results of the inspection(s) or study audit(s) and allow them an appropriate period in which to respond or take corrective action.

(vi) To issue a GLP certificate to a test facility after the approval by the GLP Authority.

(vii) To organize surveillance visits to the test facilities having GLP compliance status, to confirm compliance with the procedural provisions of the GLP regulations and OECD Principles of GLP.

(viii) To constitute working groups or committees to help the National GLP Office in discharging its functions.

5.3 **Technical Committee:**

The **Technical Committee** is a recommending Body with the responsibility to help the National GLP Office in evaluating the competence of test facilities on the basis of the inspections organized by it. All the members of the Technical Committee are from the government ministries, departments and agencies and, there is no member from a private agency/ institution / industry. Technical Committee may summon GLP inspector(s) to present any evidence/findings before it and explain the same, if needed.

**Responsibilities of the Technical Committee:**

(a) To evaluate inspection reports of test facilities and give its recommendations for consideration of the Authority.

(b) To formulate technical norms, especially when OECD norms are not adequate

(c) To prescribe qualification, training and experience norms for experts to empanel them as GLP inspectors for assessment of applicant test facilities.

(d) To advise on matters related to implementation of GLP activities, including training, emerging issues, safety aspects etc.

5.4 **GLP Inspectors**

(i) National GLP Programme has opted in its system, to empanel as its Inspectors, the experts who are currently employed with Government test facilities/ organizations, and whose qualification(s), experience, etc. are meeting those prescribed by the Technical Committee

(ii) Inspectors evaluate the technical competence of the applicant test facility in all respects for its compliance to OECD Principles of Good Laboratory Practice and OECD Test Guidelines. They are trained by National GLP Compliance Monitoring Authority and /or OECD on GLP Principles.

(iii) GLP inspectors are responsible for conducting inspection of a test facility based on the study and analysis of application received from the test facility, carrying out opening and closing briefings in the test facility and preparing inspection reports with his/her recommendations, whether or not the test facility under consideration qualify for grant of GLP compliance status, to be placed before the Technical Committee.

(iv) Inspectors are monitored by the National GLP office for their performance.

(v) Inspectors have access to confidential and commercially valuable information of the test facility, required for its assessment while conducting inspections and study audits. Inspectors shall not disclose such confidential and commercially valuable information obtained during the course of inspection

and study audit of a test facility to any one except the National GLP Office to help it in coming to a correct decision in regard to suitability of the test facility for issuance Statement of GLP Compliance status.

(vi) Inspectors will not normally enter a test facility against the will of its management. However, if there is sufficient evidence to prove that the test facility is not adhering to GLP Principles and access to data from the test facility is *essential* to protect the interest of human health and environment, National GLP Office may organize unscheduled/spontaneous inspection/study audit any time. Access to the inspection team shall have to be granted by the test facility at all reasonable times and facilities, data and records for proper inspection shall be made freely available to inspectors. Refusal to comply shall result in suspension of GLP-certificate

(vii) Inspectors are provided with a copy of the application submitted by the test facility and the same is returned to the National GLP Office

(viii) Inspectors submit all reports of test facility inspection/study audit only to the National GLP Office. No copies of such reports or related information is be provided to test facilities other than that covered during opening and closing briefings during the inspection.

## 6. Nature of the National GLP Programme

6.1 GLP certification is voluntary and any test facility in India which undertakes such studies, either for its own purpose or for others, will be eligible to seek GLP certification.

6.2 National GLP Programme will establish and continually update a network of GLP-certified laboratories.

6.3 GLP certification given to a test facility shall be valid for a period of three years. GLP-certified laboratories shall be regularly monitored to ensure for their compliance to OECD Principles of Good Laboratory Practice and Test Guidelines by organizing the surveillance visits, that could be by informing the test facility or otherwise also, if required.

6.4 In those cases, where serious deviations which may have affected specific studies are found, the GLP Authority shall consider the need to inform the relevant National GLP Authority (ies) in other OECD member countries.

6.5 Should a situation arise and where good reason exists, National GLP Programme would cooperate with a national regulatory authority of a member country in the following ways :

5.5.1 In organizing a particular study audit and by providing the results to the requesting regulatory authority.

5.5.2 By facilitating to conduct and witness a study audit/inspection at the request from the Authority(ies) of a member country either for their Inspectors or for their representative(s)' Inspectors from the member country.

Note: Indian Regulatory Authorities would have a similar access in OECD member countries

6.6 National GLP programme has in-built feature of taking action against those test facilities which have been granted GLP certificate are not found to have complied with OECD Principles of Good Laboratory Practice & Test Guidelines which might affect the validity of studies conducted in the test facility.

6.7 Test facilities interested in GLP certification would be required to give an undertaking to National GLP Programme for agreeing to abide by its Terms and Conditions.

6.8 GLP Authority (Apex Body) has its membership from the concerned Government Departments/Regulatory Authorities to ensure their inputs and to safeguard their interest.

## 7. Scope and Extent of the Programme

7.1 National GLP Programme covers the application of OECD Principles of GLP and OECD Test Guidelines for non-clinical safety testing of test items contained in:

7.1.1 Industrial chemicals

7.1.2 Pharmaceuticals

7.1.3 Veterinary drugs

7.1.4 Pesticides

7.1.5 Cosmetic products/food additives/feed additives, etc. (specify)

7.2 These test items could be synthetic chemicals, of natural or biological origin and, in some circumstances, may be living organisms.

7.3 The purpose of testing these test items is to obtain data on their properties and/or on their safety with respect to human health and/or the environment.

7.4 The scope also covers non-clinical health and environmental safety studies conducted in the laboratory, green houses, and in the field.

7.5 The laboratories having the facilities relating to the following areas of expertise can make an application to the National GLP Compliance Monitoring Authority for their certification:

7.5.1 Physical-chemical testing

7.5.2 Toxicity studies

7.5.3 Mutagenicity studies

7.5.4 Environmental toxicity studies on aquatic and terrestrial organisms

7.5.5 Studies on behavior in water, soil and air, bio-accumulation

7.5.6 Residue studies

7.5.7 Studies on effects on mesocosms and natural ecosystems

7.5.8 Analytical and clinical chemistry testing

7.5.9 Other studies, specify

## 8. What is new in GLP Certification?

8.1 With the commencement of GLP certification programme, the country gets a system for determining the compliance of the test facilities, that are involved in data generation in the testing of chemicals, against OECD Principles of Good Laboratory Practice and OECD Test Guidelines and/or from other international bodies.

8.2 National GLP programme would meet the long-standing demand of Indian test facilities involved in conducting safety studies as it establishes an international system based on harmonized policies for chemical control, mutual economic trade advantage, minimize the cost-burden associated with testing the chemicals and the generation of valid and high quality data.

8.3 It would serve as a tool for the decision-makers and the regulatory authorities in the management of the chemicals & their products. It assures the regulatory authorities for the reliability on the test data they receive when making assessments of hazards or risk.

8.4 It is to provide a base for host of future activities; the Government may like to initiate with a view to control or keep a check on the chemicals or their chemical products for the category mentioned at point 1.1, in the Introduction.

8.5 It provides a means to Indian test facilities that are involved in conducting safety studies to demonstrate their capabilities as per OECD Principles of Good Laboratory Practice and Test Guidelines, the international norms.

8.6 It facilitates mutual acceptance of test data generated for submission to regulatory authorities amongst OECD member countries.

8.7 It enables exchange of information with other member countries, concerning their procedures.

8.8 It ensures access to the information including information focusing on a particular study, to another member country

8.9 National GLP Compliance Monitoring Authority has given its commitment to OECD's Environmental Health and Safety Division that it shall abide by such OECD Council Acts on GLP that are applicable to OECD member countries.

## 9. The Mechanisms by which test facilities enter the programme and the Steps of GLP certification

### 9.1 Application

Test facilities can submit an Application in the prescribed Application Format (GLP-102) along with the prescribed Application fees to:

**Head,**
**National GLP-Programme**
**National GLP Compliance Monitoring Authority**
**Department of Science & Technology**
**Technology Bhavan New Mehrauli Road**
**New Delhi-110 016**

### 9.2. Acknowledgement of receipt of application and application fee

An acknowledgement of the receipt of the application and the fees will be sent to the test facility by the National GLP Office, Department of Science and Technology, Government of India. The application fee is not refundable. The GLP office would assign a unique number to the Application file of the applicant. This Application file number shall be used for all correspondence with the test facility.

**Conducting GLP Application Review**: The application for GLP certification will be examined and reviewed by the National GLP Office for its correctness and completeness. The test facility shall be informed about any shortcoming and requested to provide the requisite information. In case the application does not meet the eligibility criteria for GLP compliant status, the applicant will be informed accordingly.

### 9.3 Inspection Procedure

(a) Pre-Inspection

If the application is found in order, the Authority will organize a **pre-inspection** of the test facility for which a team of inspectors will be appointed by the Authority. The purpose of the pre-inspection is to enable the Authority to have an idea about the organizational, infrastructural and operational aspects of the test facility, including the type of studies being performed with a view to determine the suitability of the test facility for the final inspection.

The duration of the pre-inspection would be between 1 to 3 days depending on size and scope of the test facility on mutually-convenient dates. The findings of the pre-inspection will be communicated to the test facility in writing during the exit meeting with the test facility by the inspectors. The formal report of pre-inspection will be communicated to the facility within 30 days of the inspection. The test facility must take corrective actions and submit an Action Taken Report (ATR) within 6 months of receiving the pre-inspection report.

(b) Final Inspection

The Final Inspection of the test facility will be carried out after the pre-inspection, if the test facility is found to follow the GLP principles without serious deficiencies, as recommended in the pre-inspection report. The purpose of the final inspection is to make a detailed assessment of the test facility, including compliance with all the points listed in the OECD Principles of GLP, Document No. 1 and guidelines of the NGCMA, if any. Dates for final on-site inspection shall be decided in consultation with the test facility and the inspector(s). The inspection team shall include the Lead Inspector/inspection inspector(s) so as to be able to cover the entire scope of certification sought.

The final inspection would be carried out by a team of inspectors appointed by the Authority. The team may consist of inspectors who conducted the pre-inspection or new inspectors. Generally, the inspection would be conducted on dates mutually agreed to between the Authority and the test facility. The inspection team may wish to see and study all types of documents such as standard operating procedures, master schedule, operating and instruction manuals of instruments and equipments, study plans along with study reports, organizational charts, floor plans, list of equipment, training records of personnel, orders issued by the test facility management from time to time for appointing new staff, study directors etc., 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 will physically visit each and every part of the test facility and may request the test facility to conduct some spot-checks, such as functioning of smoke detectors, measuring temperature in animal rooms etc. Staff members of the test facility at all levels may be interviewed by the inspection team. The duration of the final inspection will be 3 to 5 days depending on the size and scope of a test facility.

The inspection team will communicate its findings in writing to the test facility during the exit meeting with the test facility after the final inspection is over. If it is found that the test facility has not been following GLP principles, the team may recommend a **verification inspection** at a later date after the test facility has taken corrective actions on the observations made by the inspection team.

### 9.4 Examination of Inspection Report: Role of the Technical Committee

Final inspection report along with ATR submitted by a test facility and the report of verification inspection (if conducted) are submitted to the Technical Committee constituted by the National GLP Compliance Monitoring Authority which, in turn, makes a recommendation for the award of GLP certificate to the concerned test facility or re-inspection of the test facility or obtaining clarifications from the test facility or rejection.

### 9.5 Issue of GLP Certificate

The recommendation of the Technical Committee for the award of GLP certificate is approved by the Chairman, National GLP Compliance Monitoring Authority and Secretary, Department of Science and Technology. The test facility will then be issued the GLP Certificate highlighting name and address of the test facility, areas of expertise and starting date of the validity of the certificate.

9.6 **Membership of the National GLP Programme**: After receiving a GLP compliance certificate, a test facility becomes a member of the National GLP Programme and has to maintain its membership by paying an annual membership of Rs.10000/-.
. Actual status of each test facility in regard to its compliance to GLP principles would be shown in the Authority's website www.indiaglp.gov.in.

A GLP-compliant test facility under the National GLP Programme shall manage and operate in accordance with the OECD Principles of Good Laboratory Practice, OECD Test Guidelines, wherever applicable and instructions, rules and guidelines issued by the National GLP Compliance Monitoring Authority, from time to time. Further, the test facility is required to submit a list of studies completed on an yearly basis along with the most recent master schedule.

9.7 **Surveillance**

GLP-compliance certification shall be valid for a period of three years. Surveillance inspection of test facility shall be undertaken by the Authority once every year. The surveillance inspection will be for a duration of 2 to 3 days to ascertain compliance to GLP principles. Surveillance inspections will be carried out by a team of inspectors appointed by the Authority. The surveillance inspection will include test facility's inspection, scrutiny of the functioning of quality assurance unit and test facility management, study audits, study of SOP, master schedule etc. Special attention will be paid to the points observed during earlier inspections. The test facility **s**hall be asked to submit the following documents to the Authority before the surveillance inspection, namely, the recent organogram, list of personnel, lists of SOPs & equipments, master schedule and floor plans. The surveillance inspection reports are placed before the Technical Committee for evaluation and recommendation for continuation of the GLP certificate.

## 10. Categories of Test Facility Inspections/Study Audits

Test facility inspections are conducted to determine the degree of conformity of test facilities and studies with the GLP Principles and the integrity of data, to assure that resulting data are of adequate quality for assessment and decision-making by National Regulatory Authorities.

The National GLP Compliance Monitoring Authority conducts inspections and study audits in the following cases:

- A pre-inspection is always carried out for new applicants, to establish whether the facility is ready for a final inspection, as described earlier.
- Final inspections are done after every three years, in case the facility continues to apply for re-certification at the end of three year period of validity of its GLP certificate.
- Surveillance inspections are done every year to ensure continued compliance of the test facility to GLP Principles.
- The final inspection as well as the Surveillance inspection will involve both general facility inspection and an audit of one or more ongoing or completed studies.
- Verification inspections may be conducted after final inspections or surveillances in case deviations from GLP Principles are observed during these inspections and the facility agrees to attend to them by submitting an Action Taken Report.
- In addition to the above-mentioned inspections, the Authority may also conduct an inspection or study audit, at the request of a regulatory authority of India or abroad.
    1. Such requests will normally be for study audits.
    2. In some cases, study audits may generate the need for a more general inspection.
    3. In other instances, specific request from a Regulatory Authority may be met from information derived from recently completed inspections and further visits to the test facility may not be necessary. It will be for the Regulatory Authority to identify and justify the need for any inspection or study audit, which it has requested.

- The NGCMA reserves the right to conduct surprise inspections, if deemed necessary.
- The NGCMA may, occasionally or upon request, invite official representatives of other authorities to participate as observers in an inspection or study audit. Such

invitations will only be made with the consent of the test facility/sponsor as appropriate.

## 11. Powers of Inspectors

While inspectors will not normally wish to enter test facilities against the will of the test facility's management, circumstances may arise where entry to the test facility and access to data are essential to protect public health or environment.
The National GLP Compliance Monitoring Authority gives powers to inspectors authorized and appointed by it to enter test facilities, carry out inspections, take samples and copies of documents and interview staff. However, it is always desirable that one inspector from the full-time staff of the NGCMA is always present during the inspection to collect the documents/samples on behalf of the Authority.

The inspectors are nominated by Head, National GLP Programme by a letter sent to the individual inspector by the National GLP Office. A sample of letter issued to inspectors for participating in the proposed inspection is enclosed at Annexure II. Copies of these letters are kept in each GLP applicant's file.

## 12. Test facility inspection and study audit procedures

The procedures for carrying out test facility's inspections and study audits for verification of GLP Compliance are in accordance with OECD Revised Guidance for the Conduct of Laboratory Inspections and Study Audits (OECD Document No.3, 1995). The Authority has also issued a Checklist for the inspectors and an Inspection Manual which describes the detailed procedures for inspecting various areas of a test facility as well as some questions, which the inspectors may ask during the inspection. The checklist and the inspection manual are guidance documents for the inspectors so that all the inspectors can conduct the inspection in as uniform and objective manner as possible.

In each section of the inspection manual there is a statement of purpose as well as an illustrative list of specific items, which could be considered during the course of a Test Facility inspection or Study Audit. These lists are not meant to be comprehensive and should not be taken as such.

GLP Inspectors will not concern themselves with the scientific design of the study or the interpretation of the findings of the studies withy respect to risk for human health or environment. These aspects are the responsibility of those regulatory Authorities to which data are submitted for regulatory purposes.

A GLP inspection would start with an opening conference and end with a closing conference. The purpose of the opening conference is to inform the management and staff of the test facility of the reason for inspection or study audit that is about to take place, and identify the test facility areas, studies selected for audit, documents and personnel likely to be involved. At the opening conference, an agenda or schedule of inspection would be handed over to the test facility management, and the inspectors would:

- outline the purpose and scope of the visit;
- describe the documentation which will be required for the test facility inspection, such as lists of on-going and completed studies, study plans,

standard operating procedures, study reports, etc. Access to and, if necessary, arrangements for the copying of relevant documents would be agreed upon at this time;

- clarify or request information as to the management structure (organization) and personnel of the test facility;

- request information as to the conduct of studies not subject to GLP principles in the areas of the test facility where GLP studies are being conducted;

- make an initial determination as to the parts of the test facility to be covered during the test facility inspection;

- describe the documents and specimens that will be needed for on-going or completed study(ies) selected for Study Audit;
- indicate that a closing conference will be held at the completion of the inspection.

The purpose of the closing conference is to inform the test facility about the findings, including deficiencies observed during the inspection. The inspection team will communicate its findings in writing to the test facility during the closing conference. The management of the test facility should essentially be present during the opening and closing meetings.

The Test Facility is asked to comment on these observations, by submitting an ATR to the National GLP Office within 2-3 weeks of the inspection. The ATR submitted by the test facility will be taken into account together with the report of the inspection or study audit in order to establish the follow up.

**13. Follow up to test facility inspection and study audits**

If a Test Facility Inspection or Study Audit reveals only minor deviations from the GLP Principles, the facility will be required to correct such minor deviations and to provide ATR to the GLP Monitoring Authority that these deviations have been corrected and where appropriate, that corrective actions have been taken to prevent such deviation recurring. The Inspector may need, at an appropriate time to return to the facility to verify that the corrective actions have been introduced.

Where no/or where only minor deviations have been found, the National GLP Compliance Monitoring Authority may, on recommendation of the Technical Committee and approval of Chairman, GLP Authority and Secretary, Department of Science and Technology, issue a certificate highlighting name and address of the test facility, areas of expertise and starting date of the validity of the certificate.

This information of grant of GLP certificate may be provided to GLP Monitoring Authorities in other OECD Member Countries, and/or to the Regulatory Authority which request a Study Audit with a detailed report of the findings.

Where serious deviations are found, the NGCMA may take appropriate actions which may include the following:

- issuance of a statement giving details of the inadequacies or faults found which might affect the validity of studies conducted in the test facility;

- issuance of a recommendation to a regulatory authority that a study be rejected;

- suspension of test facility's GLP certification or study audit and withdrawal of the test facility GLP certification from the membership of National GLP Programme.

- requiring that a statement detailing the deviations be attached to specific study reports;

The Test Facility will be informed before such actions are taken.

## 14. Appeal Procedure

Test facility can make a complaint to the GLP Authority for any of the problem or difference of opinion between the management of the test facility and inspector(s) during the course of test facility's inspection or study audit or for any of the action(s) of the GLP Authority. The complaint will be processed by the GLP Secretariat in accordance with its procedure and the outcome shall be communicated to the test facility. In those cases, where the test facility is not satisfied, it can make an appeal to the Chairman, GLP Authority, who shall appoint an independent expert to look into the problem and submit his findings to the Chairman, GLP Authority. Such recommendation shall be binding both on the test facility and the GLP Authority.

## 15. List of the Documents published by OECD

### (A) Series on: Principles of Good Laboratory Practice and Compliance Monitoring

1. OECD Principles of Good Laboratory Practice (as revised in 1997).
2. Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice (1995).
3. Revised Guidance for the Conduct of Laboratory Inspections and Study Audits (1995).
4. Quality Assurance and GLP (1999).
5. Compliance of Laboratory Suppliers with GLP Principles (2000).
6. The Application of the GLP Principles to Field Studies (1999).
7. The Application of the GLP Principles to Short-term Studies (1999)
8. The Role and Responsibilities of the Study Director in GLP Studies (1999).
9. Guidance for the Preparation of GLP Inspection Reports (1995)

10. The Application of the Principles of GLP to Computerized Systems (1995).

11. The Role and Responsibilities of the Sponsor in the Application of the Principles of GLP (1998)

12. Requesting and Carrying Out Inspections and Study Audits in Another Country (2000)

13. The Application of the OECD Principles of GLP to the Organization and Management of Multi-site Studies.

14. The application of the Principles of GLP to *in vitro* Studies

The above Documents No.1, 4, 5, 6, 7, 8, 10, 11, 13 and 14 are applicable for test facilities/Laboratories and can be down-loaded from the OECD **Web-site (http://www.oecd.org/ehs/)**. However, GLP-Secretariat can also provide these documents .

**(B) OECD – Test Guidelines :**

Test Facilities/Laboratories are advised to procure the relevant test guidelines on their own.

**16. Financial obligation on the part of applicant test facility**

The applicant test facility is required to pay the following amount depending on its applicability :

| | |
|---|---|
| **Application Fee** | Rs.10,000/-<br>(Non-refundable, to be paid along with application) |
| **Boarding & lodging facility to inspection team** | To be provided by test facility<br>(Single occupancy AC accommodation in a reasonable good hotel/guest house |
| **Travel expenditure on account of inspectors' visit to the applicant test facility for inspection/surveillance** | As per actuals<br>(Travel component may include - air, rail or road, as the case may be) |
| **Membership fee** | Rs.10,000/- per year<br>(Applicable to GLP-certified test facility) |

NOTE:(1) All payments are to be made by Demand Draft in favour of Drawing & Disbursing Officer, DST and payable at New Delhi

(2) Demand Draft for any head of payment should be posted to

Head, National GLP Programme to ensure that payments have been received

## 17. Contact Addresses

**National GLP Office:**
National GLP Compliance Monitoring Authority
Department of Science & Technology
Technology Bhavan
New Mehrauli Road
New Delhi-110 016
Telefax: 91-011-26964793

**Chairman :**
Secretary, Department of Science & Technology
Technology Bhavan
New Mehrauli Road
New Delhi-110 016
Tel: 91-011-2651 1439
Fax: 912-011-2686 3847

**Head, National GLP Programme :**
Head-National GLP Programme
Department of Science & Technology
Technology Bhavan
New Mehrauli Road
New Delhi-110 016
Telefax: 91-011-26964793