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

INFORMATION BROCHURE

Document No.GLP-100
Issue No. 07
Issue Date: June 23, 2016

NATIONAL GLP COMPLIANCE MONITORING AUTHORITY
DEPARTMENT OF SCIENCE AND TECHNOLOGY
TECHNOLOGY BHAVAN, NEW MEHRAULI ROAD
NEW DELHI-110 016
www.indiaglp.gov.in

Table of Contents

1. Introduction

The National Good Laboratory Practice (GLP) Compliance Monitoring Authority (NGCMA)/ GLP Authority was established by Government of India with the approval of the Cabinet under the administrative control of Ministry of Science and Technology, Department of Science and Technology in April 2002. The formation of the NGCMA was notified in the Gazette of India Part 1, Section 1 on August 31, 2002, which may be seen at **Annexure I.**

2. Background

2.1 GLP is a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety 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 usually/ normally synthetic chemicals, may be of natural, herbal/ plant extracts or biological origin, and in some circumstances, may be living organisms.

2.2 The application of GLP principles has the following advantages:

a) Assures the quality and integrity of data generated in GLP-certified Test Facilities (TFs).
b) Provides confidence regarding authenticity of pre-clinical data of above-mentioned test items for hazard and risk assessment to regulatory authorities.
c) Avoids duplicative testing
d) Is beneficial to animal welfare
e) Reduces time and costs for industry, government and other stakeholders
f) Facilitates exchange of information
g) Removes non-tariff trade barriers
h) Contributes to the protection of human health and environment.

2.3 Considering the above benefits, Government of India, through a decision of the Cabinet, set up the NGCMA in 2002 on following lines:

2.3.1 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 and Technology, Government of India.

2.3.2 Constitute the Apex Body with following membership:

Chairman

Secretary
Department of Science & Technology
Ministry of Science & Technology

Members

Secretary
Department of Chemicals & Petrochemicals
Ministry of Chemicals & Fertilizers

Secretary
Department of Agriculture & Co-operation
Ministry of Agriculture

Secretary
Department of Health
Ministry of Health & Family Welfare

Drugs Controller General of India
Directorate General of Health Services
Ministry of Health & Family Welfare

Secretary
Department of Commerce
Ministry of Commerce & Industry

Secretary
Ministry of Environment, Forest and Climate Change

Secretary
Department of Fertilizers
Ministry of Chemicals & Fertilizers

Secretary
Department of Consumer Affairs
Ministry of Consumer Affairs, Food and Public Distribution

Director-General
Council for Scientific and Industrial Research

Member Secretary

Head, NGCMA

2.3.3 Adopt Organization for Economic Cooperation & Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring to maintain international harmony.

2.3.4 Concerned regulatory authorities should be members of the Apex Body.

2.4 India is a full adherent to Mutual Acceptance of Data (MAD) in the OECD's Working Group on GLP. This offers the following benefits to the Indian industries:

a) Data generated by Indian GLP-certified TFs for the test items mentioned in 2.1 above is acceptable in OECD MAD adherent countries and for approval by regulatory authority(ies), before marketing the product.
b) The Indian industry is able to save expenses incurred in getting their products tested outside the country in GLP-compliant TFs.
c) There is increased business opportunity for Indian GLP-certified Test Facilities/ Contract Research Organizations (CROs).

3. OECD Programme on GLP

3.1 In the year 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 GLP for use in member countries in 1981. The programme on GLP Principles is being governed by the OECD Council Acts, namely:

3.1.1 Decision of the Council concerning the Adherence of non-Member Countries to the Council Acts related to the MAD in the Assessment of Chemicals [C(81)30(Final) and C(89)87(Final)] 26 November 1997 – C(97)114/Final

3.1.2 Decision-Recommendation of the Council on Compliance with Principles of GLP, October 1989 - C(89)87/Final amended on 9 March 1995 - C(95)8/Final

3.1.3 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.

3.2 The above system has been in operation since then. The revised OECD Principles of GLP and Compliance Monitoring (1997) are being followed.

3.3 OECD has a Working Group on GLP, comprising 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 may be seen at www.oecd.org

3.4 NGCMA has adopted the OECD Principles of GLP and Compliance Monitoring for operation of its systems and for giving recognition to those TFs which

demonstrate their compliance with the OECD Principles of GLP and OECD Test Guidelines. Head, NGCMA has been nominated as Member in the OECD's Working Group on GLP and National Coordinator for OECD Test Guidelines on GLP by the Government of India.

4. Organizational Structure of NGCMA

4.1 GLP Authority

GLP Authority is the Apex Body of the National GLP programme. The constitution and responsibilities of the Apex Body are given in the Gazette Notification dated August 31, 2002, at **Annexure I (True copy of Notification published in the Gazette of India, Part I, Section 1, on August 31, 2002).**

4.2 NGCMA Secretariat

NGCMA Secretariat implements the National GLP Programme under the administrative control of Department of Science and Technology (DST), Ministry of Science and Technology, Government of India. Head, NGCMA reports to Chairman, GLP Authority for all activities related to GLP compliance Monitoring.

4.3 Responsibilities of NGCMA Secretariat

4.3.1 To implement the National GLP programme.

4.3.2 To lay down policies and procedures for the National GLP programme as per OECD norms and National regulations, as applicable.

4.3.3 To maintain links with OECD's Working Group on GLP, to ensure the functioning of the National GLP Programme as per current international norms and take required measures to establish and maintain international recognition based on OECD Principles of GLP.

4.3.4 To coordinate with TFs associated with the programme.

4.3.5 To process the applications received for grant of GLP certification, organize and conduct GLP inspections and study audits in India and abroad.

4.3.6 To train and appoint GLP inspectors and Technical Experts for inspecting TF(s) for compliance with GLP Principles.

4.3.7 To inform the TFs of the results of the inspection(s) or study audit(s) and ensure submission of satisfactory response or corrective action within the specified time frame.

4.3.8 To issue a GLP compliance certificate to a TF.

4.3.9 To maintain all inspection/ study audit records and GLP compliance status of TF(s) associated with the programme.

4.3.10 To constitute working groups or committees to help the NGCMA Secretariat in discharging its functions.

4.3.11 To take appropriate actions if serious deviations are found during the course of inspection(s)/ study audit(s).

4.3.12 To create awareness on GLP in the country by organizing and supporting workshops, symposia, seminars and training programmes for the TF(s) etc.

4.4 Technical Committee on GLP

The Technical Committee (TC) on GLP is the recommending body constituted by Chairman, GLP Authority. Members of the TC on GLP are from the concerned Ministries/ Departments/ Agencies of Government of India including Regulatory bodies. The TC has the responsibility for assessment and evaluation of test facilities (TFs) on the basis of inspections organized and conducted by the NGCMA.

For details of working of the TC on GLP, please refer to Document No. GLP-112 "Technical Committee on GLP".

4.5 GLP Inspectors

4.5.1 National GLP Programme has empanelled inspectors, who are currently employed with Government organizations/ agencies and meet the desired qualification(s), experience and training norms of NGCMA (as referred in GLP-107 "Training and Evaluation of GLP Inspectors").

4.5.2 Inspectors evaluate the competence of the applicant TF for its compliance to OECD Principles of GLP and OECD Test Guidelines by conducting on-site GLP inspections. They are trained by NGCMA or OECD for conducting GLP inspections and Study audits.

5. Nature of the National GLP Programme

5.1 GLP certification is voluntary and any TF in India which undertakes non-clinical health and environmental safety studies will be eligible to seek GLP certification.

5.2 National GLP Programme will maintain a list of GLP-certified TFs.

5.3 GLP certification granted to a TF shall be valid for a period of three years. GLP-certified TFs shall be regularly monitored to ensure their compliance to OECD Principles of GLP and OECD Test Guidelines by organizing surveillance visits.

5.4 NGCMA would cooperate with Regulatory Authority(ies) (RAs)/ Compliance Monitoring Authorities (CMAs) of an OECD MAD adherent country in the following ways:

5.4.1 Organize a particular study audit and provide the results to the requesting RA who sought such services.

5.4.2 Facilitate and conduct a Joint GLP inspection/ study audit at the request from the RAs of an OECD MAD adherent country along with their Inspectors or representative(s).

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

5.5 NGCMA has an in-built mechanism of initiating action against the GLP certified TF not found to have complied with OECD Principles of Good Laboratory Practice & OECD Test Guidelines (Document No. GLP-113 "Policies and procedures of NGCMA for taking adverse and other decisions against test facilities"), which might affect the validity of studies conducted in the TF.

6. Scope and Extent of the National GLP Programme

6.1 National GLP Programme covers the application of OECD Principles of GLP and OECD Test Guidelines, where applicable, for non-clinical health and environmental safety testing of test items contained in:

a) Industrial Chemicals
b) Pharmaceuticals
c) Veterinary Drugs
d) Pesticides
e) Cosmetic Products
f) Food Additives
g) Feed Additives
h) Others (specify)

6.2 The test items are usually/ normally synthetic chemicals, may be of natural herbal/ plant extracts or biological origin, and in some circumstances, may be living organisms.

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

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

6.5 The TFs having the facilities relating to the following areas of expertise can apply to the NGCMA for GLP certification:

a) Physical-chemical Testing
b) Toxicity Studies
c) Mutagenicity Studies
d) Environmental Toxicity Studies on Aquatic and Terrestrial Organisms
e) Studies on Behavior in Water, Soil and Air, Bio-accumulation
f) Residue Studies
g) Studies on Effects on Mesocosms and Natural Ecosystems
h) Analytical and Clinical Chemistry Testing
i) Other Studies (Specify)

7 Salient Features of GLP Certification

7.1 With the commencement of National GLP programme, the country gets a system for determining the compliance of the TFs that are involved in data generation in the testing of chemicals, in accordance with OECD Principles of GLP and OECD Test Guidelines.

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

7.3 It serves as a tool for the decision-makers and the regulatory authorities in the management of the chemicals and their products. It assures the regulatory authorities for the reliability on the test data they receive when making assessments of hazards or risks.

7.4 It provides a base for future measures, which the Government may like to initiate, with a view to control or keep a check on the chemicals or chemical products.

7.5 It provides a means to Indian TFs, involved in conducting safety studies, to demonstrate their capabilities as per OECD Principles of GLP.

7.6 It facilitates mutual acceptance of test data generated for submission to regulatory authorities amongst OECD MAD-adherent countries.

7.7 It enables exchange of information with other OECD MAD adherent countries, concerning their procedures.

7.8 It ensures access to the information, including information focusing on a particular study to another OECD MAD-adherent countries.

7.9 Through an agreement of Mutual Acceptance of Data (MAD), NGCMA has given its commitment to OECD's Environmental Health and Safety Division that it shall abide by the OECD Council Acts on GLP which are applicable to OECD MAD adherent countries.

8 GLP Certification Process

8.1 Application

TFs can submit an application in the prescribed Application Form (Document No. GLP-102) along with prescribed application fees to GLP Cell, Quality Council of India (QCI), who extend required services to NGCMA in facilitating GLP inspections, at the following address:

GLP Cell
Quality Council of India (QCI)
2nd Floor, Institution of Engineers Building
Bahadur Shah Zafar Marg
NewDelhi-110 002
e-mail: *glpindia@qcin.org*
Website: *www.qcin.org*
Telephone: *+91-11- 2337 9321, 2337 8056*
Fax: *+91-11-2337 8678*

TFs interested in GLP certification would be required to give an undertaking to NGCMA for agreeing to abide by its Terms and Conditions of NGCMA (Document No. GLP-101) along with the application form.

8.2. Acknowledgement of receipt of application and application fee

Receipt of the application and the fee from TF is acknowledged by the GLP Cell, QCI. The application fee is not refundable. The GLP Cell, QCI assigns a unique number to the application file of the applicant in consultation with NGCMA

Secretariat. This application file number is used for all correspondence with the TF. The application is passed to NGCMA for further processing.

8.3 Review of GLP application

The application for GLP certification is examined and reviewed at NGCMA, for its correctness and completeness.

If the application is found to be complete and meets the eligibility criteria, an inspection team is constituted by NGCMA. Information to this effect and dates of pre-inspection/ inspection are intimated to the TF. In case the dates are not convenient to the applicant TF, mutually-agreeable dates are fixed.

The TF is informed of any inadequacies in its GLP application and the same is sought.

In case the application does not meet the eligibility criteria for GLP certification, the applicant TF is informed accordingly.

8.4 On-site GLP Inspections

8.4.1 Inspections conducted by NGCMA may be categorized as-Pre-inspection, Final Inspection, Verification inspection, Surveillance inspection, Extension in scope inspection, Re-certification inspection, Inspection at the request of a regulatory Authority/ GLP Compliance Monitoring Authority and Surprise inspection, as specified in Document No. GLP-104 "Procedure(s) of NGCMA Secretariat".

8.4.2 The procedure for carrying out TF inspections/ study audits for verification of GLP compliance will be in accordance with OECD Revised Guidance for the Conduct of Laboratory Inspections and Study Audits (OECD Principles of GLP Document No.3, 1995). NGCMA provides an Inspection Manual (GLP-103) for use by its inspectors which describes the detailed procedure for inspection of various areas of a TF.

8.4.3 If a TF inspection/ Study Audit reveals deficiencies from the OECD Principles of GLP, the facility shall be required to correct such deficiencies and provide an Action Taken Report (ATR) to the NGCMA, within 45 days of conduct of all types of GLP inspections except the pre-inspection, where ATR should be submitted within 6 months of conduct of the inspection.

8.4.4 The inspection findings and the ATR submitted by the TF are evaluated by the NGCMA as per Document No. GLP-110 "Evaluation Procedure(s) of Inspection Results".

8.4.5 Final inspection/ Re-certification inspection report along with ATR submitted by TF and the report of verification inspection (if conducted) are placed before the TC on GLP for recommendation (Grant of GLP compliance certificate to the concerned TF or otherwise).

8.4.6 Surveillance/ Extension in scope/ Surprise inspection report along with ATR submitted by TF and the report of verification inspection (if conducted) are placed before the TC on GLP for recommendation (continuation of GLP certificate in its previously identified areas of expertise/ extension in scope of GLP certification till the expiry of current GLP certificate or otherwise).

8.5 Issue of GLP Certificate

The recommendations of the TC on GLP are put up to Chairman, GLP Authority for appropriate decision. If approved for grant of GLP certificate, the TF is issued the GLP Certificate highlighting name and address of the test facility, areas of expertise and validity period of the certificate.

8.6 GLP-Certified Test Facilities

8.6.1 After receiving a GLP compliance certificate, the name of the TF is added to the list of GLP-Certified TFs and has to maintain its certification by paying the prescribed annual certification fee.

8.6.2 Status of each TF with regard to its compliance to OECD Principles of GLP is put up on the website of NGCMA: www.indiaglp.gov.in.

8.6.3 A GLP-compliant TF under the National GLP Programme shall manage and operate in accordance with the OECD Principles of Good Laboratory Practice and guidelines of NGCMA, if any.

8.7 Surveillance

GLP-compliance certification shall be valid for a period of three years. Surveillance inspection of test facility shall be undertaken by NGCMA usually midway through the period of validity of certificate {18 (±3) months from the date of grant of GLP certificate}. Detailed procedure followed by NCGMA for

surveillance inspection may be seen in Document No. GLP-104 "Procedures of NGCMA Secretariat".

8.8 Extension/ Reduction in scope of GLP certification

During a GLP certification cycle (validity 3 years), the scope of GLP certification may be extended/reduced as per procedure mentioned in Document No. GLP-101 "Terms & Conditions of NGCMA for obtaining and maintaining GLP certification" and GLP-104 "Procedures of NGCMA Secretariat".

8.9 Complaint/ Grievance/ Appeal Procedure

A TF can submit a complaint, grievance or an appeal to NGCMA on any issue faced by it during the process of GLP certification. These shall be processed by NGCMA in accordance with Document No. GLP-108 "Procedure(s) for Handling of Complaints, Grievances and Appeals".

9 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 (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 (2002).

14. The application of the Principles of GLP to *in vitro* Studies (2004).

15. Establishment and Control of Archives that Operate in Compliance with the Principles of GLP (2007).

16. Advisory Document of the Working Group on Good Laboratory Practice - Guidance on the GLP Requirements for Peer Review of Histopathology (2014).

17. Advisory Document of the Working Group on Good Laboratory Practice - Application of GLP Principles to Computerised Systems (2016).

The above Documents No.1, 4, 5, 6, 7, 8, 10, 11, 13, 14 15, 16 and 17 are applicable for TFs and can be down-loaded from the OECD website (http://www.oecd.org/ehs/) or NGCMA web-site (http://www.indiaglp.gov.in).

(B) OECD – Test Guidelines:

TFs are advised to procure the relevant test guidelines on their own.

10. Financial Obligation on the part of Applicant and Certified TF

Application Fee	Rs. 25,000/-* per each area of expertise for which GLP certification is being sought. (Non-refundable and to be paid along with application)
Annual Certification Fee (Applicable to GLP-certified TFs only)	Rs. 25,000/-* (Non-refundable)
Travel expenditure on account of inspectors' visit to TF for GLP inspections of NGCMA	a) Economy class Airfare/ AC-2 Tier Train fare and local transportation b) Boarding & lodging facility to Inspection Team

* Note: Applicable taxes need to be added to the application and annual certification fee

11. NGCMA has entered into a Memorandum of understanding with Quality Council of India (QCI) for efficient discharge of duties.

12. The Application for GLP certification/ Re-certification/ Extension in scope of GLP compliance of the TF**/ Documents for Surveillance Inspection, along with prescribed fee is to be submitted to GLP Cell, QCI at the address given below:

GLP Cell
Quality Council of India (QCI)
2nd Floor, Institution of Engineers Building
Bahadur Shah Zafar Marg
NewDelhi-110 002
e-mail: *glpindia@qcin.org*
Website: *www.qcin.org*
Telephone: *+91-11- 2337 9321, 2337 8056*
Fax: *+91-11-2337 8678*

** Request for extension in scope of GLP certification during a certification cycle should be submitted atleast 3 months after the conduct of the last inspection by NGCMA. This can be also done along with the submission of Surveillance inspection documents.

13. The ATRs for all GLP Inspections, where applicable and any other information, major change in organization, change in name/ legal status etc. is to be submitted to NGCMA Secretariat at the following address:

National GLP Compliance Monitoring Authority
Department of Science & Technology
Technology Bhavan
New Mehrauli Road
New Delhi-110 016
Website: *www.indiaglp.gov.in*
Email: *indiaglp@gov.in*
Tel: *+91-11-26590 242*

Approved for issue by:

(Signature with date) 23/6/16
Head, NGCMA

रजिस्ट्री सं. डी एल—33001/2002 REGISTERED No. DL—33001/2002

भारत का राजपत्र
The Gazette of India

प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं० 35] नई दिल्ली, शनिवार, अगस्त 31, 2002 (भाद्रपद 9, 1924)
No. 35] NEW DELHI, SATURDAY, AUGUST 31, 2002 (BHADRA 9, 1924)

(इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।)
(Separate paging is given to this Part in order that it may be filed as a separate compilation)

विषय-सूची

* आंकड़े प्राप्त नहीं हुए।

Attested
21/7/06
Asstt Controller (Business)
Govt of India
Department of Publication
Civil Lines Delhi-54

भाग I—खण्ड 1

[PART I—SECTION 1]

(रक्षा मंत्रालय को छोड़कर) भारत सरकार के मंत्रालयों और उच्चतम न्यायालय द्वारा जारी की गई विधिक्तर नियमों, विनियमों तथा आदेशों और संकल्पों से संबंधित अधिसूचनाएं

[Notifications relating to Non-Statutory Rules, Regulations, Orders and Resolutions issued by the Ministries of the Government of India (other than the Ministry of Defence) and by the Supreme Court]

विज्ञान और प्रौद्योगिकी मंत्रालय

(विज्ञान औ प्रौद्योगिकी विभाग)

नई दिल्ली-110016, दिनांक 5 अगस्त 2002

संकल्प

सं.डी एस टी/जीएलपी-2/2002 भारत सरकार रसायन एवं उनके उत्पादों पर मानव स्वास्थ्य एवं पर्यावरण के संबंध में सुरक्षा अध्ययन संचालित कर रही परीक्षण सुविधाओं/प्रयोगशालाओं को मान्यता/प्रमाणन प्रदान करने के लिए जी एल पी अनुपालन मानीटरन के लिए राष्ट्रीय प्रणाली की आवश्यकता को महसूस करते हुए आर्गेनाईजेशन फार इकोनोमिक कोआपरेशन एंड डिवेलपमेंट (ओ ई सी डी) के उत्तम प्रयोगशाला व्यवहारों के सिद्धांतों एवं ओ ई सी डी मार्गदर्शी के आधार पर एक जीएलपी प्राधिकरण गठित करने का संकल्प लेती है, जो इस संकल्प के प्रकाशन की तारीख से प्रभावी होगा और जिसमें निम्नलिखित सदस्य होंगे --

अध्यक्ष

1 सचिव, विज्ञान और प्रौद्योगिकी विभाग, विज्ञान और प्रौद्योगिकी मंत्रालय

सदस्य

2 सचिव, उर्वरक विभाग, रसायन एवं उर्वरक मंत्रालय

3 सचिव, कृषि एवं सहकारिता विभाग, कृषि मंत्रालय

4 सचिव, स्वास्थ्य विभाग, स्वास्थ्य एवं परिवार कल्याण मंत्रालय

5 औषधि महानियंत्रक (भारत), स्वास्थ्य सेवा महानिदेशालय

सदस्य

6 सचिव,
वाणिज्य विभाग,
वाणिज्य एवं उद्योग मंत्रालय

7 सचिव,
पर्यावरण एवं वन मंत्रालय

8 सचिव,
उर्वरक विभाग,
रसायन एवं उर्वरक मंत्रालय

9 सचिव,
उपभोक्ता मामलों का विभाग
उपभोक्ता मामले, खाद्य एवं सार्वजनिक वितरण मंत्रालय

10 महानिदेशक,
सी एस आई आर एवं
सचिव-डी एस आई आर

सदस्य-सचिव

11 प्रमुख-राष्ट्रीय जी एल पी कार्यक्रम
विज्ञान और प्रौद्योगिकी विभाग

2 जी एल पी प्राधिकरण द्वारा निम्नलिखित अधिकारों एवं कार्यों का निर्वहन किया जायेगा :

(i) लक्ष्यों के मुकाबले कार्यक्रम क्रियान्वयन की प्रगति का मानीटरन ।

(ii) उत्तम प्रयोगशाला व्यवहारों के ओ ई सी डी सिद्धांतों के आधार पर परीक्षण सुविधाओं के लिए राष्ट्रीय जी एल पी अनुपालन/मानीटरन प्रणाली की स्थापना करना ।

(iii) उत्तम प्रयोगशाला व्यवहार के ओ ई सी डी सिद्धांतों एवं ओ ई सी डी परीक्षण दिशानिर्देशों के अनुपालन पर आधारित परीक्षण सुविधाओं को जी एल पी प्रमाणन प्रदान करना ।

(iv) प्रमाणित परीक्षण सुविधाओं एवं प्रयोगशालाओं से जी एल पी प्रमाणन को निलम्बित करना/वापस लेना और/अथवा समाप्त करना, और/या आवश्यकता पड़ने पर औचित्यपूर्ण जी एल पी अनुपालन मानीटरन प्राधिकरण (ओ ई सी डी सदस्य राष्ट्र में संबंधित) को सूचित करना ।

Attested
28/8/2002

Asstt Controller (Business)
Govt of India
Department of Publication
Civil Lines, Delhi-54

(v) इस प्रकार की अन्य तकनीकी समितियों/कार्यदलों का गठन करना जिसे किसी खास कार्य व आवश्यकता अथवा कार्यक्रम को पूरा करने के लिए इसके द्वारा आवश्यक समझा जाए ।

(iv) कार्यक्रम तकनीकी समिति और कार्यदलों के सुचारु रूप से कार्य करने हेतु निरुपित किए जाने वाले नियमों एवं प्रक्रियाओं को अनुमोदन प्रदान करना

(vii) यह सुनिश्चित करना कि राष्ट्रीय जी एल पी अनुपालन मानीटरन/प्राधिकरण द्वारा मौजूदा ओ ई सी डी परिषद् के मानदण्डों के अनुसार कार्य कर रहा है, अपनी अंतर्राष्ट्रीय प्रतिस्पर्धात्मकता और पारस्परिक अभिज्ञान को कायम रखा जा रहा है, और

(viii) अपने जी एल पी प्रमाणित प्रयोगशालाओं के लिए निर्धारित/अनिर्धारित निरीक्षणों का आयोजन एवं संचालन करना ।

3 इस आयोजन में अन्य बातों के साथ-साथ निम्नलिखित की परिकल्पना की गई है :

(1) रसायनों के मूल्यांकन उद्देश्य हेतु भारतीय नियामक प्राधिकरण द्वारा केवल उन परीक्षण डाटा को स्वीकार किया जाएगा जो राष्ट्रीय जी एल पी अनुपालन मानीटरन प्राधिकरण से जी एल पी प्रमाणित प्राप्त परीक्षण सुविधाओं/प्रयोगशालाओं से प्राप्त होते हैं ।

(2) भारतीय नियामक प्राधिकरण द्वारा ओ ई सी डी सदस्य देशों तथा जी एल पी अनुपालन प्रयोगशालाओं/परीक्षण सुविधाओं को मान्यता प्रदान करना आरम्भ किया जाएगा ।

(3) भारतीय नियामक प्राधिकरण द्वारा दूसरे सदस्य राष्ट्र से यह आश्वासन स्वीकार किया जाएगा कि परीक्षण आंकड़े का सृजन उत्तम प्रयोगशाला व्यवहार के ओ ई सी डी सिद्धांतों और ओ ई सी डी परीक्षण दिशा निर्देशों के अनुसार किया गया है ।

(4) सभी हितों और सम्बद्ध एजेंसियों को शामिल कर के सरकारी एवं गैर सरकारी दोनों को उनके हितों तथा बाध्यताओं पर कार्य करने के लिए भारत सरकार की एक समेकित योजना के रूप में एक संवैधानिक अस्तित्व के रूप में राष्ट्रीय जी एल पी अनुपालन प्राधिकरण का गठन करने के लिए कानून बनाना ।

4 प्राधिकरण द्वारा सौंपे गए कार्य को पूरा करने के लिए विशेषज्ञों की नियुक्ति की जा सकती है ।

5 राष्ट्रीय जी एल पी अनुपालन प्राधिकरण का एक प्रकोष्ठ होगा जो विज्ञान और प्रौद्योगिकी विभाग के प्रशासनिक नियंत्रण के अधीन कार्य करेगा । प्रमुख राष्ट्रीय जी एल पी अनुपालन मानीटरन प्राधिकरण द्वारा जी एल पी प्राधिकरण के निर्णयों का क्रियान्वयन किया जाएगा, निर्धारित प्रक्रियाओं के अनुसार कार्यक्रम के दिन-प्रति-दिन के क्रियाकलापों का संचालन किया जाएगा, ओ ई सी डी मानदण्डों के अनुसार मानीटरन अनुपालनों के लिए अन्य सदस्य देशों के साथ उनकी प्रक्रियाओं से संबंधित औचित्यपूर्ण जानकारियों का आदान-प्रदान करेगा और उत्तम प्रयोगशाला व्यवहार तथा अनुपालन मानीटरन के सिद्धांतों पर ओ ई सी डी शृंखला को मान्यता प्रदान करने और कार्यान्वित करने से संबंधित अन्य दायित्वों का निर्वहन तथा अन्तर्राष्ट्रीय सम्पर्क कायम रखेगा ।

आदेश

आदेश दिया जाता है कि संकल्प की एक प्रति भारत सरकार के सभी मंत्रालयों/विभागों, सभी राज्य सरकारों और देश के सभी वैज्ञानिक संस्थानों को परिचालित की जाए ।

यह भी आदेश दिया जाता है कि इस संकल्प को आम जानकारी के लिए भारत के राजपत्र में प्रकाशित किया जाये ।

अमिताभ पाण्डे, संयुक्त सचिव

पर्यटन और संस्कृति मंत्रालय

(संस्कृति विभाग)

नई दिल्ली, दिनांक 25 जुलाई 2002

सं० 4-15/97 एम-II/ए एण्ड ए : राष्ट्रीय मानव संग्रहालय समिति की 24-4-2002 को आयोजित बैठक में लिए गए निर्णय के अनुसरण में, समिति ने भारत सरकार के पूर्वानुमोदन से नियमों तथा विनियमों के नियम 57 के अनुसार राष्ट्रीय मानव संग्रहालय समिति के नियमों तथा विनियमों में निम्नानुसार परिवर्तन किए हैं :

नियम संख्या 3 (i)

अध्यक्ष – प्रभारी मंत्री (पर्यटन), संस्कृति विभाग/मंत्रालय, भारत सरकार ।

आदेश दिया जाता है इस संकल्प की एक प्रतिलिपि निदेशक, इंदिरा गांधी राष्ट्रीय मानव संग्रहालय, पोस्ट बैग नं० 2, शिमला हिल्स, भोपाल-462013 को प्रेषित की जाए ।

यह भी आदेश दिया जाता है कि इस संकल्प को आम सूचना हेतु भारत के राजपत्र में प्रकाशित किया जाए ।

बी०पी० सिंह, अवर सचिव

Attested
21/10/02
Asstt Controller (Business)
Govt. of India
Department of Publication
Civil Lines Delhi-54

MINISTRY OF SCIENCE AND TECHNOLOGY
(DEPARTMENT OF SCIENCE AND TECHNOLOGY)

New Delhi, the 5th August 2002

RESOLUTION

No. DST/GLP-2/2002.—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 Deptt. 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

(1) 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.

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

(3) Indian Regulatory Authorities would accept, the assurance from another member country that test data have been generated in accordance with OECD Principles of good laboratory Practice and OECD Test Guidelines.

Attested

21/2/02

Asstt Controller (Business)
Govt. of India
Department of Publication
Civil Lines, Delhi-54

(4) 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 & 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.

ORDER

Ordered that a copy of the Resolution be communicated to all the Ministries/Departments, Government of India, all the State Governments and Scientific Institutions in the country.

Ordered also that the Resolution be published in the Gazette of India for general information.

AMITABHA PANDE, Joint Secretary

MINISTRY OF TOURISM & CULTURE
(Department of Culture)

New Delhi, the 25th July, 2002

RESOLUTION

No. 4-15/97-M. II/A&A. In Pursuance of the decision taken in its meeting on 24-4-2002, the Rashtriya Manav Sangrahalaya Samiti, with the prior approval of the Government of India, have, in accordance with Rule 57 of the Rules and Regulations, made the following alterations in the Rules and Regulations of the Rashtriya Manav Sangrahalaya Samiti.

Rule No. 3(i)

President—Minister-in-charge (ex-official), Department/Ministry of Culture, Government of India.

Ordered that a copy of this Resolution be communicated to the Director, Indira Gandhi Rashtriya Manav Sangrahalya, Post Bag No. 2 Shamla Hills, Bhopal-462013.

Ordered also that the Resolution be published in the Gazette of India for general information.

B. P. SINGH
Under Secretary

Attested
21/2/06
Asstt Controller (Business)
Govt of India
Department of Publication
Civil Lines, Delhi-54

प्रबन्धक, भारत सरकार मुद्रणालय, फरीदाबाद द्वारा मुद्रित एवं प्रकाशन नियंत्रक, दिल्ली द्वारा प्रकाशित, 2002
PRINTED BY THE MANAGER, GOVERNMENT OF INDIA PRESS, FARIDABAD, AND PUBLISHED BY THE CONTROLLER OF PUBLICATIONS, DELHI, 2002