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

APPLICATION FORM OF NGCMA

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NATIONAL GLP COMPLIANCE MONITORING AUTHORITY
DEPARTMENT OF SCIENCE AND TECHNOLOGY
TECHNOLOGY BHAVAN, NEW MEHRAULI ROAD
NEW DELHI-110 016
https://dst.gov.in/ngcma

Guidelines to fill up the application form

1. ***Organisation for Economic Co-operation and Development (OECD)*** *Principles of Good Laboratory Practice (GLP) (Document Nos. 1 - 22), Terms & Conditions of the* ***National GLP Compliance Monitoring Authority (NGCMA) for obtaining and maintaining GLP certification by a test facility (GLP-101)*** *and the Information Brochure on the* ***GLP Programme (GLP-100)*** *should be fully read and understood by the applicant. Before making an application to the NGCMA, applicant test facility (TF) should ensure that its system is being operated as per the OECD Principles of GLP and OECD Test Guidelines.*

2. *TFs may submit an application for GLP certification/ Re-certification/ Extension in scope of GLP compliance along with prescribed fee* through online portal of NGCMA* (*https://dst.gov.in/ngcma*).

   ** The application fee is non-refundable and is applicable as below:*

Application Fee	*Rs. 30,000/- per area of expertise for which GLP certification is being sought.*		
Application Fee for Extension in Scope	*1.*	*For each additional area of expertise of GLP certification*	*Rs. 30,000/-*
	2.	*For any change in the scope of GLP certification w.r.t type of study under the existing certified areas of expertise or test system or type of chemical*	*Rs.15,000/- lump sum*

3. *Application for extension in scope of GLP certification during a certification cycle should be submitted atleast 3 months after the grant of GLP certification/ re-certification by NGCMA. This can be also done along with the application for surveillance inspection (as surveillance cum extension in scope application).*

4. *Further, the application for mid-term Surveillance inspection during a certification cycle may also be submitted through the portal.*

5. *For any additional information/ clarification regarding GLP certification, please contact 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: *https://dst.gov.in/ngcma*
   E-mail: *ekta.kapoor@nic.in,*
   Tel: *+91-11-26590 249*

GLP APPLICATION FORM

Application for ☐ First Certification

☐ *Surveillance

☐ Extension in scope

☐ Surveillance cum extension in scope

☐ Re-certification

**** In case of Application for Surveillance inspection, the TF is required to submit only the documents as mentioned at Serial No. 7 (a, b,c, f & g) and 8.***

1. Details of the Test Facility (TF)

1.1 Name_____
1.2 Address_____
1.3 Telephone_____
1.4 Fax_____
1.5 E-mail_____
1.6 Name of the contact person[$] along with his/her contact details (Tel/ Fax/ e-mail)
[$]For all communications in respect to GLP certification
1.7 Tick whichever is applicable

CRO ☐
R&D Laboratory ☐
University ☐
Company/ Organization ☐
Any other (Please specify) ☐

2. (a) Is the TF

(i) Stand alone ☐
(ii) Part of a parent organization ☐

(b) If a TF is a part of parent organization, list the decisions for which the TF depends on the parent organization.

(c) Details of the Parent Organisation (if applicable)
(i) Name_____

(ii) Address_____
(iii) Telephone_____
(iv) Fax_____
(v) E mail_____
(vi) Name and contact details of the contact person (Tel/ Fax/ e-mail)_____
(vii) Legal Status (Government organization, Sole proprietorship, Partnership firm, Trust, Society, Private Limited Company, Public Limited Company registered under the relevant Acts of the country) _____

3. Date of implementation of OECD Principles of GLP in the TF (DDMMYYYY):

4. Scope of GLP certification:

(a) Tick the area(s) of expertise for which GLP compliance is being sought

Area(s) of expertise	
Physical-chemical Testing	
Toxicity Studies*****	
Mutagenicity Studies******	
Environmental Toxicity Studies on Aquatic and Terrestrial Organisms	
Studies on Behaviour in Water, Soil and Air; Bioaccumulation	
Residue Studies	
Studies on Effects on Mesocosms and Natural Ecosystems	
Analytical and Clinical Chemistry Testing	
Other Studies (Specify)	

****** For toxicity studies, please elaborate the type of studies being performed (Acute toxicity studies, Repeated dose toxicity studies, Reproductive toxicity studies, Carcinogenicity studies, Inhalation toxicity studies, Others (Please specify as applicable).*

******* For Mutagenicity studies, please elaborate the type of studies being performed (AMES test, Chromosome Aberration Test (in vitro/ in vivo), Micronucleus Assay (in vitro/ in vivo), Others (Please specify as applicable).*

b) Tick the category of test item(s) being tested:

Type of Test Item(s)	
Industrial Chemicals	
Pharmaceuticals (Human)	
Pharmaceuticals (Veterinary)	

Agrochemicals	
Cosmetics Products	
Food Additives	
Feed Additives	
Medical Devices (*Applicable only for Bio-compatibility, not applicable for batch release parameters*)	
Cell Lines	
Viruses	

c) Please give the details of biological test system(s) as given below:

S. No.	***Type of test system (e.g. Animal, Cell lines, micro-organisms, plants, etc.)***	****Species/ Strain***

**State whether bred in house/purchased from external sources. Indicate clearance from Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA)/ Review Committee on Genetic Manipulation (RCGM)/ Institutional Biosafety Committee/ Institutional Ethics Committee, as applicable.*

5. (a) Is the TF also engaged in non-GLP testing and studies?

Yes ☐
No ☐

(b) If yes, please specify the nature of testing/ area(s) of expertise and frequency of performing non-GLP studies/ tests.

6. Are there other test site(s), subcontractor(s) and/ or external scientist(s) being involved in the conduct of GLP studies? If yes, please give details

7. Furnish the following documents:
   a) Recent Organization chart(s) including names of personnel
   b) Information pertaining to TF Personnel as given below:

S. No.	***Name & Designation***	***Qualification with specialization***	***Experience (related to GLP)***	***GLP Training Details (Date, Title, Trainer, etc.)***

   c) Floor-plans with GLP marked-area. Whether all GLP areas are in the same premises. If not, details thereof.
   d) In case the TF conducts and claims GLP compliance for toxicity studies, submit the registration certificate of animal house by CPCSEA, Department of Animal

Husbandry and Dairying (DAHD), Ministry of Fisheries, Animal Husbandry and Dairying (MoFAH&D), Govt. of India.

e) In case the TF conducts and claims GLP compliance for studies involving use of human tissues/ primary cultures of human cells/ genetically modified cells and organisms, etc., submit the Approval/ clearance from the Competent Authority of Govt. of India

f) List of instrument(s)/ equipment(s) including computerized systems as given below:

S. No.	***Name of equipment***	***Model/ Make/ Type/ Identification No.***	***Date of Installation/ Commissioning***	***Calibration status***

g) List of Standard Operating Procedures (SOPs)

h) Brief description of the working of the Quality Assurance Unit (QAU)

i) Location of the archives giving details

8. Furnish master schedule reflecting all ongoing, completed and studies in the last one year as given below:

Study No.	***Unisite/ Multisite***	***GLP / Non-GLP***	***Name of Study*** *(Short Title- Test System/ Method or Description of Study)*	***Test Item /Substance#*** ***(category, Code/ Description)***	***Name of Study Director/ Principal Investigator/ Name & address of Test Site*** *(if applicable)*	***Study Initiation Date***	***Experiment Start Date***	***Experiment Completion Date***	***Study Completion Date***	***Date of Archiving***	***Study status/ Remarks*****

*Use code numbers, if there is a secrecy agreement with the sponsor*

**** *Use OG for on-going studies, C for completed studies, CAN for cancelled studies and ARC for studies which have been archived after completion*

Note: *For cancelled studies or studies terminated before completion, please provide details including reasons for cancellation/ termination*

9. Do you submit studies directly or through a sponsor to a regulatory authority? Please provide details including study number, brief description of the study, name of regulatory authority along with the address & status of acceptance as given below.

S. No.	***Study No.***	***GLP/ Non-GLP***	***Title of study***	***Test item***	***Name & address of Regulatory Authority***	***Date of submission***	***Status (Pending/ accepted/ Rejected)***

10. Furnish details of

(a) Work Timings

(b) Weekly off days

11. Declaration:

- I declare that the information furnished above is correct.
- I have read and understood the GLP Principles as enunciated in OECD Principles of GLP, Document numbers 1-22.
- I, hereby, give my consent as the Management of the TF to abide by the Terms & Conditions of NGCMA for obtaining and maintaining GLP certification (GLP-101).
- I am fully aware that this programme involves international commitment by the NGCMA, and to this effect, I commit that the applicant TF would abide by all those norms which may be stipulated by OECD's Working Party on GLP from time to time.

Place: Signature:
Date: Name:
Designation: