सत्यमेव जयते

Government of India
Ministry of Science & Technology
Department of Science & 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
www.indiaglp.gov.in

Guidelines to fill up the application form

1. ***Organisation for Economic Co-operation and Development (OECD)*** *Principles of Good Laboratory Practice (Document Nos. 1 - 17), 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 their system is being operated as per the OECD Principles of Good Laboratory Practice and OECD Test Guidelines.*

2. ***NGCMA*** *has given the sequence number for each information it needs in its application form. For each point, please use as many sheets as required, in continuation and number the pages sequentially.*

3. *The application should be in a bound form.*

4. *At the end of the application, the competent authority of the TF should sign as a token of commitment to ensure that all furnished information is correct and the management of the TF fully understands its responsibilities and commitment to NGCMA. In addition, the "Terms and Conditions of NGCMA for obtaining and maintaining GLP certification by a test facility" (GLP-101), duly signed on each page, should be submitted along with the application.*

5. *The competent authority is required to furnish his/ her full name and the position which he/ she holds.*

6. *Please submit application for GLP certification {5 hardcopies and a softcopy in CD form and by e-mail (PDF or MS Word version restricting the size to 10 MB)}, along with the non-refundable application fee @ Rs.25,000/-* for each area of expertise for which GLP certification is sought (as marked in Pt. No. 5 (b) of this Application Form) by way of Demand Draft, drawn in favour of* ***Quality Council of India*** *and payable at New Delhi, to :*

GLP CELL
Quality Council of India
Institution of Engineers Building (2nd Floor)
Bahadur Shah Zafar Marg
New Delhi –110002
e-mail: *glpindia@qcin.org*

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

7. *Incomplete applications or insufficiency in information may lead to rejection.*

GLP APPLICATION FORM

Application for ☐ First Certification

☐ Re-certification

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 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 then what are the decisions for which the TF depends on the management of the parent organization?

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

(i) Name_____
(ii) Address_____
(iii) Telephone_____
(iv) Fax_____
(v) E mail_____
(vi) Name of the contact person with contact details (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. Type of facilities offered:

(a) Tick-mark the category of chemicals being tested:

Type of chemicals	
Industrial Chemicals	
Pharmaceuticals	
Veterinary Drugs	
Pesticides	
Cosmetic Products	
Food Additives	
Feed Additives	
Others (Specify)	

b) Tick mark the area of expertise for which GLP compliance is being sought

Areas 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, Sub-acute toxicity studies, Chronic toxicity studies, Reproductive toxicity studies, Carcinogenicity studies, Inhalation toxicity studies, Others (Please specify).

** 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).

Note: GLP Certificate will include the areas of expertise

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

Yes ☐
No ☐

(b) If yes, please specify the nature of testing and area(s) of expertise. How frequently does it perform non-GLP studies and tests?

6. Are there other test sites, subcontractors and/ or external scientists being involved in the conduct of GLP studies? If yes, please give details

7. Furnish the following documents:

a) Recent Organization charts 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*

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, the details of inspection and approval/status of the animal house by Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), Ministry of Environment, Forests and Climate Change, Govt. of India. (It may be noted that GLP applications from facilities conducting toxicity studies and still awaiting CPCSEA approval for animal house will not be processed by NGCMA).

e) Approval/clearance from the office of Drugs Controller General of India for the tests involving use of human tissue/cells.

f) Details of biological test systems (species, strain, whether bred in house/purchased from external sources). If imported, please ensure & indicate clearance from CPCSEA.

g) 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*

h) List of Standard Operating Procedures (SOPs)

i) SOP of general procedures for drafting, authorizing, modifying, distributing and archiving SOPs (sample SOP to be attached)

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

k) 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. (U/M) ****	*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

*** Use U- Uni-site study, M- Multi-site study

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 the details of GLP inspections of the TF conducted by the National or any foreign GLP Compliance Monitoring Authority (CMA) as given below:

S. No.	Name of CMA & Country	Date of inspection	Result (In-compliance/ Not In-compliance/ Pending)	Areas of Expertise (Scope of certification)

11. Furnish details of

(a) Work Timings

(b) Weekly off days

12. Declaration:

- I have read and understood the GLP Principles as enunciated in OECD Principles of GLP, Document numbers 1-17.

- I, hereby, give my consent on behalf of the management of the TF to abide by the Terms & Conditions of NGCMA for obtaining and maintaining GLP certification (GLP-101).

- I declare that the information furnished above is correct.

- 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 Group on GLP from time to time.

Place:
Date:

Signature:
Name:
Designation:

Approved for issue by:

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