GLP Federal Bureau

A P P L I C A T I O N

for the granting of a GLP Certificate
under the terms of § 19b Abs. 2 Nr. 3 ChemG

1) Applicant

a) Company

Address

Telephone **Telefax**

b) Contact person (name, function)

Address

Telephone **Telefax**

2) Test Facility

a) Name, exact designation

Address

Telephone **Telefax**

Country

b) Date of Inauguration of the GLP system

3) Detailed description of studies to be conducted in the aforementioned Test Facility for submission to German Regulatory Authorities under the terms of § 19a Chemicals Act.

4) <u>Applicated areas of expertise in categories to be subject in the GLP Certificate:</u>

Physical-chemical testing	**1**	☐
Toxicity studies	**2**	☐
Mutagenicity studies	**3**	☐
Environmental toxicity studies on aquatic and terrestrial organisms	**4**	☐
Studies on behaviour in water, soil and air; bioaccumulation	**5**	☐
Residue studies	**6**	☐
Studies on effects on mesocosms and natural ecosystems	**7**	☐
Analytical and clinical chemistry testing	**8**	☐
Other studies, specify	**9**	☐

5) <u>Characterisation of the Test Facility</u>

The following documentation should be enclosed (in German or English language):

- **Administrative structures (organisation charts, number of staff)**
- **Personnel (qualification, languages spoken, further training especially GLP)**
- **Premises (ground-plans, GLP area marked)**
- **List of GLP relevant instruments**
- **Test systems**
- **List of Standard Operating Procedures (SOP)**
- **SOP of general procedures for drafting, authorization, modifying, distributing and archiving SOPs**
- **Detailed description of the working procedures of the Quality Assurance Unit with copies of all available SOPs for this purpose**
- **Example of a study plan**
- **Example of a final report**
- **Master Schedule of all planned and ongoing studies, as well as all studies completed within the last two years: GLP/Non-GLP, study code/identification, type of study, test system, test item, study initiation/ completion date, study director, status, sponsor**

6) <u>Are there other test sites, subcontractors and/or external scientists being involved in the conduct of GLP studies?</u>

7) Information on previous activity of Test Facility

a) In what countries have studies already been submitted to national Regulatory Authorities?

	Yes	No
Germany	☐	☐
EU memberstates	☐	☐
USA, Japan, Switzerland	☐	☐
Other Countries	_____	

b) List of studies submitted

Exact description of study	Date of submission	Country	Regulatory Authority

8) Are there contacts with any other sponsors in Germany?

9) Governmental GLP monitoring at the Test Facility

a) Earlier GLP inspections

Monitoring Authority/ Country	Date of inspection	Result

b) Earlier GLP study audits

Exact description of study	Monitoring Authority/ Country	Date/ Result

c) Have any GLP inspections been planned, in particular by EU memberstates or the USA, Japan and Switzerland?

10) Brief description of the official GLP monitoring system in the country concerned

Place, Date	**Signature of applicant**

Annexes

I) Declaration of consent on the part of the Test Facility to a GLP inspection conducted by the German GLP Federal Bureau

II) Applicant's agreement to bear all fees and charges and to defray advance expenses

ANNEX I
to the Application for the granting of a GLP Certificate from .....

On behalf of the test facility the responsible Mangement hereby consent to a GLP inspection of the applicated test facility by German GLP inspectors.

Place, Date	**Signature of the responsible test facility management**

ANNEX II
to the Application for the granting of a GLP Certificate from .....

The applicant agrees to bear all fees and charges related to this application for the granting of a GLP Certificate corresponding to the German legal regulations (Allgemeine Gebührenverordnung, Besondere Gebührenverordnung BMU - BMUBGebV, Bundesreisekostengesetz) as well as to defray possible advance expenses.

Place, Date	**Signature of applicant**