

# **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) Applied areas of expertise in categories to be subject in the  
GLP Certificate:**

<b>Physical-chemical testing</b>	<b>1</b>	<input type="checkbox"/>
<b>Toxicity studies</b>	<b>2</b>	<input type="checkbox"/>
<b>Mutagenicity studies</b>	<b>3</b>	<input type="checkbox"/>
<b>Environmental toxicity studies on aquatic and terrestrial organisms</b>	<b>4</b>	<input type="checkbox"/>
<b>Studies on behaviour in water, soil and air; bioaccumulation</b>	<b>5</b>	<input type="checkbox"/>
<b>Residue studies</b>	<b>6</b>	<input type="checkbox"/>
<b>Studies on effects on mesocosms and natural ecosystems</b>	<b>7</b>	<input type="checkbox"/>
<b>Analytical and clinical chemistry testing</b>	<b>8</b>	<input type="checkbox"/>
<b>Other studies, specify</b>	<b>9</b>	<input type="checkbox"/>

## 5) Characterisation of the Test Facility

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

**7) Information on previous activity of Test Facility**

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

	<b>Yes</b>	<b>No</b>
<b>Germany</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>EU memberstates</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>USA, Japan, Switzerland</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Other Countries</b>	<hr/>	

**b) List of studies submitted**

<b>Exact description of study</b>	<b>Date of submission</b>	<b>Country</b>	<b>Regulatory Authority</b>

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

**9) Governmental GLP monitoring at the Test Facility**

**a) Earlier GLP inspections**

<b>Monitoring Authority/ Country</b>	<b>Date of inspection</b>	<b>Result</b>

**b) Earlier GLP study audits**

<b>Exact description of study</b>	<b>Monitoring Authority/ Country</b>	<b>Date/ Result</b>

**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 (Chemikalienkostenverordnung, Bundesreisekostengesetz) as well as to defray possible advance expenses.**

\_\_\_\_\_

**Place, Date**

\_\_\_\_\_

**Signature of applicant**