Ordinance on Good Laboratory Practice (OGLP)

of 18 May 2005 (Status as of 1 December 2012)

The Federal Council

based on Article 5 paragraph 2 letter a of the Chemicals Act of 15 December 2000 (ChemA)[1],
Article 26 paragraph 3, Article 38 paragraph 3 and Article 39 paragraph 1 of the Environmental Protection Act of 7 October 1983[2] (EPA)
and Article 11 paragraph 2 letter a of the Federal Act of 15 December 2000[3] on Therapeutic Products (TPA)

decrees:

Section 1 General Provisions

Art. 1 Objective and purpose

1 This Ordinance lays down the Principles of Good Laboratory Practice (GLP) as the quality standard for studies, and regulates compliance monitoring.

2 The Ordinance aims to:

a. ensure that test data are reproducible;

b. promote international acceptance of tests conducted in Switzerland in order to avoid duplicate testing.

Art. 2 Scope

The Ordinance applies to non-clinical studies of substances, preparations and articles (test items) that:

a. serve to obtain data on the properties of a test item and its safety with respect to human health and the environment; and

b. provide data to be submitted to the authorities in view of a registering or licensing procedure.

AS **2005** 2795

1 SR **813.1**
2 SR **814.01**
3 SR **812.21**

Art. 3 Definitions

[1] In this Ordinance:

a. *Good Laboratory Practice (GLP)* means a quality system concerned with the organisational process and the conditions under which studies are planned, performed, monitored, recorded, archived and reported.

b.[4] *areas of expertise* means studies conducted in the following categories:

1. physical-chemical testing,
2. toxicity studies,
3. mutagenicity studies,
4. environmental toxicity studies on aquatic and terrestrial organisms,
5. studies on behaviour in water, soil and air; bioaccumulation
6. residue studies,
7. studies on effects on mesocosms and natural ecosystems,
8. analytical and clinical chemistry testing,
9. other studies, specify;

c. *study audit* means an audit of a study to verify that its data, records, reports and other elements comply with GLP Principles;

d. *test facility* means the persons, premises and operational unit(s) that are necessary for conducting studies; for multi-site studies conducted at more than one site, the test facility comprises the site at which the study director is located and all individual test sites that individually or collectively may be considered as such.

[2] Further terms relevant to GLP are defined in Annex 1.

Section 2 GLP Principles and Compliance Monitoring

Art. 4 GLP Principles

[1] The principles of GLP are listed in Annex 2.

[2] The Federal Office of Public Health (FOPH)[5], the Federal Office for the Environment (FOEN) and Swissmedic (Swiss Agency for Therapeutic Products) may issue joint guidelines on the interpretation of GLP Principles. In doing so they must take account of internationally recognised regulations.

4 Amended by Annex No 2 of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

5 The name of the administrative unit was amended in application of Art. 16 para 3 of the Publications Ordinance of 17 Nov. 2004 (SR **170.512.1**). This amendment has been applied throughout the text.

Art. 5 Application

[1] Establishments that wish to have their test facilities listed in the register (Art. 14) must apply to the notification authority (Art. 8).

[2] For each test facility, the application must include the following information:

a. name and address of the test facility;

b. site plans documenting the use of the individual premises;

c. organisation charts documenting the name and position of the test facility management, the personnel in charge of quality assurance and the study directors;

d. name and address of a contact person;

e. standard operating procedures for quality assurance;

f. a list of all standard operating procedures;

g. the relevant areas of expertise;

h. a list of all studies planned over the next six months with the relevant schedules;

i. a list of all studies conducted over the last six months, or still being carried out, in the relevant areas of expertise.

[3] On request from the competent authority, the establishments must submit other information.

[4] If conditions in a test facility are substantially modified, the establishment must submit a new application without delay. In this case the list pursuant to paragraph 2 letter i must include all studies since the last inspection. In the event of any doubt, the establishment must refer without delay to the notification authority to determine whether the modification is substantial. The notification authority gives its decision in agreement with the competent authorities concerned.

Art. 6 Inspections

[1] After receiving an application, the competent authority shall inspect the test facilities on site. During this inspection, the authority checks in particular whether the procedures, operating procedures and data obtained respect the principles of GLP.

[2] Thereafter, the authority shall inspect the test facilities again every two to three years. Prior to each inspection the authority shall request information pursuant to Article 5 paragraph 2. The list pursuant to Article 5 paragraph 2 letter i must include all studies conducted since the last inspection. The competent authority may request further data.

[3] If there is sufficient reason to assume that a test facility does not comply with the GLP Principles, the competent authority may conduct an inspection without delay.

[4] The competent authority shall produce a report on each inspection.

Art. 7 Study audits

1 The competent authority shall conduct a study audit on its own initiative or at the request of another competent Swiss or foreign authority if:

a. there is sufficient reason to assume that a test facility did not comply with GLP Principles when conducting certain studies;

b. the results of a particular study are of vital importance for assessing human or environmental safety.

2 If after completion of the study audit the competent authority concludes that the audited study did not comply with GLP Principles, it may carry out an inspection.

3 The competent authority may also carry out a study audit as part of an inspection.

4 The competent authority shall produce a report on each inspection.

Art. 8 Competent authorities

1 The notification authority in accordance with Article 4 paragraph 1 letter h of the ChemA shall coordinate the conduct of inspections and of study audits and, in agreement with the competent authorities, produce decisions on conformity with the principles of GLP.

2 The following authorities are competent to carry out inspections and study audits:

a. the FOPH and Swissmedic for studies of toxicological properties;

b. the FOEN for studies of ecotoxological properties or of environmental behaviour of the test items;

c. the FOPH, the FOEN or Swissmedic after mutual agreement for studies of all other properties.

3 Where necessary the authorities may delegate tasks to each other, or call in specialists. They may delegate all or part of the tasks and competences with which they are entrusted by virtue of this Ordinance to appropriate public corporations or individuals. The FOPH and Swissmedic may only delegate the conduct of inspections and study audits.

Art. 9 Duties and powers of the authority

1 The authority shall carry out inspections and study audits according to the guidelines in Sections A and B of Annex I of European Directive 2004/9/EC of the Parliament and of the Council of 11 February 2004[6].

2 On request, the establishment must submit to the authorities all documents and all other evidence required to assess its compliance with GLP Principles.

6 Directive 2004/9/EC of the European Parliament and of the Council of 11 Feb. 2004 on the inspection and verification of good laboratory practice (GLP); OJ No. L 050 of 20 Feb. 2004, pp. 28-43. The European Community legislation mentioned in this Ordinance can be ordered for a fee or consulted free of charge at the notification authority for chemical products, 3003 Bern; it can also be consulted at www.cheminfo.ch.

3 The authorities must be allowed to access the test facilities at all times.

4 If an establishment with test facilities has been accredited by the Swiss Accreditation Service pursuant to Article 14 of the Ordinance of 17 June 1996[7] on Accreditation and Identification, the authority shall take these results into account.

Art. 10 Reports on inspections and study audits

1 The competent authority shall provide the establishment with the draft of the inspection report and allow it an appropriate period in which to state its position thereon. On receipt of a response from the establishment or on expiry of the period, the authority shall pass the inspection report to the notification authority.

2 The competent authority shall pass the report on the study audit to the notification authority.

3 The notification authority shall decide:

a. on the basis of the inspection report, whether the test facility is operating according to the GLP Principles;

b. on the basis of the study audit report, whether the study was carried out according to the GLP Principles;

4 The provisions on study audits also apply to studies audited during an inspection.

Art. 11 Information

The notification authority shall inform the competent authorities of planned inspections and study audits, and of decisions pursuant to Article 10.

Art. 12 Obligation to notify

1 An establishment must immediately notify the notification authority if:

a. it changes its name or address;

b. one of its test facilities changes its name or address;

c. one of its test facilities is no longer willing to comply with GLP Principles.

d. there are changes in responsibilities at the level of the management of the test facility or of the quality assurance unit.

e. it intends to extend the area of expertise.

Section 3 Documentation and Conformity with GLP Principles

Art. 13

1 For any study that must be carried out according to the principles of GLP, it is necessary in the procedure of notification or authorisation:

7 SR **946.512**