Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Home Affairs DHA
Federal Office of Public Health FOPH

Federal Department of the Environment,
Transport, Energy and Communications DETEC
Federal Office for the Environment FOEN

swissmedic
Swiss Agency for Therapeutic Products

Internet-document

Date: 24.03.2022

For further details please contact: Notification Authority for Chemicals

Swiss GLP Compliance Monitoring Programme

Version EL02.08

Replaces version EL02.07 of 11 December 2020

The documentation concerning the GLP Compliance Monitoring Programme consists of this programme overview and other documents referred therein .

The Notification Authority for Chemicals is the coordination and decision authority for the good laboratory practice (GLP) for the FOEN, the FOPH and Swissmedic.
Further information:

Federal Office of Public Health, Consumer Protection Directorate, Notification authority for chemicals, phone +41 (0)58 462 73 05, cheminfo@bag.admin.ch, www.glp.admin.ch

Further information:
Federal Office of Public Health, Consumer Protection Directorate, Notification authority for chemicals, phone +41 (0)58 462 73 05, cheminfo@bag.admin.ch, www.glp.admin.ch
Swiss GLP Compliance Monitoring Programme
This document is only available in English.
Version EL02.08 of 24 March 2022

Legislation

Officially available documents (links in chapter 3.1)

Title	German Version	French Version	Italian Version	English Version (Status)
Ordinance on Chemicals (SR 813.11)	current	current	current	available
Ordinance on Biocidal Products (SR 813.12)	current	current	current	available
Ordinance on Pesticides (SR 916.161)	current	current	current	--
Ordinance on Medicinal Products (SR 812.212.21)	current	current	current	--
Ordinance on Good Laboratory Practice (SR 813.112.1)	current	current	current	01.12.2012
Directive 2004/9/EC	current	current	current	11.02.2004
Federal Personnel Law (SR 172.220.1)	current	current	current	--
Federal Personnel Ordinance (SR 172.220.11.3)	current	current	current	--
Ordinance on the Personnel of the Swiss Agency of Therapeutic Products (SR 812.215.4)	current	current	current	--

Guidelines

Edited by the GLP Compliance Monitoring Units (links in chapters 3.4 (Interpretations) and 3.5 (AGIT Guidelines)).

Approval of the GLP Compliance Monitoring Programme

This version comes into force on 24 March 2022

Signatures

Notification Authority for Chemicals (NAChem):

Date: 24 March 2022 Mauro Schindler:

GLP Compliance Monitoring Unit at the Federal Office of Public Health (FOPH):

Date: 23 March 2022 Martine Bourqui-Pittet:

GLP Compliance Monitoring Unit at the Federal Office for the Environment (FOEN):

Date: 23 March 2022 Christoph Moor:

GLP Compliance Monitoring Unit at Swissmedic (Swiss Agency for Therapeutic Products):

Date: 22 March 2022 Elisabeth Klenke:

1 Introduction

1.1 Development of the OECD Principles of GLP

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of member countries meet to co-ordinate and harmonize policies, discuss issues of mutual concern, and work together to respond to international problems. Switzerland joined the OECD on 28 September 1961 and has adopted decisions issued by the OECD Council since then.

In 1978, an expert group with Swiss representation elaborated the first version of the *OECD Principles of Good Laboratory Practice* (GLP) to promote the quality and validity of test data used for determining the safety of chemicals and chemical products. These Principles were based on the 1976 *GLP Regulations for non-clinical Laboratory Studies* of the U.S. Food and Drug Administration (FDA). The Principles of GLP were formally recommended for use in Member countries by the OECD Council in 1981. They were set out in Annex II as an integral part of the Council Decision on *Mutual Acceptance of Data in the Assessment of Chemicals* [C(81)30(Final)]. The implementation of comparable compliance monitoring procedures and international acceptance among Member countries was promoted by the Council via the Recommendation concerning the *Mutual Recognition of Compliance with Good Laboratory Practice* [C(83)95(Final)] in 1983, which outlines basic characteristics of the procedures for monitoring compliance.

A Working Group on *Mutual Recognition of Compliance with GLP* was established in 1985 and developed *i.a*. *Guides for Compliance Monitoring Procedures for Good Laboratory Practice*, which concern the requisites of administration, personnel and GLP compliance monitoring programmes. An abridged version was annexed to the 1989 Council Decision-Recommendation on *Compliance with Principles of Good Laboratory Practice* [C(89)87(Final)], which superseded and replaced the 1983 Council Act. The Principles of GLP were revised by an expert working group, reviewed by the relevant policy bodies of the Organisation and adopted on 26 November 1997 [C (97) 186(final)] by the OECD Council.

The purpose of the Principles of GLP is:

- Studies performed to assess the effects of chemicals with respect to human health and/or the environment shall be carried out and documented in such a way that the results can be understood and reproduced at any time by others. Being comprehensible is important since results are often only submitted to the authorities years later as a basis for the assessment.
- Test results obtained in compliance with GLP are to be mutually accepted by the health and environment authorities of the OECD member states. Therefore, multiple testing can be avoided, and the number of animal studies can be reduced.

1.2 Development of the Principles of GLP in Switzerland

After the publication of the 1976 FDA GLP regulations, Swiss pharmaceuticals could no longer be exported to the USA, since according to article 271 of the Swiss Penal Code, inspections in Switzerland could not be carried out by representatives of a foreign authority. This trade barrier was overcome by setting up an inspection system and a bilateral agreement with the USA on the mutual acceptance of GLP inspections. In the following years, the Intercantonal Office for the Control of Medicines (IOCM, now Swissmedic) together with representatives of industry and the Federal Office of Public Health (FOPH), published the *IOCM Guide concerning Good Laboratory Practice for non-clinical laboratory Experiments* (28 April 1980). In March 1986, this guide was replaced by *Procedures and Principles of Good Laboratory Practice (GLP) in Switzerland* based on the OECD Principles of 1981, which was in force for pharmaceuticals and chemicals until February 2000.

On 1 March 2000, the Ordinance on Good Laboratory Practice (OGLP) came into force. The GLP requirements, based on the OECD Principles as revised in 1987, and compliance monitoring were now legally binding.
However, pharmaceuticals were not within the scope of the OGLP since they were under cantonal jurisdiction. The monitoring of GLP compliance was carried out based on the 1997 revision of the OECD Principles by the IOCM and published in the IOCM's monthly report of February 2000. When the Ordinance on Medicinal Products came into effect on 1 January 2002 these products were fully integrated in the scope of the OGLP.

Due to the revision of the Swiss legislation on chemicals in 2005, the Federal Council decided to revise the OGLP consolidating all aspects related to the monitoring of the GLP Principles. The Notification Authority for Chemicals (NAChem) was established as coordinator with administrative tasks. The Principles of GLP themselves remained unchanged in this revision. The revised OGLP became effective on 1 August 2005.

Editorial changes to article 3 of the OGLP were made in 2012 to use identical terms for the areas of expertise as on the OECD level. These changes became effective on 1 December 2012.

1.3 GLP Compliance Monitoring Programme

According to the decision/recommendation of the OECD Council of 2 October 1989 on *Compliance with Principles of Good Laboratory Practice* [C (89) 87(Final)], each OECD member state is required to establish a national GLP Compliance Monitoring Programme as outlined in the *Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice*, (OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 2, (revised), 1995).

The Swiss GLP Compliance Monitoring Programme describes responsibilities and procedures including inspections of the test facilities and study audits by the national GLP Compliance Monitoring Units. It consists of this overview document and other documents referred therein.
The GLP Compliance Monitoring Programme is reviewed on an annual basis and updates can be initiated by each GLP authority (see Chapter 4). The NAChem is responsible for coordinating the revision. A new version is accepted by dated signature of the GLP authorities and archived by the NAChem. The GLP Compliance Monitoring Programme is published in English only, on the web site www.glp.admin.ch.

2 Scope of Good Laboratory Practice in Switzerland

2.1 Legal requirements

In Switzerland, compliance with GLP is required for the non-clinical safety studies supporting the notification / authorisation within the following areas:

- pharmaceuticals
- agrochemicals
- industrial chemicals
- biocides

More details are given in the product oriented legislation (see chapter 3.1)

2.2 Monitoring of GLP Compliance

The Principles of GLP are applied to non-clinical studies of test items, which are:

a. performed under laboratory, greenhouse or field conditions.
b. for the purpose of obtaining data about the characteristics and the human safety and environmental safety of a test item.
c. required by the regulatory authorities for the purpose of registering or licensing.

Test items are considered to be chemically synthesized materials such as pharmaceutical products, agrochemicals, cosmetics, veterinary medical products, medical devices, food additives, feed additives and industrial chemicals, but can also be of natural or biological origin, as well as living organisms.

According to the OGLP, the areas of expertise of a test facility should be categorised as follows:

1) physical-chemical testing, PCT
2) toxicity studies, TOX
3) mutagenicity studies, MUT
4) environmental toxicity studies on aquatic and terrestrial organisms, ECT
5) studies on behavior in water, soil and air; bioaccumulation, ENF
6) residue studies, RES
7) studies on effects on mesocosms and natural ecosystems, EMN
8) analytical and clinical chemistry testing, ACC
9) other studies, specify, OTH

For clinical studies, efficacy studies, and studies for private customers, GLP is not required. The GLP Compliance Monitoring Units do not inspect studies that are not subject to GLP regulations.
Test facilities performing bioanalytics of animal and human plasma samples may be subject to a joint inspection with the GCP Inspectorate Unit at the Clinical Trial Division at Swissmedic.

2.3 Relationship between GLP monitoring and receiving authorities

There is a close relationship between GLP monitoring and receiving authorities. Some GLP inspectors also act as assessors at the receiving authorities. This is described in the corresponding job descriptions.
Pivotal aspects on GLP and the mutual acceptance of data (MAD) system are made available to the receiving authorities in the “vademecum” document which complements OECD advisory document number 20.

3 Basis of GLP in Switzerland

3.1 Product oriented legislation

The legal basis for the GLP requirement by the receiving authorities is established in the following legislation:

- Industrial Chemicals:

Chemikalienverordnung	Ordonnance sur les produits chimiques	Ordinanza sui prodotti chimici	Ordinance on Chemicals
Artikel 43	Article 43	Articolo 43	Article 43

- Biocides:

Biozidprodukte-verordnung	Ordonnance sur les produits biocides	Ordinanza sui biocidi	Ordinance on Biocidal Products
Anhang 5	Annexe 5	Allegato 5	appendix 5

- Agrochemicals:

Pflanzenschutzmittel-verordnung	Ordonnance sur les produits phytosanitaires	Ordinanza sui prodotti fitosanitari	Ordinance on Pesticides
Anhänge 5 und 6	Annexes 5 et 6	Allegati 5 e 6	appendix 5 and 6 (no English version)

- Pharmaceuticals:

Arzneimittelverordnung	Ordonnance sur les médicaments	Ordinanza sui medicamenti	Ordinance on Medicinal Products
Artikel 67	Article 67	Articolo 67	not available

3.2 Legal Basis for GLP Monitoring

The legal basis for monitoring GLP compliance in Switzerland is established in the Ordinance on Good Laboratory Practice (OGLP).

Verordnung über die Gute Laborpraxis (GLPV)	Ordonnance sur les bonnes pratiques de laboratoire (OBPL)	Ordinanza sulla buona prassi di laboratorio (OBPL)	Ordinance on Good Laboratory Practice (OGLP)

Annexes 1 and 2 of the OGLP reproduce the definition of terms and GLP Principles defined in the OECD document No. 1 *Principles of Good Laboratory Practice (as revised in 1997*).

According to article 9 of the OGLP, inspections and study audits shall be carried out according to the guidelines in Sections A and B of Annex I of the Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the Inspection and Verification of Good Laboratory Practice (GLP). This directive is based on the OECD document No. 3 *Revised Guidance for the Conduct of Laboratory Inspections and Study Audits*.

RICHTLINIE 2004/9/EG	DIRECTIVE 2004/9/CE	DIRETTIVA 2004/9/CE	DIRECTIVE 2004/9/EC

3.3 OECD Publications

The GLP Compliance Monitoring Programme is mainly based on the OECD documents: OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring.
The inspectors use the OECD publications to interpret the Principles of GLP, even if they are not integrated into the legislation. The Directive 2004/9/EC concerning inspections and verification of the GLP Principles indicates under part B, introduction, that "*further clarification of many of the points … may be obtained by referring to the OECD consensus documents …*".

3.4 Collection of Interpretations relating to the Principles of GLP

Questions relating to the Principles of GLP may be raised by the GLP authorities or test facilities. To ensure uniform interpretation these questions are discussed among the GLP Compliance Monitoring Units. A list of interpretations of general interest is available on the GLP web site. Any changes in this list are communicated via the annual GLP Newsletter.
According to article 4 paragraph 2 of the OGLP, the published interpretations are to be considered as guidelines for the test facilities. Swiss Interpretation of the GLP Principles

3.5 AGIT Guidelines

The Working Group of Information Technology (AGIT) consists of representatives of the GLP Compliance Monitoring Units and invited experts from the industry. Several documents related to information technology in a GLP environment have been developed. These documents are considered to be interpretations of the Principles according to article 4 paragraph 2 of the OGLP. AGIT guidelines are available online (AGIT documents).

4 GLP Authorities in Switzerland

4.1 Notification Authority for Chemicals (NAChem)

The OGLP of 18 May 2005 introduced the NAChem as coordinative body for the GLP Compliance Monitoring Programme. For administrative reasons, the Notification Authority is integrated into the Federal Office of Public Health, but it represents equally the interests of all GLP Compliance Monitoring Units.

Head of the NAChem: Mauro Schindler

Address of the GLP point of contact at the NAChem:

Federal Office of Public Health
Directorate of Health Protection
Notification Authority for Chemicals
Ms. Diana Burkhalter
CH - 3003 Bern
Tel: +41 58 462 95 30
Email: diana.burkhalter@bag.admin.ch

4.2 GLP Compliance Monitoring Units

Due to the different product legislation (listed in chapter 3), there are three GLP Compliance Monitoring Units in Switzerland:

a. Federal Office of Public Health (FOPH) in the Federal Department of Home Affairs
b. Federal Office for the Environment (FOEN) in the Federal Department for the Environment, Transport, Energy and Communication
c. Swissmedic (Swiss Agency for Therapeutic Products) in the Federal Department of Home Affairs

The responsibilities of the three authorities are defined in article 8 OGLP and can be represented as follows:

Area of expertise	Swissmedic	FOPH	FOEN
physical - chemical testing (PCT)	✓	✓	✓
toxicity studies (TOX)	✓	✓	
mutagenicity studies (MUT)	✓	✓	
environmental toxicity studies on aquatic and terrestrial organisms (ECT)			✓
studies on behavior in water, soil and air; bioaccumulation (ENF)			✓
residue studies (RES)	✓	✓	✓
studies on effects on mesocosms and natural ecosystems (EMN)			✓
analytical and clinical chemistry testing (ACC)	✓	✓	✓
other studies, specify (OTH)	✓	✓	✓

The nature of the test items is considered for the assignment to one of the authorities: *e.g.* studies on pharmaceuticals are assigned in priority to Swissmedic, however, other assignments can be decided.

Despite their different responsibilities, the three GLP Compliance Monitoring Units use the same basis for their activities, and ensure that their responsibilities are executed in a uniform way. Each of the three GLP Compliance Monitoring units has a team of GLP inspectors, which is in charge of carrying out the GLP Compliance Monitoring Programme. Since 2019, inspections are carried out by mixed

teams on a routine basis, with a lead inspector from the authority that is responsible for the test facility. A description of the organisation and the address of each GLP Compliance Monitoring Unit is given below.

4.2.1 Federal Office of Public Health (FOPH)

Head of the GLP Compliance Monitoring Unit: Martine Bourqui-Pittet

Address of the GLP Compliance Monitoring Unit of the FOPH:

Federal Office of Public Health
Division of Chemicals
GLP Compliance Monitoring Unit
Ms. Martine Bourqui-Pittet
CH-3003 Bern
Tel: +41 58 463 86 65
Email: martine.bourqui@bag.admin.ch

4.2.2 Federal Office for the Environment (FOEN)

Head of the GLP Compliance Monitoring Unit: Christoph Moor
National contact point for OECD: Christoph Moor

Address of the GLP Compliance Monitoring Unit of the FOEN:

Federal Office for the Environment
Air Pollution Control and Chemicals Division
GLP Compliance Monitoring Unit
Mr. Christoph Moor
CH-3003 Bern
Tel: +41 58 462 93 84
Email: christoph.moor@bafu.admin.ch

4.2.3 Swissmedic (Swiss Agency for Therapeutic Products)

Head of the GLP Compliance Monitoring Unit: Elisabeth Klenke

Address of the GLP Compliance Monitoring Unit of Swissmedic:

Swissmedic
Division Nonclinical Assessment and GLP Inspectorate
Ms. Elisabeth Klenke
Hallerstrasse 7
CH-3012 Bern
Tel: +41 58 462 04 80
Email: elisabeth.klenke@swissmedic.ch

4.2.4 List of current GLP-inspectors

A current list of all inspectors with their contact address is available online.

4.3 Co-ordination between the GLP authorities

4.3.1 GLP Compliance Monitoring

The GLP Compliance Monitoring Units and the NAChem establish a common GLP Compliance Monitoring Programme and are responsible for its implementation.
The three GLP Compliance Monitoring Units at FOPH, FOEN and Swissmedic work in close collaboration. Their monitoring activities are based not only on the same Principles of GLP, but also on

the same interpretations of these Principles. Inspections are coordinated between GLP Compliance Monitoring Units and are performed by inspectors from the different involved units.

The final decision concerning the GLP compliance is emitted by the NAChem, based on the conclusion of the inspection or study audit report.

4.3.2 Meetings of authorities

- GLP Compliance Monitoring Programme meeting
  Every three months, all inspectors of the three GLP Compliance Monitoring Units discuss requests, interpretation issues and current inspections.

- Co-ordination meeting
  The inspectors of the three GLP Compliance Monitoring Units and the NAChem meet at least once a year to ensure the exchange of information, to discuss interpretations and current questions, to coordinate the attendance of international meetings, to prepare the GLP newsletter, and to plan monitoring activities and schedule inspections.

- Taskforce meeting
  Upon requirement, a taskforce for working on a special project can be established and additional meetings may be scheduled.

4.3.3 Discussion of questions and answers

Questions raised by other GLP Compliance Monitoring Authorities, by the Swiss Professional Association of Quality Assurance (SPAQA) or by individual test facilities are discussed between the heads of the three GLP Compliance Monitoring Units to prepare a common statement. Relevant questions are then integrated within the Swiss Interpretations of the GLP Principles.

4.3.4 Co-ordination of international activities

The participation at international meetings and activities is discussed and agreed between the heads of the three GLP Compliance Monitoring Units (see chapter 7).

4.4 Responsibilities of the GLP Authorities

4.4.1 Responsibilities of the NAChem in the area of GLP

The responsibilities of the NAChem in the area of GLP are:

- general information concerning the GLP Compliance Monitoring Programme,
- enrolment of new test facilities in the GLP Compliance Monitoring Programme,
- registration of relevant changes communicated by the test facilities,
- establishment, publication and release of decisions concerning the GLP compliance of test facilities and preparation of the statement of GLP compliance,
- compiling of the GLP inspections of the three GLP Compliance Monitoring Units,
- maintaining the GLP register,
- archiving of GLP-related documents,
- distribution of information concerning GLP (in particular: to maintain the GLP web site and publish the electronic newsletter).

GLP register and published list of GLP test facilities

The NAChem maintains a GLP register of all establishments with their inspected test facilities and, in case of study audit, their audited studies. This register is accessible for the GLP authorities exclusively.

A list of the test facilities and service providers working in compliance with GLP is published by the NAChem on the GLP web site (www.glp.admin.ch).

4.4.2 Responsibilities of the GLP Compliance Monitoring Units in the area of GLP

The GLP Compliance Monitoring Units are responsible for conducting inspections and study audits. In its area of competence the GLP Compliance Monitoring Unit has to ensure that:

- an adequate number of inspectors is available to carry out the inspections and study audits,
- inspections and study audits are planned and carried out according to article 9 paragraph 1 of the OGLP,
- if necessary, follow-up actions are taken and monitored after test facility inspections or study audits,
- a final report is written about the inspection or study audit, including an evaluation of the compliance with the GLP Principles,
- a copy of the final report is sent to the NAChem (the originals are locally archived by the individual authorities).

4.4.2.1 Internal Personnel

Internal personnel is part of the permanent staff of the GLP Compliance Monitoring Units.

Qualifications and Training

The GLP Compliance Monitoring Units have to ensure that:

- inspectors are adequately qualified and trained. Inspectors should have a university degree in a scientific, medical or veterinary discipline, or be highly experienced in an area of GLP testing. Furthermore, inspectors should be able to understand and to express themselves in at least one official Swiss language and in English.
- arrangements are made for the appropriate training of inspectors. New inspectors should have 40 hours of GLP training; this includes studying the relevant GLP documents from OECD and national documents as mentioned in the GLP Compliance Monitoring Programme. In addition, they should participate as observers in at least two test facility inspections led by experienced inspectors.
- arrangements are made for on-going training, such as by participation at OECD training courses or training courses given by inspectors from OECD member countries, OECD workshops and specific national or international workshops (validation of computerised systems, field studies etc.). Participation as an observer in inspections in OECD member countries can be considered as training opportunity.
- for each inspector the following documents are maintained and yearly updated:
  a. job description,
  b. curriculum vitae,
  c. record of qualifications, training and experience,
  d. inspections and study audits carried out.

  The records are kept at the site of the individual authorities.

Identification

The GLP Compliance Monitoring Units have to ensure that the inspectors are provided with suitable means of identification (*e.g.*, identity card of the respective authority, issued by the Swiss Confederation).

Independence

The independence of internal inspectorate personnel employed by the FOPH and FOEN is established in the following legislation:

Bundespersonalgesetz	Loi sur le personnel de la Confédération	Legge sul personale federale	Federal Personnel Law
Artikeln 21 und 23	Articles 21 et 23	Articoli 21 e 23	Articles 21 and 23 (no English version)

Bundespersonal-verordnung	Ordonnance sur le personnel de la Confédération	Ordinanza sul personale federale	Federal Personnel Ordinance
Artikel 91	Article 91	Articolo 91	Article 91 (no English version)

The independence of all the internal inspectors of Swissmedic is based on:

Verordnung des Schweizerischen Heilmittelinstituts über sein Personal	Ordonnance de l'Institut suisse des produits thérapeutiques sur son personnel	Ordinanza dell'Istituto svizzero per gli agenti terapeutici sul suo personale	Ordinance of the Swiss Agency of Therapeutic Products on the Personnel
Artikeln 43, 46, und 48	Articles 43, 46, et 48	Articoli 43, 46, e 48	Articles 43, 46, and 48 (no English version)

Confidentiality

Internal inspectorate personnel of the FOPH / FOEN are obliged to maintain confidentiality based on:

Bundespersonalgesetz	Loi sur le personnel de la Confédération	Legge sul personale federale	Federal Personnel Law
Artikel 22	Article 22	Articolo 22	Article 22 (no English version)

Bundespersonal-verordnung	Ordonnance sur le personnel de la Confédération	Ordinanza sul personale federale	Federal Personnel Ordinance
Artikel 94	Article 94	Articolo 94	Article 94 (no English version)

Internal inspectorate personnel of Swissmedic are obliged to maintain confidentiality based on:

Verordnung des Schweizerischen Heilmittelinstituts über sein Personal	Ordonnance de l'Institut suisse des produits thérapeutiques sur son personnel	Ordinanza dell'Istituto svizzero per gli agenti terapeutici sul suo personale	Ordinance of the Swiss Agency of Therapeutic Products on the Personnel
Artikel 45	Article 45	Articolo 45	Article 45 (no English version)

4.4.2.2 External Personnel

According to article 8 paragraph 3 of the OGLP, the GLP Compliance Monitoring Units can contract experts or assign third parties to conduct inspections or study audits.

Qualification and Training

The GLP Compliance Monitoring Units have to ensure that:

- the external inspectorate personnel are as well-qualified as the internal personnel (see chapter 4.4.2.1),
- the external inspectorate personnel receive the same training as the internal personnel (see chapter 4.4.2.1),
- for each inspector the following documents are maintained and updated if necessary:
  a. job description, in case of external personnel including the obligation to adhere to the provisions of the GLP Compliance Monitoring Programme,
  b. curriculum vitae,
  c. record of qualifications, training and experience,
  d. inspections and study audits carried out.

  The records are kept at the site of the individual authorities.

Identification

The list of inspectors also includes external GLP inspectors (see chapter 4.4.2.1).
The GLP Compliance Monitoring Units have to ensure that the external inspectors are provided with means of identification (e.g. national identity card and an authorization letter issued by the corresponding GLP Compliance Monitoring Unit). The authorisation letter together with the personal identification card allow the external inspector to have access to the test facility according to article 9 paragraph 3 of the OGLP.

Independence

All third persons contracted are obliged to inform the GLP Compliance Monitoring Unit about any contract during the last five years with test facilities which are or were part of the Swiss GLP Compliance Monitoring Programme. The same applies for any new contract during the assignment as external GLP inspector.
In case of any potential conflict of interest, the GLP Compliance Monitoring Unit will not assign the contracted persons or third parties to conduct inspections or study audits of specific test facilities.

Confidentiality

All third persons contracted by GLP authorities are obliged to maintain confidentiality as mentioned in article 6 of the General Terms and Conditions for Service Contracts [issued by the Swiss Federal Procurement Commission (EFV)], which is an integral part of all contracts between GLP authorities and third parties.

4.5 Archives

Each GLP Compliance Monitoring Unit as well as the NAChem has to ensure that suitable space and IT systems are available for archives.

The archives of the different authorities are organized as follows:

- NAChem: The GLP archive is integrated in the archive of the NAChem and is partially kept in electronic form.
- FOPH: The GLP archive is integrated in the archive of the Division of Chemicals and is partially kept in electronic form.
- FOEN: The archive is located in the archive of the Air Pollution Control and Chemicals Division and is partially kept in electronic form.
- Swissmedic: The GLP archive is located in lockable cabinets in the archive of Swissmedic and is partially kept in electronic form.

The NAChem has to retain the following documents in its archive for at least ten years:

- records of qualifications (curriculum vitae) and job descriptions of personnel in charge of GLP,
- the GLP Compliance Monitoring Programme (current and historical versions, incl. overview file),
- historical file of the annual reports of the inspections and study audits performed,
- the register of all establishments and their test facilities and studies audited,
- copies of all inspection reports and decisions concerning compliance of the test facilities,
- copies of all GLP statements,
- documents of correspondence with other authorities and test facilities.

All three GLP Compliance Monitoring Units have to retain the following records in their archives for at least ten years:

- records of qualifications (CV) and experience, training and job descriptions of inspectorate personnel,
- documents submitted by test facilities for the preparation of inspections,
- correspondence with test facilities relating to inspections and study audits,
- all notes taken during the inspections and study audits,
- copies of documents or materials gathered during, or after, an inspection,
- original inspection reports issued by the GLP Compliance Monitoring Unit,
- documents of correspondence with foreign authorities,
- further relevant GLP documents, if appropriate.

In addition, the FOEN is responsible for archiving the following documents:

- protocols and working documents relating to the OECD working group on GLP,
- documents resulting from the preparation of Memoranda of Understanding (MoUs).

5 Framework and Scope of Monitoring

5.1 Basis for inspections and study audits

The compliance of a test facility with the Principles of GLP is assessed by inspections or study audits, as defined in articles 6 and 7 of the OGLP.
The competence of the inspectors is outlined in the OGLP, in particular in:

- Article 8 Competent authorities,
- Article 9 Duties and powers of the authority,
- Article 10 Reports on inspections and study audits.

5.2 Enrolment in the GLP Compliance Monitoring Programme

For participating in the GLP Compliance Monitoring Programme, a written application in accordance with article 5 OGLP should be submitted to the NAChem. The competent GLP Compliance Monitoring Unit (see chapter 4.2) will discuss the request with the applicant and outline the further procedure (*e.g.*, preparation meeting, pre-inspection visit, etc.). Since the applicant is not yet part of the programme, a pre-inspection visit of the test facility is not an inspection according to art. 6 OGLP, and therefore no report will be written. The prospective test facility should already dispose of good experience in GLP studies, having completed two studies per area of expertise. Exceptions to this rule might be granted by the GLP authorities. In the GLP compliance statement of studies performed prior to the enrolment in the GLP Compliance Monitoring Programme, reference can only be made to the OECD Principles of GLP ("*This study has been performed in compliance with the OECD Principles of Good Laboratory Practice, as revised in 1997 and adopted 26 November 1997 by decision of the OECD Council [(97) 186/Final]*").
If the GLP compliance is confirmed for a prospective test facility, and a positive decision is issued, the test facility will be listed in the GLP register and the published list of GLP test facilities (see chapters 4.4.1 and 5.8).

5.2.1 Extension of area of expertise

According to art. 12 OGLP, an establishment must immediately notify the NAChem if it intends to extend the area of expertise.
The respective compliance monitoring unit shall determine whether the inspection of the new area of expertise should be conducted at the next regular inspection or whether a separate inspection should be performed after the facility completed at least one study in the new area of expertise according to the GLP Principles. In the GLP compliance statement of studies performed prior to this inspection, reference can only be made to the OECD Principles of GLP as also mentioned in chapter 5.2 since this area of expertise is not covered by the current certificate. After the inspection the studies in this area of expertise can retrospectively be considered as GLP compliant according to the Swiss OGLP via amendment to report.

5.3 Type and frequency of monitoring

5.3.1 Types of Inspections and study audits

Overview:

Type of inspection	*Frequency*	*Legal base (OGLP)*
first inspection	when a test facility enters the programme.	art. 6, paragraph 1
routine inspection	every two to three years.	art. 6, paragraph 2
inspection without delay	If there is sufficient reason to assume that a test facility does not comply with the GLP Principles (e.g. after a study audit), the competent GLP Compliance Monitoring Unit	art. 6, paragraph 3 art. 7, paragraph 2

Type of inspection	*Frequency*	*Legal base (OGLP)*
	may conduct an inspection without delay.	
re-inspection	if necessary, after all types of inspections.	art. 6, paragraph 2
final inspection	when a test facility leaves the programme.	art. 6, paragraph 2 or 3
study audit	on request of a competent authority or on own initiative of the GLP Compliance Monitoring Unit.	art. 7, paragraph 1 and 3

The GLP Compliance Monitoring Units perform inspections and study audits according to section B (*Revised Guidelines for Conducting Test Facility Inspections and Study Audits*) of Directive 2004/9/EC. Representatives of other authorities or of monitoring authorities from other countries may be invited or admitted as observers.

5.3.2 Preparation of inspections

Prior to conducting an inspection, the responsible GLP Compliance Monitoring Unit requests the test facility to submit at least the following documents, as mentioned in article 5 or article 6 paragraph 2 of the OGLP:

a. (actual) 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. In case of routine inspection, the list should cover all studies conducted since the last inspection.

This set of documents can be extended on request of GLP Compliance Monitoring Unit (for example regarding information on IT).

In case of a routine inspection, the inspection report of the last inspection will also be reviewed during the preparation of the inspection.
The Swiss GLP Compliance Monitoring Units may also conduct remote inspections – the extent of the remote activities may vary. This is discussed upfront with the test facilities.

5.3.3 First and routine inspections

These inspections include all GLP aspects of the test facility and limited audits of on-going or completed studies. The audited studies are part of the test facility inspection and therefore are not regarded as full study audits, hence the resulting observations are not reported separately but included in the inspection report. The test facility should plan on-going GLP activities at the time of inspection.

To remain in the GLP Compliance Monitoring Programme the test facilities are re-inspected approximately every two to three years, according to art. 6 paragraph 2 OGLP. The responsible GLP Compliance Monitoring Unit sets the date of these routine inspections. One study per area of expertise, but at least two studies per test facility have to be completed between two consecutive routine inspections.
If this is not the case the test facility will be informed on the minimum requirements to remain in the GLP register/list via a condition. The compliance status is changed to “pending” as described in

chapter 5.9. If this condition is not fulfilled, the test facility is removed from the GLP Compliance Monitoring Programme or the area of expertise is not confirmed. Exceptions to this rule might be granted by the GLP authorities.

5.3.4 Inspections without delay and re-inspections

These inspections are basically performed as described in section 5.3.3 with the following exceptions:

a. An inspection without delay can focus on the suspected non-compliance of the test facility.
b. A re-inspection can focus on the verification that deviations observed in a previous inspection have been corrected.

5.3.5 Final inspections

A final inspection can be performed to confirm the GLP compliance of all studies until the withdrawal of the test facility from the GLP Compliance Monitoring Programme (see also chapter 5.4) and to ensure that access to all archived GLP documents is guaranteed over a period of 10 years. The content is similar to a routine inspection, but may focus on archiving of or access to GLP documentation. For corrective actions to ensure the validity of a study, the required personnel or adequate deputies should be available.

5.3.6 Study Audits

In case there is sufficient reason to assume that a test facility has not respected the Principles of GLP while performing specific studies, or if the result of a specific study is of particular importance for assessing safety for humans and the environment, the competent GLP Compliance Monitoring Unit can conduct a study audit on its own initiative or at the request of another competent Swiss or foreign authority. A study audit is not considered to be a test facility inspection. However, 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.
Any requests made by foreign registration authorities should be sent to the NAChem via the GLP Compliance Monitoring Unit of the country in question. Study audits are normally planned in agreement with the test facility concerned; however, they can also be carried out without announcement. A study audit report is issued.

5.4 Withdrawal from the GLP Compliance Monitoring Programme

If a test facility decides to withdraw from the programme, the NAChem needs to be informed immediately. The test facility should provide an official closure date and the name of a contact person in case of a study audit request. Furthermore, the following issues need to be addressed:

- Documents and materials listed in annex 2, section 10 of the OGLP should be stored in a GLP compliant archive over a period of 10 years. The documents should be available in case of a study audit.
- Information of the withdrawal should be shared with the sponsors which have study-related data in the archive of the test facility. Access of the sponsors to these study-related records and materials should be agreed upon and documented.
- For non study specific (facility) records or records which relate to studies of more than one sponsor, test facility management should agree with the sponsors on how to ensure that these records and materials are archived in a GLP compliant archive after the closure of the test facility or archive.
- All references to GLP (e.g. “GLP compliant”, “GLP certified” or “GLP confirmed”) have to be removed from all business related documents (paper and electronic).
- Sponsors need to be informed that future work will no longer be GLP compliant.

These aspects can be subject to the final inspection (see 5.3.5).
In case the archive location changes during the 10-year period, all sponsors and the competent authorities have to be informed. Changes concerning *e.g.* the contact person or organization need to be communicated immediately to the NAChem.

After the official closure date, the NAChem removes the test facility from the GLP list. The FOEN informs the MAD adherent countries via the OECD secretariat and the EU member states via the EU commission about the withdrawal from the GLP programme.

5.5 Criteria for GLP compliance

The decision concerning GLP compliance of an inspected test facility or of an audited study depends on the deviations from the Principles of GLP that are detected.
Deviations can be classified in two categories:

- **major deviations** are deficiencies observed in the test facility or part thereof, or in one or several studies, which affect or may affect the GLP compliance of the test facility itself or the validity of the study (studies).
- **minor deviations** are deficiencies observed in the test facility or part thereof, or in one or several studies, which do not affect the GLP compliance of the test facility itself or the validity of the study (studies).

Further observations might result in recommendations, but are not considered to be a deviation. No corrective action is required for recommendations, however the test facility can inform on measures taken to respond to the observation.

5.6 Result of compliance monitoring and measures to be taken

At the closing conference of the inspection, the inspectors present the most relevant deviations to the test facility personnel. On this occasion, the test facility representatives can briefly comment on the findings. No written document will be submitted to the test facility management at that time. No decision on GLP compliance will be provided.
An inspection report is prepared in compliance with OECD Guidance Document No 9 *Guidance for the Preparation of GLP Inspection Reports*. Proof of deviation is not annexed to the report. The draft of the report is then sent to the test facility. The test facility should commentwithin a given time frame of e.g. 4 weeks with regard to accuracy and planned implementation of stipulations/conditions. The statement of the test facility is incorporated in the report and a conclusion is added after the proposed corrective actions are considered as satisfactory.
If necessary, the inspectors of a GLP Compliance Monitoring Unit discuss the final decision on GLP compliance with the other GLP Compliance Monitoring Units. In the final report signed by the inspectors, it is stated whether and to what extent the test facility operates in compliance with the Principles of GLP. A copy of the report is sent to the NAChem.

If only minor deviations are found, it is normally sufficient for the test facility to explain how and by when the deviations will be corrected. The request for corrective action is mentioned as stipulation in the inspection or audit report. Proposed stipulations, if already fulfilled according to the statement from the test facility on the draft inspection or audit report, will not be mentioned in the positive decision of GLP compliance emitted by the NAChem. Stipulation(s) need to be corrected in due time. If necessary, a new decision is issued for enforcement.

If major deviations from the Principles of GLP are observed during an inspection or study audit, there are two possible scenarios:

1) No corrective action can be taken (i.e. in the case of a study audit) – negative decision: the inspectors provide a draft report to the test facility with their observed major deviations and a negative conclusion concerning GLP compliance. The report is finalized after considering and integrating the statement from the test facility. The NAChem will emit a negative decision.

2) Corrective actions can be taken – positive decision: Request for corrective actions is described as condition(s) in the inspection or audit report. Proposed conditions, if already fulfilled according to the statement from the test facility on the draft inspection or audit report, will not be mentioned in the positive decision of GLP compliance emitted by the NAChem. If the competent GLP authority considers the submitted documents to be incomplete or inaccurate, it shall inform the test facility within 14 days. A test facility or study is only GLP compliant once

the condition(s) stated in the decision are fulfilled in the due time and quality. Otherwise the status is changed to “not in compliance” automatically (no new decision required).

In case of a negative decision or delayed/missing implementation of corrective actions according to the agreed timelines in the decision to overcome major deviations (mentioned as conditions), the test facility will be removed from the GLP Compliance Monitoring Programme. The NAChem then informs the Swiss registration authorities, as well as the other GLP Compliance Monitoring Units. The GLP Compliance Monitoring Unit of the FOEN consequently notifies the OECD and its member states.

In any case it is at the discretion of the GLP Compliance Monitoring Unit to perform a re-inspection to check whether and how the required corrective measures have been implemented.

5.7 Decision concerning GLP Compliance

Based on the statement of the inspectors in the final report, the NAChem issues the decision concerning the compliance with the Principles of GLP (according to article 10 paragraph 3 OGLP). This decision is sent to the test facility together with a copy of the final report and has to be written in an official Swiss language (French, German or Italian).

5.8 Appeal Procedure

Within 30 days after receipt of the decision, the test facility can file a complaint against the decision to the Federal Administrative Tribunal. The letter of complaint has to contain the request, the reasons for it, indicating the evidence and the signature of the person who complains or the person representing him or her. The disputed decision and the documents cited as evidence have to be enclosed with the complaint.
The Federal Administrative Tribunal decides on the complaint. In case the test facility does not agree, a complaint against this decision may be filed to the Federal Supreme Court.

5.9 Enrolment in the GLP register, confirmation of GLP compliance and GLP list

If the GLP compliance is confirmed for an inspected test facility or an audited study, and the decision becomes effective,

- the test facility (if it was a first inspection), or the study will be listed in the NAChem internal GLP register,
- for test facilities already enlisted, the information will be updated,
- a Statement of GLP compliance will be provided in case of inspection. GLP compliance of individual studies is confirmed, but not certified.
  The Statement of GLP compliance is an extract from the register, issued in English by the NAChem and signed by its head.
- the published list of GLP test facilities will be updated (see chapter 4.4.1)

The following three statuses are used to describe the GLP compliance:

- *in compliance*
  The test facility is listed in the GLP register and GLP list according to art. 14 OGLP and holds a Statement of GLP compliance.
- *not in compliance*
  The test facility has been removed due to a decision or on request of the test facility from the GLP list according to art. 14 OGLP and does not hold a Statement of GLP compliance. The OECD has been informed immediately.
- *pending for completion of appeals/ administrative procedures*
  Administrative procedures are on-going, *e.g.* appeals or positive decision not in effect due to outstanding fulfillment of conditions. Status is updated as soon as possible.

After a routine inspection or a study audit, the status of test facility or study remains *in compliance* if there were minor deviations only. If major deviations were found, the status changes to *not in*

compliance as soon as the negative decision is effective or to *pending for completion of appeals/ administrative procedures* until fulfillment of conditions or in case of an appeal.
The current status of all test facilities and study audits are communicated to the OECD in an annual overview.

5.10 Service providers

Companies providing services such as IT or archiving services to GLP test facilities or test sites are not considered to be test facilities or test sites since they have not the personnel, premises and operational units that are necessary for conducting studies. They can therefore not enrole in the GLP Compliance Monitoring Programme. However, they may receive a letter of confirmation that their services meet GLP requirements after an successful inspection verifying the quality of the services provided.
Service providers are inspected every 2-3 years, whenever possible within the frame of a test facility inspection. Inspections of service provides are planned the same way as inspections of test facilities. After completion of the test facility inspection the GLP compliance monitoring unit sends a draft inspection report to the test facility including the findings concerning the service provider. The service provider receives a draft letter from the GLP compliance monitoring unit summarizing the inspection results concerning his activities. The letter is finalized after the inclusion of the comments of the service provider. This letter will then be sent to the service provider (with copy to the NAChem). After the service provider confirmed that corrective actions sufficiently addressed any deviations, the NAChem issues a confirmation of meeting GLP requirements to the service provider and a copy thereof will be sent to the competent GLP compliance monitoring unit.

The NAChem updates the entry of the service provider in the GLP register and published list.
An invoice of CHF 100.00 will be issued by the NAChem for issuing the GLP confirmation of GLP compliance. The inspecting GLP compliance monitoring authority will issue an invoice (CHF 200.00 per hour) according to article 1, paragraph 1 of the ChemGebV.

5.11 Confidentiality

The documents made available by the test facility before, during or after the inspection or study audit, and the records written by the inspectors are not official documents according the Freedom of Information Act (FoIA) article 5 paragraph 3, but documents for personal use (Freedom of Information Ordinance (FoIO) article 1 paragraph 3). They are archived with the original inspection report.

Decisions, inspection and study audit reports are official documents. They are handled as confidential according to the exceptions in article 7 of the FoIA.

6 Contacts between the GLP authorities and the test facilities

Beside the inspections and the direct contacts with individual test facilities to address specific questions, the GLP authorities communicate usually via the following means.

6.1 GLP Newsletter

The three GLP Compliance Monitoring Units and the NAChem publish a yearly GLP Newsletter, containing information of general interest, e.g. new interpretations of the Principles of GLP. The newsletter is sent electronically to all test facilities participating in the GLP Compliance Monitoring Programme.

6.2 GLP Web site

The NAChem maintains a web site concerning *i.a.* the GLP Compliance Monitoring Programme, legal information, the GLP list as well as information on the GLP Compliance Monitoring Units (www.glp.admin.ch).

6.3 GLP Meetings

Upon request of interested parties such as SPAQA or scienceindustries (Business Association Chemistry Pharma Life Sciences), the GLP authorities attend meetings for discussions or presentations on GLP relevant topics.

7 International Co-ordination

The GLP Compliance Monitoring Units of the FOPH, FOEN and Swissmedic represent Switzerland towards foreign authorities and institutions, according to their responsibilities.

7.1 International Agreements

In addition to the multilateral decisions of the OECD, Switzerland has concluded bilateral agreements with different important trade partners concerning the mutual acceptance of the GLP Compliance Monitoring Programme. There are memoranda of understanding between the Swiss Confederation and:

a. the Food and Drug Administration (FDA), US Department of Health and Human Services of the United States,
b. the Environmental Protection Agency (EPA) of the United States,
c. the Federal Ministry of Food and Agriculture, the Federal Ministry for Youth, Family, Women and Health, and the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety of the Federal Republic of Germany,
d. the Ministry of Agriculture, Forestry and Fisheries in Japan,
e. the Ministry of Health and Welfare, Pharmaceutical Affairs Office in Japan,
f. the Ministry of Health and Welfare and the Ministry of International Trade and Industry in Japan.

Switzerland has concluded a Mutual Recognition Agreement (MRA) on conformity assessment with the European Community. Chapter 14 covers the area of GLP. The MRA came into force on 1 June 2002.

7.2 Working Groups on GLP

The GLP Compliance Monitoring Units attend the meetings of the Working Party on GLP of OECD and the GLP Working Group of the EU, and held the Chair from 2019 to 2020 of the Working Group on GLP of OECD. Furthermore, the GLP inspectors of Swissmedic participate in the biennial inspectors' working group (IWG) meeting at the European Medicines Agency (EMA). The GLP Compliance Monitoring Unit of the FOEN is the Swiss coordination office within the OECD, and informs the OECD and its member states:

- annually about inspections and audits that have been carried out and on the status of the test facilities. The NAChem prepares all necessary data from the GLP register of the test facilities in Switzerland for the GLP Compliance Monitoring Unit of the FOEN.
- immediately if there are test facilities or studies that are not in compliance.

7.3 On-site Evaluation Visits

The periodic on-site evaluation programme covers all countries that are full adherents to the OECD Council Acts on Mutual Acceptance of Data. The programme provides a mechanism for national GLP Compliance Monitoring Programmes to gain increased confidence in the compliance monitoring practices of the evaluated GLP Compliance Monitoring Units. The GLP Compliance Monitoring Programme was inspected in 2000 under the Mutual Joint Visit Programme (MJV). The last on-site evaluation visit of the GLP Compliance Monitoring Programme was performed in 2014, the next is scheduled for 2024.

7.4 Requests from national GLP Monitoring Authorities of another MAD-adherent country

Information on the GLP compliance status of a test facility and requests for study audits should be addressed to the NAChem (see contact details chapter 4.1). The procedures should follow the recommendations of the OECD advisory document number 12 or the provisions outlined in the MRA.