Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH
Notification authority for chemicals

Internet-document

Date:	December 2025
For further details please contact:	GLP authorities

GLP-Newsletter 2025

GLP compliance monitoring programme:

The new version EL02.11 has been released in December 2025 with i.a. the following updates.
Switzerland's on-site evaluation by OECD experts was successful.
Dr. Timothée Barrelet has been appointed as Mrs. Diana Burkhalter's successor in charge of GLP coordination at the Notification Authority for Chemicals. He is a scientific officer (chemist) and the deputy head of sector specialist applications, substances and coordination.

Interpretation of the Principles of GLP:

Update is in preparation.

Changes within the GLP authorities:

Swissmedic: Dr. Daniel Roth has retired in April 2025. Dr. Anja-Maria Möller has successfully finished her training as GLP inspector. She will act as an inspector starting in 2026. As part of her on-going training, Dr. Möller will attend the OECD training course in November 2026.

AGIT (ArbeitsGruppe über InformationsTechnologie):

In 2025 the Working Group on Information Technology (AGIT) published the following two revised AGIT guidelines:

- *AGIT – Guidelines for the Acquisition and Processing of Electronic Raw Data*
- *AGIT – Guidelines for the Validation of Computerised SystemsAGIT – Guidelines for the Validation of Computerised Systems*

The two AGIT guidelines have been aligned with the OECD documents published in the last years, particularly OECD Advisory Document Number 22 on GLP Data

Integrity and the OECD Advisory Document on GLP & Cloud Computing (Supplement 1 to Document Number 17 on Application of GLP Principles to Computerised Systems).
The AGIT is currently working on the revision of the Document *AGIT – Guidelines for the Archiving of Electronic Raw Data*.
The revision is nearly completed, the test facilities will be informed when the revised document is published. In addition, the AGIT is discussing the retention of electronic communication (particularly E-Mails) and the need for further guidance on this topic.

OECD-GLP Working group meeting from 1.-3.04.2025:

The reports from five on-site evaluation visits were discussed and noted. The evaluation report on Switzerland's GLP monitoring system was presented and approved after a few minor questions. There are no deviations in the Swiss GLP programme from the OECD guidelines. Some adjustments are planned for the organisation of the next 10-year round of evaluation visits. They remain an important element in building mutual trust. – The concept of a new guidance document on inspections of test phases in other countries was discussed. The requirements of the documents on field studies, multisite studies, and inspections in other countries must be taken into account and updated if necessary. – Three new countries reported on their progress in introducing GLP.

EU-GLP Working group meeting from 13.-14.02.2025:

Different OECD Working Group Documents were discussed, as well as the collaboration with receiving authorities. Information about the update of the EU GLP Website has been shared, as well information about the ongoing project (2025-2026) of the evaluation and impact assessment of the EU Directive on GLP.

SPAQA-Meeting on 23.09.2025:

The GLP Compliance Monitoring Authorities communicated the outcome of the OECD on-site evaluation from November 2024: the Swiss GLP Monitoring Programme was considered compliant. The authorities also provided information on the revision of the AGIT guidelines (see above) and the new website of the Notification Authority: https://www.anmeldestelle.admin.ch/en/good-laboratory-practice-glp. Additionally, questions from the SPAQA GLP Monitoring Authority Roundtable 2025 were addressed. The presentations and responses were made available to SPAQA for posting on their website.