



# Internet-document

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Date:

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For further details please contact:

GLP authorities

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## GLP-Newsletter 2024

### Changes within the GLP compliance monitoring units:

Dr. Alena Tierbach from the Federal Office for the Environment has successfully finished her training as GLP inspector. The requirements are set in the GLP monitoring programme of Switzerland: "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." She attended the 16th OECD training course in Mexico as final step for her training and will act as an inspector starting in 2025.

### AGIT (ArbeitsGruppe über InformationsTechnologie):

In 2024 the Working Group on Information Technology (AGIT) continued the work on the revision of the AGIT guidelines. The primary goal of the revision is to align the AGIT guidelines with the new OECD documents published in the recent years, particularly OECD Advisory Document Number 22 on GLP Data Integrity, OECD Advisory Document on GLP & Cloud Computing (Supplement 1 to Document Number 17 on Application of GLP Principles to Computerised Systems). In addition, text passages which are outdated (e.g. for technical reasons) are revised. The revision of the two AGIT documents "Guidelines for the Acquisition and Processing of Electronic Raw Data" and Guidelines for the Validation of Computerised Systems" has been completed. As soon as the AGIT has decided on the publication date of the revised guidelines, the stakeholders will be informed by email.

### OECD-GLP Working Party meeting from 16-18/04/2024:

During the meeting, two technical issues brought up during the year were discussed. Eight issues had been commented before the meeting and are summarized by the responsible CMA. The implementation of recent guidance documents by the CMAs was also discussed. These technical discussions are important for the international harmonization by creating a common understanding. Eight reports of onsite evaluations were presented and accepted. Other topics were the schedule of onsite evaluations, the OECD training course for GLP inspectors and the feedback from the OECD industry discussion group. New guidance documents and the update of the OECD Council Decision-Recommendation on Compliance with Principles of GLP were discussed and could be commented.

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:**

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December 2024

An important point on the agenda were the progress reports of countries that need to have their GLP programme evaluated, either as new OECD members or having the intention to join the system of mutual acceptance of data as adherents.

## OECD Position Paper on Good Laboratory Practice and IT Security:

On 2 December 2024, the OECD published Position Paper No. 25, highlighting key aspects of IT security. The document was prepared by a drafting group led by Denmark (Medical Products) and included representatives from Austria, Belgium, Canada, France (Medical Products), Germany, and Switzerland. It incorporates insights from a European Union publication on cybersecurity and Good Clinical Practice (GCP) and offers a comprehensive overview of IT security considerations for GLP test facilities.

## EU-GLP Working group meeting from 05.-06.03.2024:

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

## SPAQA-Meeting:

The SPAQA 2024 annual meeting took place in Basel on 17 September 2024. The GLP Compliance Monitoring Authorities provided updates on several key developments, including changes within the monitoring authorities, the revision of the Swiss interpretation of GLP principles, and the update of the GLP compliance monitoring programme. They also discussed the current activities of AGIT, including the update of guidelines to align with the most recent OECD documents, particularly Documents No. 22/23 and No. 17 Supplement, to ensure consistency and offer additional guidance on data integrity and risk-based approaches. The Swiss Monitoring Authorities informed about the on-site evaluation (November 2024) and their expectations regarding Supplement 1 to Document No. 17 on GLP and Cloud Computing. Additionally, questions for the SPAQA GLP Monitoring Authority Roundtable 2024 were addressed. The presentations and responses were made available to SPAQA for posting on their website.

### Further information:

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