



## Internet-document

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Date:

December 2022

For further details please contact:

GLP authorities

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## GLP-Newsletter 2022

### GLP compliance monitoring programme:

A new version of the GLP compliance monitoring programme dated with 24.03.2022 was published. The modifications concerned editorial changes and updates of references to legal texts.

### Interpretation of the Principles of GLP:

The document will be updated to include the outcome of the SPAQA meeting 2022. In addition, several Questions & Answers will be revised based on the recently published OECD Documents Number 22 and 23. The updated Interpretation document will be published in 2023.

### Changes within the GLP compliance monitoring units:

Dr. Martine Bourqui-Pittet changed job position in November 2022 and was succeeded by Sabine Frey who is currently trained as a GLP inspector according to the requirements in the GLP Compliance Monitoring Program.

### AGIT (ArbeitsGruppe über InformationsTechnologie):

In 2022, the members of the AGIT had five hybrid meetings. The group had in-depth discussions regarding the position paper for audit trial.

Swissmedic will take over the chair on an interim basis for 2023, due to a change of position at FOPH.

### OECD-GLP Working group meeting from:

The meeting took place from the 19.-22. April 2022 in Paris. It was the first physical meeting since the pandemic, and about 50 delegates were present on place. A majority participated online.

The meeting started with the optional session dedicated to technical discussions. It was organized by Elisabeth Klenke from Swissmedic.

The official meeting in the following three days was mainly filled with discussions on the documents that are currently in preparation, namely the advisory document on Quality assurance and GLP, a supplement to Advisory Document No. 17 about GLP and Cloud Computing, and the Position Paper

**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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on Quality Improvement Tools and GLP. Further topics were the progress reports of provisional adherents to the MAD system and collaboration with other countries.

## EU-GLP Working group meeting from 08/03/2022:

The EU-GLP Meeting took virtually place on 8. and 9. March 2022.

The main focus on Day 1 was on technical discussions on GLP inspection followed by a second day with the focus on discussions about the collaboration with receiving authorities and third countries.

## SPAQA-Meeting from 29/09/2022:

The SPAQA 2022 annual meeting took place in Basel on 22 September 2022. The GLP compliance Monitoring authorities reported on their experiences with hybrid inspections due to the COVID-19 pandemic, which can be considered in special circumstances, and presented the expectations of the Swiss Monitoring Authorities with regard to the OECD Document Nr. 22 on Data Integrity. In addition, the questions for the SPAQA GLP Monitoring Authority Roundtable 2020-2022 were answered and the answers made available to SPAQA for posting on their website.

### Further information:

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