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For further details please contact:

GLP authorities

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Interpretation of the GLP Principles:

The compliance monitoring authorities made a major revision of the document that had been issued in December 2021. Questions and answers (Q&A) that are covered or superseded by OECD Documents or OECD FAQ were removed. Likewise, Q&As that are included in the EU GLP Working Party Q&A Document were removed. The new version will be published on 15.12.23.

Changes within the GLP Compliance Monitoring Authorities:

We welcome a new member in the inspection team of the FOEN: Ms. Alena Tierbach is a biologist with a Master's degree in environmental toxicology from the University of Duisburg-Essen (Germany). As part of her Master's thesis at EAWAG in Dübendorf, she investigated the toxicity of various nanoparticles in algae. After completing her Master's degree, she worked first as a research assistant and later as a doctoral student on biotransformation processes in zebrafish and cell lines. She developed mass spectrometric methods for the characterization and measurement of biotransformation enzymes (glutathione S-transferases) and their transformation products in the respective test systems. After successfully completing her doctorate, she worked at the Ecotox Center on the risk assessment of micropollutants in water and soil before moving to the FOEN in April 2023 to support the Biocides and Plant Protection Products Section.

AGIT (ArbeitsGruppe über InformationsTechnologie):

In 2023, the AGIT members said farewell to two long-term members, S. Albertini und S. Hassler, and welcomed M. Haak and P. Crick. Together with L. Michel and J.-M. Jehl, they represent the Swiss GLP industry stakeholders. The group is currently revising the published guidelines to ensure compatibility with OECD Documents No. 17 Supplement as well as Nos. 22 and 23. The updated guidelines will be published all at once. The stakeholders will be informed accordingly.

OECD-GLP Working Party Meeting

The meeting took place from the 12 to 14 March 2023 in National Harbor/ USA in conjunction with SQA meeting. The meeting started with the optional session dedicated to technical discussions and was organized by Elisabeth Klenke from Swissmedic. The meeting in the following two days centered on

The notification authority for chemicals is the coordination and decision authority for the good laboratory practice (GLP) for the FOEN, the FOPH and Swissmedic.

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discussion of on-site-evaluation reports, as the programme was restarted after the pandemic. Furthermore, documents that are currently in preparation, e.g., the supplement to Advisory Document No. 17 about GLP and Cloud Computing, were discussed and new topic proposals taken under consideration.

SPAQA Meeting:

The SPAQA 2023 annual meeting took place in Basel on 25 September 2023. The GLP compliance Monitoring authorities presented some relevant information about the responsible inspectors, the activities of the AGIT in relation to the newly published OECD documents especially OECD Document No. 17 Supplement and OECD Documents No. 22/23/24 (see above, AGIT), the revision of the interpretations (see above, interpretations) as well as the on-site evaluation planned in 2024, and presented the expectations of the Swiss Monitoring Authorities with regard to the OECD Document No. 23 on Quality Assurance. In addition, the questions for the SPAQA GLP Monitoring Authority Roundtable 2023 were answered. The presentations and the answers were made available to SPAQA for posting on their website.

EMA Inspectors Working Group Meeting

The meeting was held on 25 May 2023 and Elisabeth Klenke participated virtually. This group has a focus on pharmaceuticals and medical devices and was restarted after longer break. The discussions included the mandate and workplan of the group as well as the interaction with other EMA working groups.

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