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

Internet-document

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For further details please contact: GLP authorities

GLP-Newsletter 2020

GLP compliance monitoring programme:

A revised version of the GLP Compliance Monitoring Programme was issued on 11 December 2020. In chapter 5.3.2 Preparation of inspections, the following information was added:
The Swiss GLP Compliance Monitoring Units may also conduct remote inspections – the extent of the remote activities may vary. This is discussed in a pre-inspection meeting with the test facilities.

Interpretation of the Principles of GLP:

The next update of the Swiss Interpretation of the GLP Principles will be published within the next 6 months. The Notification Authority for Chemicals will inform the representatives of the test facilities accordingly.

AGIT (ArbeitsGruppe über InformationsTechnologie):

In September 2020, the members of the AGIT published a new position paper to address the question if a formal validation of spreadsheets used for data processing in a GLP study is in any case mandatory. The document is available on the GLP website (link). This document specifies the AGIT's position and its rationale for the approach without validation. It outlines the GLP requirements as well as a list of elements that should be considered. Currently, the AGIT is discussing the audit trial review.

OECD-GLP Working group meeting from 16.-18.02.2020

The meeting took place in Sendai, Japan, following an invitation from the Japanese society of quality assurance who organized the Global Quality Assurance Conference back-to-back at the same location. The first day was dedicated to the organisation of the next training course for GLP inspectors and technical questions. During the main meeting, Turkey was accepted as member of the system of mutual acceptance of data (MAD). Other countries presented their preparations for becoming adherent to MAD. New guidance documents and questions from industry were discussed. I (Christoph Moor) had the chance to lead the meeting as chair for the second time, which was a great personal experience.

EU-GLP Working group meeting (22-23.01.2020):

The EU-GLP Working group could met just before the pandemic on the 22-23 January 2020 on could happen in a face to face form. For the first time was UK not present due to Brexit as they are now consider as 3rd country and the official collaboration way between EU and UK is from now the OECD. The meeting serves to consolidate opinions for the OECD meeting. Different documents were discussed as the Guidance for receiving authorities and the document about the possible influence of

the sponsor on the conclusions of studies. A Q&A was proposed concerning interim report as no consensus could be found as the acceptance is linked to local legislation. In EU, according to the new European GMO directive, GLP compliance will be required in the EU and the decision's process will be adapted concerning GLP directive in order to fit with the Treaty of Lisbon, allowing the Commission to undertake changes in the directive directly. An interesting initiative was presented by the Nordic countries in order to align theirs practices like for grading findings. Therefor they made a questionnaire that has been now extended to other volunteer countries. As for Switzerland, EU observe a significant reduction of GLP facilities unfortunately.

SPAQA-Meeting

Due to the Covid-19 pandemic, the face-to-face event planned for May 2020 was cancelled. However, the GLP compliance monitoring authority addressed questions raised by test facilities and provided respective answers to the inquiring parties.

Further information:
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