Schweizerische Eidgenossenschaft
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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 2018

GLP compliance monitoring programme:

A revision of the GLP Compliance Monitoring Programme has been started in July 2018. The document includes now the steps to be considered in case a test facility decides to withdraw from the programme voluntarily. Furthermore, references as well as contact information were updated. The revision will only be finalized in February 2019 due to a change of the legal framework. The Notification Authority for Chemicals will inform the test facilities via e-mail.

Interpretation of the Principles of GLP:

The document „Swiss Interpretation of the GLP Principles" has been updated 26 November 2018 (Link).

The withdrawal from the GLP Compliance Monitoring Programme will be described in the revised GLP Compliance Monitoring Programme. Therefore, the actions to be undertaken when a test facility decides it will no longer work according to GLP are not described in the document „Swiss Interpretation of the GLP Principles" (former interpretation 10.9) anymore. The updated Interpretation 10.9 describes a collective amendment procedure for final reports if study-related data for a high number of studies is moved to a different archive location during the 10-year archiving period.

Changes within the GLP compliance monitoring units:

After working more than 25 years in the Federal Office of Public Health, Olivier Depallens retired on November 30, 2018. We thank him for his dedicated contribution to the GLP system in Switzerland and around the world. Surely, we will miss Olivier as a friend, highly committed and with a great ability to explain and discuss GLP and other issues involving chemical regulations. We wish him all the best for his future life, and more time for taking care of grandchildren, travelling, and hiking!

Diana Burkhalter is the new contact person for GLP matters at the common notification authority for chemicals. She already had the role as a deputy. Her email is diana.burkhalter@bag.admin.ch.

AGIT (ArbeitsGruppe über InformationsTechnologie):

AGIT (Arbeitsgruppe Informationstechnologie) is a working group that was founded in 1998 with representatives of the GLP Compliance Monitoring Units and invited experts from industry. Its main objective is to set up guidelines based on legislative requirements and practical experience to support test facilities introducing technology tools to computerized systems in practice. Seven guidelines on computerized systems and one position paper have been issued until 2016. Following the issue of the OECD GLP Advisory Document number 17 in April 2016, the AGIT decided to revise these

documents. The revision work ended in December 2017 and all new versions were made available on the Swiss GLP website on January 31, 2018 [See AGIT under Gute-laborpraxis (GLP)].

In May 2018, the AGIT started to discuss aspects regarding validation of spreadsheets. This discussion will be continued in 2019.

OECD-GLP Working group meeting from 06/03 – 08/03/2018:

The first day started with a meeting of the steering group for the Training Course for GLP Inspectors that will take place in October 2019 in South Africa. In the afternoon, we discussed lessons learnt from on-site evaluation visits, i. e. the mutual visit programme between the countries. During the regular meeting, we discussed the reports of the on-site evaluations of 2017. Several proposals for guidance documents were presented and commented. The advisory document No. 19: “Management, Characterisation and Use of Test Items” was finalized and handed over to the Joint Meeting for declassification. For the next two years, the Swiss inspector Christoph Moor was elected as Chair of the Working Group, Louise Calder from Australia as Vice-Chair.

EU-GLP Working group meeting:

The EU Working Group on GLP met on 24 and 25 January 2018 in Brussels. On the first day, the focus was on technical issues including an update on the comments for the OECD Advisory Document Nr. 19 “Management, Characterisation and Use of Test Items”, which was issued in the meantime (April 2018). Furthermore, the representatives discussed the application of the GLP Principles to in silico analyses and virus clearance studies. On the second day, the EU agencies EMA, EFSA and ECHA reported their activities with regard to GLP. Other relevant agenda items included a discussion regarding the application of GLP to studies with medical devices in context with the updated EU legislation as well as the collaboration of the EU with third countries. An update on Good In Vitro Method Practice (GIVIMP) was also presented.

SPAQA-Meeting from 05/03/2018

The annual GLP Roundtable took place at the SPAQA 2018 Annual Meeting on 5 March 2018.

The GLP Compliance Monitoring Authorities presented the new collaboration between the monitoring units and gave an overview of the AGIT works. Answers to the questions presented by the QA professionals gave rise to interesting discussions. The finalized Q&A document is available on-line (link).