

SPAQA Annual Meeting 2017, 13 March 2017

News from the Monitoring Authorities



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Updates on

- staff
- AGIT activities
- new processes: service provider
- GLP website
- European activities

New inspectors

- In 2016 joined
 - Dr. Tatjana Petkovic (Swissmedic)
 - Dr. Eva Rached (Swissmedic)
 - Dr. Michael Aeschbacher (FOEN)
 - Dr. Martine Bourqui (FOPH)
- Have already participated or will participate in inspections as «observers»

Training for inspectors

Newcomers:

- should have 40 hours of GLP training (studying the relevant GLP documents from OECD and national documents as mentioned in the GLP Compliance Monitoring Programme)
- participate as observers in at least two test facility inspections led by experienced inspectors.

All inspectors:

- on-going training, such as by participation at OECD training courses
- participation as an observer in inspections in OECD member countries can be considered as training opportunity.

Training - goals

- Harmonization
 - Within the monitoring authorities under the same monitoring programm
 - within a GLP CMU

- Discussion/ updates of documents
 - Workshops on GLP interpretations (all)
 - Update of GLP Monitoring Programm

- International activities
 - OECD/EU/EMA Working Group on GLP
 - On site evaluations in other OECD MAD countries

Highlights

- Dr. Christoph Moor
 - 2017-2018 Vice Chair OECD Working Group on GLP
 - 2019-2020 Chair OECD Working Group on GLP

Arbeitsgruppe Informationstechnologie (AGIT)

April 2016

**OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE
MONITORING**

Number 17

Advisory Document of the Working Group on Good Laboratory Practice

Application of GLP Principles to Computerised Systems

Newsletter July 2016

“We do not expect that immediate changes are necessary if a test facility followed so far the recommendations of Swiss interpretations of GLP principles and AGIT guidelines.”

Arbeitsgruppe Informationstechnologie (AGIT)

- Consequences for the AGIT
 - Review and revision of the AGIT documents
 - In line with OECD No. 17
 - Update
 - battery-driven e-books or appropriate portable PCs...
 - Current status
 - Two guidelines have been reviewed and revised
 - Packages of approx. 3 guidelines will be published online
 - Test facility and SPAQA will be informed accordingly (email from Notification Authority)

Service Provider

- Definition: Companies providing services to GLP test facilities or test sites are not considered to be test facilities or test sites and cannot enrol in the GLP Compliance Monitoring Program as such.
- Can obtain a letter of confirmation of GLP compliance from the Notification Authority
- See also GLP Interpretation 0.6
- New process since June 2016

GLP Compliance Monitoring Programm – Update in June 2016

- Service providers are inspected every 2-3 years, whenever possible within the frame of a test facility inspection. Inspections of service providers are planned the same way as inspections of test facilities.
- After completion of the test facility inspection the GLP compliance monitoring unit sends a draft inspection report to the test facility including the findings concerning the service provider.
- The service provider receives a draft letter from the GLP compliance monitoring unit summarizing the inspection results concerning his activities including findings that need to be corrected in order that the compliance can be confirmed.

Process II/II

- The letter is finalized after the inclusion of the comments of the service provider. This letter will then be sent to the service provider (with copy to the NAChem).
- Once the service provider confirmed the corrective actions, the NAChem issues a confirmation of GLP compliance to the service provider and a copy thereof will be sent to the competent GLP compliance monitoring unit.
- The NAChem updates the entry of the service provider in the GLP register and published list.

Published information on website

Service Provider	Last Inspect.	Service provided
Envigo CRS (Switzerland) Ltd. 4414 Füllinsdorf	Jan 2016	archive
PDS Pathology Data System Ltd. 4133 Pratteln	Apr 2014	IT services
Sispace AG 4657 Dulliken	May 2016	archive
ZSH Archives 4414 Füllinsdorf	Jul 2015	archive

Website

- Notification Authority: New web site but with the same content
 - New address:
<https://www.anmeldestelle.admin.ch/chem/en/home/themen/gute-laborpraxis.html>
 - direct link www.glp.admin.ch has been maintained

Updated/ new EU documents

- Updated: Q&A document
- New: GLP Compliance Monitoring of international multi-site studies
- Available on the EC website
(http://ec.europa.eu/growth/sectors/chemicals/good-laboratory-practice_de)

Thank you for your attention.
Any questions?