Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

GLP News

- On site Evaluation Visit
- Update MRA

SPAQA GLP Roundtable
08 December 2014

On site Evaluation Visit

OECD Review of the Swiss GLP Compliance Monitoring Program

Period:
17 – 21 November 2014

Team:
Mrs Elisa Gredilla, ENAC, Spain (team leader)
Mr Masaya Yamamoto, NIHS, Japan

Positive feedback:
Good coordination between 3 monitoring units

Follow up:
The on site evaluation report (not yet available) should be discussed at the next OECD GLP meeting in April 2015

Update MRA

- Agreement between the EU and Switzerland on mutual recognition in relation to conformity assessment (SR 0.946.526.81)
- MRA contains 20 chapters, chapter 18 on Good Laboratory Practice
- Annual revision of the content (in particular legal basis) Basis of MRA: equivalence of legal requirements

Update chapter 18

Concern: List of EU and CH legislative provisions requiring the application of GLP

- COM proposed to list all acts as “equivalent requirement” also where no corresponding Swiss provision.
  Argument: equivalence concerning application of GLP, and OECD MAD
- Addition of new legislative provisions by COM

CH Legislative Provisions

CH provisions concerning:

- **Chemicals**
- **Medical Products**
- **Biocides**
- **Pesticides**

For more details see Swiss GLP Compliance monitoring programme chapter 3.1

EU Legislative Provisions – Food

Regulation (EU) No 234/2011

authorisation procedure for food additives, food enzymes and food flavourings

Article 5(7) on the general provisions on data for risk assessment requires that toxicological studies shall be conducted in facilities which comply with principles of good laboratory practice

New: Regulation (EU) No 503/2013

authorisation of genetically food and feed

- *Toxicological studies should be performed in accordance with GLP*
- *Studies other than toxicological studies, they should be conducted under ISO or GLP standards*

EU Legislative Provisions –Feed

Regulation (EC) No 429/2008
authorisation of feed additives
- (Annex II) *studies shall be performed and documented according to appropriate quality standards (e.g. GLP)*
- *in vivo or in vitro studies are carried out outside the Community shall be conducted under GLP or ISO standards*

EU Legislative Provisions – Chemicals

Regulation (EC) No 1907/2006 [REACH]
Registration of Substances

Regulation (EC) No 1272/2008 [CLP]
Classification and Labelling of substances and mixtures

[Directives 67/548/EEE and 1999/45/EC]

Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of GLP or other international standards recognised as being equivalent by the Commission

EU Legislative Provisions – Medicinal Products

Directive 2001/83/EC (as last amended by 2012/26/EU)
medicinal products for human use
Non-clinical (pharmaco-toxicological) studies shall be carried out in conformity with the provisions related to Good Laboratory Practice.

New: Regulation (EU) No 536/2014
Clinical trials on medicinal products
Non-clinical information submitted in an application dossier shall be based on data derived from studies complying with GLP

EU Legislative Provisions –Veterinary Products

Directive 2001/82/EC (as last amended by 2009/9/EC)
veterinary medicinal products
pharmacological, toxicological, residue and safety tests shall be carried out in conformity with the provisions related to GLP

EU Legislative Provisions – Plant Protection Products (I)

Regulation (EC) No 1107/2009

placing of plant protection products on the market

- *Data protection shall apply to tests concerning active substance, safener or synergist, adjuvants that were certified compliant with GLP*
- *List of tests should indicate which tests are compliant with GLP*

EU Legislative Provisions – Plant Protection Products (II)

Regulation (EU) No 283/2013
data requirement for active substances

Regulation (EU) No 284/2013
data requirements for plant protection products

Tests and analyses shall be conducted in accordance with GLP where testing is done to obtain data on the properties or safety with respect to human or animal health or the environment.

EU Legislative Provisions – Biocidal Products

Regulation (EU) No 528/2012
making available on the market and use of biocidal products

- Ecotoxicological and toxicological tests should be conducted according to GLP or other international standards recognised as being equivalent by the Commission
- Tests on physico-chemical properties and safety-relevant substance data should be performed at least according to international standards

EU Legislative Provisions – Cosmetic products / Detergents

Regulation (EC) No 1223/2009

Cosmetic products

non-clinical safety studies carried out after 30 June 1988 for the purpose of assessing the safety of a cosmetic product shall comply with GLP

Regulation (EC) No 648/2004

Detergents

Tests for the biodegradability of surfactants should be carried out according to ISO 17025 or GLP

GLP can be requested for some tests

Thank you for your attention