

# GLP News

Pirkko Puranen, Senior Inspector

## Background: international GLP framework?

- MAD = Mutual Acceptance of Data
- Non-clinical safety studies performed in one country can be accepted by receiving authorities in other countries, if authorities inspecting test facilities/ studies accept each others inspections
- Saves resources (and decreases number of animal experiments needed)

## International co-work

- Meetings and platforms to discuss about harmonized interpretations between national GLP authorities and to create guidance for facilities and authorities
- Forums for cowork between authorities, facilities and receiving authorities
- Evaluation system to evaluate new applicant countries for MAD agreement (OSE = on-site-evaluations)
- Evaluations to show that members of MAD still fulfil requirements (OSE)
- Training of GLP inspectors to confirm harmonization
- Umbrella organisation for GLP is OECD (Organisation for Economic Co-operation and Development)

## International GLP meetings

- Nordic GLP WG 12.12.2018
- EU GLP WG 23. – 24.1.2019
- OECD GLP WG 5. – 7.3.2019
- OECD GLP Inspectors Training Course 7. – 10.10.2019
- Nordic GLP WG 10.12.2019
- EU GLP WG 22. – 23.1.2020
- OECD GLP WG 17. – 18.2.2020

## Some items discussed recently

## Improving co-work with receiving authorities

- Receiving authorities = authorities assessing safety of chemicals and medicines and granting registrations and marketing authorisations (in Finland Fimea and TUKES, in EU EMA, ECHA, EFSA)
- Better access for receiving authorities to OECD GLP facility data base
- Guidance document for receiving authorities under preparation

## New technologies, how to apply GLP?

- Biological substances, cell lines, GMOs (more guidance in the new Test Item document)
- Nanotechnologies – no need for specific guidance
- QSAR = quality structure-activity relationship models, not testing, can it be done in GLP?

## Risk based approach for inspections

- Inspection frequency defined based on risk assessment
- Risk assessment based on result of the last inspection and the GLP-scope and size of the facility
- No common recommendations or guidance yet



## Out-sourcing GLP inspections

- Possible to outsource inspections in national GLP programme to another (MAD) country

## New documents

- Management, characterisation and use of test item (2018)
- FAQ on [www.oecd.org](http://www.oecd.org)
- Guidance for OSE-evaluators
- No documents for comments at this moment

## In the near future

- OECD GLP OSE (on-site-evaluation) of Fimea in 2021
- Each member country is evaluated once in 10 years
- Team of two OECD GLP WG members (France and Argentina) will evaluate GLP programme of Fimea
- One week: management of GLP programme, national co-work with other authorities, training of inspectors, performing a GLP inspection in practice on-site

## New mailbox of Fimea:

- GLP@fimea.fi

## [www.oecd.org](http://www.oecd.org)

- New published documents
- Documents for public comments
- New member countries in MAD