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SPAQA

Behörden Diskussionsrunde

GLP at EMA – Current and Future Topics

Basel
17 November 2010
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Head of Division Preclinical Review
and GLP Compliance Monitoring Unit
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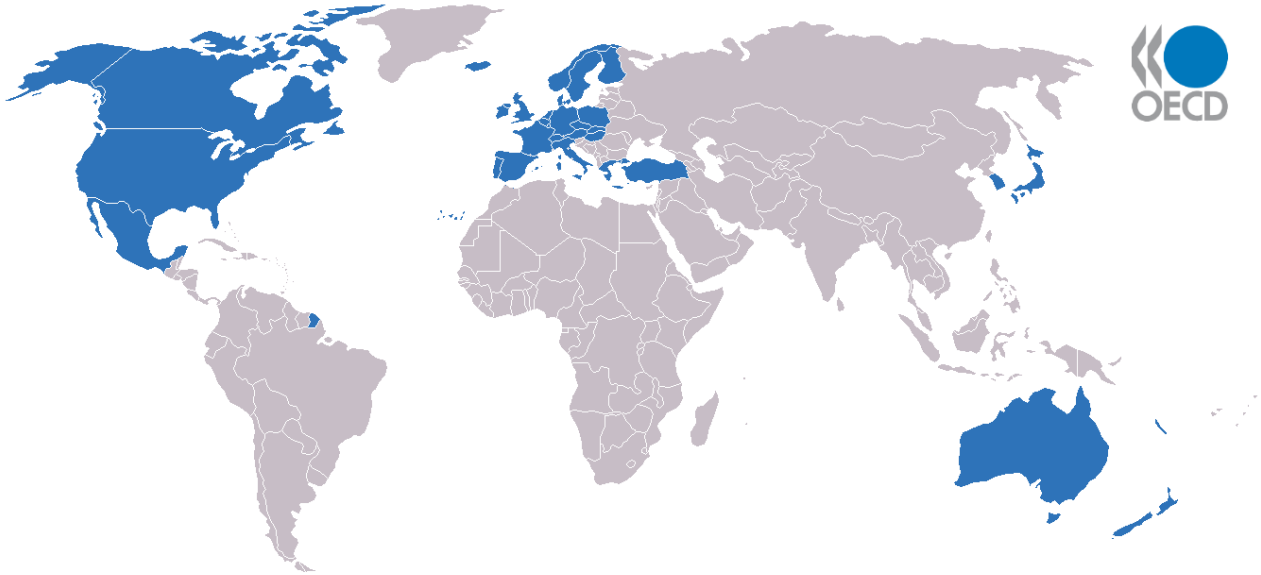
GLP-Global

OECD: Organization for Economic Co-operation and Development
Adherence of Switzerland since 28 September 1961



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GLP-Regional

EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Chemicals, Metals, Forest-based & Textile Industries
Chemicals

Annual GLP Working Group Meetings

Attended by

- The representatives of the GLP monitoring authorities and officials of the Permanent Representations of the European Member States
- Switzerland, Norway, Turkey, Croatia, as well as the representatives of the European Medicines Agency (EMA) and OECD participate as observers.

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GLP-Regional

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

(Ad hoc) GLP Inspectors Working Group at EMA

Attended by

- EMA representatives, and the representatives of the GLP monitoring authorities and officials of the Permanent Representations of the European Member States, and GLP representative from the European Commission
- Switzerland as observer
  - EU: GLP-Mutual Recognition Agreement (MRA) with Switzerland
  - Declaration of Conflicts of Interest with Respect to Items on the Agenda

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Topics (1)

This year‘s meeting: 28 October 2010, EMA London EMEA

- Requesting and reporting GLP inspections for centrally authorised products
- Applicability of GLP
  - EMA Guidelines are developed or revised which include reference to the applicability of GLP
  - a mechanism is required to distribute such Guidelines to Monitoring Authorities for comments.
  - Example: Guideline On Validation Of Bioanalytical Methods:

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Draft Guideline Validation of Bioanalytical Methods

European Medicines Agency

London, 19 November 2009
Doc. Ref: EMEA/CHMP/EWP/192217/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

DRAFT

GUIDELINE ON VALIDATION OF BIOANALYTICAL METHODS

DRAFT AGREED BY THE EFFICACY WORKING PARTY	September 2009
ADOPTION BY CHMP FOR RELEASE FOR CONSULTATION	19 November 2009
END OF CONSULTATION (DEADLINE FOR COMMENTS)	31 May 2010

Comments should be provided using this template to EWPSecretariat@emea.europa.eu

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Draft Guideline Validation of Bioanalytical Methods

SCOPE

- This guideline provides requirements for the validation of bioanalytical methods.
- In addition, specific aspects of the bioanalytical method itself will be addressed, e.g. the actual analysis of samples from toxicokinetic studies and clinical trials.
- Furthermore, this guideline will describe when partial validation or cross validation may represent an appropriate alternative approach to the complete validation of an analytical method.
- Some special techniques such as radio-labelled analysis methods using 14C labelled drugs, are not covered here, but even in such cases efforts should be made to apply to the principles of this guideline.

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Draft Guideline Validation of Bioanalytical Methods

STUDY REPORT

- "The study director should sign and date the final report to indicate acceptance of responsibility for the validity of the data and to indicate the extent to which the study is complies with the principles of good laboratory practice."
- "The validation report should include complete documentation of the protocol, conduct and evaluation of the analysis, in accordance with the principles of GLP-rules and in compliance with EU and ICH guidelines. Information regarding conducted audits/inspection should be included in the report."

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Draft Guideline Validation of Bioanalytical Methods

RESULT

390 pages of comments….

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Draft Guideline Validation of Bioanalytical Methods

- Guideline On Validation Of Bioanalytical Methods not expected before next April
  - Still extensive discussions on inclusions of comments
  - authorities comments not yet included

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Topics (2)

- Certification of Quality and non-clinical data for small and medium sized enterprises developing cell advanced therapy (CAT) medicinal products.
  - The EMA agreed to co-ordinate further with the CAT secretariat and GLP delegates from Member States.

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Thank you for your attention!