Lääkealan turvallisuus- ja kehittämiskeskus | Säkerhets- och utvecklingscentret för läkemedelsområdet | Finnish Medicines Agency

GCP/GLP -rajapinta bioanalyyttisissä tutkimuksissa

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Guidance

- **GLP säädökset ja ohjeet**
- OECD
- Mutual Acceptance of Data (MAD-sopimus), tiedon vastavuoroinen
- hyväksyntä 1981
- OECD Principles on Good Laboratory Practice
- OECD Consensus Documents
- EU
- Direktiivit 2004/9/EC ja 2004/10/EC
- Suomen kansallinen lainsäädäntö
- EU direktiivien vaatimukset on viety Suomen lainsäädäntöön, ei
- kansallisia lisävaatimuksia
- lääkelaki (395/1987)
- kemikaalilaki (744/1989)

GCP

- ICH guidance to industry
  - Validation of analytical methods: definitions and terminology, June 1995
  - Validation of analytical procedures: methodology, November 1996
- *FDA Guidance for Industry*
  - *Bioanalytical method validation, May 2001*
- EMA Guideline
  - Guideline on Validation of Bioanalytical Methods, 1 Feb 2012
  - Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples, adopted 28 Feb 2012

GCP

- ICH GCP Guideline: (ICH GCP 2.13): ”Systems with procedures that assure the quality of every aspect of the trial should be implemented
- GUIDELINE ON THE INVESTIGATION OF BIOEQUIVALENCE (2010):”The bioanalytical part of bioequivalence trials should be performed in accordance with the principles of GLP.”

Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples, adopted 28 Feb 2012

- Scope:
  - Provide information to laboratories that perform analysis or evaluation of human samples collected as part of clinical trial, to develop and maintain required quality system

- Index f.ex.:
  - Organization
  - Personnel
  - Contracts
  - Trial conduct
  - Patients safety
  - QA….

GCP/GLP compliance

- The validation of bioanalytical methods and the analysis of study samples should be performed in accordance with the principles of Good Laboratory Practice (GLP)
- As human bioanalytical studies fall outside of the scope of GLP the sites conducting the human studies are not required to be monitored as part of a national GLP compliance program
- In addition, for clinical trials in humans the principles of Good Clinical Practice (GCP) should be followed.
    - Declaration of Helsinki