GLP in the European Union - Overview and Role of the Commission and the Member States

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• What is GLP? How has it developed?

• The role of the Member States

• The Role of the European Commission
Good Laboratory Practice - Definition:

- **Quality system** concerned with the organisational process and the conditions under which **non-clinical** health and environmental **safety studies** are planned, performed, monitored, recorded, archived and reported.
GLP – General Objectives:

- promote the **quality and validity of data** generated in the testing of chemicals
- facilitate their **recognition**
- **protection** of human health and the environment
GLP – Detailed Objectives:

• Assurance of quality and validity of test data
• Avoidance of duplicative testing
• Animal welfare
• Time and resource efficiency
• Avoidance of non-tariff barriers to trade
GLP - History:

- **1976**: GLP regulation of FDA on non-clinical laboratory studies
- **1978**: OECD establishes expert group
- **1983**: Recommendation concerning compliance monitoring
- **1987/88**: EU adopts GLP Directives
- **1989**: OECD Council Decision-Recommendation on Compliance
  - Guides for Compliance Monitoring Procedures for GLP
  - Guidance for the Conduct of Laboratory Inspections and Study Audits
- **1995**: REVISED GUIDANCE FOR GLP MONITORING AUTHORITIES FOR COMPLIANCE MONITORING PROCEDURES FOR GOOD LABORATORY PRACTICE (GUIDES) + New expert group on GLP - Principles
- **1997**: Adoption of Revised GLP- Principles
- **1999**: Amendment of EU GLP Directives following OECD
• Directive 2004/10/EC
  • on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of GLP

• Directive 2004/9/EC
  • on the inspection and verification of GLP

• Internal Market

For Chemicals:


– Directive 88/379/EEC (extending testing requirements to all preparations, replaced by Dir. 1999/45/EC)

– Regulation (EEC) 793/93 (risk assessments of existing substances)
GLP in the EC - Legal Framework

• Internal Market

Directives for special chemicals:
  • Medicinal Products (Directive 2001/83/EC amended by 2003/63/EC)
  • Veterinary Medicinal Products (Directive 2001/82/EC)
  • Plant Protection Products (91/414/EEC)
  • Biocides (98/8/EC)
  • Feed Additives (87/153/EEC)
  • Food Additives (89/397/EEC; 93/99/EEC)
  • Cosmetics (76/768/EEC, 93/35/EEC as amended)

• External Trade Implications: Art. 133
GLP: Role of the Member States

Practical implementation of GLP Principles and compliance monitoring:

– adoption of necessary legal measures
– creation of national compliance programmes
– inspections and study audits
– annual reports
Article 3.1 of Directive 2004/10/EC:

Member States shall adopt the measures necessary for verification of compliance with the principles of good laboratory practice. These measures shall include, in particular, inspections and study checks in accordance with the recommendations of the OECD in this area.
GLP: Role of the Member States

- Acceptance of data from other MS

- Co-operation in OECD
GLP in the EU - Practicalities

Role of the Commission inside the EU:

– ensure uniform application of the GLP principles and compliance monitoring in all Member States
– facilitate acceptance of data among MS
What we do to achieve this:

- Regular meetings of Member State experts in the Working Group on Good Laboratory Practice
- Management of lists of inspected laboratories (CIRCA website)
- Build up contacts between receiving authorities and monitoring authorities (e.g. EMEA)
- Specific exercises for confidence building: evaluation visits
The GLP web site

Role of the Commission outside the EU:

– supplement and co-ordinate views of MS in international fora (OECD)
– correct application of MAD Decision between EU and other OECD countries
– acceptance of data through formal agreements on Mutual Recognition (MRA) (Japan, Switzerland, Israel)
OECD:


- Countries can have confidence in the quality and rigour of safety tests
GLP in the EU - Enlargement

Assistance to enlargement candidate countries and new Member States

- Invitation to GLP working group
- Mutual Joint Visits (Poland)
- Twinnings (e.g. Sweden-Poland)
- Acceptance of data through formal Protocols to the Europe Agreements (PECAs):
  - Hungary, Czech Republic
  - Option for Turkey and Croatia
GLP in the EU - Conclusions

• EU has strong interest in effective and correct implementation of GLP in the Member States:
  – Necessity for Internal Market
  – High level of protection of Health and Environment

• Commission and MS have their roles in close co-operation

• GLP is there for you (receiving authorities): make use of it!
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