



European Commission

Directorate-General Enterprise
and Industry

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

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Brussels, 19/1/2006

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Outline

- What is GLP? How has it developed?
- The role of the Member States
- The Role of the European Commission

Good Laboratory Practice - Definition:

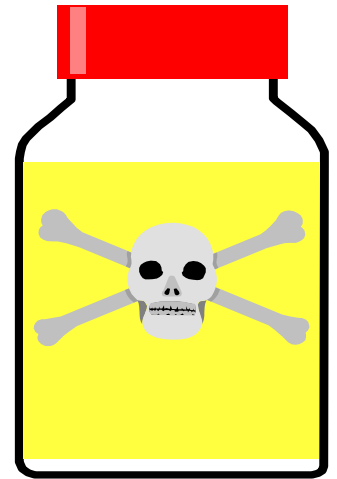
- **Quality system** concerned with the organisational process and the conditions under which **non-clinical** health and environmental **safety studies** are planned, performed, monitored, recorded, archived and reported.

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

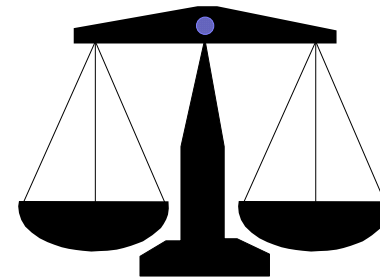


GLP - History:

- **1976 : GLP regulation of FDA on non-clinical laboratory studies**
- 1978 : OECD establishes expert group
- 1981 : OECD Council Decision on Mutual Acceptance of Data (MAD):
GLP-Principles contained in Annex II
- 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**

GLP in the EC - Legal Framework

- **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
- = Codified versions of Directive 87/18 EEC and Directive 88/320/EEC + amendments.



GLP in the EC - Legal Framework

- Internal Market



For Chemicals:

- Directive 67/548/EEC (classification, packaging and labelling of chemical substances)
- 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**

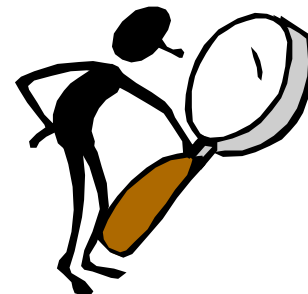
GLP: Role of the Member States

Practical implementation of GLP Principles and compliance monitoring:

- adoption of necessary legal measures
- creation of national compliance programmes
- inspections and study audits
- annual reports

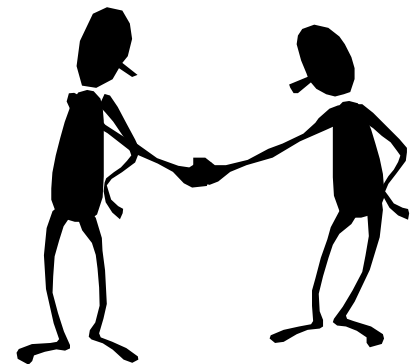
Article 3.1 of Directive 2004/10/EC:

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



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

http://europa.eu.int/comm/enterprise/chemicals/legislation/glp/index_en.htm

The screenshot shows a Microsoft Internet Explorer browser window displaying the EU website for Good Laboratory Practice (GLP). The browser title is "EUROPA - European Commission - Enterprise & Industry - Chemicals - Legislation - GLP - Microsoft I...". The address bar shows the URL: http://europa.eu.int/comm/enterprise/chemicals/legislation/glp/index_en.htm. The website header features the "Enterprise and Industry" logo and a navigation menu: "EUROPA > European Commission > Enterprise & Industry > Chemicals > Legislation > GLP". A search bar and "Contact | Search" link are also present. The main content area is titled "CHEMICALS" and "GOOD LABORATORY PRACTICE". It includes a sidebar with "Chemicals overview" and a main list of links and sections:

- Activities:**
 - Sustainable development
 - Ind. competitiveness
 - Calls for tender
 - Studies
 - Conferences
 - Enlargement
- Legislation:**
 - Market restrictions
 - Dangerous preparations
 - Safety data sheets
 - Good lab practice**
 - Fertilizers
 - Detergents
 - Drug precursors
 - Explosives
 - Derogations
- Information:**
 - REACH
 - Databases
 - Useful links
 - Site map
 - Search

The main content area lists the following sections and links:

- GOOD LABORATORY PRACTICE**
- ▶ [What is GLP?](#)
- ▶ **European legislation**
 - [GLP Directives](#)
 - [Product oriented Directives](#)
 - [Mutual acceptance of data](#)
- ▶ **Contact points**
 - [European Commission](#)
 - [OECD](#)
 - [Associations and federations](#)
 - [National authorities](#)
- ▶ **Practical implementation**
 - [Implementation of the GLP Directives in the European states](#)
 - [Inspected test facilities](#)

The Windows taskbar at the bottom shows the Start button, several open applications (Inbox - Microsoft..., EUROPA - Europ..., Microsoft Power..., Sic Watch - Infor...), and the system clock showing 14:07.


The password-protected CIRCA web site

CIRCA - Communication & Information Resource Centre Administrator - Microsoft Internet Explorer ...

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Library > Top

Abstract:Top library section Contents: 7 Subsection(s) - 0 document(s)

List items containing [] in Any Field [v]

	Title+	Items	Owner	Size	Date	Version	Language
<input type="checkbox"/>	CIRCA Technical Information	5					
<input type="checkbox"/>	GENERAL DOCUMENTS (GEN)	3					
<input type="checkbox"/>	INSPECTED LABORATORIES (LAB)	3					
<input type="checkbox"/>	MEETING DOCUMENTS (MEET)	4					
<input type="checkbox"/>	NOT IN COMPLIANCE NOTIFICATIONS (NICs)	13					
<input type="checkbox"/>	TF Archiving	2					
<input type="checkbox"/>	The GLP Directives	2					

Administration Contact Information User Preferences Comments Technical Support IG Home Page Site Map X © ? >>

Find in this group [] Go

Communication & Information Resource Centre Administrator Local intranet

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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)

GLP in the EU - Foreign Relations

OECD:

- The OECD Principles of GLP are an integral part of the 1981 [Council Decision on the Mutual Acceptance of Data in the Assessment of Chemicals](#) (revised 1997)
- Countries can have confidence in the quality and rigour of safety tests

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 !**



The End

Disclaimer :

This presentation does not constitute any formal commitment on behalf of the European Commission and represents the views and opinions of its author only.