



## **OECD EVENT**

### **Multilateral Symposium between Monitoring Authorities, Regulatory Authorities and Test Facilities on the Implementation of the OECD Principles of Good Laboratory Practice**

***Villa Tuscolana, Frascati (Rome), Italy  
10 – 11 April 2008***

## **Preface**

This symposium aims at providing an open forum where the public sector and the private sector can informally meet and discuss current Good Laboratory Practice (GLP) issues of interest to all partners involved. The event is meant to be the first one of a series of conferences of similar approach to be held regularly.

An overview is given of the degree of implementation of the OECD Principles of GLP in Member and Non-member Countries, promotion of better co-operation among Monitoring Authorities (MAs), Regulatory Authorities (RAs) and Test Facilities (TFs) in respect to Part II of the 1989 Council Decision and the Mutual Acceptance of Data (MAD) and achievement of better understanding and interaction among all partners.

This event is organized by the OECD GLP Working Group (WG) and features the participation of selected representatives of the public sector (MAs, RAs and relevant agencies and scientific institutions such as EMEA), of the private sector (TFs and relevant industrial organisations), as well as of other interested parties.

# Programme

## April 10, Day 1

**08.00 - 09.00 am**

*Registration*

**09.00 am**

*Opening of the Conference and welcome address (S. Caroli, F. Liem, M. Schmahl, D. Turnheim)*

**Session 1. Chairpersons: A. Gray, H. Liddy. The point of view of the OECD and MAs**

**09.30 am**

*Current state of the implementation of the OECD GLP Principles in the OECD Member Countries and Non-member economies in light of the outcome of the 1998 – 2002 Pilot Project of Mutual Joint Visits, D. Turnheim (GLP WG, OECD).*

**10.00 am**

*Quest for harmonisation: differences and similarities in national programmes for GLP monitoring. A senior inspector's viewpoint, Th. Helder (The Netherlands).*

**10.30 am**

*Future issues including broadening the scope of the GLP Principles, F. Liem (EPA, USA)*

**11.00 am**

*Coffee break*

**11.30 am**

*OECD Principles of GLP: what is working and what needs work, C. T. Viswanathan (FDA, USA).*

**12.00 am**

*Complying with different quality systems: GLP Principles and ISO/IEC 17025 accreditation, E. Feller (Israel).*

**12.30 am**

*Critical aspects in implementing the OECD Monograph 14 "The application of the Principles of GLP to in vitro studies", H. Beernaert (Belgium).*

**01.00 pm**

*Lunch break*

**Session 2. Chairpersons: S. Caroli, K. Rautalahti. The point of view of GLP RAs.**

**02.30 pm**

*Relationship between Receiving Authorities and Monitoring Authorities. The EMEA experience, E. Cooke, B. Cuddy (EMEA, EU).*

**03.00 pm**

*Collaboration between Monitoring Authorities, Regulatory Authorities and Test Facilities on GLP Principles provides confidence in data quality and an emphasis on sound science, B. Grim, Th. Steeger (EPA, USA).*

**03.30 pm**

*National GLP programmes and implication of pharmaceuticals, pesticides and other chemicals Regulatory Authorities, N. Nakashima (Japan).*

**04.00 pm**

*General discussion*

**05.00 pm**

*Closure of the first day*

**April 11, Day 2**

**Session 3. Chairpersons: D. Abdon, H.-P. Saxer. The point of view of TFs**

**09.00 am**

*GLP 30 years on: challenges for industry, M. Goodwin (BARQA, UK).*

**09.30 am**

*Implementation of the OECD GLP Principles at Test Facilities in Japan, S. Sakata (Society of Quality Assurance, Japan).*

**10.00 am**

*Risk-based assessment applied to QA GLP audits. How to fulfil regulatory requirements while making the best use of our common sense, knowledge, talents and resources? A. Piton (SoFAQ, France).*

**10.30 am**

*Critical aspects regarding the application of the GLP Principles to new compounds such as biotechnology products, M. Brunetti (GIQAR, Italy).*

**11.00 am**

*Coffee break*

**11.30 am**

*International GLP. Key issues from a Test Facility point of view*, M. Preu, K. Ertz (Bayer CropScience, Germany).

**12.00 am**

*Differences in the interpretation of the GLP Principles by OECD Monitoring Authorities. The point of view from the pharmaceutical industry*, R. Lowing (Sanofi-Aventis).

**12.30 am**

*OECD and US GLP applications*, D. Huntsinger (BASF, USA).

**01.00 pm**

*Role and Responsibilities of Test Facility Management and Sponsor related to studies performed according to the Good Laboratory Practice Principles*, R. Hendriks, W. Coussement (Johnson & Johnson, Janssen Pharmaceutica, Belgium).

**01.30 pm**

*Developments in consultation and training in the GLP arena: 1980 to 2020*, D. Long (France).

**02.00 pm**

Lunch break

**03.30 pm**

**Session 4. Chair and participants: M. Brunetti, S. Caroli, M. B. Goodwin, Th. Helder, F. Liem, A. Piton, K. Rautalahti, S. Sakata, M. Schmahl, D. Turnheim. Round Table The GLP Principles and current needs. What next?**

**05.00 pm**

*Closure of the second day and of the Conference.*