



# INTERNATIONAL SYMPOSIUM ON PHARMACEUTICAL REFERENCE STANDARDS

Symposium organised by the  
European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe

**9-10 October 2008, Strasbourg, France**

Duration: 2 days, Working language: English

## PROGRAMME

Registration: 8h00 onwards

**Thursday 9<sup>th</sup> October 2008**

*8h45 - 9h00*     **Welcome address**  
**Dr Susanne Keitel**, Director, EDQM/Council of Europe

### SESSION 1

#### Pharmacopoeial Reference Standards

**Moderator: Prof. Henk J. De Jong**, Chair of the European Pharmacopoeia Commission

*9h00 - 9h30*     **Definitions and guidelines**  
**Prof. John Miller**, Head of the Laboratory Dept, EDQM/Council of Europe

*9h30 - 10h00*     **The United States Pharmacopeia (USP) Reference Standards Programme**  
**Dr William F. Koch**, Chief Metrology Officer for the USP

*10h00 - 10h30*     **The Japanese Pharmacopoeia (JP) Reference Standards Programme**  
**Dr Shigeo Kojima**, Pharmaceuticals and Medical Devices Agency (PMDA), JP

*10h30 - 11h00*     **Coffee Break**

*11h00 - 11h45*     **The European Pharmacopoeia Reference Standards Programme**

- **Chemical Reference Standards**
- **Biological Reference Standards**

**Dr Ulrich Rose**, Scientific Officer, Laboratory Dept, EDQM/Council of Europe

*11h45 - 12h15*     **Discussion with the panel of speakers**

*12h30 - 14h00*     **Lunch**



## **SESSION 2a: WORKSHOP I**

### **Chemical and Herbal Reference Standards**

#### **Moderators:**

**Prof. Dr Jos Hoogmartens**, Member of the Ph. Eur. Commission and Chair of Group of Experts n° 7 on Antibiotics **and**  
**Dr Ulrich Rose**, Scientific Officer, Laboratory Dept, EDQM/Council of Europe

- 14h00 - 14h30 Certified reference materials: a possible approach for Pharmacopoeias and pharmaceutical industry?**  
**Dr Steve Wood**, LGC Limited (UK)
- 14h30 - 15h00 Non-compendial applications of standards - Needs and expectations from the industry**  
**Dr Hanno Binder**, Sandoz GmbH (A)
- 15h00 - 15h30 New technologies in characterisation**  
**Prof. Markus Veit**, International Drug Regulatory Affairs Services (D)
- 15h30 - 16h00 Coffee Break**
- 16h00 - 16h30 Standards for herbal drugs and preparations**  
**Dr Keith Helliwell**, William Ransom Son PLC (UK)
- 16h30 - 17h00 Standards for impurities**  
**Dr Andrea Lodi**, Deputy Head of the Laboratory Dept, EDQM/Council of Europe
- 17h00 - 17h30 Discussion with the panel of speakers**

## **SESSION 2b: WORKSHOP II**

### **Biological Reference Standards**

#### **Moderators:**

**Dr Maria Sol Ruiz**, Vice-Chair BWP/CHMP/EMA **and**  
**Dr Karl-Heinz Buchheit**, Deputy Head, Dept Biological Standardisation,  
OMCL Network & HealthCare

- 14h00 - 14h30 International Reference Standards**  
**Dr David Wood**, WHO Family and Community Health
- 14h30 - 15h00 Needs and expectations for Biological Reference Standards - Viewpoint from the industry**  
**Dr Sylvie Uhlrich**, Sanofi Pasteur (F)
- 15h00 - 15h30 Qualification of protein reference standards**  
**Mrs Anne Munk Jespersen**, Novo Nordisk (DK)
- 15h30 - 16h00 Coffee Break**
- 16h00 - 16h30 International units or milligrams for well-characterised biologicals**  
**Dr Adrian Bristow**, National Institute for Biological Standards and Control (UK)
- 16h30 - 17h00 Place of standards in the context of biosimilars**  
**Dr Martin Schiestl**, Sandoz GmbH (A)
- 17h00 - 17h30 Discussion with the panel of speakers**



**Friday 10<sup>th</sup> October 2008**

**SESSION 3: Perspectives from the regulators & industry**

**Moderator: Dr Susanne Keitel**, Director, EDQM/Council of Europe

- 8h30 - 9h30 A Regulator's Viewpoint & Expectations**
- **European Union: Dr Jean-Louis Robert**, Joint CHMP/CVMP Quality Working Party (QWP, EMEA)
  - **The Russian Federation: Prof. Dr Valeria L. Bagirova**, Scientific Center for Expertise of Medical Products (ZRU)
- 9h30 - 10h00 A Regulator's Viewpoint – Audits and GMP-Inspections, Reference material**  
**Dr Matthias Heuermann**, Landesinstitut für Gesundheit und Arbeit NRW (D)
- 10h00 - 10h20 Characterisation of primary reference standards**  
**Dr Christian Kulinna**, Boehringer Ingelheim Pharma GmbH & Co (D)
- 10h20 - 10h40 Establishment and use of secondary standards**  
**Dr Mark Bradley**, Novartis Pharma AG (CH)
- 10h40 - 11h10 Coffee Break**
- 11h10 - 11h40 Reference standards quality system**  
**Dr Matthew Borer**, Eli Lilly and Company (USA)
- 11h40 - 12h10 Generic industry viewpoint**  
**Dr Antony Raj Gomes**, Shasun Chemicals and Drugs Ltd (India)
- 12h10 - 12h40 Discussion with the panel of speakers**
- 12h40 - 14h00 Lunch**

**CLOSING SESSION**

**Moderators:**

**Prof. John Miller**, Head of the Laboratory Dept, EDQM/Council of Europe **and**  
**Mr Jean-Marc Spieser**, Head of Department of Biological Standardisation, OMCL Network & HealthCare,  
EDQM/Council of Europe

- 14h00 - 14h15 Conclusions – Chemical and herbal reference standards workshop**  
**Prof. Dr Jos Hoogmartens**, Member of the Ph. Eur. Commission and Chair of Group of experts n° 7 on Antibiotics
- 14h15 - 14h30 Conclusions - Biological reference standards workshop**  
**Dr Maria Sol Ruiz**, Vice-Chair BWP/CHMP/EMEA
- 14h30 - 15h30 Round Table Discussion -**  
*With the participation of:* **Prof. Henk J. De Jong**, Chair of the European Pharmacopoeia Commission; **Dr Erling Ehrin**, WHO Collaborating Centre for Chemical Reference Substances; **Dr Susanne Keitel**, Director, EDQM/Council of Europe; **Mrs Suzette Kox**, European Generic Medicines Association (EGA); **Dr Jean-Louis Robert**, Joint CHMP/CVMP Quality Working Party (QWP, EMEA); **Dr Maria Sol Ruiz**, Vice-Chair BWP/CHMP/EMEA; **Mr Shigeki Tsuda**, Society of Japanese Pharmacopoeia; **Dr Sylvie Uhlrich**, Representative from the Industry (EVM-EFPIA); **Dr David Wood**, WHO Family and Community Health
- 15h30 - 15h45 Closing remarks**  
**Dr Susanne Keitel**, Director, EDQM/Council of Europe



### **Scientific Programme Committee**

**Dr M. Borer**, Eli Lilly and Company (USA)

**Mr P. Castle**, European Directorate for the Quality of Medicines & HealthCare (EDQM), deceased

**Dr E. Charton**, European Directorate for the Quality of Medicines & HealthCare (EDQM)

**Mr V. Egloff**, European Directorate for the Quality of Medicines & HealthCare (EDQM)

**Dr S. Keitel**, Director, European Directorate for the Quality of Medicines & HealthCare (EDQM)

**Mrs S. Kox**, European Generic Medicines Association (EGA)

**Prof J. Miller**, European Directorate for the Quality of Medicines & HealthCare (EDQM)

**Dr L. Rago**, World Health Organization (WHO)

**Dr J. L. Robert**, Chairman Certification Steering Committee of the EDQM, Joint CHMP/CVMP Quality Working Party (QWP, EMEA)

**Mr J. M. Spieser**, European Directorate for the Quality of Medicines & HealthCare (EDQM)

**Prof. J. H. Trouvin**, Chairman of the Biotechnology working party (BWP)

**Dr M. Wierer**, European Directorate for the Quality of Medicines & HealthCare (EDQM)

**Dr R. Williams**, United States Pharmacopeia (USP)

**Dr D. Wood**, World Health Organization (WHO)

### **Further Information**

For further information, please contact the EDQM Public Relations Division & Documentation:

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Updated programme - Registration form and hotel reservation forms

More information is available on the EDQM website: [www.edqm.eu](http://www.edqm.eu)