

**THE EUROPEAN PHARMACOPOEIA 6<sup>TH</sup> EDITION**

**23-24 May 2007 (Two days)**

**Shanghai Institute for Food & Drug Control**

**PROGRAMME**

**WEDNESDAY 23 MAY 2007**

**9:00-9:15 Opening remarks and general introduction**

*Welcome addresses*

Director Shanghai State Food and Drug Administration

Director of the European Directorate for the Quality of Medicines & HealthCare, EDQM, Council of Europe

**9:15- 9:45** Dr Agnès Artiges, Director of the European Directorate for the Quality of Medicines & HealthCare, EDQM, Council of Europe

*European regulations for medicines: How does the system work? Relationship between EU/EMEA and the EDQM of the Council of Europe. Place and roles of the EDQM and the European Pharmacopoeia. General organisation of the EDQM.*

**9:45-10:10** Dr Yongjian Yang, Head of Chemical Drug Division, State Institute for Food & Drug Control (SIFDC), Shanghai, China

*Role and Missions of the SIFDC*

**10:10-10:30** Dr Claude Coune, Head of Department of Publications and Multimedia, EDQM, Council of Europe

*Elaboration and revision of the European Pharmacopoeia.*

**10:30-11:00 Coffee Break**

**11:00-11:45** Dr Andrea Lodi, Deputy Head of the Laboratory Department, EDQM, Council of Europe

*How to use the European Pharmacopoeia: Understanding the general notices, general chapters, general monographs and monographs on dosage forms. How to use them in practice.*

**11:45-12:15** Open discussion with the speakers

**12:15-13:15 Lunch Break**

**13:15-14:00** Dr Andrea Lodi

*Cases studies of specific monographs (active substances and excipients), use of reference standards*

**14:00-14:45** Dr Andrea Lodi

*How to use the general monograph 'Substances for pharmaceutical use' to control impurities and decision trees for impurities. How to interpret chromatograms and list of impurities.*

**14:45-15:05** Open discussion with the panel of speakers

**15:05-15:25 Coffee Break**

**15:25-16:10** Dr Vincent Egloff, Head of Division Reference Substances & Samples, EDQM, Council of Europe

*Identification of the need and uses of a reference standard. Overview of the policy and process used to establish and distribute a reference standard*

**16:10-16:35** Open discussion with the panel of speakers

**16:45-17:45** *Questions and answers*

Topics covered: General questions on the EDQM, the European regulatory framework and harmonisation; Technical questions on PhEur monographs and texts; Publications and services; Reference standards; Electronic version of the European Pharmacopoeia

**THURSDAY 24 MAY 2007**

**8:30-9:00** Dr Agnès Artiges

*Pharmacopoeias and international harmonisation process*

**9:00-10:00** Dr Claude Coune

*The European Pharmacopoeia Publications (printed and electronic publications)*

**10:00-10:15** Open discussion with the speakers

10:15-10:35 Coffee break

**10:35-11:05** Mrs Caroline Larsen Le Tarnec, Public Relations Unit, EDQM, Council of Europe  
*EDQM Internet sites: How to make the best use of the online services, specialised databases and the new users' support: the HELPDESK.*

**11:05-12:35** Ms Corinne Pouget, Head of the Certification Division and Mrs Pascale Poukens-Renwart, Scientific Officer, Certification Division, EDQM, Council of Europe  
*Certification of suitability to the European Pharmacopoeia monograph: Methodology, process to obtain a certificate. Common Deficiencies*

**12:35-13:30 Lunch break**

**13:30-15:00** Ms Corinne Pouget and Mrs Pascale Poukens-Renwart  
*Variations, revisions, updates and renewals to certificates*  
*Certification of suitability Programme of inspections: why it was established, who is involved and how it works.*  
*Technical advice: how to obtain advice and the benefits of exchanging information*

**15:00-15:30** Chinese experience (to be confirmed)

**15:30-16:00** Open discussion with the panel of speakers

**16:00 Final addresses and Closure of the meeting**

**16:15-17:15** *Questions and answers*

**Topics covered:** General questions on the EDQM, the European regulatory framework and harmonisation;  
Technical questions on PhEur monographs and texts; Publications and services; Reference standards;  
Electronic version of the European Pharmacopoeia

**CERTIFICATION ONE TO ONE CONSULTATIONS (20 minutes maximum)**

**Wednesday 23 May 2007: starting from 9:45 to 12:15 and 13:15 to 17:45**

**Thursday 24 May 2007: Starting from 16:15 to 17:15**

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