

## **THE 5<sup>th</sup> EDITION EUROPEAN PHARMACOPOEIA SYMPOSIUM**

Hall W2, Meeting Room M9, SNIEC, Shanghai, China

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### **SYMPOSIUM PROGRAMME**

**TUESDAY 27 JUNE 2006**

Opening remarks and general introduction

#### **SESSION I: THE EUROPEAN PHARMACOPOEIA**

##### **THE EUROPEAN PHARMACOPOEIA – GENERAL CONCEPTS**

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

**14:00 - 14:15** Dr Claude Coune, Head of the Department for Publications & Multimedia, European Directorate for the Quality of Medicines (EDQM), Council of Europe

##### **SPECIFIC MONOGRAPHS – A DETAILED ANALYSIS**

*Useful cases studies of specific monographs (active substances and excipients). Use of reference standards. How to use the general monograph 'Substances for pharmaceutical use' to control impurities and decision trees for impurities.*

**14:15 - 14:35** Dr Claude Coune

##### **AN OVERVIEW OF EDQM PUBLICATIONS AND ONLINE SERVICES**

*The European Pharmacopoeia publications (printed and electronic publications): 5<sup>th</sup> Edition European Pharmacopoeia and its supplements, Pharmeuropa, PharmeuropaBio, Standard Terms.*

*How to make the best use of the online services, specialised databases and the new users' support: the HELPDESK*

**14:35 - 15:00** Mrs Caroline Larsen Le-Tarnec, Head of the Public Relations Unit & Documentation, European Directorate for the Quality of Medicines (EDQM), Council of Europe

#### **SESSION II: THE CERTIFICATION PROCEDURE**

##### **THE CERTIFICATION OF SUITABILITY TO THE EUROPEAN PHARMACOPOEIA MONOGRAPH (CEP)**

- Overview of the Certification procedure
- How to obtain a certificate: avoid the most common deficiencies found in the application dossiers
- CEP and follow up: revision and renewals
- Programme of inspections
- Technical advice: how to obtain advice and the benefits of exchanging information

**15:00 - 16:00** Dr Corinne Pouget, Head of the Division for Certification of Substances, European Directorate for the Quality of Medicines (EDQM), Council of Europe

Final addresses and Closure of the meeting

**Do not forget to visit the EDQM stand during your visit to CPhI: 1G04**

You will be able to meet 'one-to-one' with EDQM staff and pick up brochures and more information on our activities and publications.

For more information about the EDQM, visit the website: <http://www.pheur.org>