PROGRAMME: TRAINING SESSION 6TH EDITION
11-12 December 2008 – Location: Local Government House, London SW1P 3HZ, UK

European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

2008 TRAINING SESSION: LONDON
THE EUROPEAN PHARMACOPOEIA 6TH EDITION: WHAT'S NEW, WHAT TO EXPECT & HOW TO PREPARE
(FOCUS ON CHEMICAL PRODUCTS)

Duration: 1,5 days, Location: Local Government House, Smith Square, London SW1P 3HZ, UK
Working language: English

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PROGRAMME

THURSDAY 11 DECEMBER 2008
8:00-9:00 Registration and Welcome Coffee
9:00-9:15 Opening remarks and general introduction

9:15-9:45 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.
Dr Andrea Lodi, Deputy Head of the Laboratory Department, EDQM, Council of Europe

9:45-10:15 General concepts in the European Pharmacopoeia: theory and rationale
Dr Michael Wierer, Deputy Head, European Pharmacopoeia Department, EDQM, Council of Europe

10:15-10:45 Coffee break

10:45-11:15 Specific monographs: a guide through the different sections
Dr Michael Wierer, Deputy Head, European Pharmacopoeia Department, EDQM, Council of Europe

11:15-11:45 How to use the general monograph 'Substances for pharmaceutical use' and decision trees for impurities. How to interpret chromatograms and list of impurities.
Dr Michael Wierer, Deputy Head, European Pharmacopoeia Department, EDQM, Council of Europe
11:45-12:00 Open discussion with the panel of speakers
12:00-13:30 Lunch break

13:30-14:00 How to participate in the elaboration of the European Pharmacopoeia
Mr Christopher Jarvis, Publications and Multimedia Department, EDQM, Council of Europe

14:00-14:45 Identification of the need and uses of a reference standard. Overview of the policy and process used to establish and distribute a reference standard
Dr Andrea Lodi, Deputy Head of the Laboratory Department, EDQM, Council of Europe

14:45-15:00 Open discussion with the panel of speakers
15:00-15:30 Coffee Break

15:30-16:15 The European Pharmacopoeia Publications (printed and electronic publications)
Mr Christopher Jarvis, Publications and Multimedia Department, EDQM, Council of Europe

16:15-16:45 EDQM Internet sites: How to make the best use of the online services, specialised databases and the new users' support: the HELPDESK
Mrs Fiona Gilchrist, Deputy Head of Public Relations and Documentation Division, EDQM, Council of Europe

16:45-17:45 Questions and answers
Topics covered: General questions on the EDQM & the European regulatory framework; Technical questions on PhEur monographs and texts including harmonisation ; Publications and services ; Internet site

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FRIDAY 12 DECEMBER 2008 (MORNING ONLY)

8:00-8:30 Welcome Coffee

8:30-9:00 International Harmonisation of Pharmacopoeial monographs
Dr Michael Wierer, Deputy Head, European Pharmacopoeia Department, EDQM, Council of Europe

9:00-9:45 Certification of suitability to the European Pharmacopoeia monograph: Methodology, process to obtain a certificate.
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
Ms Fiona McLeod, Scientific Administrator, Certification of Substances Division, EDQM, Council of Europe

9:45-10:15 Coffee Break

10:15-11:00 Common Deficiencies
Dr Declan Byrne, Scientific Administrator, Certification of Substances Division, EDQM, Council of Europe

11:00-11:30 Variations, revisions, updates and renewals to certificates
Ms Fiona McLeod, Scientific Administrator, Certification of Substances Division, EDQM, Council of Europe
Questions and answers

11:30 Final addresses and Closure of the meeting

11:30-12:30 Questions and answers
Topics covered: General questions on the EDQM & the European regulatory framework; Technical questions on PhEur monographs and texts including harmonisation ; Internet sites ; Certification

FOR REGISTRATION OR MORE INFORMATION PLEASE VISIT THE WEBSITE: www.edqm.eu