2017 TRAINING SESSION: STRASBOURG
EUROPEAN PHARMACOPOEIA TRAINING SESSION - CHEMICALS
11-12 JULY 2017, STRASBOURG, FRANCE

PROGRAMME

TUESDAY, 11 JULY 2017

8:15-9:00  Registration

9:00-9:05  Opening & Welcome address
Dr Pierre Leveau, Head of the Quality, Safety & Environment Division, EDQM, Council of Europe

9:05-9:45  European regulations for medicines: Place and role of the EDQM and the European Pharmacopoeia
Dr Pierre Leveau, Head of the Quality, Safety & Environment Division, EDQM, Council of Europe

9:45-10:30  General concepts in the European Pharmacopoeia: theory and rationale
Mrs Isabelle Mercier, European Pharmacopoeia Dept., EDQM, Council of Europe

10:30-11:00  Coffee break

11:00-11:30  Specific monographs: a guide through the different sections
Mrs Sylvina Iossiphova, European Pharmacopoeia Dept., EDQM, Council of Europe

11:30-12:00  How to use the general monograph 'Substances for pharmaceutical use' and decision trees for impurities.
Dr Ulrich Rose, Head of Division A, European Pharmacopoeia Dept., EDQM, Council of Europe

12:00-13:00  Workshop and Discussion: How to interpret the tests for related substances including open discussions
Dr Ulrich Rose

13:00-14:15  Lunch break

14:15-14:40  How to participate in the elaboration of the European Pharmacopoeia
Ms Aurélie Barth, European Pharmacopoeia Dept., EDQM, Council of Europe

14:40-15:30  European Pharmacopoeia Reference Standards: Overview of the policy and process used to establish and distribute a reference standard
Dr Stefan Almeling, Deputy Head of the Laboratory Department, EDQM, Council of Europe

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

16:00-16:30  Coffee break

16:30-17:00  General presentation of the Certification Procedure
The place of Certification as a regulatory tool
Comparison of CEP and Active Substance Master File
Ms Annick Dégardin, Scientific officer, Certification Department, EDQM, Council of Europe

17:00-17:30  Open discussion
WEDNESDAY 12 JULY 2017 (MORNING)

9:00-10:00  Content of the dossier for a CEP - How to build a successful application
Mr Lennart Seidler, Scientific officer, Certification Department, EDQM, Council of Europe

10:00-10:30  Revisions of CEPs
Dr Andrew McMath, Head of the Revisions section, Certification Department, EDQM, Council of Europe

10:30-10:45  Open discussion with the panel of speakers

10:45-11:15  Coffee break

11:15-11:45  The EDQM inspection programme
Dr Sotirios Paraschos, Inspector, Certification Department, EDQM, Council of Europe

11:45-12:05  Use of a CEP
Dr Pascale Poukens-Renwart, Head of the Scientific Support section, Certification Department, EDQM, Council of Europe

12:05-12:30  Open discussion with the panel of speakers

12:30-13:30  Lunch break