2018 TRAINING SESSION
THE EUROPEAN PHARMACOPOEIA
24-25 MAY 2018, ZAGREB, CROATIA

PROGRAMME

THURSDAY 24 MAY 2018

8:00-9:00 Registration

9:00-9:15 **Opening remarks**
Susanne Keitel, Director of the European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe

Welcome address
Rosanna Stanić, Senior Advisor Specialist, Department for Medicinal Products and Medical Devices, Ministry of Health

9:15-9:35 **National Agency for Medicinal Products and Medical Devices (HALMED): Role at national and European level**
Siniša Tomić, Head of Agency, HALMED

9:35-9:55 **Croatian Pharmacopoeia: tradition, use and development**
Planinka Jakšić, Principal Advisor for Pharmacopoeia, HALMED

9:55-10:30 **EDQM and the European Pharmacopoeia: role in the European Regulatory Network**
Susanne Keitel, Director, EDQM, Council of Europe

10:30-10:45 **Discussion**

10:45-11:15 *Coffee break*

11:15-11:45 **General concepts in the European Pharmacopoeia: theory and rationale**
Cathie Vielle, European Pharmacopoeia Department, EDQM, Council of Europe

11:45-12:15 **Specific monographs: a guide through the different sections**
Ulrich Rose, European Pharmacopoeia Department, EDQM, Council of Europe

12:15-12:45 **Discussion**

12:45-14:00 *Lunch break*

14:00-14:40 **Impurity Control in the European Pharmacopoeia**
Ulrich Rose, European Pharmacopoeia Department, EDQM, Council of Europe

14:40-15:00 **How to participate in the elaboration of the European Pharmacopoeia**
Cathie Vielle, European Pharmacopoeia Department, EDQM, Council of Europe

15:00-15:15 **Discussion**

15:15-15:45 *Coffee break*

15:45-16:45 **European Pharmacopoeia reference standards: Overview of the policy and process used to establish and distribute a reference standard**
Jochen Pauwels, Laboratory Department, EDQM, Council of Europe

16:45-17:00 **Discussion**

17:00 *Close of Day 1*

17:05 *Reception*

FRIDAY 25 MAY 2018 (MORNING)

8:30-9:15 **General presentation of the Certification Procedure**
The place of Certification as a regulatory tool
Comparison of CEP and Active Substance Master File (ASMF)
Pascale Poukens-Renwart, Certification of Suitability Department, EDQM, Council of Europe

9:15-10:15 **Content of the dossier - The Top Deficiencies identified in dossiers**
Nimet Filiz, Certification of Suitability Department, EDQM, Council of Europe

10:15-10:30 **Discussion**

10:30-11:00 *Coffee break*

11:00-11:20 **The EDQM inspection programme**
Pascale Poukens-Renwart, Certification of Suitability Department, EDQM, Council of Europe

11:20-11:50 **Revisions of CEPs**
Nimet Filiz, Certification of Suitability Department, EDQM, Council of Europe

11:50-12:20 **Use of a CEP**
Pascale Poukens-Renwart, Certification of Suitability Department, EDQM, Council of Europe

12:20-12:45 **Discussion**

Close of the meeting