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