EUROPEAN PHARMACOPOEIA WORKSHOP
10-11 SEPTEMBER 2019, ISELIN, NEW JERSEY, USA

PROGRAMME

TUESDAY, 10 SEPTEMBER

07:30-08:30 *Registration & Breakfast Buffet*

08:30-08:35 **Opening & Welcome Address**
Susanne Keitel, Director, EDQM

08:35-09:20 **EDQM and the European Pharmacopoeia: role in the European regulatory network**
Susanne Keitel, Director, EDQM

09:20-10:20 **General Concepts in the European Pharmacopoeia**
Cathie Vielle, Head of the European Pharmacopoeia Department, EDQM

10:20-10:35 **Discussion**

10:35-11:00 *Coffee break*

11:00-11:45 **Specific monographs on substances for pharmaceutical use**
Ulrich Rose, Head of Division A, European Pharmacopoeia Department, EDQM

11:45-12:00 **Use of Reference Standards (RS) in specific monographs (RS for identification and RS for assay)**
Jochen Pauwels, Laboratory Department, EDQM

12:00-12:15 **Discussion**

12:15-13:15 *Lunch break*

13:15-14:15 **Impurity Control in the European Pharmacopoeia**
Ulrich Rose, Head of Division A, European Pharmacopoeia Department, EDQM

14:15-14:30 **Use of RS for impurity control, including RS for system suitability, RS for peak identification and RS for quantification of related substances**
Jochen Pauwels, Laboratory Department, EDQM

14:30-14:45 **Discussion**

14:45-15:15 **Specific Monographs on Finished Products (*containing chemically defined APIs*)**
Ulrich Rose, Head of Division A, European Pharmacopoeia Department, EDQM

15:15-15:25 **Use of RS for Finished Products, focussing on identification, assay, related substances and dissolution test**
Jochen Pauwels, Laboratory Department, EDQM

15:25-15:40 **Discussion**

15:40-16:10 *Coffee break*

16:10-17:10 **Specific Monographs on Biotherapeutic Products**
Mihaela Buda, European Pharmacopoeia Department, EDQM, Council of Europe

17:10-17:25 **Role of RS in monographs for Recombinant Biotherapeutics focussing mainly on peptide mapping and glycan analysis**
Jochen Pauwels, Laboratory Department, EDQM, Council of Europe

17:25-18:00 **Discussion**

18:00 **Networking Reception**

WEDNESDAY, 11 SEPTEMBER

07:30-08:30 *Breakfast Buffet*

08:30-09:30 **General presentation on the Certification of Suitability (CEP) Procedure**
Susanne Keitel, Director, EDQM

09:30-09:45 **Discussion**

09:45-10:15 **Nitrosamine impurities in sartans: the EDQM holistic approach to address the issue**
Susanne Keitel, Director, EDQM

10:15-10:45 *Coffee break*

10:45-11:15 **New and revised Ph. Eur. General Chapters**
Ulrich Rose, Head of Division A, European Pharmacopoeia Department, EDQM

11:15-11:35 **The Ph. Eur. enabling QbD and Continuous Manufacturing**
Cathie Vielle, Head of the European Pharmacopoeia Department, EDQM

11:35-11:50 **Discussion**

11:50-12:20 **How to participate in the Elaboration of the European Pharmacopoeia**
Mihaela Buda, European Pharmacopoeia Department, EDQM

12:20-12:40 **International Harmonisation and Collaboration Initiatives**
Cathie Vielle, Head of the European Pharmacopoeia Department, EDQM

12:40-12:55 **Discussion**

12:55-14:00 *Lunch break*

14:00-14:30 **Find your way in Pharmeuropa - Knowledge database & Ph. Eur. Online: Useful hints and other practicalities**
Pierre Leveau, Head of the Reference Standards and Logistics Department, EDQM

14:30-14:45 **Discussion**

14:45-15:30 **European Pharmacopoeia Reference Standards: Establishment**
Jochen Pauwels, Laboratory Department, EDQM

15:30-15:45 **Discussion**

15:45-16:15 *Coffee break*

16:15-17:15 **European Pharmacopoeia Reference Standards: Handling, dispatch, where to find useful information and other practicalities**

17:15-17:30 **Discussion**

17:30 *End of workshop*