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, focusing 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 focusing 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 Phar meuropa - 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