DRAFT PROGRAMME: TRAINING WEBINARS 7-8 July 2020

EUROPEAN PHARMACOPOEIA TRAINING WEBINARS
7-8 JULY 2020

PROGRAMME

Tuesday, 7 July 2020
Morning Session: General Concepts & Methods
(Webinar 1 for remote participation)

9:00-9:10 **Opening & Welcome address**
Susanne Keitel, EDQM, Council of Europe

9:10-9:50 **European regulations for medicines: Place and role of the EDQM and the European Pharmacopoeia (Ph. Eur.)**
Susanne Keitel, EDQM, Council of Europe

9:50-10:25 **General concepts in the European Pharmacopoeia**
Ulrich Rose, European Pharmacopoeia Department, EDQM, Council of Europe

10:25-10:40 **Q&A Session**

10:40-10:55 ***Pause in the presentations - Break***

10:55-11:15 **General methods: Concrete examples**
Bruno Spieldenner, European Pharmacopoeia Department, EDQM, Council of Europe

11:15-11:30 **Q&A Session**

11:30 Close of the webinar 1

Tuesday, 7 July 2020
Afternoon Session: Ph. Eur. Monographs
(Webinar 2 for remote participation)

14:00-14:45 **Specific monographs on substances for pharmaceutical use and on Finished Products (containing chemically defined APIs)**
Sylvina Iossiphova and Aurelie Barth, European Pharmacopoeia Department, EDQM, Council of Europe

14:45-15:00 **Q&A Session**

15:00-15:45 **Impurity Control in the European Pharmacopoeia: Theory and practical examples**
Ulrich Rose, European Pharmacopoeia Department, EDQM, Council of Europe

15:45-16:00 **Q&A Session**

16:00-16:15 ***Pause in the presentations - Break***

16:15-16:45 **How to participate in the Elaboration of the European Pharmacopoeia**
Isabelle Mercier, European Pharmacopoeia Department, EDQM, Council of Europe

16:45-17:00 **Q&A Session**

17:00 Close of the webinar 2

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Wednesday, 8 July 2020
Morning Session: Ph. Eur. Reference Standards & Databases
(Webinar 3 for remote participation)

09:00-09:35 **European Pharmacopoeia Reference Standards: Establishment and use of Ph. Eur. Reference standards**
Bart Blanchaert, Laboratory Department, EDQM, Council of Europe

09:35-10:05 **European Pharmacopoeia reference standards: Handling, dispatch, where to find useful information and other practicalities**
Pierre Leveau, Reference Standards and Logistics Department, EDQM, Council of Europe

10:05-10:30 **Q&A Session**

10:30-10:45 ***Pause in the presentations - Break***

10:45-11:15 **Find your way in Pharmeuropa, the Knowledge database & Ph. Eur. Online: Useful hints and other practicalities**
Christopher Jarvis, IT & Publications Division, EDQM, Council of Europe

11:15-11:30 **Q&A Session**

11:30 Close of the webinar 3

Afternoon Session: Certificate of Suitability (CEP) Procedure
(Webinar 4 for remote participation)

13:30-14:15 **General presentation of the Certification of Suitability (CEP) Procedure**
Annick Degardin, Certification of Suitability Department, EDQM, Council of Europe

14:15-15:00 **How to build a successful CEP application and avoid frequent deficiencies**
Rita Almeida, Certification of Suitability Department, EDQM, Council of Europe

15:00-15:15 **Q&A Session**

15:15-15:30 ***Pause in the presentations - Break***

15:30-16:05 **Revisions and renewal of CEPs: Principles, frequent changes and sister files**
Tiago Goncalves, Certification of Suitability Department, EDQM, Council of Europe

16:05-16:25 **The EDQM inspection programme**
Thomas Hecker, Certification of Suitability Department, EDQM, Council of Europe

16:25-16:55 **Use of a CEP**
Pascale Poukens-Renwart, Certification of Suitability Department, EDQM, Council of Europe

16:55-17:15 **Q&A Session**

17:15 *Close of the webinar 4*