European Pharmacopoeia Training Session

24 October 2023 - Hybrid

Draft programme

(subject to change)

08:00-08:30 | Registration

08:30-08:45 | Opening & Welcome Address

Cathie Vielle, EDQM, Council of Europe

Speaker to be confirmed, New Jersey Pharmaceutical Quality Control Association (NJPQCA)

08:45-09:30 | EDQM and the European Pharmacopoeia (Ph. Eur.): role in the European regulatory network

Cathie Vielle, EDQM, Council of Europe

09:30-10:15 | Working principles of the Ph. Eur., working parties, procedures

Mihaela Buda, EDQM, Council of Europe

10:15-10:30 | Discussion

10:30-11:00 | *Coffee break*

11:00-11:30 | International Cooperation Initiatives

Dirk Leutner, EDQM, Council of Europe

11:30-12:30 | Structure & General Concepts of Ph. Eur.: General Notices; General Monographs; Monographs; General Chapters; the Knowledge database

Bruno Spieldenner, EDQM, Council of Europe

12:30-12:45 | Discussion

12:45-13:45 | *Lunch break*

13:45-15:15 | Substances monographs, medicinal product monographs and biotherapeutic texts

- Substances monographs & Medicinal product monographs: Aurelie Barth, EDQM, Council of Europe

- Biotherapeutic texts: Mihaela Buda, EDQM, Council of Europe

15:15-15:45 | *Coffee break*

15:45-16:05 | How to participate in the elaboration of the European Pharmacopoeia

Cathie Vielle, EDQM, Council of Europe

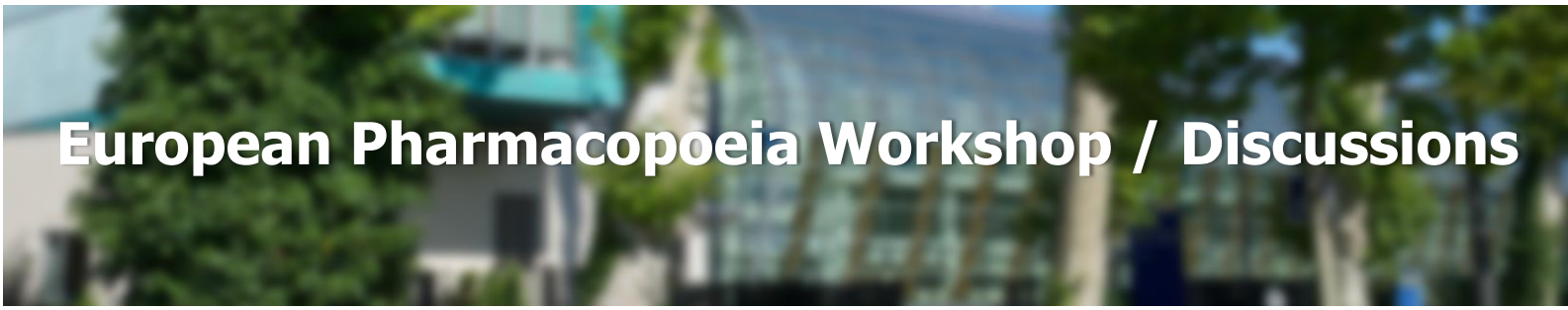
16:05-16:50 | Ph. Eur. Online Licenses: Structure Overview; Tips/Tricks; Communicating updates: Pharmeuropa Online vs EDQM website vs Ph. Eur. Online

Evangelos Tasopoulos, EDQM, Council of Europe

Bruno Spieldenner, EDQM, Council of Europe

16:50-17:20 | Discussion

17:20 | Close of the training day



25 October 2023 - In person only

Draft programme

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Moderator: Cathie Vielle, EDQM, Council of Europe

08:30-09:30 | Flexibility in the Ph. Eur.: Concepts related to analytical procedures (validation, implementation, comparability of alternative procedures)

- Bruno Spieldenner, EDQM, Council of Europe
- Mihaela Buda, EDQM, Council of Europe

09:30-10:15 | Analytical Quality by Design (AQbD) in the Ph. Eur.: challenges and opportunities / Continuous manufacturing: what we have done, what we need to do

- Mihaela Buda, EDQM, Council of Europe
- Bruno Spieldenner, EDQM, Council of Europe
- Dirk Leutner, EDQM, Council of Europe

10:15-10:45 | *Coffee break*

10:45-11:15 | Challenges related to the control of impurities in complex APIs and excipients

- Bruno Spieldenner, EDQM, Council of Europe
- Dirk Leutner, EDQM, Council of Europe
- Matthieu Antoni, EDQM, Council of Europe

11:15-11:45 | Genotoxic impurities, nitrosamines and individual monographs

- Bruno Spieldenner, EDQM, Council of Europe
- Aurelie Barth, EDQM, Council of Europe

11:45-12:15 | mRNA vaccines, ATMPs, mAb performance standards, new technologies

Mihaela Buda, EDQM, Council of Europe

12:15-13:15 | *Lunch break*

13:15-13:45 | Phasing out the rabbit pyrogen test: vision on potential global strategy

Mihaela Buda, EDQM, Council of Europe

13:45-15:00 | Communication channels: how to improve, unmet needs

Evangelos Tasopoulos, EDQM, Council of Europe

15:00-15:15 | Closing remarks

Petra Doerr, Director, EDQM, Council of Europe
Speaker to be confirmed, New Jersey Pharmaceutical Quality Control Association (NJPQCA)

15:15 | Close of the event