Collaboration, Innovation and Scientific Excellence: the European Pharmacopoeia 11th Edition

International Conference

19-21 September 2022

Strasbourg, France

PROGRAMME

Organised by the
European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe
on the occasion of the launch of the
11th Edition European Pharmacopoeia

edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Day 1 - Monday, 19 September 2022

13:30-14:00 **Registration**

OPENING SESSION

14:00-14h10 **Welcome Address**
Bjørn Berge, Deputy Secretary General, Council of Europe

PLENARY SESSION

Moderator: Petra Doerr, EDQM, Council of Europe

14:10-14:15 **Opening Remarks**
Petra Doerr, Director, EDQM, Council of Europe

14:15-14:45 **The impact of the COVID pandemic: a global perspective**
Mariângela Batista Galvão Simão, Assistant Director-General, Access to Medicines and Health Products, World Health Organization (WHO)

14:45-15:10 **Next challenge for Europe: shaping EU medicines legislation**
Sylvain Giraud, Head of Unit, Directorate-General for Health and Food Safety, European Commission

15:10-15:40 **Coffee break**

Moderator: Prof. Torbjörn Arvidsson,
Former Chair of the European Pharmacopoeia Commission

15:40-16:00 **European Pharmacopoeia 11th Edition at a glance**
Cathie Vielle, EDQM, Council of Europe

16:00-16:20 **Collaboration matters: the work of a National Pharmacopoeia Authority**
Tobias Gosdschan, Swissmedic, Switzerland

16:20-16:50 **EDQM pan-European networks: success built on trust, complementarity and mutual benefits**
Petra Doerr, Director, EDQM, Council of Europe

16:50-17:20 **Moderated Panel Discussion**

17:20 **Close of Day 1**

Day 2 - Morning - Tuesday, 20 September 2022

08:00-08:30 Welcome

FEATURED SESSIONS
08:30-10:30

Four sessions will run in parallel. Interpretation into French will not be provided during the featured sessions.

Session 1A Flexibility in the Ph. Eur.: a paradigm shift? (Part I) Auditorium: Cassin	Session 2 Challenges related to the control of impurities in complex APIs and excipients Room: Londres 1	Session 3 Herbals Room: Madrid 1	Session 4 Pharmacopoeial Harmonisation Room: Amsterdam
Moderator: Prof. Torbjörn Arvidsson, Former Chair of the European Pharmacopoeia Commission	**Moderator**: Eva Nadal, Chair of Ph. Eur. Group of Experts 7	**Moderator**: Salvador Cañigueral, Chair of Ph. Eur. Group of Experts 13B and Chair of the Ph. Eur. Commission	**Moderator**: Cathie Vielle, EDQM, Council of Europe
Flexibility in general texts of the Ph. Eur. Bruno Spieldenner, EDQM, Council of Europe	**Challenges in establishment of reference standards for antibiotics** Heiko Dueckert, EDQM, Council of Europe	**An alternative and simplified approach to identification and test for minimum content of TCM herbal drugs by HPTLC** Eike Reich, CAMAG, Switzerland	**The Future of PDG: expansion of PDG, maintenance of ICH Q4B and further harmonisation activities of the PDG** Yujiro Kameyama, Japanese Pharmacopoeia, PMDA, Japan Dirk Leutner, EDQM, Council of Europe Kevin Moore, USP, USA
Continuous manufacturing and Ph. Eur.: PAT chapter and related topics Øyvind Holte, Chair of the PAT Working Party	**Obstacles faced during development of monographs for antibiotics with complex impurity profiles** Martin Laven, Medical Products Agency, Sweden	**HPLC assays for hydroxyanthracene derivatives replacing photometric assays** Rudolf Bauer, Karl-Franzens-Universität Graz, Institute of Pharmaceutical Sciences, Austria	**WHO perspective as observer to the PDG** Luther Gwaza, WHO
2.2.46: adjustment of chromatographic conditions Anders Karlsson, AstraZeneca, Sweden	**CEPs for complex APIs - assessor's constraints and considerations** Ute Fischer, BfArm, Germany	**Contaminant pyrrolizidine alkaloids** Robert Burman, Chair of the PA Working Party	**Motivation and expectations for harmonisation from the Indian Pharmacopoeia** Rajeev Singh Raghuvanshi, IPC, India
The challenge of N-nitrosamines detection in APIs - Input of chapter 2.5.42 Hervé Rebière, ANSM, France	**Challenges in setting standards for non-biological complexes (NBC) - iron sucrose story** Erik Philipp, CSL Vifor Ltd., Switzerland	**Essential oils** Klaus Reh, Chair of Ph. Eur. Group of Experts 13A	**Perspective of the Chinese Pharmacopoeia** Song Zonghua, Chinese Pharmacopoeia Commission (ChP)
	Expectations and complexity in setting standards for polymeric excipients Johanna Eisele, Evonik Operations GmbH, Germany	**Nitrosamine and herbals: considerations from industry** Barbara Steinhoff, German Medicines Manufacturers' Association (BAH), Germany	**Panel Discussion: Expectations and future challenges for pharmacopoeial harmonisation** Marieke van Dalen, APIC Stephen Corrigan, IFPMA Adrian Bone, IPEC Federation

10:30-11:00 **Coffee break (& Mini training Room: Madrid 1)**

INTERACTIVE SESSIONS

Time	Open Debate	Roundtables		
11:00-11:40	**Procedure 4 (P4)** **Moderator**: Marija Malešević, Chair of the P4 Expert Group **Auditorium: Cassin**	**Table 1: Monographs on biotherapeutic products** **Room: Londres 2** **Table 2: Pyrogenicity** **Room: Madrid 2** **Table 3: Potential presence of *N*-nitrosamines in herbals** **Room: Madrid 2**	**Table 4: Quality & functionality requirements of excipients** **Room: Londres 2** **Table 5: Monographs on medicinal products containing chemically defined APIs** **Room: Bruxelles** **Table 6: General chapters updates & needs** **Room: Madrid 2**	**Table 7: Homeopathy & technical guide** **Room: Rome** **Table 8: European Paediatric Formulary** **Room: Bruxelles** **Table 9: Particulate contamination in parenteral preparations** **Room: Londres 2** **Table 10: Comparability of alternative analytical procedures** **Room: Rome**
11:40-11:50	*Transfer participants*			
11:50-12:30	**3Rs** **Moderator**: Lukas Bruckner, Swiss Delegation of the Ph. Eur. Commission **Auditorium: Cassin**	**Table 1: Monographs on biotherapeutic products** **Room: Londres 2** **Table 2: Pyrogenicity** **Room: Madrid 2** **Table 3: Potential presence of *N*-nitrosamines in herbals** **Room: Madrid 2**	**Table 4: Quality & functionality requirements of excipients** **Room: Londres 2** **Table 5: Monographs on medicinal products containing chemically defined APIs** **Room: Bruxelles** **Table 6: General chapters updates & needs** **Room: Madrid 2**	**Table 7: Homeopathy & technical guide** **Room: Rome** **Table 8: European Paediatric Formulary** **Room: Bruxelles** **Table 9: Particulate contamination in parenteral preparations** **Room: Londres 2** **Table 10: Comparability of alternative analytical procedures** **Room: Rome**

12:30-13:30 **Lunch break**

Day 2 - Afternoon - Tuesday, 20 September 2022

FEATURED SESSIONS

Four sessions will run in parallel. Interpretation into French will not be provided during the featured sessions.

13:30-15:30

Session 1B	Session 5	Session 6	Session 7
Flexibility in the Ph. Eur.: a paradigm shift? (Part II) **Auditorium: Cassin**	**Supporting microbiological and viral safety** **Room: Londres 1**	**Cell and gene therapies** **Room: Madrid 1**	**Certification of Suitability** **Room: Amsterdam**
Moderator: Jaana Vesterinen, FIMEA, Finland **AQbD in the Ph. Eur.** Mihaela Buda, EDQM, Council of Europe **Pharmacopoeial standard development for biotherapeutic products - industry perspective** Erin Wang & Matthew Borer, Eli Lilly and Company, USA **Flexible and robust monographs** Martijn Van der Plas, Medicines Evaluation Board, the Netherlands **An industry perspective incl. AQbD** Cyrille Chery, UCB, Belgium	**Moderator**: Lukas Bruckner, Swiss Delegation Ph. Eur. Commission **Ph. Eur. achievements in the control of extraneous agents for human and vet vaccines** Catherine Lang & Gwenael Cirefice, EDQM, Council of Europe **High Throughput Sequencing: How could the Ph. Eur. helps in the exercise to validate HTS methods?** Siemon Ng, Notch Therapeutics, Canada **European Pharmacopoeia's Pyrogenicity project** Emmanuelle Charton, EDQM, Council of Europe **Impact for pharma industry** Shahjahan Shaid, GSK Vaccines, Belgium	**Moderator**: Marie-Thérese Duffour, ANSM, France **Evolution in regulatory expectations** Violaine Closson-Carella, ANSM, France **Ph. Eur. activities in the cell and gene therapies field** Solène Le Maux & Olga Kolaj-Robin, EDQM, Council of Europe **OMCL point of view** Juergen Scherer, Paul-Ehrlich-Institut, Germany **Case studies** Aline Le Tiec, Novartis, France	**Moderator**: Susanne Keitel, Former EDQM Director, Member of the CEP Steering Committee **Recent updates regarding CEPs** Tiago Goncalves, EDQM, Council of Europe **Nitrosamines in active substances - A quality assessor's point of view** Gernot Hirn, AGES, Austria **"CEP of the Future" Project** Nimet Filiz, EDQM, Council of Europe **The CEP of the Future – API manufacturers' perspective** Marieke van Dalen, APIC, the Netherlands

15:30-16:00 **Coffee break (& Mini training Room: Madrid 1)**

INTERACTIVE SESSIONS

Time	Open Debate	Roundtables		
16:00-16:40	**General Discussion on Communication channels** **Moderator**: Evangelos Tasopoulos, EDQM, Council of Europe **Auditorium: Cassin**	**Table 11: Bioassay** **Room: Madrid 2** **Table 12: Microbiological examination of ATMPs** **Room: Londres 2** **Table 13: Challenge for herbals due to climate change** **Room: Bruxelles**	**Table 14: Data analysis** **Room: Londres 2** **Table 15: DNA reactive impurities: strategy for individual monographs** **Room: Madrid 2** **Table 16: How to use/apply a monograph: tips and tricks** **Room: Londres 2**	**Table 17: Technical guide** **Room: Rome** **Table 18: Elemental impurities in plastic materials** **Room: Madrid 2** **Table 19: Labelling section in dosage form monographs** **Room: Rome** **Table 20: Analytical Quality by Design (AQbD) and monographs** **Room: Bruxelles**
16:40-16:50	*Transfer participants*			
16:50-17:30	**Unmet needs?** **Moderator**: Tobias Gosdschan, Swissmedic, Switzerland **Auditorium: Cassin**	**Table 11: Bioassay** **Room: Madrid 2** **Table 12: Microbiological examination of ATMPs** **Room: Londres 2** **Table 13: Challenge for herbals due to climate change** **Room: Bruxelles**	**Table 14: Data analysis** **Room: Londres 2** **Table 15: DNA reactive impurities: strategy for individual monographs** **Room: Madrid 2** **Table 16: How to use/apply a monograph: tips and tricks** **Room: Londres 2**	**Table 17: Technical guide** **Room: Rome** **Table 18: Elemental impurities in plastic materials** **Room: Madrid 2** **Table 19: Labelling section in dosage form monographs** **Room: Rome** **Table 20: Analytical Quality by Design (AQbD) and monographs** **Room: Bruxelles**

17:30 **Close of Day 2**
19:00 **Official Conference Reception (Villa Sturm)**

08:00–08:30 Welcome

CLOSING PLENARY SESSION

EUROPEAN PHARMACOPOEIA: WHAT TO EXPECT FOR THE FUTURE

Moderator:
Salvador Cañigueral, Chair of the European Pharmacopoeia Commission

08:30-09:40 **Alternatives to Animal Testing (3Rs)**
Ph. Eur. Recent Achievements and Roadmap, Emmanuelle Charton, EDQM, Council of Europe
BSP methods and standards to come, Lukas Bruckner, Swiss Delegation to the Ph. Eur. Commission
Participation in international cooperation platforms/initiatives: WHO - NC3Rs initiatives, Richard Allen Isbrucker, WHO

09:40-10:10 **Towards the 12th Edition of the European Pharmacopoeia: what's in the pipeline?**
An overview of current and future activities, Bruno Spieldenner and Emmanuelle Charton, EDQM, Council of Europe

10:10-10:40 **Coffee break**

10:40-11:35 **Towards the 12th edition of the European Pharmacopoeia: new approaches and technologies in the quality control of medicines: next challenges for the European Pharmacopoeia**
Adapting Ph. Eur. to new approaches and technologies for quality control, Michel Ulmschneider, Chair of the Spectroscopy and Data Analysis (SDA) and General Methods (MG) Working Parties
ICH Q5A (viral safety), High-throughput sequencing (HTS), Laurent Mallet, EDQM, Council of Europe
Activities in the field of nanomedicines, Gerrit Borchard, Chair of the Non-biological Complexes (NBC) Working Party

11:35-11:55 **CEP of the Future and Future of CEPs**
Helene Bruguera, EDQM, Council of Europe

11:55-12:15 **Final Conclusions & Closing Remarks**
Salvador Cañigueral, Chair of the European Pharmacopoeia Commission
Petra Doerr, Director, EDQM, Council of Europe

12:15 **Close of the conference**