EUROPEAN PHARMACOPOEIA: TACKLING FUTURE CHALLENGES OF THE QUALITY OF MEDICINES TOGETHER

International Conference organised by the European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe, on the occasion of the publication of the 9th Edition of the Ph. Eur.
27-28 September 2016, Tallinn, Estonia
Duration: 2 days. Working language: English

PROGRAMME

27 September
8:00-9:00 Registration

OPENING SESSION

9:00-9:30 **Welcome Addresses**
Dr Susanne Keitel, EDQM, Council of Europe
Mr Jevgeni Ossinovski, Estonian Minister of Health and Labour
Dr Kristin Raudsepp, Estonian State Agency of Medicines (Raviviamet)

PLENARY SESSION

The EDQM in the context of the European Regulatory Environment
Moderator: Dr Jean-Louis Robert,
Outgoing Chair of the European Pharmacopoeia Commission

9:30-10:00 **The European Commission, European Union (EU)**
Dr Andrzej Rys, Director Health Systems and Products, European Commission (tbc)

10:00-10:30 **The European Medicines Agency (EMA)**
Dr Guido Rasi, Executive Director, EMA

10:30-11:00 **The Heads of Medicines Agencies (HMA)**
Prof Klaus Cichutek, Paul-Ehrlich-Institute, Federal Institute for Vaccines and Biomedicines, DE, Chair of the HMA Management Group

11:00-11:30 Coffee break

11:30-12:00 **The European Directorate for the Quality of Medicines & HealthCare**
Dr Susanne Keitel, EDQM, Council of Europe

12:00-12:30 **Discussion**

12:30-13:45 Lunch

WORKSHOP SESSIONS

Four workshops will be run in parallel with each session being repeated once, except for the Biotherapeutic Products workshop which consists of two different sessions

WORKSHOPS	SETTING PHARMACOPOEIAL STANDARDS FOR BIOTHERAPEUTIC PRODUCTS	CONTROL OF ELEMENTAL IMPURITIES	NEW TECHNOLOGIES	INTERNATIONAL HARMONISATION
Tuesday, 27 September 2016 (afternoon)				
14:00-17:30	**Bolera 1+2**	**Grande 1+2**	**Grande 3**	**Duetto**
Wednesday, 28 September 2016 (morning)				
9:00-12:30	**Bolera 1+2**	**Grande 1+2**	**Grande 3**	**Duetto**

WORKSHOP: SETTING PHARMACOPOEIAL STANDARDS FOR BIOTHERAPEUTIC PRODUCTS

27 September

Moderator: Mr Peter M. Jongen,
Chair of Ph. Eur. Group of Experts on Biological Substances (Group 6)

- **The Need for Monographs on Biotherapeutic Products**
  Dr Emmanuelle Charton, EDQM, Council of Europe
- **The Ph. Eur. Strategy for Mab /Outcome of the Infliximab Pilot Phase**
  Dr Mihaela Buda, EDQM, Council of Europe
- **Perspective of a European Assessor**
  Dr Brigitte Brake, Federal Institute for Drugs and Medical Devices (BfArM), DE
- **Perspective of an OMCL**
  Dr Jaana Vesterinen, Finnish Medicines Agency Laboratory (FIMEA), FI

  Coffee break

- **Industry's Perspective (1)**
  Mrs Erin Wang, Eli Lilly and Company, USA
- **Industry's Perspective (2)**
  Dr Kowid Ho, F. Hoffmann- La Roche Ltd, CH
- **The United States Pharmacopeia (USP) Strategy on Biotherapeutic Products**
  Dr Jaap Venema, USP

WORKSHOP: SETTING PHARMACOPOEIAL STANDARDS FOR BIOTHERAPEUTIC PRODUCTS

28 September

Moderator: Dr Jaana Vesterinen,
Chair of Ph. Eur. Group of Experts on Raw Materials for the Production of Cellular and Gene Transfer Products

- **Perspective of the World Health Organization (WHO)**
  Dr David Wood, WHO

- **Biological Standards**
  Mr Peter M. Jongen, Chair of Ph. Eur. Group of Experts on Biological Substances (6)

- **Physicochemical Standards**
  Dr Sylvie Jorajuria, EDQM, Council of Europe

- **The United States Pharmacopeia (USP) Policy for Reference Standards**
  Dr Jaap Venema, USP

- **Perspective of the Pharmaceuticals and Medical Devices Agency of Japan (PMDA) on Biotherapeutics**
  Dr Takao Yamori, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

  Coffee break

- **Feedback from Users**
  Panel discussion with: Mr Peter M. Jongen, Dr Emmanuelle Charton, Dr Mihaela Buda, Dr Brigitte Brake, Dr Jaana Vesterinen, Mrs Erin Wang, Dr Kowid Ho and Dr Sylvie Jorajuria.

WORKSHOP: CONTROL OF ELEMENTAL IMPURITIES

27 September afternoon session & 28 September morning session

Moderator: Dr Jean-Louis Robert,
Outgoing Chair of the European Pharmacopoeia Commission

- **Presentation of the ICH Q3D Guideline**
  Dr Mark Schweitzer, Former Chair of the Q3D Expert Working Group, Novartis, USA

- **Impact of the Guideline in Europe**
  Dr Sven-Erik Hillver, Medical Products Agency (MPA), SE

- **Impact of the Guideline on the Certification Procedure**
  Mrs Hélène Bruguera, EDQM, Council of Europe

- **Impact of the Guideline on the Ph. Eur.**
  General Monographs and Chapters:
  Mr Bruno Spieldenner, EDQM, Council of Europe
  Individual Monographs:
  Dr Michael Türck, Chair of Ph. Eur. Working Party on Heavy Metals (HM) and Chair of Group of Experts on Inorganic and Organic Chemistry (9)

- **Impact on the Users: Perspective of a Finished Product Manufacturer**
  Dr Mike J. James, European Federation of Pharmaceutical Industries and Associations (EFPIA), GlaxoSmithKline, UK

Coffee break

- **Impact on the Users: Perspective of an Excipient Manufacturer**
  Dr David R. Schoneker, Colorcon, USA

- **Feedback from Users**
  Panel discussion with the moderator and the speakers.

WORKSHOP: NEW TECHNOLOGIES

27 September afternoon session & 28 September morning session

Moderator: Dr Michael J. Morris,
Chair of Ph. Eur. Group of Experts on Process Analytical Technology (PAT)
and former Chair of the European Pharmacopoeia Commission

- **New and revised General Chapters in the Ph. Eur.**
  Dr Ulrich Rose, EDQM, Council of Europe

- **Chemometrics and chemical imaging**
  Prof Dr Michel Ulmschneider, Chair of the Ph.Eur. Working Party on Vibrational Spectroscopy and Analytical Data Modelling (VSADM)

- **Modern hyphenated techniques in impurity control**
  (tbc)

- **HPTLC for herbal drugs and herbal drug preparations**
  Prof Dr Salvador Canigueral, Chair of Ph. Eur. Group of Experts on Phytochemistry A (13A)

  Coffee break

- **Quality aspects in continuous manufacturing**
  Dr Eric J.M. Meier, QA lead for Continuous Manufacturing, Novartis, CH

- **Feedback from Users**
  Panel discussion with the moderator and the speakers.

WORKSHOP: INTERNATIONAL HARMONISATION

27 September afternoon session & 28 September morning session

Moderator: Prof Henk De Jong,
Chair of Ph. Eur. Working Party on Propellants (HFA Working Party) and
former Chair of the Ph. Eur. Commission

- **Functionality-related Characteristics (FRCs) and co-processed excipients**
  Prof Anne Gayot, Chair of Ph. Eur. Working Party on FRC (FRC Working Party)

- **Update on Harmonisation Initiatives**
  Latest news on Harmonisation of Excipients (Pharmacopoeial Discussion Group)
  Mrs Isabelle Mercier, EDQM, Council of Europe

  The WHO Good Pharmacopoeial Practices (GPhP) Initiative
  Dr Sabine Kopp, World Health Organization (WHO)

- **Packaging materials: current developments**
  Dr Ellen Pel, EDQM, Council of Europe

  Coffee break

- **Water for Injections/Use of Reverse Osmosis**
  Dr Gerard Lee, Chair of Ph. Eur. Working Party on Water for Pharmaceutical Use (WAT Working Party)

- **Feedback from Users**
  Panel discussion with the moderator and the speakers.

Closing remarks

19:00-22:00 Transfer by bus from the Hotel to the Official Dinner

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28 September

9:00-12:30 Workshop Sessions (cont.)

12:30-14:00 Lunch

CLOSING PLENARY SESSION

Moderator: Dr Marianne Ek, MPA, SE
Former Chair of the European Pharmacopoeia Commission & Chair of Ph. Eur. Group of Experts on Organic Chemistry – Synthetic Products B (Group 10B)

14:00-14:30 **Replacement of animal tests in the European Pharmacopoeia**
Dr Karl-Heinz Buchheit, EDQM, Council of Europe

14:30-15:00 **The 9th Edition of the European Pharmacopoeia: Achievements and hot topics**
Mrs Cathie Vielle, EDQM, Council of Europe

15:00-15:30 Coffee break

Moderator: Dr Tobias Gosdschan
Chair elect of the European Pharmacopoeia Commission

15:30-16:30 **Reports from the Workshop Sessions**
Mr Peter M. Jongen, Dr Jaana Vesterinen, Dr Jean-Louis Robert, Dr Michael J. Morris and Prof Henk De Jong.

16:30-16:45 Discussion

16:45-17:00 **Final Conclusions**
Dr Tobias Gosdschan, Chair elect of the European Pharmacopoeia Commission

17:00-17:15 **Closing Remarks**
Dr Susanne Keitel, EDQM, Council of Europe

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