EDQM and European Pharmacopoeia: State-of-the-art Science for Tomorrow’s Medicines

International Conference organised by the European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe,

on the occasion of


19-20 June 2019, Strasbourg, France

DRAFT PROGRAMME
Wednesday, 19 June 2019

Registration

OPENING SESSION

Welcome Addresses

PLENARY SESSION

- European Commission (EC)
- Heads of Medicines Agency (HMA)
- European Directorate for the Quality of Medicines & HealthCare (EDQM), European Pharmacopoeia (Ph. Eur.)

Coffee break and poster session

- Contributions of the European Network of Official Medicines Control Laboratories (OMCL) to the Protection of Public Health
- The Certification of Suitability Procedure - 25 years of a success story
- Panel Discussion

Lunch break

WORKSHOP SESSIONS

Five workshops will run in parallel with each session being repeated once, except for Biotherapeutics, Certification, 3Rs and ATMPs and OMCL Network. French interpretation will not be provided during the workshop sessions.

<table>
<thead>
<tr>
<th>Time &amp; Meeting Place</th>
<th>EDQM Building</th>
<th>Palais de l’Europe Building</th>
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<tr>
<td>14:30-17:30</td>
<td>Impurities</td>
<td>Biotherapeutics</td>
<td>General Methods</td>
<td>Finished Product Monographs</td>
<td>OMCL Network</td>
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WORKSHOP: IMPURITIES
19 June 2019

- Impurity Control in the European Pharmacopoeia (Ph. Eur.)
- Experience of implementation of ICH Q3D within the Certification Procedure (CEPs)
  
  *Coffee break*

- Challenges linked to the Control of Antibiotics

- Control of Impurities: Challenges linked to the Establishment and Procurement of Reference Standards

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

THE NEED FOR MONOGRAPHS ON BIOTHERAPEUTICS
(ACTIVE PHARMACEUTICAL INGREDIENTS AND FINISHED PRODUCTS)
19 June 2019

- Biotherapeutic Products in the Ph. Eur.: have all the challenges been tackled?

- Reference Standards for Biotherapeutic Products
  
  *Coffee break*

- Industry’s Perspective

- Perspective of a Regulatory Authority

- Feedback from Users
  Panel discussion with the moderator and the speakers.
• Chromatographic Separation Techniques and Challenges related to harmonisation

• Feedback on the work of the Ph. Eur. General Methods Working Party

• Reference Standards for Ph. Eur. Chapters

  Coffee break


• Analytical QbD: Industry’s Perspective

• Continuous manufacturing: what impact on the Pharmacopoeia

• Feedback from Users
  Panel discussion with the moderator and the speakers.

WORKSHOP: FINISHED PRODUCT MONOGRAPHS
19 June 2019

• Experiences of The U.S. Pharmacopeial Convention (USP)

• Perspective of a Regulatory Authority

• Perspective of an OMCL

  Coffee break

• Industry’s Perspective

• Experiences of the European Pharmacopoeia (Ph. Eur.)

• Feedback from Users
  Panel discussion with the moderator and the speakers.
WORKSHOP: OMCL NETWORK
19 June 2019

- Official Control Authority Batch Release (OCABR): benefits, challenges and perspectives
- Market Surveillance Studies: OMCL contribution to quality and safety of medicines on the market
- Active Pharmaceutical Ingredient (API) Testing: how OMCLs can support the control of APIs

Coffee break

- The contributions of OMCLs in the fight against Falsified and Illegal Medicines
- Feedback from Users
  Panel discussion with the moderator and the speakers.

Close of the first day - Conference Reception
Thursday, 20 June 2019

WORKSHOP SESSIONS

Four workshops will run in parallel with each session being repeated once, except for Biotherapeutics, Certification, 3Rs and OMCL Network. French interpretation will not be provided during the workshop sessions.

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<tr>
<td>09:00-12:00</td>
<td>Impurities</td>
<td>3Rs &amp; ATMPs</td>
<td>General Methods</td>
<td>Finished Product Monographs</td>
<td>Certification</td>
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WORKSHOP: IMPURITIES
20 June 2019

- Impurity Control in the European Pharmacopoeia (Ph. Eur.)
- Experience of implementation of ICH Q3D within the Certification Procedure (CEPs)

Coffee break

- Challenges linked to the Control of Antibiotics
- Control of Impurities: Challenges linked to the Establishment and Procurement of Reference Standards
- Feedback from Users
  Panel discussion with the moderator and the speakers.

WORKSHOP: THE 3R’s AND ATMPs
20 June 2019

- Achievements of the Biological Standardisation Programme and the Ph. Eur. in the field of the 3Rs
- The 3Rs: perspectives for the future
- Feedback from Users
  Panel discussion with the moderator and the speakers.

Coffee break

- ATMPs: how can Ph. Eur. fulfil its role for tomorrow’s medicines? Viewpoint of an OMCL/Regulator
Viewpoint of Industry

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

WORKSHOP: GENERAL METHODS
20 June 2019

- Chromatographic Separation Techniques and Challenges related to harmonisation
- Feedback on the work of the Ph. Eur. General Methods Working Party
- Reference Standards for Ph. Eur. Chapters
  
  Coffee break

- Feedback on the work of the Ph. Eur. in the field of VSADM Working Party
- Analytical QbD: Industry’s Perspective
- Continuous manufacturing: what impact on the Pharmacopoeia
- Feedback from Users
  Panel discussion with the moderator and the speakers.

WORKSHOP: FINISHED PRODUCT MONOGRAPHS
20 June 2019

- Experiences of The U.S. Pharmacopeial Convention (USP)
- Perspective of a Regulatory Authority
- Perspective of an OMCL
  
  Coffee break

- Industry’s Perspective
- Experiences of the European Pharmacopoeia (Ph. Eur.)
- Feedback from Users
  Panel discussion with the moderator and the speakers.
WORKSHOP: CERTIFICATION
20 June 2019

- EU Active Substance Master File (ASMF) work-sharing: viewpoint of a regulator
- EU Active Substance Master File (ASMF) work-sharing and CEPs: viewpoint of industry
- The International Pharmaceutical Regulators Programme (IPRP) and its Quality Working Group for generics

Coffee break

- What’s new in the Certification of Suitability Procedure
- Update on quality guidelines for the control of active substances
- Feedback from Users
  - Panel discussion with the moderator and the speakers.
CLOSING PLENARY SESSION

- International Developments

- International Pharmacopoeial Harmonisation

Coffee break

- Reports from the Workshop Sessions and Discussions

- Final Conclusions and Closing Remarks

Close of the conference

More information is available [here](#)

Email: prdd@edqm.eu

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