International Conference organised by the European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe
The place of the Certification Procedure in the global regulatory environment
19-20 September 2017

Duration: 1.5 days, Location: NH City Prague, Czech Republic
Working language: English

PROGRAMME
Tuesday, 19 September 2017

8:00-9:00 Registration

9:00-9:10 Opening remarks
Dr Susanne Keitel, Director of the European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe

Welcome Address
Dr Tom Philipp, Deputy Minister for Health Insurance, Ministry of Health, Czech Republic

PLENARY SESSION
Moderator: Dr Jean Louis Robert, Chair of the Certification Steering Committee

9:10-09:30 New developments of the European Pharmacopoeia and their impact on the Certification Procedure
Prof. Torbjörn Arvidsson, Vice Chair of the European Pharmacopoeia Commission

09:30-09:50 Place of the Certification Procedure in 2017 within the European regulatory framework and beyond
Ms Hélène Bruguera, Head of Certification of Substances Department, EDQM, Council of Europe

09:50-10:10 Experience with CEPs from a European regulatory authority perspective
Dr Blanka Hirschlerova, State Institute for Drug Control (SUKL), Czech Republic

10:10-10:30 Experience with CEPs from the perspective of finished products manufacturers
Ms Helen Robbins, Association of the European Self-Medication Industry (AESGP) & Dr Koen Nauwelaerts, Medicines for Europe (former EGA)

10:30-11:00 Coffee break

11:00-11:30 Experience with CEPs from the perspective of API manufacturers
European Chemical Industry Council (Cefic) / Active Pharmaceutical Ingredients Committee (APIC)
Dr Marieke Van Dalen, Cefic/APIC

11:30-11:55 Experience with CEPs from the perspective of Indian manufacturers
Mr Gopal Joshi, Indian Pharmaceutical Alliance (IPA)
11:55-12:20 Experience with CEPs from the perspective of Chinese manufacturers
Ms Hong Xie, Technical expert, Quality Control & Application Committee of China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE)

12:20-12:45 Discussion

12:45-14:00 Lunch break

WORKSHOP SESSIONS
There will be three parallel workshops (1st Session: 14:00-15:30 and 2nd Session: 16:00-17:30)
You are required to choose two workshops you wish to participate in when registering.

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<tr>
<th>Time</th>
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<th>Workshop 2 Zurich 3-4</th>
<th>Workshop 3 Brussels 1-2</th>
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<td>1st Session 14:00-15:30</td>
<td>How to build a good CEP application</td>
<td>GMP inspections of API manufacturers</td>
<td>How to successfully prepare electronic submissions for CEPs</td>
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<td>15:30-16:00</td>
<td>Coffee Break</td>
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<tr>
<td>2nd Session 16:00-17:30 (Repeated)</td>
<td>How to build a good CEP application</td>
<td>GMP inspections of API manufacturers</td>
<td>How to successfully prepare electronic submissions for CEPs</td>
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- **WORKSHOP 1: How to build a good CEP application**

  **Moderator: Dr Andrew McMath**, Revisions Section Head, Certification of Substances Department, EDQM, Council of Europe

  - Starting materials for active substances
    **Dr Kristopher Olofsson**, Medical Products Agency, Sweden
  - Top 10 Deficiencies
    **Mr Cristian Sampaolesi**, New Applications Section Head, Certification of Substances Department, EDQM, Council of Europe
  - ICH Q3D
    **Ms Lisa Moore**, Health Products Regulatory Authority, HPRA, Ireland
  - Discussion

- **WORKSHOP 2: GMP inspections of API manufacturers**

  **Moderator: Dr Florence Benoit-Guyod**, Inspection Section Head, Certification of Substances Department, EDQM, Council of Europe

  - EDQM Inspection Programme
    **Dr Sotirios Paraschos**, Scientific Officer, Inspection Section, Certification of Substances Department, EDQM, Council of Europe
  - Experience of National Competent Authority with inspections of APIs
    **Dr Manuel Ibarra**, Spanish Agency of Medicines and Medical Devices (AEMPS), Spain
  - API Regulatory compliance: GMP Inspections and Marketing Authorisation
    **Dr Isabella Marta**, Italian Medicines Agency (AIFA), Italy
  - Discussion
WORKSHOP 3: How to successfully prepare electronic submissions for CEPs

Moderator: Ms Fiona McLeod, Scientific Officer, Certification of Substances Department, EDQM, Council of Europe

- EU roadmap for electronic submissions
  Ms Karin Gröndahl, Medical Products Agency (MPA), Sweden
- eCTD, CESP, CESSP
  Mr Kevin Horan, Health Products Regulatory Authority (HPRA), Ireland
- EDQM roadmap for electronic submissions
  Ms Cornelia Bigler-Weber, Scientific Assistant, Certification of Substances Department, EDQM, Council of Europe
- Discussion

19:30 Official Dinner

Wednesday, 20 September 2017
PLENARY SESSION
Moderator: Dr Susanne Keitel, Director, EDQM, Council of Europe

Update on worldwide initiatives

9:00-09:30 An overview of international initiatives in the regulatory sphere
Ms Cordula Landgraf, Swissmedic, Switzerland

09:30-10:00 The EU ASMF Work-sharing programme
Ms Nienke Rodenhuis, Medicines Evaluation Board (MEB), the Netherlands

10:00-10:30 The International Generic Drug Regulators’ Programme (IGDRP) initiative
Mr Gary Condran, Health Canada, IGDRP

10:30-11:00 International cooperation for inspections of API manufacturers
Dr Monika Mayr, European Medicines Agency (EMA)

11:00-11:30 Coffee break

Use of CEPs outside Europe

11:30-11:45 CEPs: Views from Anvisa, Brazil
Ms Jeanne Sophie Cavalcante Lemos Gautier, Anvisa, Brasil

11:45-12:00 CEPs: Views from South Africa
Mr Mabatane Davis Mahlatji, Medicines Control Council, South Africa

12:00-12:15 CEPs: Views from Canada
Dr Alison Ingham, Therapeutic Products Directorate (TGA), Health Canada

12:15-12:30 Discussion

12:30-12:40 Closing remarks

12:40 Lunch