Chairmanship of the Czech Republic
Council of Europe
May – November 2017

Présidence de la République tchèque
Conseil de l'Europe
Mai – Novembre 2017

*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 <u>two</u> workshops you wish to participate in when registering.

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

- **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*