PROGRAMME: TRAINING SESSION ON BIOLOGICALS
7-8 February 2017 – Location: EDQM Premises, Strasbourg, France

EUROPEAN PHARMACOPOEIA TRAINING SESSION ON

BIOLOGICALS

7 - 8 February 2017

Duration: 1.5 days
Working language: English
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PROGRAMME

TUESDAY, 7 FEBRUARY 2017

8:15-9:00 Registration

9:00-9:15 **Opening & Welcome address**

9:15-9:45 **European regulations for medicines:**
Place and roles of the EDQM and the European Pharmacopoeia.
Relationship systems between authorities, applicants and Pharmacopoeias framed by the EU Directive 2001/83/EC and International harmonisation of Pharmacopoeia.
Mrs Cathie Vielle, Head of the European Pharmacopoeia Dept., EDQM, Council of Europe

9:45-10:15 **General concepts in the European Pharmacopoeia**
An overview of the general monographs and chapters
Mrs Cathie Vielle

10:15-10:45 *Coffee break*

10:45-11:45 **A Guide through texts of relevance for biologicals including:**
- *Biotherapeutic products, bacterial endotoxins test and microbiological requirements*
- *Ph. Eur. Commission policy and approaches in the Replacement, Reduction and Refinement (3Rs) of animal testing.*

Dr Emmanuelle Charton, Deputy Head, European Pharmacopoeia Dept., EDQM, Council of Europe

11:45-12:00 **Questions & Answers**

12:00-13:30 *Lunch break*

13:30-15:30 **A guide through texts of relevance for biologicals including (continued):**
Raw materials for the production of cell and gene therapy products (including Q&A)
Dr Celine Pugieux-Amarantos, Div. B, European Pharmacopoeia Dept., EDQM

Host Cells proteins (including Q&A)
Dr Gwenael Cirefice, Div. B, European Pharmacopoeia Dept., EDQM

A guide through monograph sections with emphasis on synthetic peptides (including Q&A)
Dr Olga Kolaj-Robin, Div. B, European Pharmacopoeia Dept., EDQM

Products of natural origins (incl. Heparins) (including Q&A)
Dr Gwenael Cirefice, Div. B, European Pharmacopoeia Dept., EDQM

15:30-15:50 **How to contribute to the elaboration of Ph. Eur. Texts**
Dr Mihaela Buda, Div. B, European Pharmacopoeia Dept., EDQM

15:50-16:10 *Coffee break*

16:10-16:50 **Ph. Eur. Reference standards for physico-chemical tests:**
Role, use and establishment process (30')
Questions & Answers (10')
Dr Sylvie Jorajuria, Head of the Biology section, DLab Dept., EDQM, Council of Europe

16:50-17:30 **Overview of Biologicals Standardisation Programme (BSP)**
- *Validation of methods*
- *Establishment of reference standards*

Questions & Answers (10')
Dr Eriko Terao, Scientific Administrator, DBO Dept., EDQM, Council of Europe

17:30 *Close of first day*

WEDNESDAY, 8 FEBRUARY: WORKSHOP SESSIONS

9:00-12:00 **Workshop 1:**
BIOTHERAPEUTIC PRODUCTS (including monoclonal antibodies)
Mihaela Buda, Olga Kolaj-Robin, Sylvie Jorajuria and Dr Marie-Emmanuelle Behr-Gross

Monograph case study: **Etanercept**

Practical session 1: Interpretation of monographs in practice: **Filgrastim Concentrated Solution** and **Teriparatide**

10:15-10:35 *Coffee break*

Practical session 2: **Etanercept Case Study** (continued): discussion on technical aspects; general *vs* product specific monographs.

12:00 *Close of the training*

OR

9:00-12:00 **Workshop 2:**
PLASMA DERIVED PRODUCTS & VACCINES FOR HUMAN USE
Gwenael Cirefice, Sebastien Jouette, Catherine Milne, Celine Pugieux-Amarantos, Eriko Terao, Eva Vitkova, Catherine Lang

Vaccines for human use:

- **Navigating through the monographs and texts applicable to human vaccines**; the 3Rs and recent developments
- **The importance of the 3Rs for vaccines incl. achievements through the BSP**
- **Practical exercises**

10:15-10:35 *Coffee break*

Plasma derived products:

- **A journey inside the blood product monographs;** general considerations applicable, relationship between the monographs, pyrogenicity
- **The use of reference standards for plasma-derived products**
- **Practical exercises**

12:00 *Close of the training*