EUROPEAN PHARMACOPOEIA TRAINING SESSION ON
BIOLOGICALS
7 - 8 February 2017
Duration: 1.5 days
Working language: English

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:
BIOOTHERAPEUTIC 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
Gwenaël 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