EUROPEAN PHARMACOPOEIA TRAINING SESSION ON

BIOLOGICALS

4-5 February 2020

Working language: English

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PROGRAMME

TUESDAY, 04 FEBRUARY

08:15-9:00 *Registration*

09:00-9:05 Opening & Welcome address

SETTING THE SCENE

09:05-09:45 The regulatory framework for medicines in Europe: Place and role of the EDQM and the European Pharmacopoeia
Susanne Keitel, Director, EDQM, Council of Europe

09:45-10:30 General concepts in the European Pharmacopoeia (Ph. Eur.)
An overview of the general monographs and chapters, individual monographs, with a specific focus on biologicals
Cathie Vielle, Head of European Pharmacopoeia Dept., EDQM, Council of Europe

10:30-11:00 *Coffee break*

11:00-12:30 Ph. Eur. Reference Standards (RS) for physico-chemical tests
Role, use and establishment process (including Q&A)
Sylvie Jorajuria, Laboratory Department, EDQM, Council of Europe

Overview of Biologicals Standardisation Programme (BSP)
Validation of methods and the establishment of reference standards (including Q&A)
Catherine Milne, Department of Biological Standardisation, EDQM, Council of Europe

12:30-13:45 *Lunch break*

PUTTING THEORY INTO PRACTICE

Interactive sessions consisting of presentations, quizzes and Q&A

13:45-15:45 Specific European Pharmacopoeia texts & Use of RS for Biologicals

Microbiology chapters: sterility, efficacy of antimicrobial preservation, microbiological quality of non-sterile products, rapid microbiological methods, viral safety, TSE
Emmanuelle Charton, European Pharmacopoeia Dept., EDQM, Council of Europe

Microbiological assay of antibiotics
Sylvie Jorajuria, Laboratory Department, EDQM, Council of Europe

Pyrogens, monocyte activation test, bacterial endotoxins, recombinant Factor C
Emmanuelle Charton, European Pharmacopoeia Dept., EDQM, Council of Europe
Gwenaël Cirefice, European Pharmacopoeia Dept., EDQM, Council of Europe

15:45-16:15 *Coffee break*

16:15-18:00 Specific European Pharmacopoeia texts & Use of RS for Biologicals (cont.)

A guide through individual monographs: case studies using a synthetic peptide and a recombinant DNA protein
Olga Kolaj-Robin, European Pharmacopoeia Dept., EDQM, Council of Europe

CRS for biologicals, including synthetic peptides
Sylvie Jorajuria, Laboratory Department, EDQM, Council of Europe

General chapters supporting individual monographs: host cell proteins, residual DNA, peptide mapping, capillary electrophoresis, glycan analysis, …
Gwenaël Cirefice, European Pharmacopoeia Dept., EDQM, Council of Europe
Mihaela Buda, European Pharmacopoeia Dept., EDQM, Council of Europe
Olga Kolaj-Robin, European Pharmacopoeia Dept., EDQM, Council of Europe

18:00 *Close of first day*

WEDNESDAY, 05 FEBRUARY

PUTTING THEORY INTO PRACTICE

Interactive sessions consisting of presentations, quizzes and Q&A

09:00-10:45 Specific European Pharmacopoeia texts & Use of RS for Biologicals (cont.)

Individual monographs on biotherapeutics, including monoclonal antibodies: how to address complexity, flexibility of requirements, bioassays; case studies
Mihaela Buda, European Pharmacopoeia Dept., EDQM, Council of Europe
RS for biotherapeutics: peptide mapping and glycan mapping
Sylvie Jorajuria, Laboratory Department, EDQM, Council of Europe

10:45-11:15 *Coffee break*

11:15-12:30 Specific European Pharmacopoeia texts & Use of RS for Biologicals (cont.)

Vaccines for human use: general versus specific requirements, adventitious agents, the 3Rs
Gwenaël Cirefice, European Pharmacopoeia Dept., EDQM, Council of Europe

12:30-13:45 *Lunch break*

PUTTING THEORY INTO PRACTICE

Interactive sessions consisting of presentations, quizzes and Q&A

13:45-15:00 Specific European Pharmacopoeia texts & Use of RS for Biologicals (cont.)

Advanced therapy medicinal products (ATMPs): the regulatory framework, raw materials for the production of ATMPs, microbiological quality, gene therapy products
Céline Pugieux-Amarantos, European Pharmacopoeia Dept., EDQM, Council of Europe
Olga Kolaj-Robin, European Pharmacopoeia Dept., EDQM, Council of Europe
Emmanuelle Charton, European Pharmacopoeia Dept., EDQM, Council of Europe

HOW TO INTERACT WITH THE EDQM

15:00-15:30 How to participate in the Elaboration of the European Pharmacopoeia
Mihaela Buda, European Pharmacopoeia Dept., EDQM, Council of Europe

15:30-16:00 Find your way in Pharmeuropa, the Knowledge database & Ph. Eur. Online: Useful hints and other practicalities
Hans-Joachim Bigalke, Head of IT and Publications Division, EDQM, Council of Europe

16:00 *Close of the training*