European Directorate for the Quality of Medicines & HealthCare
COUNCIL OF EUROPE CONSEIL DE L'EUROPE

2010 TRAINING SESSION: STRASBOURG

GUIDE FOR THE ELABORATION AND USE OF MONOGRAPHS ON IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS (IVMPS)

Duration: 1.5 days
Location: Room 550, EDQM premises, 7 allée Kastner, 67081 Strasbourg, France,
Working language: English
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PROGRAMME

THURSDAY 18 MARCH 2010

8:00-9:00 Registration and welcome coffee

9:00-9:15 Opening remarks and general introduction

9:15-9:45 European regulations for IVMPs: How does it work?
Relationship between EU/EMA and the EDQM of the Council of Europe. Place and roles of the EDQM and the European Pharmacopoeia. General organisation of the EDQM.

***Mrs Cathie Vielle**, Head of the European Pharmacopoeia Department, EDQM, Council of Europe*

9:45-10:15 European regulations for IVMPs: the role of EMA
Place and roles of the European Medicines Agency.

***Dr Nikolaus Kriz**, Scientific Administrator, European Medicines Agency (EMA)*

10:15-10:45 How to participate in the elaboration of the European Pharmacopoeia
Terms of reference of Group 15V, conditions to add a monograph on the work programme of Group 15V, requests for revisions, which products are taken into account to draft the monograph, manufacturer consultation prior to Pharmeuropa, how is a text elaborated/revised (scheme), implementation period.

***Mrs Cathie Vielle**, Head of the European Pharmacopoeia Department, EDQM, Council of Europe*

10:45-11:15 Coffee break

11:15-11:45 General concepts in the European Pharmacopoeia with a view on vaccines for veterinary use
Overview of what is prescribed by the General Notices, the General monograph on vaccines for veterinary use, relevant general chapters, how to read them together, tests to be performed during the development of the vaccine

***Dr Emmanuelle Charton**, Deputy Head of the European Pharmacopoeia Department, EDQM, Council of Europe*

11:45-12:15 Open discussion with the panel of speakers

12:15-13:45 Lunch break

13:45-14:15 General monograph and general chapters, links with specific monographs
How to use the general monograph 'Vaccines for veterinary use'.

***Mrs Catherine Lang**, Scientific Administrator, European Pharmacopoeia Department, EDQM, Council of Europe*

14:15-14:35 MUMS issue
How to take into account the minor use issue and ensure compliance with the European Pharmacopoeia.

***Dr Karen Quigley**, Scientific Administrator, European Medicines Agency (EMA)*

14:35-15:05 Guide for the elaboration and use of monographs on IVMPs
What is the Guide for the elaboration and use of monographs on IVMPs intended for? What is the status of the Guide?

***Dr Lukas Bruckner**, Chair of Ph. Eur. Group of Experts on Veterinary sera and vaccines (S)*

15:05-15:25 General chapter *5.2.6* "Evaluation of safety of veterinary vaccines and immunosera". Detailed overview of the chapter.

***Dr Céline Lorteau Sourgen**, Agence nationale du médicament vétérinaire (AFSSA-ANMV) (FR)*

15:25-15:45 General chapter *5.2.7* "Evaluation of efficacy of veterinary vaccines and immunosera". Detailed overview of the chapter.

***Dr Peer Lyng Frandsen**, Head Medicines Control Office, Danish Medicines Agency (DK)*

15:45-16:15 Coffee break

16:15-16:45 Case studies for General chapter *5.2.6.* Practical applications.

***Dr Céline Lorteau Sourgen**, Immunological Assessment Unit, Agence nationale du médicament vétérinaire (AFSSA-ANMV) (FR)*

16:45-17:15 studies for General chapter *5.2.7.* Practical applications (1)

***Dr Hok Liang Oei**, Senior Assessor, Medicines Evaluation Board - Veterinary Medicinal Products Unit (NL)*

17:15-17:45 Case studies for General chapter *5.2.7.* Practical applications (2).

***Dr Rosario Bullido**, Head of Immunological Medicines Evaluation Unit, Department of Medicines for Veterinary Use, Spanish Medicines and Medical Devices Agency (ES)*

17:45-18:15 Open discussion with the panel of speakers

19:30- Official Dinner at the Art Café Restaurant

FRIDAY 19 MARCH 2010 (MORNING ONLY)

9:00-9:40 The EDQM website and the European Pharmacopoeia Publications.
Overview of EDQM website, how to profit most from the EDQM online version and other online publications.

***Dr Hans-Joachim Bigalke**, Deputy Head, Publications & Multimedia Department, EDQM, Council of Europe*

09:40-10:10 General *chapter 5.2.5* "Substances of animal origin for the production of veterinary vaccine", followed by case studies. Detailed overview of the chapter and practical applications.

***Dr Anna Maria Brady**, Veterinary Medicines Directorate (VMD) (UK)*

10:10-10:40 Coffee break

10:40-11:10 Alternative methods and validation of methods
How to use alternative methods, how to validate them?

***Dr Lukas Bruckner**, Chair of Ph. Eur. Group of Experts on Veterinary sera and vaccines (S)*

11:10-11:40 Alternative methods and validation of methods
The point of view of a licensing Authority.

***Dr Carmen Jungbäck**, Head of Section Viral Vaccines, Paul Ehrlich Institut (DE)*

11:40-12:10 Discussion

12:10-12:40 Closing remarks

12:40 Lunch