EDQM TRAINING SESSION
Veterinary Batch Release Network

29 OCTOBER 2019, STRASBOURG, FRANCE
Working language: English
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Programme

TUESDAY, 29 OCTOBER 2019

8:15-9:00  Registration

9:00-9:10  Welcome address
Michael Wierer, EDQM, Council of Europe

9:10-09:35 Current marketing authorisation procedure for IVMPs in the EU
Jacques Léchenet, Boehringer Ingelheim, France

09:35-09:45 Discussion

09:45-10:15 New developments in the European Pharmacopoeia (Ph. Eur.) for control of IVMPs
Renata Kovacova, Institute for State Control of Veterinary Biologicals and Medicaments (ISCVBM), Slovakia

10:15-10:30 Discussion

10:30-11:00 Coffee break

11:00-11:40 An overview of the European OCABR/OBPR for IVMPs; legal context, key principles, outline of the procedure and tools
Catherine Milne, EDQM, Council of Europe

11:40-12:00 Discussion

12:00-12:20 The OMCL Network: Quality Assurance and Mutual Joint Audit/ Visit Schemes: Importance of QA for OMCLs performing batch release
Maria Silvana Bellini, EDQM, Council of Europe

12:20-12:30 Discussion

12:30-14:00 Lunch break

14:00-14:25 Role and functions of OMCL/CA in performing OBPR
Renata Kovacova, Institute for State Control of Veterinary Biologicals and Medicaments, Slovakia

14:25-14:35 Discussion

14:35-15:00 Role and functions of OMCL/CA in performing OCABR
Gabor Kulcsár, Directorate of Veterinary Medicinal Products, National Food Chain Safety Office, Hungary

15:00-15:10 Discussion

15:10-15:40 Coffee break
15:40-16:05 Role and function of MAH in OCABR/OBPR
Severine Desprels, Boehringer-Ingelheim, France

16:05-16:15 Discussion

16:15-16:40 Importance of Interaction between OMCL/CA and MAH: tools and examples
Michael Mühlebach, Paul-Ehrlich-Institut (PEI), Germany

16:40-16:50 Discussion

16:50- 17:15 EDQM Biological Standardisation Programme Contributions to the Quality Control of IVMPs
Michael Wierer, EDQM, Council of Europe

17:15-17:25 Discussion

17:25 Closing remarks

17:35 Close of the Day 1