

EDQM TRAINING SESSION Veterinary Batch Release Network

29 OCTOBER 2019, STRASBOURG, FRANCE

Working language: English

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*