EDQM TRAINING SESSION
Veterinary Batch Release Network

29-30 OCTOBER 2019, STRASBOURG, FRANCE
Working language: English

Draft Programme (subject to change)

TUESDAY, 29 OCTOBER 2019

8:15-9:00 Registration
9:00-9:10 Welcome address
9:10-09:35 Current marketing authorisation procedure for IVMPs in the EU
09:35-09:45 Discussion
09:45-10:15 New Developments in the European Pharmacopoeia (Ph.Eur.) for control of IVMPs
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
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
12:20-12:30 Discussion
12:30-14:00 Lunch break
14:00-14:25 Role and functions of OMCL/CA in performing OBPR
14:25-14:35 Discussion
14:35-15:00 Role and functions of OMCL/CA in performing OCABR
15:00-15:10 Discussion
15:10-15:40 Coffee break

15:40-16:05 Role and function of MAH in OCABR/OBPR

16:05-16:15 Discussion

16:15-16:40 Importance of Interaction between OMCL/CA and MAH: tools and examples

16:40-16:50 Discussion

16:50-17:15 EDQM contributions to the quality control of IVMPs: BSP, PTS

17:15-17:25 Discussion

17:25 Closing remarks

17:35 Close of the Day 1

***

WEDNESDAY, 30 OCTOBER 2019 (MORNING)

This part of the workshop is RESTRICTED to CA/OMCL participants.

8:30-9:00 Registration

9:00-10:10 Practical aspects of Protocol Review

10:10-10:30 Coffee break

10:30-11:30 Working Groups and Practical Exercises

11:30-12:30 Presentation of group results and discussion

12:30-13:00 Final discussion and Conclusion

13:00 Close of the meeting