

Essentials of European Veterinary Regulatory Affairs

8th February 2022



Programme

Time	Presentation	Presenter
10:00	Introduction from TOPRA	Cristina Dragan, Regulatory Intelligence and Symposium Manager, TOPRA
10:05	Introductions for all	Mel Munro
10:15	Setting the Scene – Overview of Veterinary Medicine Regulations and Agencies	Mel Munro
11:15	Break – 15 minutes	
11:30	Marketing Authorisation Application Dossiers - what is in them? Vaccine focus	Mel Munro
12:30	Introduction to Summary of Product Characteristics (SPC) workshop	Mel Munro
12:35	Lunch break and opportunity to review workshop material – 55 mins	
13:30	Summary of Product Characteristics (SPC) workshop – review of answers	Mel Munro
13:45	Marketing Authorisation Application Dossiers - what is in them? Pharmaceutical focus	Andrew Hewitt
14:45	Break – 15 minutes	
15:00	European Regulatory Procedures	Andrew Hewitt
15:30	Variations, Renewals and Pharmacovigilance	Andrew Hewitt
16:00	Close	

ENABLING AND PROMOTING EXCELLENCE IN THE HEALTHCARE REGULATORY PROFESSION

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