

Essentials of European Veterinary Regulatory Affairs

21st February 2024



Programme

Time	Presentation	Presenter
10:00	Introduction from TOPRA	TBC
10:05	Introductions for all	Luisa Pachés
10:15	Setting the Scene – Overview of Veterinary Medicine Regulations and Agencies	Pascale Canning and Luisa Pachés
11:15	Break – 15 minutes	
11:30	Marketing Authorisation Application Dossiers - what is in them? Vaccine focus	Michael Fontaine
12:30	Introduction to Summary of Product Characteristics (SPC)	Pascale Canning
12:35	Lunch break and opportunity to review discussion material	
13:15	SPC discussion	Luisa Pachés and Pascale Canning
13:45	Marketing Authorisation Application Dossiers - what is in them? Pharmaceutical focus	Pascale Canning
14:45	Break – 15 minutes	
15:00	European Regulatory Procedures	Luisa Pachés
15:30	Variations, Renewals and Pharmacovigilance	Pascale Canning
16:00	Close	

ENABLING AND PROMOTING EXCELLENCE IN THE HEALTHCARE REGULATORY PROFESSION

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