



CRED: A Regulatory Update on Veterinary Variations in the EU

17 October 2019, London, UK

Course Chair: Laure Bidois, Cyton UK

Time	Presentation	Speaker
9:00	Registration and Coffee	
9:30	Welcome from TOPRA	Samantha Alsbury TOPRA
9:40	Welcome from Chairman <ul style="list-style-type: none"> • Overview of the day 	Laure Bidois Cyton UK
9:45	Theory of procedures and legislation <ul style="list-style-type: none"> • New legislation • Current legislation • Worksharing, super grouping • Article 34 referral to MRP status 	Beate Gasser BASG - <i>Austrian Federal Office for Safety in Health Care</i>
10:45	Break	
11:15	Procedures <ul style="list-style-type: none"> • MA transfers and variations following mergers and acquisitions • Line extensions • Grouping, worksharing and annual reporting • Practical advice and recommendations 	Laure Bidois Cyton UK
12:15	Lunch	
13:15	Type 2 variations case study	Kevin Yount Bayer Animal Health GmbH
14:45	Break	
15:15	A regulators perspective <ul style="list-style-type: none"> • Experience with variations • Pharmaceutical and biological products • Variations which do not require assessment 	Wiebke Godow BVL - <i>Federal Office of Consumer Protection and Food Safety, Germany</i>
16:15	Panel discussion	All
16:45	Chairpersons close	
17:00	Close of Workshop	

Delegates will be encouraged to ask questions throughout the day so as to ensure the meeting is as interactive as possible.