AGENDA

2nd Munich Workshop on Clinical Development of Veterinary Medicinal Products: Biologicals / Novel Therapies
17. April 2015
Munich, NH Hotel Deutscher Kaiser

Time	Topic	Session chair
08:30 – 09:00	Registration	
09:00 – 09:15	Welcome and Introduction	
	Session 1: Strategic planning	
09:15 – 10:45	Keynote speech Workshop part 1 • Regulations and guidelines – friend or foe? • Differences in regulations in different regions • Approaches for Minor use / minor species • Importance of defining the indication • Importance of defining suitable laboratory methods	Regina Wolf Klifovet AG
10:45 – 11:00	Coffee-Break	
	Session 2: animal disease models	
11:00 – 12:30	Keynote speech Workshop part 2 • *In-vivo* models • Defining suitable efficacy parameters • Laboratory method development • Statistical significance versus clinical relevance • Interpretation of results • Consequences for SPC	Klaus Hellmann Klifovet AG
12:30 – 13:30	Lunch	
	Session 3: Field Studies	
13:30 – 15:00	Keynote speech Workshop part 3 • Considerations for studies under field conditions • Interpretation of guidelines • Developing study outlines • Interpretation of results	Claudia Schneider Klifovet AG
15:00 – 15:15	Coffee break	
	Session 4: Safety studies and Risk Assessments	
15:15 – 16:45	Keynote speech Workshop part 4 • Laboratory Safety Studies • Data from field studies • How is safety data linked to efficacy? • Interpretation of results • Benefit versus risk assessment	Beate Lohr Klifovet AG
16:45 – 17:00	Closing remarks	