KLIFOVET AG

7 th Munich Seminar on Veterinary Clinical Studies (Based on VICH GL9 (Good Clinical Practice))

Program: Version 09FEB10

Day 1	Items	Presented by*
09:00	Come to together Coffee	All
09:15	1. Introduction and history	Klaus Hellmann
09:30	2. Investigator responsibilities	Malcolm Pott
10:15	3. Sponsor responsibilities	Malcolm Pott
10:30	Coffee break	All
10:45	4. Monitoring of Clinical Studies (incl. investigator selection, motivation, and focus on laboratories in multicentric studies)	Isabel Radeloff
11:15	Workshop 1: Group work on Case Studies	All
12:00	Workshop 1: Presentations, discussions	All
13.00	Lunch and Coffee	All
14:15	5. Study design of field studies Antimicrobials Antiparasitics Local Indications	 Bernd Stephan Klaus Hellmann Malcolm Pott
15.00	6. Formal requirements to the Protocol and the Report	Klaus Hellmann
15:30	Coffee break	All
15:45	Workshop 2: Group work on Study Design	All
16:30	Workshop 2: Presentations, discussions	All
17:30	End of Day 1	All
19:00	Dinner in Munich	Voluntary, **invited**

Day 2		
08:30	7. Clinical supplies requirements	Klaus Hellmann
09:00	8. Obtaining regulatory approval for clinical studies in the EU	Klaus Hellmann
09.30	9. Experiences using Electronic Data Capture (EDC) solutions in EU multicentre field studies	Isabel Radeloff
10:15	Coffee Break	All
10:45	10. Data management	Isabel Radeloff
11:15	11. Statistical planning and conduct	Torsten Küneth
13:00	Lunch	All
14.30	12. Critical summaries Part IV: layout and essentials	Beate Lohr
15.00	13. Expectation of Regulatory Assessors to Critical Summaries	Gesine Hahn, tbc
16:00	Closing of Seminar	Klaus Hellmann
16:15	End of Seminar	

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