KLIFOVET AG
Quality in Animal Health

8th Munich Seminar on Veterinary Clinical Studies (Based on VICH GL9 (Good Clinical Practice))

Program

03MAY11	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 General requirements Biologicals Anticancer Antiparasitics Internal Medicines	 Klaus Hellmann Klaus Hellmann / Gesine Hahn Isabel Radeloff Malcolm Pott
15:45	Coffee break	All
16.00	6. Formal requirements to the Protocol and the Report	Klaus Hellmann
16:30	Workshop 2: Group work on Study Design	All
17:15	Workshop 2: Presentations, discussions	All
18:00	End of Day 1	All
19:30	Dinner in Munich	Voluntary, invited

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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. Data management	Isabel Radeloff
10:00	Coffee Break	All
10:30	10. Experiences using Electronic Data Capture (EDC) solutions in EU multicentre field studies	Gabriele Braun
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
16:00	Closing of Seminar	Klaus Hellmann
16:15	End of Seminar	

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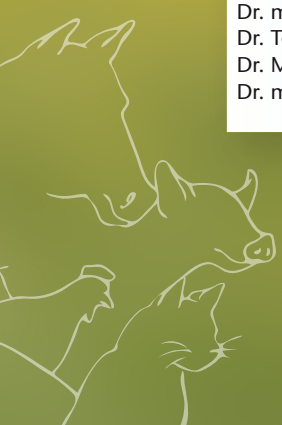
Dr. med. vet. Gesine Hahn, BVL, Berlin, D, Chair of CVMP Efficacy working party
Dr. med. vet. Klaus Hellmann, Dipl. ECVPT, Auditor EOQ, Director KLIFOVET AG, München, D
Dr. Torsten Küneth, Dipl. Math., München, D
Dr. Malcolm Pott, MRCVS, Cadport, Maidenhead, UK
Dr. med. vet. Isabel Radeloff (EOQ Auditorin), Dr. med. vet. Beate Lohr und Dr. med. vet. Gabriele Braun, KLIFOVET, München, D



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