KLIFOVET AG

13th Munich Workshop on VICH GCP and Veterinary Clinical Studies

April 21st – 22nd, 2016

NH Hotel Deutscher Kaiser, Arnulfstr. 2, 80335 München/ Germany

Day 1 – April 21st

Time	Topic	Presenter
12:00 – 12:30	Registration and Snacks	
12:30 – 13:00	Welcome and introduction to veterinary GCP	Klaus Hellmann Klifovet AG, Germany
13:00 – 13:30	Strategic planning – How to get on the right track • What is strategic planning? • What is involved with strategic planning in the context of clinical development? • How to adapt your strategy?	Regina Wolf Klifovet AG, Germany
13:30 – 14:15	Dose finding and confirmation – Defining suitable efficacy parameter • How to define suitable efficacy parameters • Statistical significance versus clinical relevance • Interpretation of results • Consequences for SPC	Klaus Hellmann Klifovet AG, Germany
14:15 – 14:45	Coffee Break	
14:45 – 15:15	Considerations for studies under field conditions • General requirements • Study design • Formal requirements to the study protocol	Claudia Schneider Klifovet AG, Germany
15:15 – 16:00	The view of regulatory assessor in clinical efficacy studies • What needs to be covered • Which are the potential pitfalls in dossiers? • The importance of efficacy on benefit/ risk assessment	Gabriel Beechinor Health Products Regulatory Authority Ireland
16:00 – 17:15	Workshop: Design of clinical studies – Preparing a study outline	All
From 19:00	Networking Dinner	Voluntarily, invited

Day 2 – April 22nd

Time	Topic	Presenter
08:30 – 09:15	Responsibilities in clinical studies • Sponsor • Monitor • Investigator	Gabriele Braun Klifovet AG, Germany
09:15 – 09:45	Setting up clinical studies in the field • Investigator selection • Patient recriutment and follow-up	Kerstin Adler Klifovet AG, Germany
09:45 – 10:45	Workshop: Monitoring of clinical studies – A case study	All
10:45 – 11:15	Coffee Break	
11:15 – 11:45	Clinical supplies requirements and obtaining regulatory approval	Klaus Hellmann Klifovet AG, Germany
11:45 – 12:15	Assuring quality in clinical studies • Background – Quality management of clinical studies • Elements for quality • QA vs. QC • Quality assurance and auditing • How to prepare a study site for an inspection	Klaus Hellmann Klifovet AG, Germany
12:15 – 13:15	Lunch break	
13:15 – 14:15	Practical statistics planning and assessment • Population and sample • Distribution and probability • Types of data and their evaluation • Hypotheses and errors • Confidence intervals and sample sizes	Nicole Krämer Staburo Statistical Consulting GmbH, Germany
14:15 – 14:45	Coffee break	
14:45 – 15:15	Data Management • GCP requirements • Electronic vs. Paper data • Data capturing and processing • Data analysis and reporting	Dejan Cvejić Klifovet AG, Germany
15:15 – 15:45	Benefit/ Risk assessment – The approach of the regulatory authorities	Gabriel Beechinor Health Products Regulatory Authority, Ireland
15:45 – 16:00	Closing remarks	Klaus Hellmann