Practical Implementation of GCP in Veterinary Field Studies

23-24 October 2019 • 29-30 April 2020 London

A practical two-day course

Chair:
Julian Braidwood Managing Director, Triveritas Ltd

Expert trainers:
Marie-Pascale Tiberghien Independent Animal Health Consultant
Sue Lester Founding Director, Triveritas Ltd

Benefits of attending:

- Understand the regulatory requirements and study design
- Know how to design protocols and apply them
- Take away practical advice on how to set up clinical trials
- Clarify the pharmacovigilance requirements
- Gain a better understanding of data handling and ‘appropriate’ statistics
- Discover how to produce the final report
- Assure quality in laboratory field studies

Fees and payment

EARLY BOOKING DISCOUNT Book BEFORE 20 September 2019
£1199.00 + VAT = £1438.80 • €1679.00 + VAT = €2014.80

FULL PRICE Book AFTER 20 September 2019
£1399.00 + VAT = £1678.80 • €1959.00 + VAT = €2350.80

Multiple booking discount for 2nd or subsequent delegates - 15%
£1189.15 + VAT = £1426.98 • €1665.15 + VAT = €1998.18

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7835
Why you should attend
This seminar will take many aspects of animal health and veterinary research and development through a typical clinical trial, and pay attention to compliance with Good Clinical Practice (GCP) as outlined in the two guidelines on safety and efficacy produced by FEDESA and the CVMP. The course will address a typical case study where a practical approach will be made to setting up, running and monitoring clinical trials followed by an audit of these studies to satisfy the stringent requirements seen in Europe. Standard documentation utilised for recording data, performing audits and a typical protocol will be supplied for use in delegates’ own laboratories.

Who should attend?
• Personnel involved in the animal health industry who are responsible for monitoring clinical veterinary studies and setting up protocols and studies, both in laboratory and field environments, to comply with GCP
• Quality assurance professionals who are required to audit these types of studies
• Clinical project managers and regulatory affairs personnel who will benefit by gaining an overview of the conduct of studies, the regulatory requirements and European perspectives

Chair
Julian Braidwood is Managing Director of Triveritas, a contract product development company offering a comprehensive range of services to the animal health industry. He qualified with Honours as a veterinary surgeon in 1982. After two and a half years in mixed practice, he entered the veterinary pharmaceutical industry in the field of product development and registration. He has worked in all aspects of product development with five different companies and was responsible for all veterinary product development in two of these. He has been involved in the development and registration of a large number of veterinary products internationally and has worked with all of the key regulatory authorities.

Expert trainers
Marie-Pascale Tiberghien is an animal health consultant. She has a veterinary qualification (DVM) and an MSc in Applied Statistics and has more than 20 years’ experience in the veterinary pharmaceutical industry in Europe (UK, France, Germany). She has been employed by Young’s Animal Health, Merial and Bayer in roles from clinical development to R&D project management and marketing. She has designed and implemented clinical and field trials (Phase 2 and 3) in the UK and France, and provides methodological support for Phase 4 (post-marketing authorisation) studies, eg design and analysis.

Sue Lester qualified in Biology and Chemistry and worked in a veterinary laboratory before joining the animal health industry where she has now worked for nearly 20 years. Sue rapidly became a leading international expert in quality assurance (GCPv, GLP and GMP). She has a Diploma in Research Quality Assurance and is a Fellow of the British Association of Research Quality Assurance (BARQA). Sue was a founding member of the BARQA Animal Health Committee, and is the author of a chapter on GCPv in the textbook Veterinary Clinical Trials from Concept to Completion. Having been employed by four companies, Sue was a founding director of Triveritas, a leading international contractor to the animal health industry, and is responsible for all aspects of quality assurance.

Programme
Day one

• The regulatory requirements and study design
  • Overview of GCP status covering VICH guidelines
  • An indication where trials must comply
  • Ethical aspects of GCP in all studies
  • Field study vs laboratory studies – regulatory GCP and GLP compliance
  • European anomalies
  • Project planning and timescales
  • Types of trials
  • Project design and teamwork
  • A case study

• Protocol design and application
  • Protocol production and approval
  • Protocol content and special points for inclusion
  • A case study

• Setting up clinical trials – a practical case study
  • Case report form design and supportive documentation
  • Investigator selection
  • Responsibilities of the monitor and the principal Investigator
  • Test material
  • In-life activities
  • Study close-out and reporting
  • Principal differences between laboratory and field studies

• Pharmacovigilance requirements and considerations
  • Recent regulatory developments
  • Impact on clinical studies

Day two

• Data handling and ‘appropriate’ statistics
  • Review of the current CVMP statistics guidelines
  • Types of data
  • Types of statistics
  • Evaluation of data
  • A case study

• Producing the final report
  • Data and QC
  • Archiving data
  • A case study

• Assuring quality in laboratory and field studies
  • Standard operating procedures (SOPs) writing, use and review
  • The QA function
  • Interaction between GLP, GCP and GMP in veterinary studies
  • Pre-study involvement
  • Protocol review
  • Audit planning
  • In-life audit
  • Sponsor/site trial master file review

Discussion sessions will take place throughout the two days

Previous attendees have said:
‘Very good! Presenters were all quite knowledgeable; very helpful.’
Kevin Yount, Bayer
‘Well presented, good pace, good participant involvement, very knowledgeable speakers.’
Paul McKiernan, Elanco Animal Health
‘Concise, thorough and engaging.’
Sophie Nixon, Probiotics International Ltd

A certificate of attendance for professional development will be available to each participant who completes the course

Three easy ways to book
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Early booking is recommended as places are limited

In-house training

This course is also available in-house and can be tailored to your specific needs. Our experts come to you, saving you time and money.

To get a FREE consultation call Aleksandra, our in-house training expert, on +44 (0) 20 7749 4730 or email inhouse@management-forum.co.uk

Group discounts are available, please email info@management-forum.co.uk for more information

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