PRACTICAL IMPLEMENTATION OF GCP IN VETERINARY FIELD STUDIES

21 &22 January 2009 Conf. No. V1-8309 W

MANAGEMENT FORUM

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If you have NOT received confirmation seven days after registering, please contact Registration Department.

REGISTRATION INFORMATION

Date
21 January 2009 Start: 09.30 – Finish: 17.00
22 January 2009 Start: 09.00 – Finish: 16.30

Registration & Coffee
21 January 2009 09.00

Venue
The Cavendish London, 81 Jermyn Street (main entrance in Duke Street), St James's, London SW1Y 6JF.

Directions
Nearest Underground station: Piccadilly Circus. Map available on Website under Hotels and Venues.

Accommodation
A limited number of bedrooms have been reserved at The Cavendish London, 81 Jermyn Street (main entrance in Duke Street), St James's, London SW1Y 6JF, at a special rate of £178.73 +17.5% VAT – inc. full English breakfast, subject to availability.
Hotel Tel: +44(0)20 7930 2111.
Hotel Fax: +44(0)20 7839 4369.
Email: Reservations@thecavendishlondon.com
All bookings should be made directly with the hotel quoting Management Forum and your credit card number.

Fee
£1,150 +17.5% VAT. The fee includes course documentation as well as mid-session refreshments and lunch. Invoice and confirmation will be forwarded to you.

Conference No. V1-8309

Discounted Rates
Available on application for personnel from non-profit making organisations and registered charities.
Group discount available on request.

Cancellation Policy:
Over 14 days prior to the Seminar: Cancellation fee of £75. 7/14 days prior to the Seminar: 50% of the fee. Fewer than 7 days or if no notification received: Registrant liable to pay FULL seminar fee.
NB: Cancellations must be received in writing by lesley@management-forum.co.uk.

In the event of circumstances beyond its control, Management Forum reserves the right to alter the programme, the speakers, the date or the venue.

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A TWO DAY PRACTICAL COURSE

PRACTICAL IMPLEMENTATION OF GCP IN VETERINARY FIELD STUDIES

Benefits in 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

Chairman:
Julian Braidwood Managing Director, Triveritas
Speakers:
Professor George Gettinby Professor of Statistics, Department of Statistics and Modelling Science, University of Strathclyde
Sue Lester Founding Director, Triveritas

Register on-line at www.management-forum.co.uk or telephone +44 (0) 1483 730071

CPD CERTIFIED
The CPD Certification Service

21 & 22 January 2009
The Cavendish Hotel, London

MANAGEMENT FORUM

INTRODUCTION

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 GCP as outlined in the two guidelines on safety and efficacy produced by FEDESA and the CVMP. The meeting 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 the delegates' company laboratories.

WHO SHOULD ATTEND

Personnel involved in the Animal Health Industry who are responsible for monitoring Clinical Veterinary Studies, setting up protocols and studies, both in the Laboratory and Field environment to comply with Good Clinical Practice guidelines. It will be immediately relevant to Quality Assurance professionals who are required to audit these types of studies. Clinical Project Managers and Regulatory Affairs personnel will also benefit from this course by gaining an overview of the conduct of studies, the regulatory requirements and European perspectives.

ATTENDANCE LIMITED – EARLY REGISTRATION RECOMMENDED

This limitation, a unique feature of all MANAGEMENT FORUM seminars, will give participants the opportunity for a thorough discussion of issues to be covered by the programme.

A Certificate of Attendance for Professional Development will be given to each participant who completes the course.

CHAIRMAN

Julian Braidwood is Managing Director of Triveritas which is 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.

SPEAKERS

Professor George Gettinby is Professor in Statistics, Department of Statistics and Modelling Science, University of Strathclyde. A Consultant Data Analyst to the pharmaceutical industry and international agencies, with particular consultancy interests in the analysis of data associated with the research, development and manufacture of veterinary and medical preparations. He is a Member of various associations including the Royal Statistical Society, the Association of Consultants to the Biosciences Industries and the Veterinary Products Committee.

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 ICH 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

Data Handling and 'Appropriate' Statistics
- Review of the current CVMP statistics guidelines
- Types of data
- Types of statistics
- Evaluation of data
- A case study

Pharmacovigilance Requirements and Considerations
- Recent regulatory developments
- Impact on clinical studies

DAY TWO

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

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