VETERINARY STATISTICS

29 & 30 October 2009, Conf. No. V10-8109 **W**

MANAGEMENT FORUM

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

REGISTRATION INFORMATION

Dates
29 October 2009 Start: 09.30 – Finish: 17.00
30 October 2009 Start: 09.00 – Finish: 16.30

Registration & Coffee
29 October 2009 09.00

Venue
Harrington Hall Hotel, 5-25 Harrington Gardens, London SW7.

Directions
Nearest Underground station: Gloucester Road.
Map available on Website under Hotels and Venues.

Accommodation
A limited number of bedrooms have been reserved at the Harrington Hall Hotel, 5-25 Harrington Gardens, London SW7, at a special rate of £123.34 (single) inc. full English breakfast, £138.27 (double) inc. full English breakfast. All + VAT, only valid up to 14 days before the conference – subject to availability.
Hotel Tel: +44(0)20 7396 9696.
Hotel Fax: +44(0)20 7396 9090.
Email: book.london@nh-hotels.com
All bookings should be made directly with the hotel quoting Management Forum and your credit card number.

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

Conference No. V10-8109

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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An Introduction to

VETERINARY STATISTICS

MANAGEMENT FORUM

A practical two day training course

Benefits in Attending:

- **Learn** the Key Principles for Good Statistical Design
- **Compare** Clinical Data Sets
- **Know** How Much Data Should You Collect
- **Understand** Statistical Principles and the EMEA/CVMP Guideline
- **Clarify** the Bioequivalence Guideline
- **Consolidate** Your Understanding with Case Studies
- **Discuss** Residue Guidelines
- **Hear** the New Developments
- **Take Part** in Workshops Sessions

With:

Professor George Gettinby
Professor in Statistics, Department of Statistics and Modelling Science, University of Strathclyde, Scotland

Marie-Pascale Tiberghien
EMEA Ruminant Marketing Manager, Merial, France

Register on-line at www.management-forum.co.uk or telephone +44 (0)1483 730071, fax 730008

CPD CERTIFIED
The CPD Certification Service

29 & 30 October 2009
Harrington Hall Hotel, London

INTRODUCTION

Statistical principles are widely used to underpin claims for efficacy and safety for a large number of animal health and veterinary products. In recent years these principles have been embodied in EMEA/CVMP guidelines, and they are used for the development of both pharmaceutical and biological products.

The overall goal of this workshop is to give non-statistical attendees an appreciation and understanding of the key statistical methods for designing, implementing and analysing clinical trials. This is achieved by introducing the underlying statistical principles and software approaches, followed by discussions on their application and relevance to regulatory guidelines.

WHO SHOULD ATTEND

This seminar is intended for members of the animal health and veterinary pharmaceutical industry who have to deal with the collection, analysis and evaluation of scientific data. In particular, it should be of value to trial monitors, trial investigators, animal health scientists, auditors and clinical researchers.

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 the complex issues to be covered by the programme.

SPEAKERS

Professor George Gettinby is Professor in Statistics, Department of Statistics and Modelling Science at the University of Strathclyde. A Data Analyst with experience of working for the pharmaceutical industry and agencies, and with particular interests in the analysis of data associated with the research, development and manufacture of veterinary and medical products. He is a member of various associations including the Royal Statistical Society, the Association of Consultants to the Biosciences Industries, and various government committees.

Marie-Pascale Tiberghien is EMEA Ruminant Marketing Manager, Merial, France. She has a Veterinary qualification (DVM) and an MSc in Applied Statistics and has more than 20 years experience in the veterinary pharmaceutical industry. She has designed and implemented clinical and field trials (Phase 2 and 3) in the UK and France, and has been employed by Rhone Mérieux/Merial since 1995 in a variety of roles from Clinical Development to R&D Project Management and most recently Marketing.

DOCUMENTATION

Delegates will receive a course material folder containing comprehensive documentation provided by the speakers, which will be a valuable source of reference for the future.

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

PROGRAMME

Day One — 29 October 2009

- **Welcome and Introduction**
- **Key Principles for Good Statistical Design**
  - Experimental units
  - Randomisation
  - Blocking
  - Case studies
- **Comparing Clinical Data Sets**
  - The statistical test
  - Interpretation of software output
- **How Much Data Should You Collect?**
  - Sample size estimation
  - Using available software for estimating sample size and statistical power
- **Workshop**

Day Two — 30 October 2009

- **Statistical Principles – EMEA/CVMP**
  - Primary and secondary endpoints
  - Superiority versus non-inferiority studies
  - Interim analyses
  - All randomised versus per protocol
- **Bioequivalence Guideline**
  - Crossover design
  - Criteria for bioequivalence
  - Worked example
- **Case Study and Consolidation**
- **Brief Discussion on Residue Guidelines**
- **New Developments**
  - Meta analysis
  - Software
- **Workshop**