DEVELOPING MEDICINES FOR COMPANION ANIMALS IN THE EU

3, 4, 5 & 6 February 2014, Conf. No V2-8314

MANAGEMENT FORUM

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

Registration Information

Dates

3 February 2014	Start: 09.30 – Finish: 17.15
Conference Dinner	**Start: 19.30**
4 February 2014	Start: 09.00 – Finish: 17.00
5 February 2014	Start: 09.00 – Finish: 17.00
6 February 2014	Start: 09.00 – Finish: 12.30

Registration & Coffee

3 February 2014 09.00

Venue and Accommodation

The Rembrandt Hotel, 11 Thurloe Place, London SW7 2RS
Hotel Tel: +44(0)20 7589 8100.
Hotel Fax:+44(0)20 7225 3476.
Email: ***reservations_rembrandt@sarova.co.uk***
Subject to availability, a limited number of bedrooms have been reserved at the hotel at a special rate. **All bookings should be made directly with the hotel or online at *www.sarova.com/rembrandt*, quoting promo code 'manforum'.**

Directions

Opposite V&A Museum. Nearest underground station: South Kensington.
www.sarova-rembrandthotel.com/location-local-attractions

Fee

£2,000 + VAT if applicable. The fee includes course documentation as well as mid-session refreshments, lunch and conference dinner. Invoice and confirmation will be forwarded to you.

Conference No. V2-8314

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 *registrations@management-forum.co.uk***
Management Forum reserves the right to cancel/alter the programme, the speakers, the date or venue. If an event is cancelled Management Forum is not responsible for airfare, hotel or other costs incurred by registered delegates.

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MANAGEMENT FORUM

Updated Programme

DEVELOPING MEDICINES FOR COMPANION ANIMALS IN THE EU

Key topics to be covered on this course:

- EU Regulatory Framework
- Product Development
- Process Scale Up and Validation
- How to 'Block Out Studies'
- Part III: the Toxicological Package
- User Safety: Risk Assessment
- Environmental Risk Assessment
- Pre-Clinical Development
- Clinical Trial Applications
- Clinical Development
- Target Species Tolerance
- Minor Use and Minor Species (MUMS)
- Regulatory Strategies and Procedures
- Writing the Regulatory Submission

Chairman:
Ray Harding, Consultant

Tutors:
Julian Braidwood, Managing Director, Triveritas Ltd
Dr Raymond Munden, Pharmaceutical Consultant

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3, 4, 5 & 6 February 2014
The Rembrandt Hotel, London

INTRODUCTION AND OBJECTIVES

The development of a veterinary medicine is complex, time consuming and expensive. It requires teamwork from individuals with different scientific training and a wide range of skills. Everyone involved must be aware of the main stages in the development programme and be able to relate his or her responsibilities to the expertise and needs of the scientists and commercial members of the team.

This course has been designed to demonstrate how pharmaceutical, pharmacological, toxicological and clinical investigations and regulatory management are brought together in the development programme. It will take the participants through all of the stages in the development of a veterinary medicinal product for companion animals, for which a marketing authorisation is sought in the European Union. Presentations will cover pharmaceutical and process development, toxicological, pharmacological, safety risk assessments, clinical development, and regulatory submissions. An important part of the course will be devoted to working on case studies in the workshop sessions.

The course will provide a comprehensive introduction to the entire development programme for companion animal medicines.

WHO SHOULD ATTEND

The course has been designed for anyone who has limited experience in only one of the disciplines in veterinary medicine development, such as pharmaceutical or analytical development, clinical trials, regulatory affairs or quality assurance. Anyone learning the role of project manager, as well as more experienced personnel seeking to review special problems encountered in product development, will benefit from the comprehensive programme delivered by experienced professionals.There will be ample opportunity for informal discussion during the proceedings.

If possible please bring a laptop with you to use during the workshop sessions.

CHAIRMAN

Ray Harding, Consultant, has worked in the veterinary pharmaceutical industry since 1979 and was previously employed by Glaxo, Pitman Moore and Rhône Mérieux. He established the team at Cyton Biosciences Ltd in 1997 to provide specialist services in new product development and registration for the bioscience industries in Europe. After managing Cyton since it was founded he left the company in 2012 and has taken the role of independent consultant.

TUTORS

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 and related companies.

Dr Raymond Munden has over 30 years experience in pharmaceutical research and development and was formerly Head of Analytical Services Europe for GlaxoSmithKline.

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

PROGRAMME

Day One — 3 February 2014

SESSION ONE: TUTOR - RAY HARDING

09.30 ▶ Introduction and Objectives of the Course

09.45 ▶ EU Regulatory Framework
- Understanding the regulatory objectives
- EU legal framework
- Legal base of regulatory procedures and dossier requirements

10.30 ▶ Coffee

10.45 ▶ EU Regulatory Framework...*continued*

11.30 ▶ Assessing Development Candidates
- New chemical entities and older products

11.45 ▶ Project Team: R&D and Marketing
- Defining marketing objectives
- Costs and profitability
- The Project Manager and Project Team

12.15 ▶ Discussion

12.30 ▶ Lunch

SESSION TWO: TUTOR – DR RAYMOND MUNDEN

13.30 ▶ Product Development
- Physical and chemical characteristics of the drug substance
- Process development
- Requisites of an ideal product
- Formulation development
- Requirements of different formulation types

15.15 ▶ Tea

15.30 ▶ Product Development....*continued*
- Optimising performance of problem drug substances
- Analytical development and setting specifications
- Stability testing
- Transfer to production

16.30 ▶ Workshop: Understanding How to "Block Out Studies"
- Pharmaceutical studies
- Toxicological studies
- Pharmacokinetic studies
- Clinical studies

Led by Ray Harding

17.15 ▶ End of Day One

19.30 ▶ Conference Dinner at a Local Restaurant

PROGRAMME

Day Two — 4 February 2014

SESSION THREE: TUTOR – RAY HARDING

09.00 ▶ Part III: The Toxicological Package
- The objective of Part III
- The data required

09.45 ▶ User Safety: Risk Assessment
- Reviewing toxicology studies
- Setting the scenario
- Risk assessment
- Risk management

10.15 ▶ Pharmacokinetics and Bioequivalence
- Role of pharmacokinetic studies in product development
- Bioequivalence studies
- Exemptions from bioequivalence studies

11.00 ▶ Coffee

11.15 ▶ Environmental Risk Assessment
- Phase I Assessment

11.30 ▶ Introduction to Workshop
- Objectives of the workshop and review case studies
- Planning approach to workshop and workshop teams

12.30 ▶ Lunch

SESSION FOUR: TUTOR - RAY HARDING

13.30 ▶ Workshop Session

15.15 ▶ Tea

15.30 ▶ Planning Pre-Clinical and Clinical Development
- Preparing pilot batches
- PKs and target animal tolerance
- Approaches to dose selection
- Clinical trial applications

16.00 ▶ EU Regulatory Strategies and Procedures
- Full and abbreviated applications
- Generic applications
- Centralised Procedure
- Decentralised, MRP and National Procedures

17.00 ▶ End of Day Two

PROGRAMME

Day Three — 5 February 2014

SESSION FIVE: TUTOR – JULIAN BRAIDWOOD

09.00 ▶ Clinical Development
- Selecting a dose
- Field studies
  - Multi-centred
  - Controlled
  - Randomised
  - Blinded
- Efficacy guidelines

10.30 ▶ Coffee

11.00 ▶ Target Species Tolerance
- VICH guideline
- Field safety

11.45 ▶ Minor Use and Minor Species (MUMS)
- What are minor species?
- What are minor uses?
- Approaches to preparation of clinical data

12.30 ▶ Lunch

SESSION SIX: TUTOR - RAY HARDING

13.30 ▶ Final Workshop Session

15.00 ▶ Tea

15.15 ▶ Final Workshop Session (continued)

17.00 ▶ End of Day Three

Day Four — 6 February 2014

SESSION SEVEN: TUTOR – RAY HARDING

09.00 ▶ Workshop Presentations
- Presentation by each team
- Review and discussion of each presentation

10.45 ▶ Coffee

11.15 ▶ Writing and Managing the EU Regulatory Submission
- Seeking Scientific Advice
- Writing the Marketing Authorisation Application
- Summary of Product Characteristics and labelling
- Working with Writers on Detailed and Critical Summaries in the EU
- Pre-submission Advice and Oral Hearings

12.00 ▶ Concluding Remarks

12.30 ▶ End of Course and Lunch

PROGRAMME

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