DEVELOPING MEDICINES FOR COMPANION ANIMALS

Gain a Comprehensive Understanding of the Development Process

Benefits of Attending

- Understand the EU Regulatory Framework
- Clarify the Data Required in the Toxicological Package
- Review User Safety: Risk Assessment
- Consider Environmental Risk Assessment
- Understand the Scope and Limitations of Pre-Formulation Development
- Gain Knowledge on Pharmaceutical Development
- Plan your Pre-Clinical and Clinical Development
- Clarify the Requirements on Target Species Tolerance
- Discuss Regulatory Strategies and Procedures
- Plan How to Write the Regulatory Submission

Chairman:
Ray Harding Director Drug Safety Research Unit, UK

Speakers:
Julian Braidwood Managing Director, Triveritas Ltd

Dr Raymond Munden Consultant

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

CPD CERTIFIED
The CPD Certification Service

4 - 6 February 2009
The Rembrandt Hotel, London

MANAGEMENT FORUM

INTRODUCTION AND OBJECTIVES

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

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 their 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.

IF POSSIBLE, PLEASE BRING A LAPTOP WITH YOU FOR THE WORKSHOP SESSIONS

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.

CHAIRMAN

Ray Harding Managing Director, Cyton Biosciences Limited, UK. Ray established Cyton Biosciences Limited in 1997 to provide specialist services in new product development and registration for the bioscience and animal health industries in Europe.

SPEAKERS

Julian Braidwood Managing Director, Triveritas. Triveritas provides specialist contract services to animal health companies developing veterinary vaccines and medicines by performing registration and regulatory maintenance, international trials, QA, project/study management and training.

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

Day One — 4th February 2009

Session One: **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 (cont.)**

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: **Ray Harding**

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

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

15.00 ▶ **Tea**

15.15 ▶ **Pharmacokinetics and Bioequivalence**

15.45 ▶ **Environmental Risk Assessment**
Phase I Assessment

16.00 ▶ **'Safety' Expert Report**

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

Led by Ray Harding

17.15 ▶ **End of Day One followed by Drinks Reception**

Day Two — 5th February 2009

Session Three: **Raymond Munden**

09.00 **Pre-Formulation Development**
- Scope/limitations
- Physical characteristics of the drug
- Chemical characteristics of the drug
- Analytical development

09.45 **Pharmaceutical Development**
- Selection of dosage form
- Pharmaceutical aspects
- Analytical aspects and regulatory issues

10.30 **Coffee**

10.45 **Process Scale Up and Validation**
- Effect of product type
- Facilities/personnel
- Regulatory issues

11.30 **Expert Report on 'Quality'**

12.00 **Introduction to Workshop**
- Objectives of the workshop and review case studies
- Planning approach to workshop and workshop teams

Led by Ray Harding

12.30 **Lunch**

Session Four: **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**

Day Three — 6th February 2009

Session Five: **Julian Braidwood**

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

10.30 **Coffee**

10.45 **Target Species Tolerance**
- Current requirements
- New VICH consultation

11.15 **'Clinical' Expert Report**
- Pre-clinical, clinical, PK and clinical data
- Target species tolerance
- Risk/benefit ratio

12.00 **Lunch**

Session Six: **Ray Harding**

13.00 **Final Workshop Session**

14.30 **Workshop Presentations**
- Presentation by each team
- Review and discussion

15.30 **Tea**

15.45 **Writing the Regulatory Submission**
- Writing the dossier
- Summary of product characteristics and labelling
- Working with Experts

16.15 **Discussion**

16.30 **Concluding Remarks**

16.45 **End of Course**

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

DEVELOPING MEDICINES FOR COMPANION ANIMALS

APPLICATION TO REGISTER

4-6 February 2009, Conf. No. V2-8109

Please PRINT your details:

Title..... First name .....
(Dr, Mr, Mrs, etc)

Family name.....

Position .....

Department.....

.....

Company .....

Address .....

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City ..... Post Code.....

Country .....

Tel No. ..... Fax No.....

E-mail Address.....

Secretary's name.....

Signature.....

Substitutions may be made at any time at no extra charge

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Expiry date...../.....

☐ Cheque enclosed payable to Management Forum Limited

☐ Bank transfer on receipt of invoice

W

YOU MAY REGISTER BY:-

FAX +44 (0) 1483 730008

Management Forum Ltd, 98-100 Maybury Road, Woking, Surrey GU21 5JL, UK

www.management-forum.co.uk

E-mail: registrations@management-forum.co.uk

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

REGISTRATION INFORMATION

Dates 4-6 February 2009

Times

4 February 2009	Start 09.30 – Finish 17.15
Drinks Reception	Start 17.15 – Finish 18.15
5 February 2009	Start 09.00 – Finish 17.00
6 February 2009	Start 09.00 – Finish 16.45

Registration & Coffee

4 February 2009	09.00

Venue
The Rembrandt Hotel, 11 Thurloe Place, London SW7.

Directions
Opposite V&A Museum.
Nearest Underground station: South Kensington.
Map available on Website under Hotels and Venues.

Accommodation
A limited number of bedrooms have been reserved at The Rembrandt Hotel, 11 Thurloe Place, London SW7, at a special rate of £131.07 (Superior), £148.93 (Executive) both including English breakfast. excluding 17.5% VAT – subject to availability.
A special rate for Friday, Saturday and Sunday of £118.30 (Superior) including English breakfast excluding 17.5% VAT – subject to availability when booked as additional nights.
Hotel Tel: +44(0)20 7589 8100.
Hotel Fax: +44(0)20 7225 3476.
Email: reservations_rembrandt@sarova.co.uk
All bookings should be made directly with the hotel or online at www.sarova.com/rembrandt, quoting promo code 'manforum'.

Conference Fee
£1,575 +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. V2-8109

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.

Exhibition spaces and promotional opportunities will be available at this meeting.
For further information please contact Judith Black
(email: judith.black@management-forum.co.uk)