MANAGEMENT FORUM

THE 10th ANIMAL HEALTH SUMMER SCHOOL

WORKING THROUGH VETERINARY DRUG DEVELOPMENT IN THE EU AND USA

A PRACTICAL FIVE-DAY COURSE WITH INTERACTIVE WORKSHOPS

Residential and Non-Residential Options Available

Social Programme includes conference dinner, theatre trip and opportunity for late night shopping

Discount for Animal Health Institute Members USA

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CPD CERTIFIED
The CPD Certification Service

Programme to include:

- EU Regulatory Framework
- US Regulatory Framework
- EU and USA Differences and Similarities
- The Global Development Programme
- Pharmaceutical Development and the CMC Package
- Understand How to 'Block Out Studies'
- MRLs Part A Safety and Part IIIA of the MAA
- US FDA Approach to HFS Studies
- User Safety Risk Assessment in the EU
- EU and USA Regulatory Strategies and Procedures
- Pharmacokinetics and Bioequivalence
- MRLs Part B Residues and Part IIIB of the MAA
- FDA Evaluation of Consumer Safety
- Planning Pre-Clinical and Clinical Development
- Environmental Risk Assessment Phases I and II
- EU and US Clinical Development
- EU and US Target Animal Safety
- Minor Use and Minor Species (MUMS)
- Managing the USA Regulatory Submission
- Writing and Managing the EU Regulatory Submission

Chairman

Ray Harding, Consultant to the Animal Health Industry, UK

Tutors:

Dr Katie Barrett, Programme Director for Agrochemical & Veterinary Programmes, Huntingdon Life Sciences, UK

Julian Braidwood, Managing Director, Triveritas, UK

Dr Raymond P Munden, Pharmaceutical Consultant, UK

Dr David Petrick, Regulatory Director, Triveritas, USA

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

10 - 14 June 2013
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. Furthermore, different approaches taken by the regulatory authorities in the European Union and the USA mean that a comprehensive development programme must be designed in order for the product to be commercialised in both the American and European regions.

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 the stages in the development of a veterinary medicinal product for which a marketing authorisation is sought in the European Union and the USA. Presentations will cover pharmaceutical and process development, toxicological, pharmacological, residues and ecotoxicological studies, safety risk assessments, clinical development, regulatory and marketing input and project management.

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

WHO SHOULD ATTEND

This 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.

Previous delegates who have benefited from this course include Clinical Scientists, Pharmaceutical Scientists and Regulatory Affairs, R & D, Development and Marketing Managers. There will be ample opportunity for informal discussion during the proceedings.

PLEASE BRING A LAPTOP WITH YOU FOR USE DURING THE WORKSHOP SESSIONS

CHAIRMAN:

Ray Harding, *Consultant to the Animal Health industry, UK.*

TUTORS

Dr Katie Barrett, *Programme Director for Agrochemical & Veterinary Programmes, Huntingdon Life Sciences, UK*

Julian Braidwood, *Managing Director, Triveritas, UK*

Dr Raymond P Munden, *Pharmaceutical Consultant, UK*

Dr David Petrick, *Regulatory Director, Triveritas, USA*

Day One - Monday 10 June 2013

Tutors: Ray Harding, Dr David Petrick and Dr Ray Munden

09.30 ▶ Introduction and Objectives of Course

09.45 ▶ EU Regulatory Framework for Regulation of Veterinary Medicines
- What is the EU?
- EU legal framework for regulation of veterinary medicines
- Legal base of procedures and data requirements

10.45 ▶ Coffee

11.00 ▶ US Regulatory Framework for Regulation of Veterinary Drugs
- Current governing laws and regulations
- Federal Agency jurisdictions

12.00 ▶ EU and USA: Differences and Similarities
- INAD and NAD in USA
- Phased submission in USA vs Marketing Authorisation Application in EU
- EU MRLs vs. US HFS Section
- EU Renewal, Variations, Extensions vs. US Supplements
- EU Certificate of Suitability & EDMFs vs. US DMFs
- Different requirements for User Safety and Environmental Risk Assessments

12.30 ▶ The Global Development Programme
- Requirements for EU
- Requirements for USA
- Achieving a global development programme

13.00 ▶ Lunch

14.00 ▶ Pharmaceutical Development and the CMC Package
- Characterising the active substance
- Formulation development
- Analytical development and setting specifications
- Process scale-up and validation
- Stability studies and shelf life

15.15 ▶ Tea

15.30 ▶ Pharmaceutical Development and the CMC Package (continued)

16.30 ▶ Exercise in Groups: Understanding 'How to Block Out Studies'
- Pharmaceutical studies
- Manufacturing pilot batches/lots
- Toxicological studies
- Pharmacokinetic/metabolism/residue studies
- Clinical studies

17.00 ▶ End of Day 1

19.30 ▶ *Conference dinner at a local restaurant.*

Day Two - Tuesday 11 June 2013

Tutors: Ray Harding and Dr David Petrick

09.00 ▶ MRLs Part A Safety and MAA Part IIIA
- The toxicological data requirements
- Determining the NOEL and ADI
- Part IIIA of the MAA

09.45 ▶ USA FDA Approach to HFS Studies
- Toxicology studies
- Margins of safety

10.15 ▶ User Safety Risk Assessment in the EU
- Reviewing toxicology studies
- Setting the scenario
- Risk assessment and management

10.45 ▶ Coffee

11.00 ▶ Introduction to Workshop

11.15 ▶ Workshop Session 1

13.00 ▶ Lunch

14.00 ▶ Workshop Session 1 (Continued)

15.00 ▶ Tea

15.15 ▶ USA Regulatory Strategies and Procedures
- Applications for NCEs and supplements
- Generic drug applications

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

17.00 ▶ End of Day 2

FREE EVENING. *Participants may wish to work on case studies. For information the Victoria and Albert Museum is opposite the hotel and is open until 5.45pm. Harrods and Harvey Nichols Department Stores are within walking distance and are open until 8pm Mon.-Fri. There are also many restaurants near by.*

Day Three - Wednesday 12 June 2013

Tutors: Ray Harding, Dr David Petrick and Dr Katie Barrett

09.00 ▶ Pharmacokinetics and Bioequivalence
- ADME studies
- Bioequivalence

10.00 ▶ MRLs Part B Residues and MAA Part IIIB
- 'Hot' and 'cold' residue studies
- How to determine Maximum Residue Limits
- Analytical methods for residues
- Determining the withdrawal period

10.45 ▶ Coffee

11.00 ▶ FDA Evaluation of Consumer Safety
- Human food technical safety section
- Residue issues

11.30 ▶ Planning Pre-clinical and Clinical Development
- Pilot batches/lots
- Pharmacokinetics and residues
- Approaches to dose selection
- Target animal safety
- Clinical trial applications

12.30 ▶ Lunch

13.30 ▶ Environmental Risk Assessment Phases I and II
- Critical evaluation of your data package
- Phase I Assessment
- Refining Risk Assessment
- Phase II Assessment Tiers A and B
- What to do if risk assessment gives cause for concern

14.30 ▶ Workshop Session 2

15.00 ▶ Tea

15.15 ▶ Workshop Session 2 (Continued)

17.00 ▶ End of Day 3

FREE EVENING. *For information, late night shopping is available in Knightsbridge which is 5 minutes walk away. There is also a gym and swimming pool next door to the hotel, these are open to residents at a discounted rate. There are many restaurants within walking distance.*

Day Four - Thursday 13 June 2013

Tutors: Julian Braidwood and Dr David Petrick

09.00 ▶ EU and US Clinical Development
- Dose selection
- Field studies
- VICH guidelines
- Claim driven approach in US
- Protocol review and concurrence with CVM
- Value of VICH guidance

10.45 ▶ Coffee

11.00 ▶ EU and US Target Animal Safety
- Pivotal target animal safety studies
- Filed safety studies
- New VICH Guideline on TAS

11.45 ▶ Minor Use and Minor Species (MUMS)
- MUMS Approaches in EU and USA
- What are Minor Uses?
- What are Minor Species?
- Approaches to preparation of clinical data

12.30 ▶ Lunch

13.30 ▶ Workshop Session 3

15.00 ▶ Tea

15.15 ▶ Workshop Session 3 (Continued)

17.00 ▶ End of Day 4

Register on-line at www.management-forum.co.uk or telephone +44 (0) 1483 730071. If you require further information contact andrea.james@management-forum.co.uk

EVENING ENTERTAINMENT – THEATRE TRIP

Drinks and sandwiches will be served at 18.00 hours and a buffet supper will be served on our return to the hotel.

Past musicals we have been to include: Chicago, Mamma Mia, My Fair Lady and Top Hat .

Day Five - Friday 14 June 2013

Tutors: Ray Harding and Dr David Petrick

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

10.45 ▶ Coffee and Checkout

11.15 ▶ Managing the USA Regulatory Submission
- Systems of review at CVM
- Team interaction
- Company and regulator interactions

11.45 ▶ Writing and Managing the EU Regulatory Submission
- 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

12.15 ▶ Concluding Remarks

12.45 ▶ Lunch and End of Course

A buffet lunch will be served in the conference room, sandwiches will be available as a packed lunch for those who need to leave promptly.

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

MANAGEMENT FORUM

EARLY REGISTRATION IS RECOMMENDED

WORKING THROUGH VETERINARY DRUG DEVELOPMENT IN THE EU AND USA

MANAGEMENT FORUM

Application to Register

10 - 14 June 2013
Conf. No. V6-8013

Please PRINT your details:

Title ..... First Name.....
(Dr, Mr, Mrs, etc)
Family name .....
Position .....
Department.....
Company .....
Company VAT No. .....
Address .....
.....
City ..... Post Code .....
Country.....
Tel No. .....
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Secretary's Name .....
Signature .....

Substitutions may be made at any time at no extra charge

Payment by either: ☐ VISA ☐ MASTERCARD ☐ AMEX

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

☐ Cheque enclosed payable to Management Forum Limited

☐ Bank transfer on receipt of invoice **W**

To Register

+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 **10-14 June 2013**

Registration & Coffee
10 June 2013 **09.00**

Times:

10 June 2013	**09.30 – 17.00**
11 June 2013	**09.00 – 17.00**
12 June 2013	**09.00 – 17.00**
13 June 2013	**09.00 – 17.00**
14 June 2013	**09.00 – 12.45**

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

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

Conference Fee. Please Tick:

☐ **Residential: £3,350 + VAT (if applicable)** includes course documentation as well as mid-session refreshments and lunch. 4 night's hotel accommodation (bed & breakfast), conference dinner, theatre trip and buffet supper

☐ **Non-Residential: £2,800 + VAT (if applicable)** includes course documentation as well as mid-session refreshments and lunch. **Excludes** hotel accommodation, evening meals, conference dinner and theatre trip

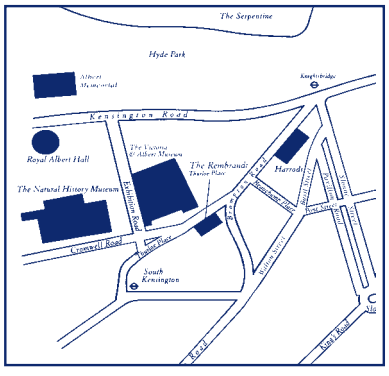
☐ **Please Tick:** **Discount for members of the Animal Health Institute, USA**

Please book any extra nights' accommodation through Management Forum – details on request.

Conference No. V6-8013

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.



The Rembrandt Hotel

11 Thurloe Place, London SW7 2RS
Tel: +44 (0)20 7589 8100 Fax: +44 (0)20 7225 3476

The nearest tube station to the Rembrandt Hotel is South Kensington, which is served by the District, Circle and Piccadilly Lines. The hotel is ten minutes walk from the station, and is situated opposite the Victoria & Albert Museum.

There is a direct tube link from Heathrow Airport to South Kensington, on the Piccadilly Line.

The hotel has a leisure club and swimming pool, available to guests at a nominal fee.