



## THE 8TH 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 and  
Theatre Trip**

### Programme to include:

- EU Regulatory Framework
- US Regulatory Framework
- EU and USA Differences
- The Global Development Programme
- Pharmaceutical Development
- Understand How to 'Block Out Studies'
- Developing the Toxicological Package in the EU
- US FDA Approach to HFS Studies
- User Safety Risk Assessment in the EU
- EU and USA Regulatory Strategies and Procedures
- Pharmacokinetics and Bioequivalence
- Metabolism and Residues
- EU MRLs Dossier: Residues and Withdrawal Periods
- FDA Evaluation of Consumer Safety
- Planning Pre-Clinical and Clinical Development
- Environmental Risk Assessment
- EU and US Clinical Development
- EU and US Target Animal Safety
- EU Clinical DACS
- Managing the USA Regulatory Submission
- Writing the EU Regulatory Submission

**25% Discount  
for Animal  
Health  
Institute  
Members  
USA**

Chairman:

**Ray Harding** Consultant, Cyton Biosciences Ltd., 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](http://www.management-forum.co.uk)  
or telephone +44 (0)1483 730071, fax 730008.**



**13-17 June 2011  
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, pharmacovigilance, 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.**

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

## CHAIRMAN

**Ray Harding** Consultant, Cyton Biosciences Limited, UK.

## TUTORS

**Dr Katie Barrett** Programme Director for Agrochemical and Veterinary programmes, Huntington Life Sciences, UK.

**Julian Braidwood** Managing Director, Triveritas, UK.

**Dr Raymond Munden** Pharmaceutical Consultant, UK.

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

## Day One – Monday 13 June

**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
  - Legal base of procedures and data requirements
- 10.30 ▶ **Coffee**
- 10.45 ▶ **US Regulatory Framework for Regulation of Veterinary Drugs**
- Current governing laws and regulations
  - Federal Agency jurisdictions
- 11.30 ▶ **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
- 12.30 ▶ **Lunch**
- 13.30 ▶ **EU and USA: Differences and Similarities (continued)**
- Different requirements for User Safety and Environmental Risk Assessments
- 14.00 ▶ **The Global Development Programme**
- Requirements for the EU
  - Requirements for the USA
  - Achieving a global development programme
- 14.30 ▶ **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
- 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 14 June

**Tutors: Ray Harding and Dr David Petrick**

- 09.00 ▶ **Developing the Toxicological Pack in the EU**
- MRLs Part A Safety and Part IIIA
  - The toxicological data requirements
  - Determining the NOEL and ADI
- 09.30 ▶ **USA FDA Approach to HFS Studies**
- Toxicology studies
  - Margins of safety
- 10.00 ▶ **User Safety Risk Assessment in the EU**
- Reviewing toxicology studies
  - Setting the scenario
  - Risk assessment and management
- 10.30 ▶ **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. Dinner may be taken in the hotel. Please quote Management Forum when ordering. Drinks are not included. 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.

## Day Three – Wednesday 15 June

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

- 09.00 ▶ **Pharmacokinetics and Bioequivalence**
- ADME studies
  - Bioequivalence
- 09.30 ▶ **Metabolism and Residues**
- Understanding metabolism and residues
  - 'Hot' and 'cold' residue studies
- 10.00 ▶ **EU MRLs Dossier: Part B Residues**
- Deriving 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**
- Phase I Assessment
  - Refining Risk Assessment
  - Phase II Assessment Tiers A and B
- 14.30 ▶ **Workshop Session 2**
- 15.00 ▶ **Tea**
- 15.15 ▶ **Workshop Session 2 (continued)**
- 17.00 ▶ **End of Day 3**

**FREE EVENING** Dinner arrangements as for Day Two. 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.

## Day Four – Thursday 16 June

**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
- 10.30 ▶ **Coffee**
- 10.50 ▶ **EU and US Target Animal Safety**
- New VICH Guideline on TAS
- 11.20 ▶ **EU Clinical Detailed and Critical Summary (DACs)**
- Preclinical, PK and clinical data
  - Target species tolerance
  - Benefit/Risk Assessment
- 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](http://www.management-forum.co.uk)  
or telephone +44 (0) 1483 730071.  
If you require further information contact  
[andrea.james@managementforum.co.uk](mailto:andrea.james@managementforum.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 Mary Poppins.

## Day Five – Friday 17 June

**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 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
- 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.**



**EARLY  
REGISTRATION  
RECOMMENDED**

## WORKING THROUGH VETERINARY DRUG DEVELOPMENT IN THE EU AND USA



**Application  
to Register**

**13-17 June 2011,  
Conf. No. V6-8011**

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..... Fax No. ....

E-mail.....

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**

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Management Forum Ltd, 98-100

Maybury Road, Woking, Surrey GU21 5JL, UK

www.management-forum.co.uk

E-mail: [registrations@management-forum.co.uk](mailto:registrations@management-forum.co.uk)

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

**To  
Register**

**Registration  
Information**

**Dates** 13-17 June 2011

**Registration & Coffee**  
13 June 2011 09.00

**Times**

13 June 2011 09.30 – 17.00

14 June 2011 09.00 – 17.00

15 June 2011 09.00 – 17.00

16 June 2011 09.00 – 17.00

17 June 2011 09.00 – 12.45

**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.

**Conference Fees: Please tick**

**Residential: £3,200 + VAT** includes 4 nights accommodation, all meals (including conference dinner) and theatre trip.

**Non-Residential: £2,500 + VAT** (excludes conference dinner and theatre trip)

**Please tick 25% discount for members of the Animal Health Institute, USA**

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

**Conference No. V6-8011**

**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.

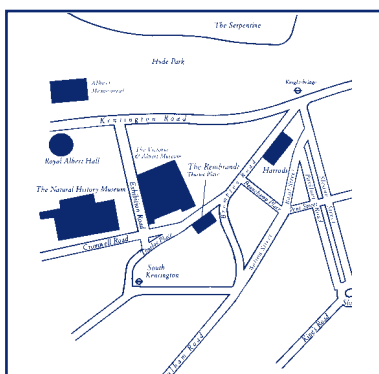
Fewer than 7 days or if no notification received:

Registrant liable to pay FULL seminar fee.

**NB: Cancellations must be received in writing by [registrations@management-forum.co.uk](mailto:registrations@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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If you do not wish to receive selected third party mailings please contact [nick@management-forum.co.uk](mailto:nick@management-forum.co.uk)



### The Rembrandt Hotel

11 Thurloe Place, London SW7 2RS

Tel: +44 (0)20 7589 8100 Fax: +44 (0)20 7225 3363

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. Map available on Management Forum Website under Hotels and Venues.

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.**