UPDATED PROGRAMME

MANAGEMENT FORUM

THE 7TH 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

25% Discount for Animal Health Institute Members USA

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

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 or telephone +44 (0)1483 730071, fax 730008.

CPD CERTIFIED
The CPD Certification Service

14-18 June 2010
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 their 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.

Programme : Day One – Monday 14 June

10.00 – 17.00

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

10.00 ▸ **Introduction and Objectives of Course**

10.15 ▸ **EU Regulatory Framework for Regulation of Veterinary Medicines**
- What is the EU?
- EU legal framework
- Legal base of procedures and data requirements

11.00 ▸ **Coffee**

11.15 ▸ **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

13.00 ▸ **Lunch**

14.00 ▸ **EU and USA: Differences and Similarities (continued)**
- Different requirements for User Safety and Environmental Risk Assessments

14.30 ▸ **The Global Development Programme**
- Requirements for the EU
- Requirements for the USA
- Achieving a global development programme

15.00 ▸ **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

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**

PROGRAMME

Day Two – Tuesday 15 June

09.00 – 17.00

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 restaurant or a lighter meal in the lounge or conservatory. 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 16 June

09.00 – 17.00

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.*

PROGRAMME

Day Four – Thursday 17 June

09.00 – 17.00

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**
- 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**

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 18 June

09.00 – 12.45

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.

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MANAGEMENT FORUM

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

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.

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.

FORTHCOMING EVENTS

For a full list of forthcoming conferences and seminars please visit our website at: **www.management-forum.co.uk.** You may make a registration and request a brochure on-line.

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

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

CHAIRMAN

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

TUTORS

Dr Katie Barrett joined Huntingdon Life Sciences in June 1995 as head of Ecotoxicology Department and is now Programme Director for Agrochemical and Veterinary programmes. She is also actively involved in liaising on behalf of clients with regulatory authorities and preparing risk assessments for both veterinary and agrochemical products. She has served on a number of working groups for OECD and SETAC, developing guidance documents and guidelines for novel test species including sediment organisms, dung fauna and beneficial insects. She is currently a member of the UK OECD shadow group, commenting on new draft guidelines, and represents NOAH on the IFAH Ecotoxicology working group.

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. After two and a half years in mixed practice he entered the veterinary pharmaceutical industry in the field of product development and registration. He has worked in all aspects of product development with five different companies and was responsible for all veterinary product development in two of these. He has been involved in the development and registration of a large number of veterinary products internationally and has worked with all of the key Regulatory Authorities.

Dr Raymond Munden has over 30 years experience in pharmaceutical research and development and was formerly Head, Analytical Services Europe for GlaxoSmithKline. He has led project teams that developed numerous pharmaceutical products that were successfully taken to market. He also has expertise in stability protocol design and testing, stability storage facilities, experimental design and degradation chemistry. He is now a consultant for all aspects of pharmaceutical development.

Dr David M. Petrick is qualified both as a veterinarian and a lawyer and has over 30 years experience in bringing novel animal health products to the market place in USA and EU. Dave has worked in Regulatory Affairs and Product Development for American Cyanamid Company and was Senior Director of Worldwide Regulatory Affairs at Schering-Plough Animal Health. He is an experienceed regulatory negotiator with FDA, USDA and EPA and currently is Regulatory Director, Triveritas USA.

EARLY REGISTRATION RECOMMENDED

WORKING THROUGH VETERINARY DRUG DEVELOPMENT IN THE EU AND USA

MANAGEMENT FORUM

APPLICATION TO REGISTER

14-18 June 2010, Conf. No. V6-8110

Please PRINT your details:

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

Position .....

Department.....

.....

Company .....

Address.....

.....

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

Payment by either: ☐ VISA ☐ MASTERCARD ☐ AMEX

Card No. | | | | | | | | | | | | | | | |

Card Security No. | | | | / | | | | AMEX

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

☐ Cheque enclosed payable to Management Forum Limited

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

YOU MAY REGISTER BY:-

+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 14-18 June 2010

Registration & Coffee
14 June 2010 09.30

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 accommodation, conference dinner and theatre trip

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

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

Conference No. V6-8110

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.

If you do not want to receive future mailings from Management Forum please contact nick@management-forum.co.uk
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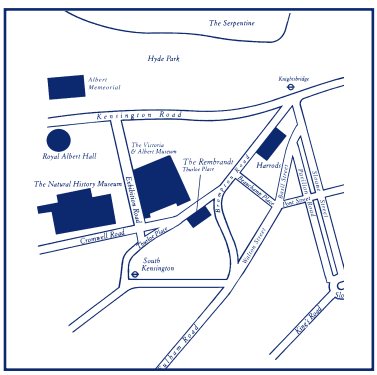

The Rembrandt Hotel

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.