Updated Programme

DEVELOPING MEDICINES FOR COMPANION ANIMALS

MANAGEMENT FORUM

Three Day Course with a Residential Option

Key topics to be covered on this comprehensive three day course:

- EU Regulatory Framework
- Pre-Formulation Development
- Pharmaceutical Development
- Process Scale Up and Validation
- Detailed and Critical Summary (DACS) on 'Quality'
- Part III: the Toxicological Package
- User Safety: Risk Assessment
- Environmental Risk Assessment
- 'Safety' DACS
- Pre-Clinical Development
- Clinical Trial Applications
- Clinical Development
- Target Species Tolerance
- 'Clinical' DACS
- Regulatory Strategies and Procedures
- Writing the Regulatory Submission

Chairman:
Ray Harding Managing Director, Cyton Biosciences Ltd

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

CPD CERTIFIED
The CPD Certification Service

8, 9 & 10 February 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 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,* Managing Director, Cyton Biosciences Limited,** established Cyton Biosciences Limited in 1997 to provide specialist services in new product development and registration for the bioscience industries in Europe.

TUTORS

***Julian Braidwood,* Managing Director of Triveritas** 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, Analytical Services Europe for GlaxoSmithKline.

Day One — 8th February 2010

PROGRAMME

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 (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: **Tutor – Dr Raymond Munden**

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

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

15.15 ▶ **Tea**

15.30 ▶ **Process Scale Up and Validation**
- Effect of product type
- Facilities/Personnel
- Regulatory issues

16.00 ▶ **Detailed and Critical Summary on 'Quality' (DACS)**

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

Day Two — 9th February 2010

PROGRAMME

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

10.30 **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 **'Safety' Detailed and Critical Summary**

12.00 **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**

Day Three — 10th February 2010

PROGRAMME

Session Five: **Tutor – 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**

11.15 **'Clinical' Detailed and Critical Summary**
- Pre-Clinical, clinical, PK and clinical data
- Target species tolerance
- Risk/benefit ratio

12.00 **Lunch**

Session Six: **Tutor – 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 Writers of Detailed and Critical Summaries

16.15 **Discussion**

16.30 **Concluding Remarks**

16.45 **End of Course**

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

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

8, 9 & 10 February 2010, Conf. No. V2-8110

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.....

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 **8, 9 & 10 February 2010**

Times	**8 February 2010**	**Start 09.30 – Finish 17.15**
	Conference Dinner	**Start 19.30**
	9 February 2010	**Start 09.00 – Finish 17.00**
	10 February 2010	**Start 09.00 – Finish 16.45**

Registration & Coffee

	8 February 2010	**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
The Rembrandt Hotel, 11 Thurloe Place, London SW7.
Hotel Tel: +44(0)20 7589 8100.

Please tick:

Conference fee: Residential Rate

☐ **£1,950 + VAT** to include accommodation for the nights of 8 & 9 February, all meals, course documentation and conference dinner.

Conference fee: Non-Residential Rate

☐ **£1,595 + VAT** to include course documentation as well as mid-sessions refreshments and lunch (excludes conference dinner).
Invoice and confirmation will be forwarded to you.

Conference No. V2-8110

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.

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)

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