VETERINARY PHARMACEUTICAL SUBMISSIONS IN THE EU

23 & 24 March 2009, Conf. No. V3-8309

MANAGEMENT FORUM

APPLICATION TO REGISTER

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YOU MAY REGISTER BY:-

+44 (0) 1483 730008
Management Forum Ltd
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
23 March 2009 Start: 09.30 – Finish: 17.00
24 March 2009 Start: 09.00 – Finish: 17.00

Registration & Coffee
23 March 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'.

Fee
£1,100 +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. V3-8309

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.

The information you provide will be held on our database and will not be used for third party mailings.
If you wish your name to be deleted from our database please contact Vicki Elliott at Management Forum. Email: vicki@management-forum.co.uk

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Website: www.management-forum.co.uk

UPDATED PROGRAMME

VETERINARY PHARMACEUTICAL SUBMISSIONS IN THE EU

A Two Day Practical Course

Benefits of Attending:

- Understand the EU Regulatory Framework
- Learn the Pharmaceutical Data Requirements
- Know How to Comply with the Safety Requirements
- Review the User Safety: Risk Assessment
- Consider the Environmental Risk Assessment
- Receive Guidance on the 'Safety' Expert Report
- Consider the Pre-Clinical and Clinical Requirements
- Take Away Regulatory Strategies and Procedures
- Know How to Write the Regulatory Submission

With:
Ray Harding Managing Director, Cyton Biosciences Ltd.

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

CPD CERTIFIED
The CPD Certification Service

23 & 24 March 2009
The Rembrandt Hotel, London

MANAGEMENT FORUM

INTRODUCTION AND OBJECTIVES

This course will take the participants through all the constituent parts of the application for marketing authorisation for a veterinary medicinal product for which a marketing authorisation is sought in the European Union. Presentations will cover the regulatory framework, pharmaceutical, toxicological and pharmacological data, safety risk assessments, pre-clinical and clinical data, Expert Reports 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 regulatory dossier for a veterinary medicinal product in the European Union.**

WHO SHOULD ATTEND

Personnel in the following departments: Registration, Research and Development and Clinical Trials. It will also be valuable to those seeking to review special problems encountered in the registrations of veterinary medicines. There will be ample opportunity for discussion during the proceedings.

TUTOR

Ray Harding established Cyton Biosciences Limited in 1977 to provide specialist services in new product development and registration for the bioscience industries in Europe. 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. Cyton Biosciences won the Queen's Award for Enterprise in 2003.

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.

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.

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

PROGRAMME

Day One — 23 March, 2009

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 (continued)

11.30 Part II: Pharmaceutical Data Requirements

12.15 Discussion

12.30 Lunch

14.00 Workshop Session
Planning a dossier to contain:
- Pharmaceutical studies
- Toxicological, pharmacokinetic, metabolism and residue studies
- Clinical studies

14.45 Part III: The Toxicological Package
- The objectives of the Maximum Residue Limits dossier and Part III
- The data required

15.15 User Safety Risk Assessment
- Reviewing toxicology studies
- Setting the scenario
- Risk assessment and management

15.45 Tea

16.00 Pharmacokinetics and Bioequivalence

17.00 End of Day One

Day Two — 24 March, 2009

09.00 Environmental Risk Assessment
- Phase I and II Assessments

09.30 'Safety' Expert Report

10.00 Part IIIB Residues
- Metabolism and residue studies
- Withdrawal period

10.30 Coffee

10.45 Part IV Pre-Clinical Data
- Pharmacodynamics and pharmacokinetics
- Target species tolerance
- Resistance

11.15 Part IV Clinical Data and 'Clinical' Expert Report
- Clinical trials and Part IV Expert Report

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

12.30 Lunch

14.00 Workshop Session

15.00 Tea

15.15 Workshop Presentations
- Presentation by each team
- Review and discussion

15.45 Writing the Regulatory Submission
- Writing the dossier
- Summary of Product Characteristics and labelling
- Working with Experts

16.45 Discussion

17.00 End of Course