VETERINARY PHARMACEUTICAL SUBMISSIONS IN THE EU

5 & 6 December 2011, Conf. No. V12-8311 **W**

MANAGEMENT FORUM

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To Register

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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
5 December 2011 Start: 09.30 – Finish: 17.00
6 December 2011 Start: 09.00 – Finish: 17.00

Registration & Coffee
5 December 2011 09.00

Venue
The Rembrandt Hotel, 11 Thurloe Place,
London SW7 2RS.

Directions
Opposite V&A Museum.
Nearest Underground station: South Kensington.
Map available on Website under Hotels and Venues.

Accommodation
Subject to availability, a limited number of bedrooms have been reserved at The Rembrandt Hotel, 11 Thurloe Place, London SW7 2RS, at the special rate excluding VAT of £137.50 (Superior), £154.17 (Executive), both including English breakfast.
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
£1,200 + VAT if applicable. The fee includes course documentation as well as mid-session refreshments and lunch. Invoice and confirmation will be forwarded to you.

Conference No. V12-8311

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.
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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Updated Programme

MANAGEMENT FORUM

VETERINARY PHARMACEUTICAL SUBMISSIONS IN THE EU

A Two Day Practical Course

Benefits of Attending

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

With:

Ray Harding Consultant, Cyton Biosciences Ltd.

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

CPD CERTIFIED
The CPD Certification Service

5 & 6 December 2011
The Rembrandt Hotel, London

INTRODUCTION AND OBJECTIVES

This course will take 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 EU, including the Maximum Residue Limits dossier. Presentations will cover the regulatory framework, pharmaceutical, toxicological and pharmacological data, safety risk assessments, pre-clinical and clinical data, Detailed and Critical Summaries 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 working in the following departments: Regulatory Affairs, Research and Development and Clinical Trials and Marketing. 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 1997 to provide specialist services in new product development and registration for the bios-cience 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.

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

PROGRAMME

Day One — 5 December 2011

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

10.45 ▶ Coffee

11.00 ▶ **Part II: Pharmaceutical Data Requirements**
- Formulation and analytical data
- Manufacturing process
- Stability studies

12.15 ▶ Discussion

12.30 ▶ Lunch

14.00 ▶ **Workshop Session**
Planning a dossier to contain
- Pharmaceutical development studies
- Toxicological, pharmacokinetic, metabolism and residue studies
- Pre-clinical and Clinical studies

14.45 ▶ **Part IIIA: Consumer and Environmental Safety Data Requirements**
- The Toxicological Package
- Maximum Residue Limits dossier: Safety File
- Part IIIA of the Marketing Authorisation Application

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 1

Day Two — 6 December 2011

09.00 ▶ **Environmental Risk Assessment**
- Phase I and II Assessments

09.30 ▶ **Part IIIB Residues**
- Metabolism and residue studies
- Maximum Residue Limits dossier: Residues File
- Withdrawal period
- Part IIIB of the Marketing Authorisation Application

10.15 ▶ **'Safety and Residues' Detailed and Critical Summaries**

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' Detailed and Critical Summary**
- Clinical trials
- Clinical Detailed and Critical Summary

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

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 writers of Detailed and Critical Summaries

16.45 ▶ Discussion

17.00 ▶ End of Course