VETERINARY PHARMACEUTICAL SUBMISSIONS IN THE EU

30 September & 1 October 2013, Conf. No V9-8113

MANAGEMENT FORUM

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To Register

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

Registration Information

Dates
30 September &
1 October 2013

Times
30 September 2013 Start: 09.30 – Finish: 17.00
1 October 2013 Start: 09.00 – Finish: 17.00

Registration & Coffee
30 September 2013 09.00

Venue and Accommodation
The Rembrandt Hotel, 11 Thurloe Place,
London SW7 2RS
Hotel Tel: +44(0)20 7589 8100.
Hotel Fax:+44(0)20 7225 3476.
Email: ***reservations_rembrandt@sarova.co.uk***
Subject to availability, a limited number of bedrooms have been reserved at the hotel at a special rate.

All bookings should be made directly with the hotel or online at *www.sarova.com/rembrandt*, quoting promo code 'manforum'.

Directions
Opposite V&A Museum. Nearest underground station: South Kensington.
www.sarova-rembrandthotel.com/location-local-attractions

Fee
£1,260 + 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. V9-8113

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*
Management Forum reserves the right to cancel/ alter the programme, the speakers, the date or venue. If an event is cancelled Management Forum is not responsible for airfare, hotel or other costs incurred by registered delegates.

For Promotional Opportunities email: robert@management-forum.co.uk

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MANAGEMENT FORUM
Celebrating 30 Years

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
- Consider the Pre-Clinical and Clinical Requirements
- Take Away Regulatory Strategies and Procedures
- Know How to Write the Regulatory Submission

With
Ray Harding, Consultant to the Animal Health Industry

Register online at www.management-forum.co.uk or by phone on +44 (0)1483 730071, fax 730008

30 September & 1 October 2013
The Rembrandt Hotel, London

INTRODUCTION AND OBJECTIVES

This course will take the participants through all of 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, 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 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, 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.

REGISTER NOW

Reserve your place and register now:
www.management-forum.co.uk
Tel: +44 (0) 1483 730071
Fax: +44 (0) 1483 730008
Any questions email:
andrea.james@management-forum.co.uk

TUTOR

***Ray Harding* Consultant**, has worked in the veterinary pharmaceutical industry since 1979 and was previously employed by Glaxo, Pitman Moore and Rhône Mérieux. He established the team at Cyton Biosciences Ltd. in 1997 to provide specialist services in new product development and registration for the bioscience industries in Europe. After managing Cyton since it was founded he left the company in 2012 and has taken the role of independent consultant.

DOCUMENTATION

Participants will receive a course material folder containing comprehensive documentation provided by the Tutor, which will be a valuable source of reference for the future.

If possible, please bring a laptop with you to use during the workshop sessions.

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

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.

PROGRAMME

Day One — 30 September 2013

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

11.00 ▶ **Coffee**

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

12.15 ▶ **Discussion**

12.30 ▶ **Lunch**

13.30 ▶ **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 ▶ **Tea**

15.30 ▶ **User Safety Risk Assessment**
- Reviewing toxicology studies
- Setting the scenario
- Risk assessment and management

16.00 ▶ **Pharmacokinetics and Bioequivalence**

17.00 ▶ **End of Day One**

Day Two — 1 October 2013

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

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

10.30 ▶ **Coffee**

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

11.15 ▶ **Part IV Clinical Data**
- Dose determination
- Clinical Trials

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

12.30 ▶ **Lunch**

13.30 ▶ **Workshop Session**

15.00 ▶ **Tea**

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

15.45 ▶ **Writing and Managing the Regulatory Submission**
- Writing the dossier
- Summary of Product Characteristics and labelling
- Working with writers of Detailed and Critical Summaries
- Submission and Follow-up

16.45 ▶ **Discussion**

17.00 ▶ **End of Course**