PHARMACOVIGILANCE FOR THE VETERINARY INDUSTRY

5 & 6 October 2010, Conf. No. V10-8610 **W**

MANAGEMENT FORUM

APPLICATION TO REGISTER

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YOU MAY REGISTER BY:-

FAX +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
5 October 2010 Start: 09.30 – Finish: 17.00
6 October 2010 Start: 09.00 – Finish: 16.00

Registration & Coffee
5 October 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
A limited number of bedrooms have been reserved at The Rembrandt Hotel, 11 Thurloe Place, London SW7, at a special rate of £133.92 (Superior), £152.18 (Executive) both including English breakfast. Excluding VAT – subject to availability.
A special rate for Friday, Saturday and Sunday of £120.87 (Superior) including English breakfast excluding 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
£1,200 + VAT. The fee includes course documentation as well as mid-session refreshments and lunch. Invoice and confirmation will be forwarded to you.

Conference No. V10-8610

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.

MANAGEMENT FORUM LTD., 98-100 Maybury Road, Woking, Surrey GU21 5JL, UK
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PHARMACOVIGILANCE FOR THE VETERINARY INDUSTRY

MANAGEMENT FORUM

Gain a Practical Understanding of the Requirements to Ensure Your Company's Pharmacovigilance Strategy is Compliant

Benefits of Attending:

- **Understand** the EU Pharmacovigilance Requirements
- **Know** How to Handle Animal SARs
- **Learn** How to Handle Human SARs
- **Discover** the Wider Scope of Pharmacovigilance
- **Take Part** in Pharmacovigilance Case Studies
- **Hear** About Electronic Communication in Pharmacovigilance
- **Discover** Principles of Pharmacovigilance and Data Resources
- **Understand** the Requirements of Signal Detection and Analysis
- **Be Prepared** for Pharmacovigilance Inspections
- **Gain** Practical Experience with a Pharmacovigilance Workshop on PSURs
- **Discuss** Risk Management and Know How to Deal with an Alert

With:

Declan O'Rourke Director, Ortec Consultancy, UK

Lisa Woods Scientific Office – Veterinary Pharmacovigilance, Irish Medicines Board, Ireland

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

CPD CERTIFIED
The CPD Certification Service

5 & 6 October 2010
The Rembrandt Hotel, London

BENEFITS OF ATTENDING

'Ensure your pharmacovigilance strategy is compliant.'

As truly pan-European requirements for product development and registration have become a reality, there is an accompanying need for a consistent, homogenous and harmonised approach for the monitoring of adverse drug reactions and the sharing of safety information across the EU. The various EU Pharmacovigilance guidelines intend to achieve this. This seminar will provide an interpretation of the new regulations and detailed guidance on how SARs should be handled, the requirements of PSURs and Pharmacovigilance Inspections. This will be reinforced by interactive case-based discussions and workshops. In addition, an overview of some of the future issues in respect of global harmonisation and electronic communication will be considered.

If you require any further information regarding this event please contact Andrea James on: andrea.james@management-forum.co.uk

There will be an option to discuss individual cases for review by the group. Please bring case details with you.

WHO SHOULD ATTEND

Personnel in the veterinary industry from the following departments: **Research and Development, Veterinary Services, Adverse Reaction Monitoring, Regulatory Affairs and Registration. Drug Safety Officers** and all those involved and interested in the daily practice of pharmacovigilance within the EU will find this seminar beneficial.

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

SPEAKERS

Declan O'Rourke Director, Ortec Consultancy. He has over 20 years experience in industry where he held technical, marketing, product development, clinical development, production and pharmacovigilance roles. He is a veterinary surgeon, holds a Diploma in Marketing, a Master of Business Administration and was awarded a Fellowship of the Royal College of Veterinary Surgeons in 1990. He now directs Ortec Consultancy specialising in EU pharmacovigilance and represented IFAH-EU in the VICH Working Group on pharmacovigilance. He is a member (Pharmaceutical Industry) of the Veterinary Residues Committee and will be a member (Risk Analyst) of the Veterinary Products Committee (VPC).

Lisa Woods Scientific Officer - Veterinary Pharmacovigilance, IMB. Lisa is an animal science graduate and joined the IMB in 2006, assuming full time responsibility for all aspects of pharmacovigilance in 2007. She represents the IMB on a number of pharmacovigilance related working groups at the EMEA including; CVMP Pharmacovigilance Working Party, EudraVigilance Veterinary Joint Implementation Group and Joint Human & Veterinary Pharmacovigilance Inspectors Working Group.

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.

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

PROGRAMME

Day One

- **Welcome and Introduction**
- **An Overview of EU Pharmacovigilance**
  - What are the requirements?
- **Pharmacovigilance (Ph V) in the Revised EU Legislation**
- **How to Handle Animal SARs**
- **Handling Human SARs**
- **Understanding the Wider Scope of Pharmacovigilance**
- **Discussion followed by Lunch**
- **Pharmacovigilance Case Studies**
- **Electronic Communication in Pharmacovigilance**
  (including VEDDRA)
- **Discussion and Close of Day One**

Day Two

- **Principles of Pharmacovigilance and Data Resources**
- **Signal Detection and Analysis: What is Required?**
  - Company
  - Authority
- **Pharmacovigilance Inspections: Are you Ready?**
- **Discussion followed by Lunch**
- **Practical Workshop on PSURs**
  - Format
  - What is required?
  - Analysis of data
  - Incidence calculation
- **Risk Management**
  - Dealing with an alert
- **Discussion and Close of Seminar**