PHARMACOVIGILANCE INSPECTIONS FOR THE VETERINARY INDUSTRY

11 February 2010, Conf. No. V2-8210 **W**

MANAGEMENT FORUM

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

REGISTRATION INFORMATION

Date 11 February 2010

Times Start: 09.30 Finish: 17.00

Registration & Coffee 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
£550 + VAT. The fee includes course documentation as well as mid-session refreshments and lunch. Invoice and confirmation will be forwarded to you.
Conference No. V2-8210

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.

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MANAGEMENT FORUM

PHARMACOVIGILANCE INSPECTIONS FOR THE VETERINARY INDUSTRY

Pharmacovigilance Inspections - Are you prepared?

Benefits of Attending:

- Understand the European Legislative Requirements for Pharmacovigilance Inspections/Auditing
- Clarify the Role of the Qualified Person (QP)
- Gain Knowledge on Pharmacovigilance Inspections and Competent Authorities Expectations
- Know How to Prepare for Pharmacovigilance Audits

With:

Declan O'Rourke
Ortec Consultancy (formerly Director VMRD, Pfizer Animal Health)

Caroline Evans
Pharmacovigilance Assessor, Veterinary Medicines Directorate (VMD)

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

CPD CERTIFIED
The CPD Certification Service

11 February 2010
The Rembrandt Hotel, London

INTRODUCTION

European legislative requirements relating to veterinary pharmacovigilance have changed and Competent Authorities have begun carrying out pharmacovigilance inspections. The CVMP began inspections in 2009.

This seminar will address key issues covering: Impact of changing EU legislation, the role of the Qualified Person (QP), preparing for pharmacovigilance audits and inspections, inspection expectations in key areas and interactions with Competent Authorities. This is an excellent opportunity to become fully prepared to handle the changes this legislation has brought to the veterinary industry.

WHO SHOULD ATTEND

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

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 course.

COURSE LEADER

Declan O'Rourke MVB FRCVS, Director, Ortec Consultancy, formerly Director, VMRD, Pfizer Animal Health. He graduated from University College Dublin in 1979 and spent a couple of years in practice, both in the UK and Canada. In 1983 he joined the Milk Marketing Board of England and Wales where he was responsible for the Mastitis Control Service. Following this he joined industry where he has held technical, marketing, product development and production positions with Mallinckrodt Veterinary and Pfizer Animal Health. Declan holds a Diploma in Marketing and a Master of Business Administration from Thames Valley University and was awarded an FRCVS in 1990. He currently represents IFAH-EU in the VICH Working Group on pharmacovigilance, and will be a member of the Veterinary Residues Committee from January 2009.

Caroline Evans has been a member of the Veterinary Medicines Directorate (VMD) for many years. She previously had responsibility for assessing pharmaceutical product licence applications. She became deputy manager of the Suspected Adverse Reaction Surveillance Scheme (SARSS) and in 1991 she took on the prime responsibility for developing and managing the human SAR report side of the scheme. She is a member of the EU Pharmacovigilance Working Party and until 2005 was chairman of the VEDDRA (Veterinary Dictionary for Drug Regulatory Affairs) sub group. Caroline took on the responsibility for veterinary pharmacovigilance audits for the VMD in August 2006.

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PROGRAMME

Welcome and Introduction

Detailed Description of Pharmacovigilance (DDPS)

The European Legislative Requirements for Pharmacovigilance Inspections/Auditing

- Legal base for inspections
- Roles of MAHs, Agency, CAs
- Monitoring of compliance

The Role of the Qualified Person

- The responsibilities of the QP

Lunch

Pharmacovigilance Inspections and Competent Authorities

- When may inspections be conducted?
- Who will conduct the inspections?
- What will the inspectors be looking for?
- Inspection findings and outcomes

Preparing for Pharmacovigilance Audits

- The scope of pharmacovigilance inspections
- Preparation for an inspection: best practice

Discussion will take place throughout the day