VETERINARY PHARMACOVIGILANCE: INCLUDING AN UPDATE ON VOLUME IXb

21 & 22 November 2012, Conf. No V11-8412

MANAGEMENT FORUM

Application to Register

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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

21 & 22 November 2012

Times

21 November 2012 Start: 09.30 – Finish: 17.00

22 November 2012 Start: 09.00 – Finish: 16.30

Registration & Coffee

21 November 2012 09.00

Venue and Accommodation

Harrington Hall Hotel, 5-25 Harrington Gardens, London SW7

Hotel Tel: 0870 7350358 (UK)

+34 91 398 46 61 (Overseas)

Email: **bookings@nh-hotels.com**

A limited number of bedrooms have been reserved at the Hotel at a special rate.

All bookings should be made directly with the hotel quoting Management Forum and your credit card number.

Directions

Nearest Underground station: Gloucester Road. Map available on Website under Hotels and Venues.

Fee

£1,250 + 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. V11-8412

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 cancel/alter the programme, the speakers, the date or the venue.

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

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MANAGEMENT FORUM

What you need to do and the implications of the changes?

Topics to be addressed at this seminar:

- The Role of the Marketing Authorisation Holder
- The European QP for Pharmacovigilance (PV)
- Adverse Event Reporting
- Requirements for Periodic Safety Update Reports
- Company-Sponsored Post-Authorisation Safety Studies
- Literature Searches
- Signal Detection
- Benefit-Risk Assessments
- Risk Management/Minimisation
- Crisis Management
- Communication with the Public
- Pharmacovigilance Inspections and Competent Authorities

With

Declan O'Rourke, Director, Ortec Consultancy, UK

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

21 & 22 November 2012
Harington Hall Hotel, London

INTRODUCTION

Volume IXb is the new key document on Pharmacovigilance guidelines used by the Veterinary regulatory authorities. The purpose of this course is to examine the new aspects and impacts of Volume IXb for Pharmacovigilance Inspections, compliance, adverse event reporting, and the roles and responsibilities of the Company and of the European Qualified Person for Pharmacovigilance in terms of safety assessments in the European Union. It will also discuss detailed guidance on how SARs should be handled, the requirements of PSURs and Pharmacovigilance Inspections. The new Volume IXb provides greater clarity to old issues, as well as detailing a number of new aspects for the Pharmacovigilance Professional to contend with. There are many new areas to be considered in Volume IXb and this seminar will provide an excellent opportunity to understand the implications of the changes.

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.

ATTENDANCE LIMITED – EARLY BOOKING 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

COURSE LEADER

Declan O'Rourke has over 20 years experience in industry where he has 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 Special Lecturer in Veterinary Pharmaceutical Development at Nottingham Veterinary School, Council member of British Cattle Veterinary Association, Director of British Veterinary Association and a member of the Veterinary Residues Committee and the Veterinary Products Committee (VPC).

DOCUMENTATION

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

REGISTER NOW

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

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

PROGRAMME

Day One 21 November 2012

- **Welcome and Introduction**
- **An Overview of EU Pharmacovigilance**
  - What are the requirements?
  - The role of the Marketing Authorisation Holder
  - The role of the Competent Authority
- **The European QP for Pharmacovigilance (PV)**
  - The roles and responsibilities of the EU QP PV
- **Adverse Event Reporting**
  - Definitions
  - Impact of VICH guidelines
  - Expedited vs periodic
  - How to handle animal SARs
  - Handling human SARs
  - Understanding the wider scope of pharmacogivilance
- **Pharmacovigilance Case Studies**
- **Electronic Communication in Pharmacovigilance (including VEDDRA)**

Day Two 22 November 2012

- **Company-Sponsored Post-Authorisation Safety Studies**
- **Literature Searches**
- **Practical Workshop on PSURs**
  - Format and content of the PSUR
  - Analysis of data
  - Incidence calculation
  - Compliance and the PSUR
  - Addendum Reports
  - Bridging Reports
- **Signal Detection/Benefit Risk & Risk Management**
  - The pharmacovigilance system
  - Signal Detection and Analysis: What is required?
  - Benefit-Risk assessments
  - Risk management/minimisation
  - Crisis Management
  - Communication with the Public
- **Pharmacovigilance Inspections: Are you Ready?**
  - What are inspectors looking for?
  - Inspection findings and outcomes
- **Discussion will take place throughout the two days**