

# VETERINARY PHARMACOVIGILANCE: INCLUDING AN UPDATE ON VOLUME IXb

2 & 3 October 2013, Conf. No V10-8313



Application to Register

Please PRINT your details:

Title ..... First Name.....  
(Dr, Mr, Mrs, etc)  
Family name .....  
Position .....  
Department.....  
Company .....  
Company VAT No. ....

Address .....  
City ..... Post Code .....

Country.....  
Tel No. ....  
Fax No.....

E-mail .....  
Secretary's Name .....

Payment by either:  VISA  MASTERCARD  AMEX

Card No. 


Card Security No. 

--	--	--	--

 /  AMEX  
Expiry date...../.....

Cheque enclosed payable to Management Forum Limited  
 Bank transfer on receipt of invoice

+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.

If you do not want to receive future mailings from Management Forum please contact [nick@management-forum.co.uk](mailto:nick@management-forum.co.uk)  
If you do not wish to receive selected third party mailings please contact [nick@management-forum.co.uk](mailto:nick@management-forum.co.uk)

MANAGEMENT FORUM LTD, 98-100 Maybury Road, Woking, Surrey GU21 5JL, UK  
Tel: +44 (0)1483 730071 Fax: +44 (0)1483 730008  
Website: [www.management-forum.co.uk](http://www.management-forum.co.uk)

Dates  
2 & 3 October 2013  
Times  
2 October 2013 Start: 09.30 – Finish: 17.00  
3 October 2013 Start: 09.00 – Finish: 16.30

Registration & Coffee  
2 October 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\\_rembbrandt@sarova.co.uk](mailto:reservations_rembbrandt@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](http://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](http://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. V10-8313  
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](mailto: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](mailto:robert@management-forum.co.uk)

Registration Information

# VETERINARY PHARMACOVIGILANCE: INCLUDING AN UPDATE ON VOLUME IXb

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

JOIN US ON



LinkedIn

facebook

With  
**Declan O'Rourke**, Director, Ortec Consultancy, UK

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



2 & 3 October 2013  
The Rembrandt 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](http://www.management-forum.co.uk)  
Tel: +44 (0) 1483 730071  
Fax: +44 (0) 1483 730008  
Any questions email:  
[andrea.james@management-forum.co.uk](mailto: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

2 October 2013

- ▶ **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 pharmacovigilance
- ▶ **Pharmacovigilance Case Studies**
- ▶ **Electronic Communication in Pharmacovigilance (including VEDDRA)**

### Day Two

3 October 2013

- ▶ **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**