

# Advanced Veterinary Pharmacovigilance

**1-2 Feb 2022, London**

+ 3 more dates - see back page for full schedule



## Programme at a glance:

- ✓ The DDPS and the PSMF
- ✓ PV training
- ✓ Product safety reviews
- ✓ Company core safety information
- ✓ Compliance and PV
- ✓ PV reporting in licensing/distribution agreements
- ✓ Signal detection/benefit-risk and risk management
- ✓ Audits and inspections: are you ready?
- ✓ Risk Management Dealing with an Alert

*Full programme inside*

★★★★★ "This was a very valuable course which I would highly recommend to other professionals in the industry. I couldn't have asked for a better speaker to be honest. I found Declan very honest and forthcoming with information and opinions. He provided clear and concise responses to any queries (I had a few haha) and was very approachable. The presentations were thorough and it was clear that a lot of effort was put in to ensure that all areas were covered. The webinar organisation and customer service is fantastic. Staff are extremely attentive and a pleasure to deal with."

**Kiera Hamilton, Pharmacovigilance Manager, Norbrook Laboratories Limited**

★★★★★ "Very informative. The course lived up to all my expectations."

**Marianne Valentin Hansen, Drug Safety Specialist, Pharmacosmos**

★★★★★ "Not easy to make such 2 days-training not face 2 face, but the sharing of a lot of examples, and experiences kept my focus on!"

**Fanny Bellebeau-Barbier, Local responsible of pharmacovigilance, Boehringer Ingelheim**

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## Course overview

**The purpose of this seminar is to provide a comprehensive, yet practical, assessment of the main requirements of Volume IXB, the new key document on pharmacovigilance guidelines used by the veterinary regulatory authorities to ensure a compliant reporting company.** The programme will also consider the potential impact of Brexit on pharmacovigilance and the implications of the proposed EU Regulation (2019/6) on Veterinary Medicinal Products.

Interactive sessions throughout the two days will give delegates the opportunity to discuss key issues of current concern with our experienced trainer.

### Programme to include:

- Overview of European regulatory framework
- The key requirements of Volume IXB
- The detailed description of the pharmacovigilance system (DDPS) and the pharmacovigilance system master file (PSMF)
- PV training
- Product safety reviews
- Company core safety information compliance and PV
- PV reporting in licensing/distribution agreements
- Signal detection
- Benefit-risk assessments
- Risk management
- Crisis management
- Implications of the proposed EU pharmacovigilance legislation

## Who should attend?

This seminar will be beneficial to those who have some experience of veterinary pharmacovigilance and is a good follow-on course from the Introduction to Veterinary Pharmacovigilance, which is also run by Management Forum. Adverse event monitoring and drug safety officers, including QPPVs and deputy QPPVs, together with personnel from regulatory affairs and registration departments, will find this event useful.

**The course can be used as part of the training to become a QPPV or deputy QPPV**

★★★★★ *"The webinar was very well organized. We got all needed information in advance, the speaker was amazing and the presentation focused on all aspects of PV."*

Jan Subert, New Business Development Manager, Cymedica s.r.o.

★★★★★ *"I am very happy for having joined the course and for getting very good materials (presentations) and references from it, very didactic."*

Maria Bermudez Espinosa, Doctor, LETI

★★★★★ *"Excellent"*

Gaultier Purper, QP, Reprobiol SPRL

## Expert trainer



### Declan O'Rourke

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 a Fellowship of the Royal College of Veterinary Surgeons. He now directs Ortec PV Consultancy Ireland specialising in pharmacovigilance and represented IFAH-EU in the VICH Working Group on pharmacovigilance.

He is Honorary Associate Professor in Veterinary Pharmaceutical Development at Nottingham Veterinary School and Past President of British Cattle Veterinary Association.



## The DDPS and the PSMF

- The DDPS
- The DDPS – what happens now?
- The PSMF – purpose and maintenance
- Transition from DDPS to PSMF

## PV training

- Requirements for PV training
- Who trains whom and when?
- Training records, maintenance and updates
- Role of QA and HR in training

## Product safety reviews

- The safety review committee
- Timings for safety review
- Record keeping for safety review meetings

## Company core safety information

- Core safety information
- How to determine what to include and what to exclude in a company core data sheet (CCDS)
- Maintenance and development of a CCDS

## Compliance and PV

- Basic principles
- Measuring compliance
- Quality versus quantity in safety reports

## PV reporting in licensing/distribution agreements

- What types of agreements exist?
- Audits of pharmacovigilance capabilities in partners
- What agreements need to be in place for PV reporting?
- PV reporting agreements – what needs to be covered?
- Monitoring PV agreements – what happens if it goes wrong?

## Signal detection/benefit-risk and risk management

- The pharmacovigilance system
- Signal detection and analysis: what is required?
- Benefit-risk assessments
- Risk management/minimisation
- Crisis management
- Communication with the public

## Audits and inspections: are you ready?

- What are inspectors looking for?
- Inspection findings and outcomes
- Implications of the proposed EU pharmacovigilance legislation

## Risk Management Dealing with an Alert

### 📍 Run this programme in-house for your whole team

Coming to Management Forum for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through

to feedback and follow-up after the programme. With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of

designing and delivering the appropriate solution for each client. For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact **Yesim Nurko** on +44 (0)20 7749 4730 or email [inhouse@management-forum.co.uk](mailto:inhouse@management-forum.co.uk)



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## Schedule and prices

### Three ways to book:

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forum.co.uk

 **Telephone**  
+44 (0)20 7749 4730

Ref	Date	Location	Price	Early booking price	Until*
11841	<b>1-2 Feb 2022</b>	Venue TBC	GBP <b>1,399</b> + VAT = 1,678.80 EUR <b>1,959</b> + VAT = 2,350.80 USD <b>2,182</b> + VAT = 2,618.40	GBP <b>1,199</b> + VAT = 1,438.80 EUR <b>1,679</b> + VAT = 2,014.80 USD <b>1,870</b> + VAT = 2,244.00	<b>28 Dec</b>
11666	<b>4-5 May 2022</b>	Live webinar	GBP <b>1,199</b> + VAT = 1,438.80 EUR <b>1,719</b> + VAT = 2,062.80 USD <b>1,942</b> + VAT = 2,330.40	GBP <b>999</b> + VAT = 1,198.80 EUR <b>1,439</b> + VAT = 1,726.80 USD <b>1,630</b> + VAT = 1,956.00	<b>30 Mar 22</b>
11842	<b>1-2 Aug 2022</b>	Venue TBC	GBP <b>1,399</b> + VAT = 1,678.80 EUR <b>1,959</b> + VAT = 2,350.80 USD <b>2,182</b> + VAT = 2,618.40	GBP <b>1,199</b> + VAT = 1,438.80 EUR <b>1,679</b> + VAT = 2,014.80 USD <b>1,870</b> + VAT = 2,244.00	<b>27 Jun 22</b>
11773	<b>21-22 Nov 2022</b>	Live webinar	GBP <b>1,199</b> + VAT = 1,438.80 EUR <b>1,719</b> + VAT = 2,062.80 USD <b>1,942</b> + VAT = 2,330.40	GBP <b>999</b> + VAT = 1,198.80 EUR <b>1,439</b> + VAT = 1,726.80 USD <b>1,630</b> + VAT = 1,956.00	<b>17 Oct 22</b>

 **Your choice of date & location** We can present this course on an in-house basis, tailored to your requirements, at your location and/or online. Contact us at [inhouse@management-forum.co.uk](mailto:inhouse@management-forum.co.uk) or see inside the brochure for more details of how this can be a more cost-effective approach.

 **Multiple booking discounts** Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.

\* Note the early booking discount cannot be combined with any other offers or promotional code

### The 'Small Print'

#### FEE

The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

#### PLEASE NOTE

Falconbury Ltd reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, Falconbury will refund the registration fee and disclaim any further liability.

#### TERMS AND CONDITIONS

The rest of the 'Small Print', the event cancellation policy and the terms and conditions are on our website, please visit [management-forum.co.uk/content/terms-and-conditions](http://management-forum.co.uk/content/terms-and-conditions)



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