MANAGEMENT forum

This course qualifies for 12 CPD hours for your Continuing Professional Development records

BOOK BEFORE 22nd March to save £200

Introduction to Veterinary Pharmacovigilance

26-27 Apr 2022, Live webinar
+ 2 more dates - see back page for full schedule

A basic training course for those working on drug safety in the EU. This course has been designed to provide basic training and a good introduction to those concerned with veterinary pharmacovigilance. *INCLUDES: Interactive workshop and discussion sessions*

Programme at a glance:

- What is pharmacovigilance?
- The current regulatory framework and its global impact
- Adverse event reporting
- Causality assessment
- Pharmacovigilance case studies
- Electronic communication in pharmacovigilance
- Minimising the impact of data with errors
- Clinical trial AE reporting requirements
- Literature searches
- PSURs
- Practical workshop on PSURs

Full programme inside

★★★★★ *"Very informative and interesting webinar. Well explained by the speaker, who was very knowledgeable and experienced."*

Aimee Wright, R & D Manager (Agricultural), EVANS VANODINE INTERNATIONAL PLC

★★★ *"I am pleased with the webinar. I feel like I learned a lot. For now I will try to get some real experience with writing PSUR and adverse events and then I would like to proceed with the advanced webinar on veterinary pharmacovigilance."*

Natascha van Heugten-Cappelle, QPPV, Aesculaap BV

★★★★ *"Covered everything I currently need."*

George Winthorpe, GxP Quality Assurance Auditor, Animal and Plant Health Agency

Introduction to Veterinary Pharmacovigilance

26-27 Apr 2022, Live webinar
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Course Overview

This two-day event has been designed to provide an essential overview of veterinary pharmacovigilance and will offer practical guidance and basic training for all those working in drug safety in the EU.

Our experienced trainer will clarify roles and responsibilities, explain commonly used terminology and take participants through all the key aspects of this complex subject. There will be plenty of time for interaction and questions and answers to enable participants to get a good understanding of the issues involved. The use of industry case studies will demonstrate real-life scenarios to help embed learning.

Benefits of attending:

- **Gain** an overview of the European regulatory framework
- **Be aware** of Volume IXb
- **Learn** about VICH
- **Understand** adverse event reporting
- **Hear about** causality assessment
- **Minimise** the impact of data with errors
- **Know** the requirements for periodic safety update reports (PSURs)
- **Get to grips** with literature searches
- **Understand** the implications of the proposed EU pharmacovigilance legislation and Brexit

Who should attend?

The course will be beneficial to those new to veterinary pharmacovigilance, support staff and experienced personnel who require a better understanding of drug safety in their current role. Adverse event monitoring and drug safety officers, together with regulatory affairs and personnel from registration departments, will also find this seminar useful.

★★★★★ *"Thoroughly enjoyed this 2-day interactive training course. Presentation content was very comprehensive and informative. Declan has a wealth of experience and shared practical knowledge/approach on how to handle common PV scenarios."*

Oluwafemi Odugbesan, Boehringer Ingelheim Vetmedica GmbH

★★★★★ *"Good course."*

Sean O'Sullivan, Bimeda Animal Health Ireland

★★★★ *"Content: quite good. Too many abbreviations in the first two lectures, for newbies this is very frustrating. Presentation was way above expectations given the nature of it (webinar). Speaker also good, knew what he was talking about, mostly knew his audience and extreme level of intensity throughout the course."*

Stian Mørch Aaen, Research Manager, Aqua Pharma Group

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.

What is pharmacovigilance?

- Beneficial and harmful effects of veterinary medicinal products
- Key definitions

The current regulatory framework and its global impact

- Overview of European regulatory framework, including Volume IXB and implications of the proposed EU pharmacovigilance legislation
- Implications for global environment – link to VICH
- Practical applications of definitions

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

Causality assessment

- The principles of causality assessment with practical examples
- Medical evaluation of individual reports of adverse events
- Strategies for follow-up

Pharmacovigilance case studies

Electronic communication in pharmacovigilance

- Reporting in EV Vet
- VEDDRA

Minimising the impact of data with errors

- Consistent assessment and coding

Clinical trial AE reporting requirements

- Post-authorisation safety studies
- Phase IV studies

Literature searches

- Peer-reviewed worldwide literature
- Local journals and magazines

PSURs

- Format and content of the PSUR
- Analysis of data
- Incidence calculation
- Compliance and the PSUR
- Addendum reports
- Bridging reports

Practical workshop on PSURs

Introduction to Veterinary Pharmacovigilance

Schedule and prices

Three ways to book:

Online
management-forum.co.uk/2211

Email
bookings@management-forum.co.uk

Telephone
+44 (0)20 7749 4730

Ref	Date	Location	Price	Early booking price	Until*
11599	**26-27 Apr 2022**	Live webinar	GBP **1,199** + VAT = 1,438.80 EUR **1,719** + VAT = 2,062.80 USD **1,942** + VAT = 2,330.40	GBP **999** + VAT = 1,198.80 EUR **1,439** + VAT = 1,726.80 USD **1,630** + VAT = 1,956.00	**22 Mar 22**
11405	**5-6 Jul 2022**	Venue TBC	GBP **1,399** + VAT = 1,678.80 EUR **1,959** + VAT = 2,350.80 USD **2,182** + VAT = 2,618.40	GBP **1,199** + VAT = 1,438.80 EUR **1,679** + VAT = 2,014.80 USD **1,870** + VAT = 2,244.00	**31 May 22**
11725	**18-19 Oct 2022**	Live webinar	GBP **1,199** + VAT = 1,438.80 EUR **1,719** + VAT = 2,062.80 USD **1,942** + VAT = 2,330.40	GBP **999** + VAT = 1,198.80 EUR **1,439** + VAT = 1,726.80 USD **1,630** + VAT = 1,956.00	**13 Sep 22**

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 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