IPI Academy

MANAGEMENT forum

Presented by
Management Forum

The Animal Health Summer School: Working Through Veterinary Drug Development in the EU and USA

17-20 June 2024

This practical four-day course provides a comprehensive understanding of veterinary medicine development in the EU and USA.

Format:
Classroom

CPD:
24 hours for your records

Certificate of completion

Course overview

This intensive four-day course provides a thorough understanding of how to develop a veterinary medicine in the EU and USA.

The development of a veterinary medicine is complex, time consuming and expensive. It requires teamwork from individuals with different scientific training and a wide range of skills. Everyone involved must be aware of the main stages in the development programme and be able to relate his or her responsibilities to the expertise and needs of the scientists and commercial members of the team. Furthermore, different approaches taken by the regulatory authorities in the EU and the USA mean that a comprehensive development programme must be designed in order for the product to be commercialised in both regions.

The event has been designed to demonstrate how pharmaceutical, pharmacological, toxicological and clinical investigations and regulatory management are brought together in the development programme. It will take participants through all the stages in the development of a veterinary medicinal product for which a marketing authorisation is sought in the EU and the USA. Presentations will cover pharmaceutical and process development, toxicological, pharmacological, residues and environmental studies, safety risk assessments, clinical development, regulatory and marketing input and project management.

Gain a comprehensive understanding of the processes for the EU and USA, including:

- EU and US regulatory frameworks, strategies and procedures
- EU Maximum Residues Limits applications and consumer safety evaluation in the marketing authorisation
- US FDA approach to Human Food Safety studies
- User safety risk assessment
- Environmental risk assessment
- EU and US target animal safety
- Planning pre-clinical and clinical development
- Overview of the Chemistry Manufacturing and Controls package
- Limited Markets applications and Minor Use and Minor Species (MUMS)
- Writing and managing regulatory submissions

Who should attend?

This course has been designed for anyone who has limited experience in only one of the disciplines in veterinary medicine development, such as pharmaceutical or analytical development, clinical trials, regulatory affairs or quality assurance. Anyone learning the role of project manager, as well as more experienced personnel seeking to review special problems encountered in product development, will benefit from the comprehensive programme delivered by experienced professionals.

Previous delegates who have benefited from this course include clinical scientists, pharmaceutical scientists, marketing managers and personnel from regulatory affairs, R&D and development.

Programme

Day 1

EU regulatory framework for regulation of veterinary medicines

- What is the EU?
- EU legal framework for regulation of veterinary medicines
- Legal base of procedures and data requirements

US regulatory framework for regulation of veterinary drugs

- Current governing laws and regulations
- Federal agency jurisdictions

EU and USA: differences and similarities

- Phased submission in USA vs marketing authorisation application in EU
- EU Maximum Residues Limits vs US Human Food Safety section
- EU variations vs US supplements
- EU Certificate of Suitability and Active Substance Master Files vs US Drug Master Files
- Different requirements for user safety and environmental risk assessments

The global development programmes

- Requirements for EU
- Requirements for USA
- Achieving a global development programme

USA regulatory strategies and procedures

- Applications for New Animal Drug Applications and supplements
- Generic drug applications

EU regulatory strategies and procedures

- Full and abbreviated applications
- Centralised procedure, Decentralised, Mutual/Subsequent Recognition and National procedures

Workshop - session 1

Day 2

Safety dossier of the EU Maximum Residue Limits application

- The toxicological data requirements
- Determining the NOEL and ADI

USA FDA approach to Human Food Safety studies

- Toxicology studies
- Margins of safety

Residues dossier requirements in EU

- 'Hot' and 'cold' residue studies
- How to determine maximum residue limits
- Analytical methods for residues
- Determining the withdrawal period

FDA evaluation of consumer safety

- Human food technical safety section
- Residue issues

Environmental risk assessment Phases I and II

- Critical evaluation of your data package
- Phase I assessment
- Refining risk assessment
- Phase II assessment Tiers A and B
- What to do if risk assessment gives cause for concern

User safety risk assessment

- Reviewing toxicology studies
- Setting the scenario
- Risk assessment and management

Workshop - session 2

Day 3

Pharmacokinetics and bioequivalence

- ADME studies
- Bioequivalence

EU and US clinical development

- Dose selection
- Field studies
- VICH guidelines
- Claim-driven approach in US
- Protocol review and concurrence with CVM
- Value of VICH guidance

EU and US target animal safety

- Pivotal target animal safety studies
- Other safety studies

Limited Markets and Minor Use and Minor Species (MUMS)

- MUMS approaches in EU and USA
- What are minor uses?
- What are minor species?
- Approaches to preparation of clinical data

Workshop - session 3

Day 4

Workshop - presentations

Pharmaceutical development and the CMC package

- Characterising the active substance
- Formulation development
- Analytical development and setting specifications
- Process scale-up and validation
- Stability studies and shelf life

Managing the USA regulatory submission

- Systems of review at CVM
- Team interaction
- Company and regulator interactions

Writing and managing the EU regulatory submission

- Writing the marketing authorisation application
- Summary of product characteristics and labelling
- Working with writers on detailed and critical summaries in the EU
- Pre-submission advice and oral hearings

Presenters

David Petrick

Dr David Petrick has over 30 years' experience in bringing novel animal health products to the marketplace. During his professional career he has worked in Regulatory Affairs and Product Development for both American Cyanamid Company and Schering-Plough Animal Health.
In 2004 he founded the Delta Consortium Regulatory Consulting Limited, serving as a consultant in Regulatory Affairs for animal health companies. In 2009 he joined Triveritas and was a part of the opening of Triveritas, USA. In 2004 Dr Petrick joined Velcera, a venture capital funded animal health company and was the Executive Vice President of Research Development and Regulatory Affairs. Velcera was sold to a major pharmaceutical company in 2010.
He holds a degree in veterinary medicine from the University of Pennsylvania, and a law degree from Seton Hall University. He is a member of the American Veterinary Medical Association, the American Bar Association, the New Jersey Bar Association and the New Jersey Bar.

Andrew Hewitt

Dr Andrew Hewitt is a veterinarian with over 14 years of experience in Veterinary Medicinal Product development in a clinical and regulatory capacity. In his current position as Senior Advisor for Veterinary Product Development at knoell, Andrew manages all aspects of regulatory input in product development and registration, from early proof of concept right through to post authorisation work. Taking advantage of previous his previous role as a clinical practitioner in the UK, and investigator and monitor on clinical trials, Andrew brings a broad range of clinical and regulatory knowledge to projects. With extensive experience interacting with regulatory authorities in most major global animal health markets, Andrew has a particular interest in strategic regulatory planning during product development.

Course date

17-20 June 2024	**Classroom** London *Course code 13742*	GBP **2,399** EUR **3,359** USD **3,743**

How to book

Online:
ipi.academy/2050

Alternatively contact us to book, or if you have any queries:

Email:
info@ipi.academy

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Discounts

- Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

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
IPI Academy (and our training partners) 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, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews

★★★★☆

Very clear and complete presentation. Very experimented speakers

Florian Lamarque
Planificateur
Ceva Santé Animale
Jun 19 2023

★★★★★

The programme is very complete as it is and nicely balanced with workshop and presentation […] All three were very nice and clear speakers with good atmosphere.

Clélia Stevenin
Regulatory Affairs Manager
Boehringer Ingelheim France
Sep 12 2022

★★★★☆

There was a good level of information provided and some good real examples added that made it easier to understand. The speakers were clearly knowledgeable and able to share knowledge

Angela Thornton
Dechra Pharmaceuticals plc
Sep 12 2022

★★★★★

The webinar was prepared in a high quality manner.

Michel Salatiel Guzman Gomez
Boehringer Ingelheim Vetmedica GmbH
Jun 21 2021

Run this programme in-house for your whole team

Coming to IPI Academy 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 our training advisers:

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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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