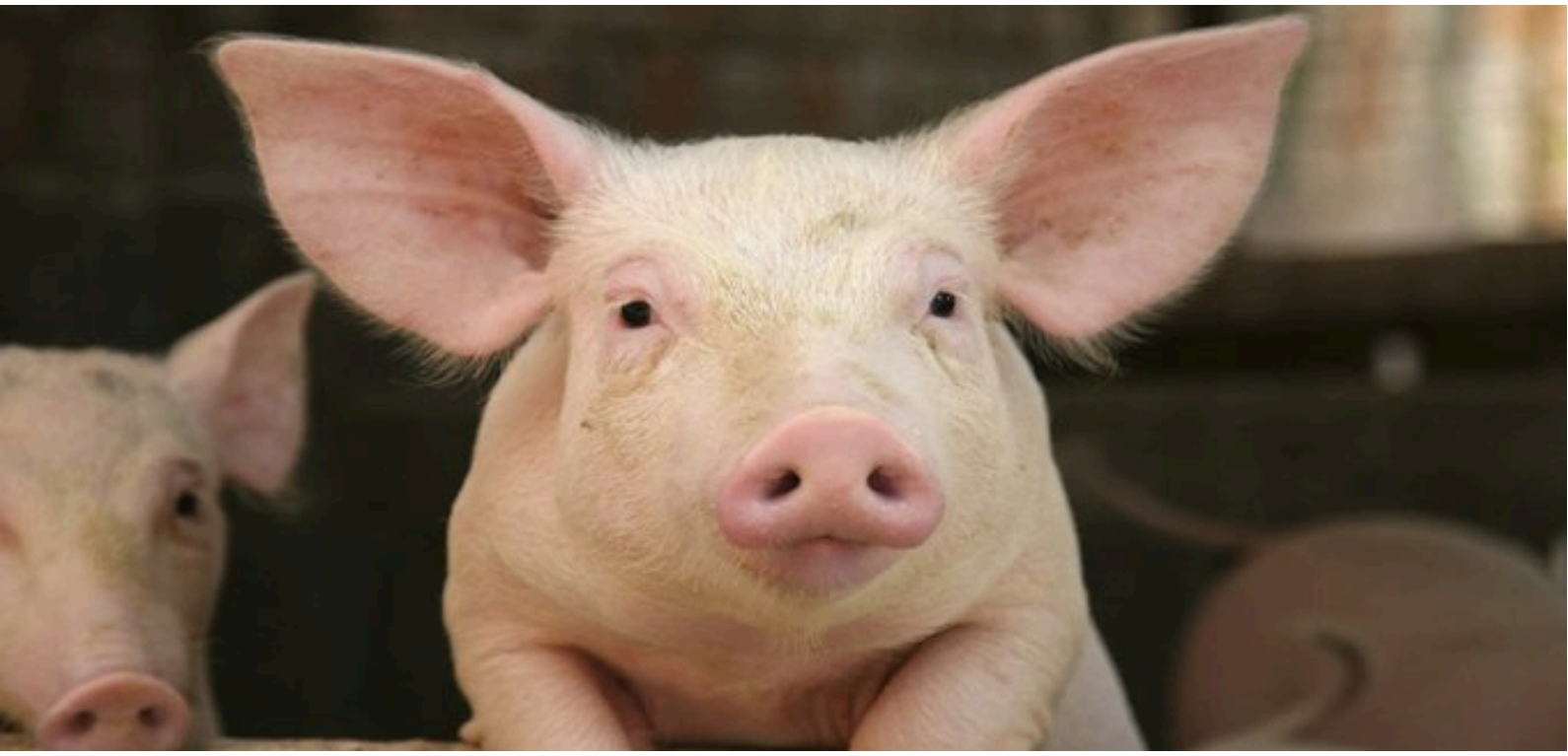
IPI Academy

MANAGEMENT forum



Presented by
Management Forum

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

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

Format:
Bespoke training

CPD:
24 hours for your records (depending on your requirements)

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.

Benefits of attending

- **Explore** EU and US regulatory frameworks, strategies and procedures
- **Learn** the EU Maximum Residues Limits applications and consumer safety evaluation in the marketing authorisation
- **Understand** US FDA approach to Human Food Safety studies
- **Clarify** user safety risk assessment and environmental risk assessment
- **Know** EU and US target animal safety
- **Plan** pre-clinical and clinical development
- **Gain** an overview of the Chemistry Manufacturing and Controls package
- **Look** at limited Markets applications and Minor Use and Minor Species (MUMS)
- **Grasp** 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.

Reviews

★★★★★

I was hoping to learn about the reg process for companion animals - the course more than delivered on this!

Scott J. Roberts
Reader in Translational Skeletal Research
Royal Veterinary College
Jun 17 2024

★★★★☆

Nice training with committed speakers, participants were involved. Content is dense but well explained.

Anne Trotel
Clinical Project Manager
Ceva Animal Health
Jun 17 2024

★★★★☆

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

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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