IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Veterinary Pharmaceutical Submissions in the EU

19-20 May 2025
+ 25-26 November 2025

Presentations will cover the regulatory framework, pharmaceutical, toxicological and pharmacological data, safety risk assessments, pre-clinical and clinical data, critical expert reports and regulatory submissions.

Format:
Live online, Classroom

CPD:
12 hours for your records

Certificate of completion

Course overview

Obtaining a marketing authorisation for a veterinary medicine can be a costly and time-consuming process and this practical two-day course will equip participants with the key information to achieve a successful application.

The programme will take delegates through all of the constituent parts of the application for marketing authorisation for a veterinary medicinal product in the European Union, including the maximum residue limits dossier.

Presentations will cover the regulatory framework; pharmaceutical, toxicological and pharmacological data; safety risk assessments; pre-clinical and clinical data; critical expert reports and regulatory submissions.

An important part of the programme will be devoted to working on case studies in the workshop sessions and there will be ample opportunity for discussion throughout the two days with the expert trainer and fellow professionals.

Benefits of attending

- **Understand** the EU regulatory framework
- **Learn** the pharmaceutical data requirements
- **Know how** to comply with the safety requirements
- **Review** the user safety risk assessment
- **Consider** the environmental risk assessment
- **Receive** guidance on preparing critical expert report
- **Consider** the pre-clinical and clinical requirements
- **Take away** regulatory strategies and procedures
- **Acquire** the skills to write the regulatory submission

Who should attend?

Personnel working in the following departments:

- Regulatory affairs
- Research and development
- Clinical trials
- Marketing

The course will also be valuable to those seeking to review special problems encountered in the registration of veterinary medicines.

Programme

Day 1

EU regulatory framework

- Understanding the regulatory objectives
- EU legal framework
- Legal base of regulatory procedures and dossier requirements

Part 2: Pharmaceutical data requirements

- Formulation and analytical data
- Manufacturing process
- Stability studies

Maximum Residue Limits (MRLs) and MA Part 3B residues data

- MRL dossier: safety file and residue file
- Residue depletion studies
- Setting the withdrawal period

Pharmacokinetics and bioequivalence

Workshop session 1

Planning a dossier to contain:

- Pharmaceutical development studies
- Toxicological, pharmacokinetic, metabolism and residue studies
- Pre-clinical and clinical studies

Day 2

Part 3A of the marketing authorisation (MA) application

- Pharmacology and toxicology studies
- User safety risk assessment
  - Setting the scenario
  - Risk assessment and management
- Environmental risk assessment
  - Phase I and II assessments

Part 4A: Pre-clinical data

- Pharmacodynamics and pharmacokinetics
- Bioequivalence studies
- Resistance
- Dose determination and confirmation
- Target species tolerance

Part 4B: Clinical data

- Clinical trials

EU regulatory strategies and procedures

- Full and abbreviated applications
- Generic applications
- Centralised procedure
- Decentralised, MRP and national procedures

Writing the regulatory submission

- Writing the dossier
- Summary of product characteristics and labelling
- Working with writers of detailed and critical summaries

Presenters

Dave Parry

David Parry is a chemist with over 14 years of experience in in veterinary medicinal product development and registration. In his current position as CMC team leader at knoell, David works with manufacturers in developing formulations and the commercial manufacturing process. Taking advantage of his previous roles in pharmaceutical research and development and process development, David brings a broad range of chemistry, manufacturing and regulatory knowledge to projects. With extensive experience interacting with regulatory authorities in most major global animal health markets and working with contract manufacturing organisations, David is involved with all aspects of regulatory support from early stage development through to post approval product maintenance.

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 dates

19-20 May 2025	**Live online** 09:00-16:30 **UK (London)** (UTC+01) *Course code 14539*	GBP **1,499** EUR **2,099** USD **2,399**
25-26 November 2025	**Classroom** London *Course code 15096*	GBP **1,499** ~~1,699~~ EUR **2,099** ~~2,379~~ USD **2,407** ~~2,719~~ **Until 21 Oct**

How to book

Online:
ipi.academy/1753

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

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

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

★★★★★

Excellent. Hoped to achieve better understanding of clinical and quality parts of the dossier and this was very well accomplished.

Päivi Jutila
Regulatory Affairs Manager
Vetcare Ltd
Nov 26 2024

★★★★★

Very content with the course! The length of each chapter was nicely timed, breaks were ideal. The case we studied was a very good way to summarize all the information [seen] and it generated a lot of interesting questions/dilemmas. I would recommend.

Emma Vanmechelen
Regulatory Affairs Specialist
DeLaval
Nov 26 2024

★★★★★

Very nice. I would recommend.

Magali Rigo
RA Pharma Manager
Boehringer Ingelheim Animal Health
Dec 12 2023

★★★★☆

I wanted to get some good practices on how to manage dossier from a strategic and admin standpoint. Recommendations were given during the training so I think info I wanted to get was given.

Karine Tanan
Principal Scientist, Scientific and Regulatory Affairs
Cargill R and D Centre Europe
Dec 12 2023

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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