IPI Academy

MANAGEMENT forum

Presented by
Management Forum

A Practical Approach to Veterinary Vaccine Development and Registration in the EU

6-7 November 2025

This event has been designed to give practical advice and guidance on how to successfully develop market approval in the EU. The programme will take participants through a step-by-step approach to the process and will also provide key guidance on how to maintain MA once achieved.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

Demand for biologics in veterinary medicine is increasing. However, developing vaccines and successfully obtaining market authorisation brings its own complex and challenging issues.

This course has been designed to give practical advice and guidance on how to successfully develop a veterinary vaccine and achieve market approval in the EU, ensuring that participants gain a comprehensive insight into the necessary requirements.

The programme will take a step-by-step approach to the process and will include a workshop to help delegates gain a better understanding of the requirements in practice. There will be ample time for discussion throughout the two days with our expert faculty and fellow professionals.

Sponsored by:

Benefits of attending

- **Recognise** the key legislation and guidance and how to use this to plan an effective veterinary vaccine development
- **Understand** what data you need to generate for your application and how to present this in your dossier
- **Gain** an insight into the different routes to market and how to submit your dossier for market approval
- **Learn** how and when to seek regulatory advice during development
- **Consider** the implications of the ongoing review of the Veterinary Medicines Regulations

Who should attend?

This event will be beneficial to all those working with veterinary vaccines from development to market approval.

The programme will be of particular interest to:

- New entrants to registration departments
- Veterinary medicinal product manufacturers
- Registration managers
- Research and development departments
- Academics with an interest in commercialising opportunities
- Personnel from micro/small and medium-sized enterprises (SMEs)

Programme

Day 1

A practical guide to the EU regulatory framework for veterinary vaccines

- Regulatory bodies
- Key legislation and guidance
- Update on the legislation review

Meeting the requirements of the marketing authorisation dossier – part 2: quality

- Legislation and guidance
- Layout and content of the Part 2 dossier

Meeting the requirements of the marketing authorisation dossier – part 3: safety

- Legislation and guidance
- Data requirements for the demonstration of safety
- Layout of the Part 3 dossier

Meeting the requirements of the marketing authorisation dossier – part 4: efficacy

- Legislation and guidance
- Data requirements for the demonstration of efficacy
- Layout of the Part 4 dossier

Day 2

Using the summary of product characteristics (SmPC) as a tool for development

Planning a vaccine development – introduction and workshop

Workshop - groups report back and Q&A

Preparing the dossier submission

- Marketing authorisation dossier – Part 1: Administrative documentation, DACS and benefit risk assessments and product information
- Tips on dossier writing and e-submissions

European licensing procedures and regulatory strategy

- Centralised procedure
- Decentralised procedure
- Mutual recognition procedure
- Regulatory strategy

Seeking regulatory advice and development of novel vaccines

- Meetings with regulators
- Scientific advice
- Innovation Task Force (ITF)

Procedures aimed at promoting innovation and vaccine availability

- Minor use/minor species (MUMS) classification
- Small/medium enterprise (SME) designation
- EMA network strategy 2020

Presenter

Mel Munro

Dr Mel Munro has worked as a consultant in veterinary medicinal product development and registration for over 20 years. She provides regulatory advice on all areas of biologicals product development taking client projects from proof of concept through to Marketing Authorisation (MA). On a day-to-day basis, she advises on regulatory strategy, performs technical due diligence and gap analyses and prepares strategic development plans and expert reports. She is also experienced in negotiation with the regulators and preparing regulatory documentation. Over her career she has been involved in numerous biologicals projects ranging from more 'conventional' vaccines to novel biologicals such as products of rDNA technology, GMO's, monoclonal antibodies, DNA vaccines and gene therapy.

Course date

6-7 November 2025

Live online
08:30-15:30 **UK (London)** (UTC+00)
Course code 15303

GBP **1,299** ~~1,499~~
EUR **1,819** ~~2,099~~
USD **2,087** ~~2,399~~
Until 02 Oct

How to book

Online:
ipi.academy/2114

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

★★★★★

Content was great. Presentation and speakers kept me engaged, so very good too. The Interactive Workshop on Product Development was a very helpful exercise

Lillian Sibanda
Assistant Director
Australian Pesticides And Veterinary Medicines Authority
Mar 11 2024

★★★★★

The presentations were clear and precise and a good source for information after the the training.

Gabriele Hoesch
Manager Quality Transfer, Launch & Projects
Boehringer Ingelheim Vetmedica GmbH
Jul 10 2023

★★★★☆

It was a very good training regarding all aspects: organisation, speakers, documents, timing. A lot and very useful information.

Yasmina Mallouk
Quality Assurance Auditor
Boehringer Ingelheim
Jul 10 2023

★★★★★

My intent was to get an overall picture of the lay out of a vaccine registration dossier, content and submission timelines. Thanks to the extensive course, I got a full and complete tool box.

Frédérique Cernicchiaro
Specialiste Pharmacovigilance Globale
Boehringer Ingelheim
Mar 17 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:

ALEKSANDRA BEER
Tel: +44 (0)20 7749 4749
Email: inhouse@ipiacademy.com

YESIM NURKO
Tel: +44 (0)20 7749 4749
Email: inhouse@ipiacademy.com

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.

10-12 Rivington Street
London EC2A 3DU

ipi.academy
Tel: +44 (0)20 7749 4749
Email: info@ipiacademy.com