IPI Academy

MANAGEMENT forum

Presented by
Management Forum

A Practical Approach to Developing the CMC Package for Veterinary Pharmaceutical Products

5 November 2024

Understanding the chemistry, manufacturing and controls (CMC) requirements for veterinary pharmaceuticals is essential to support successful registration in the EU. Regulations for CMC of veterinary pharmaceuticals are complex and are regularly updated, making pharmaceutical product development challenging. This course is designed to guide you through the essential steps in development of the formulation and manufacturing process, in a manner that will ensure regulatory compliance for clinical trial applications and marketing authorisation applications.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Overview

Understanding the chemistry, manufacturing and controls (CMC) requirements for veterinary pharmaceuticals is essential to support successful registration in the EU.

Regulations for CMC of veterinary pharmaceuticals are complex and are regularly updated, making pharmaceutical product development challenging. Information presented in the CMC section (Part 2) of the veterinary pharmaceutical dossier enables you to demonstrate successful pharmaceutical development and support post approval change management.

This course is designed to guide you through the essential steps in the development of the formulation and manufacturing process, in a manner that will ensure regulatory compliance for clinical trial applications and marketing authorization applications. Requirements for a range of veterinary dosage forms will be addressed with reference to guidance and legislation applied by EU regulators. Pharmaceutical development, manufacturing activities and the content of the CMC (Part 2) regulatory submission will be covered with consideration of VICH and EU provisions.

Benefits of attending

- **Understand** the EU regulatory framework governing CMC aspects of veterinary pharmaceutical development
- **Gain** a detailed review of product development steps to fulfill requirements for Development Pharmaceutics
- **Confirm** the manufacturing and stability protocol to meet EU regulatory expectations
- **Review** the impact of the CMC data package on post-approval change management
- **Learn** from experienced CMC regulatory experts and gain an understanding of the complexities and opportunities in the development of veterinary pharmaceutical products

Who should attend

This course will be beneficial to personnel in the following departments and roles:

- Regulatory Affairs
- Quality Assurance and Manufacturing
- Research and Development
- CMC technical writers

Programme

EU CMC guidelines for veterinary pharmaceuticals

- EU legal requirements for CMC
- EMA CMC guidelines
- EMA Scientific Advice for CMC

Development requirements for the active substance

- New substance: process development and production of clinical and regulatory batches
- Supplier qualification
- Transfer of test methods
- Setting the specification

Development Pharmaceutics - Part 1 Formulation and Analytical Development

- Dosage form selection
- Excipient selection and compatibility
- Preliminary stability
- Antimicrobial preservative and antioxidants
- Packaging selection
- Analytical method development and validation

Programme

Development Pharmaceutics - Part 2
Process Development

- Quality by Design
- Scale-up pilot scale to engineering batch
- Developing in-process controls
- Selection of sterilization method
- Process validation protocol

Manufacturing and stability considerations for EU regulations

- Scheduling for submission batches
- Stability protocol
- Bracketing and matrixing

Programme

Part 2 - dossier and expert report preparation

- Data requirements for the Part 2 dossier
- Presentation of the CMC development package
- Specification for starting materials
- Specification for dosage form
- Method validation
- Shelf life and in-use shelf life

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.

Craig Evans

Craig Evans is a chemist with over 13 years experience in the veterinary medicines field, working on everything from initial registrations to post-approval activities including change controls captured with variations. Craig works directly with multiple pharmaceutical companies, providing expert knowledge relating to a variety of areas of veterinary medicines. Craig has in depth knowledge of CMC activities, and has an excellent working understanding of Regulatory Guidelines in the EU.

Course date

5 November 2024

Live online
09:00-16:45 **UK (London)** (UTC+00)
Course code 14329

GBP **549** ~~649~~
EUR **789** ~~929~~
USD **893** ~~1,049~~
Until 01 Oct

How to book

Online:
ipi.academy/2715

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

Email:
info@ipi.academy

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

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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