PTI

REGULATORY AFFAIRS FOR VETERINARY MEDICINE

LIVE Online Academy

23 November - 1 December 2020

PTI

Understand the regulations surrounding the authorisation and maintenance of veterinary medicinal products in the EU

COURSE OVERVIEW

Veterinary medicines follow a strict regulatory framework to ensure the wellbeing of animals and to keep animals healthy in the food chain for human consumption.

This course is designed for the regulatory professional to give a complete guide to the regulatory guidelines surrounding the authorisation of veterinary medicinal products in the EU. The course will provide you with fundamental regulatory knowledge to help you unpick the complexity of the system and apply your knowledge to achieve fast product approval and effective product maintenance.

You will explore the regulatory landscape for veterinary medicines and examine the European licensing procedure for product approval. You will discuss in detail the submission process, analysing areas such as quality and efficacy.

Dr Mel Munro

Dr Mel Munro has worked in the regulation of animal health medicinal products since 2002. In her currently role at the veterinary product development consultancy group, Triveritas, she is responsible for all aspects of veterinary vaccine development. Mel spends most of her time providing strategic and expert regulatory advice on new product developments including assisting clients with Start-to-Finish projects - taking ideas from proof of concept all the way through to Marketing Authorisation. In addition to providing regulatory strategy she also has extensive experience in the preparation of documents and dossiers for regulatory submissions and runs regulatory procedures on behalf of clients. Over her career she has been involved in the development of conventional veterinary medicinal products but more recently has worked on several high-tech products containing novel recombinant antigens and various novel veterinary biotherapeutics.

Dr Andrew Hewitt

Dr Andrew Hewitt is a veterinarian who has been working in Veterinary Medicine Product Development in a clinical and regulatory capacity since 2007. In his current role with global animal health product development CRO Triveritas, Andrew manages regulatory affairs projects covering all aspects of product development and maintenance from early proof of concept right through to post authorisation work. Andrew also acts a back up Qualified Person for Pharmacovigilance (QPPV), delivering pharmacovigilance services for Triveritas and its clients. Taking advantage of previous experience as a clinical practitioner in the UK and investigator and monitor on clinical trials, Andrew brings a broad range of knowledge to regulatory projects and has a particular interest in strategic regulatory planning.

SESSION ONE 13:00 GMT NOVEMBER 23

Welcome and Introductions

Overview of the regulatory landscape for veterinary medicines in Europe

- The institutions and bodies
- European and Member State Law

The rules governing veterinary medicines in Europe

- Veterinary Medicinal Product Legislation (the Community Code and European Pharmacopoeia)
- Guidelines, Opinions and Recommendations

Update on the Veterinary Medicine Legislation Review

What aspects of the current legislation will be changing?

Q&A Session

SESSION TWO 13:00 GMT NOVEMBER 24

Overview of the EU submission – Pharmaceuticals Dossier

Gain an insight into what goes into a Marketing Authorisation (MA) Dossier

- Part 2 – Quality
- Part 3 – Safety and Residues
- Part 4 – Target Animal Safety and Target Animal Efficacy

Overview of the EU submission – Immunologicals Dossier

Gain an insight into what goes into a Marketing Authorisation (MA) Dossier

- Part 2 - Quality
- Part 3 - Safety
- Part 4 - Efficacy

Q&A Session

SESSION THREE 13:00 GMT NOVEMBER 30

Tips on drafting the dossier – Part 1

- Application Form
- The SPC, Labels and Product information
- DACs and Benefit-Risk Assessment

Tips on drafting the dossier Parts 2 to 4

- How to prepare executive summaries
- Electronic submissions and the VNeeS format
- Overview of the submission platforms

European licensing procedures

- Licensing options available in the EU
- Committees involved in scientific evaluation of the product dossier
- The Centralised, Decentralised and Mutual Recognition

Q&A Session

SESSION FOUR 13:00 GMT DECEMBER 1

Marketing Authorisation (MA) maintenance

- Variations

Other European Regulatory procedures

- Scientific Advice
- Maximum Residue Limits (MRLs)
- Generics

Pharmacovigilance overview for veterinary medicines

- Legislation and Vol. 9B
- Responsibilities of the Marketing Authorisation Holder (MAH) and Qualified Person for Pharmacovigilance (QPPV)
- Documenting your PV System (the DDPS)
- Standard Operating Procedures (SOPs) and training

Q&A Session

WHO IS THIS COURSE FOR?

This course has been specifically designed for those working in the development of new veterinary medicinal products

- Regulatory Affairs
- Document Management
- Project Managers in Regulatory Affairs
- Research & Development

For information contact our training consultants

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Receive 15% off for 5+ bookings