The Workshop Team
Workshop Moderator: Claire Davidson,

Session 1: Ruby Singh, FDA, USA (with help from Philippe Sabot, Merial)
Session 2: Ken Noda and Atsushi Yamamoto, MAFF, Japan, and Jean-Pierre Orand, ANSES, France
Session 3: Jason Todd, Veterinary Medicines Directorate, UK (with help from Philippe Sabot, Merial)
Session 4: Gilly Cowan, GALVmed and Rishendra Verma, Regulatory expert, India (with help from Philippe Sabot, Merial)
Session 5: Kevin Rice, FDA, USA (with help from Erik de Ridder, Elanco)
Session 6a: Jean-Pierre Orand, ANSES, France (with help from Erik de Ridder, Elanco)
Session 6b: David Murphy, European Medicines Agency (with help from Rick Clayton, HealthforAnimals)
Session 7: Melanie Leivers and David Mackay, European Medicines Agency
Specific objectives are to review and discuss:

- The essential elements of a regulatory system for the marketing authorisation of veterinary products and the opportunities for stimulating the entry of new quality assured, safe and effective products on the market.

- The roles of legislation and guidance documents, and alignment with international standards.

- Good manufacturing practices (GMP), authorisation procedures for veterinary products and pharmacovigilance.

- The benefits and hurdles of mutual recognition of marketing authorisation processes from other regions with internationally recognised regulatory systems, including GMP.

- The benefits and hurdles of the formation of regional organisations to pool resources and the advantages of alignment with international standards.

- The processes necessary for market control of veterinary products. How to tackle falsified products? What are the critical elements and where should resources be focussed?
Introduction

Objectives

to review and discuss – share knowledge and experience

- The essential elements of a regulatory system
- The roles of legislation and guidance documents
- Authorisation procedures, GMP and pharmacovigilance
- Mutual recognition - benefits and hurdles
- Formation of regional organisations - benefits and hurdles
- Market control of veterinary products