OMICS Group Conferences
Accelerating Scientific Discovery

3rd International Conference on
Pharmaceutical Regulatory Affairs

October 21-23, 2013 DoubleTree by Hilton Hotel San Francisco Airport, USA

USA and EU regulatory submissions for veterinary medicines

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Abstract

The USA and the EU are the 2 major animal health markets in the world.

A combined USA/EU drug development approach allows pharmaceutical companies to co-ordinate resources, shorten development times, promote financial efficiency and ultimately expand revenue. However, a combined approach faces many challenges, as both the USA and EU have significantly different regulatory frameworks, timeframes and requirements. In such a highly regulated industry, knowledge of both USA and EU regulatory requirements, procedure, policy and standards is crucial in order to conduct joint USA/EU programs of development, prepare dossiers for submission and obtain Marketing Authorizations in both territories.

This presentation will describe the similarities and differences between the USA and EU requirements for obtaining a Marketing Authorization for a Veterinary Medicinal Product.

Biography

Karolina Bate has a bachelor's degree in Pharmacology and a PhD in Immunology from the University of Wales, Cardiff. She jointed Cyton Biosciences Ltd in 2007 and currently holds the position of Projects Director. Cyton Biosciences Ltd is a regulatory consultancy based in the UK, which is part of the global Knoell Group.