Combination Products: A Comprehensive Overview of Premarket Opportunities and Postmarket Challenges!

Oct 28 2014 8:30AM - Oct 28 2014 4:30PM | Washington Marriott Wardman Park 2660 Woodley Road, NW, Washington, DC 20008 USA

Overview

An estimated 30% of all new healthcare products under development today are combination products and the global drug-device combination products market is expected to grow to $115B by 2019. In order to tackle the clinical problems of the future, combination products will be used to treat a wide range of diseases from heart attack and stroke to Alzheimer's, cancer, diabetes and beyond! In fact, every area of medicine will benefit because we can potentially erase the damage of disease or injury not just stop it.

This tutorial will highlight the regulatory strategies needed to get products to market. This tutorial will also look at change management concerns including changes, design changes, documentation and reporting. A case study of a fictitious product will also be utilized for practical application of all these elements.

Who Should Attend

Pharmaceutical, academic and government senior-level professionals and decision-makers involved in:

- Drug Development and R&D
- Pharmaceutical and Medical Device Professionals
- Regulatory, Clinical and Other Professionals Responsible for Developing Drug/Device Combinations
- Regulatory Affairs Professionals

Learning Objectives

At the conclusion of this tutorial, participants should be able to:

- Identify regulatory considerations that need to be made to ensure successful management of combination products
- Discuss the impact of post-approval changes
- Recognize changes that require a post-market submission
- Discuss the challenges (engineering, biotechnical, clinical) in developing a combination product

Instructor(s)

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Contact Information

Printable Registration Form

Registration Questions
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