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

Overview and successful strategies for INDs and NDAs

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Abstract

The Federal Food, Drug, and Cosmetic Act (FFDCA) defines a drug as an article that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and that is intended to affect the structure or any function of the body.

A Notice of Investigational Exemption (IND) is required to initiate clinical studies with an investigational drug or biologic in the United States. In addition to the regulations, there are a number of FDA and International Committee on Harmonization (ICH) guidances that are applicable to the format and content of an IND. Once an initial IND is submitted, the Sponsor must wait 30 days before initiating clinical trials under the IND.

A successful regulatory strategy requires a strong understanding of the regulations, guidances, and effective communications with internal stakeholders and with the FDA. Under the IND regulations, there are several types of meetings an IND Sponsor may request with the FDA to ensure there is a common understanding of the chemistry, nonclinical, and clinical studies required to support product approval and the desired product labeling. Opportunities to expedite drug development include successful negotiations with the FDA and effective utilization of Orphan Drug, Fast Track, and the recently enacted Breakthrough Therapy designations.

An approved NDA is required in order to market a drug in the United States. An NDA contains the results from the nonclinical and clinical studies generated throughout development and chemistry, manufacturing, and controls information. In reviewing the NDA, the FDA assesses whether the drug is safe and effective in its proposed use(s), whether the proposed labeling is appropriate, and whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality and purity.

Biography

Michelle Carpenter, Esq. is a seasoned regulatory affairs professional with more than 20 years of global industry experience. Ms. Carpenter has extensive experience in leading negotiations with the FDA and has been involved in the approval and launch of 7 products. Throughout her career she has also had responsibility for Quality Assurance, Project Management, Healthcare Compliance, and Clinical functions. Most recently, she served as Senior Vice President of Regulatory Affairs and Clinical Development for Acucela, a Seattle-based pharmaceutical company. Ms. Carpenter received her law degree from Golden Gate University School of Law in San Francisco, with an emphasis in Health Law and her undergraduate degree from the University of California at Santa Barbara.