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Combination products: Current regulations, challenges and global trends

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Abstract

Combination products are a significant area of the FDA that is rapidly evolving, and eliciting significant interest world-wide. Combination products encompass multi-faceted applicability to a broad repertoire of devices, drugs and biologics targeting high-profile disease indications. The scope and potential for these products in the US and emerging markets is limitless. The FDA Office of Combination Products (OCP) is focused on formulating regulations and guidance documents. The OCP also assigns the primary agency (CBER, CDER, CDRH) jurisdiction for review of the product contingent on the primary mode of action. However, with rapidly advancing technological breakthroughs and overlapping product types the assignment of the primary medical center jurisdiction, applicable policies and management strategies can prove challenging. EU regulators recommend following the FDA regulations for combination products. In addition, international developers could encounter dilemmas during the product development and clinical evaluation of these products in the absence of clearly defined global harmonized regulations. This presentation will provide a comprehensive overview on the current status of regulations, challenges and future trends in the US and other countries.

Biography

Chitra Edwin is a consultant, and principal for Biotechnology Consulting Solutions, Ltd. She has significant product development and management experience in biotechnology, device and IVD companies. She has been a key member in the development of products for infectious diseases, and oncology that have regulatory approval. She is an Adjunct Associate Professor of Pharmaceutical Sciences, University of Cincinnati. Dr. Edwin obtained her Ph.D. from the University of Minnesota, and post-doctoral training at the Harvard Medical School, and the Dana Farber Cancer Institute. She has RAPS certification. She is a Board member of Opus Institutional Review Board (IRB).