Development and approval of combination products : a regulatory perspective

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Abstrak

A step-by-step, integrated approach for successful, FDA-approved combination drug products Using a proven integrated approach to combination drug development, this book guides you step by step through all the preclinical, clinical, and manufacturing stages. Written from an FDA regulatory perspective, the book not only enables you to bring a successful combination drug product to market, it also sets forth the most efficient and effective path to FDA approval. The book begins with an introductory chapter presenting definitions and basic regulatory principles of combination products. Next, it reviews manufacturing and controls, preclinical testing models, pharmacology, clinical testing, regulatory submissions, FDA reviews, and approvals. Among the key topics examined are: The pharmacology, safety pharmacology, and toxicology supporting human clinical trials of combination products Approaches to clinical trial protocol design and execution Chemical, physicochemical, and analytical aspects of manufacturing controls and validation that lead to stable components for combination products Key sponsor/FDA meetings and negotiations essential for approval and commercialization Case studies involving such actual combination products as Mylotarg, Herceptin, and HercepTest help you better understand how to implement the author's practical guidelines. References at the end of each chapter enable you to find more information on any stage of the development, manufacturing and approval processes.