



FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics

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Since the enactment of the first drug law in 1848, the legislation surrounding drug development has evolved into a maze of regulations that can be hard to navigate. Not only are existing regulations constantly reviewed and updated, the increasingly rapid rate of development in the pharmaceuticals field creates new issues that need to be addressed by new legislation. Written in plain language without confusing jargon or legalese, FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics provides a roadmap to the myriad and sometimes confusing regulations that govern this constantly changing field.

The book examines the pertinent aspects of the Federal Food, Drug, and Cosmetic Act as they apply to human drug and device development, research, manufacturing, and marketing. It focuses on the new drug approval process, cGMPs, GCPs, quality system compliance, and the corresponding documentation requirements. Although there are a number of references on these topics, this book is unique in that it is written in a general, easy to read prose style. It presents information drawn from a wide range of resources in a single, easy to use format.

FDA approval can be a lengthy and expensive process. In order for a pharmaceutical manufacturer to place a product on the market for human use, a multiphase procedure must be followed. Providing a reference for students, professionals, and especially those who are charged with the day-to-day tasks of assuring regulatory compliance under FDA guidelines, this book demystifies the inner workings of the FDA and allows you to understand how it operates with respect to product approval.

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