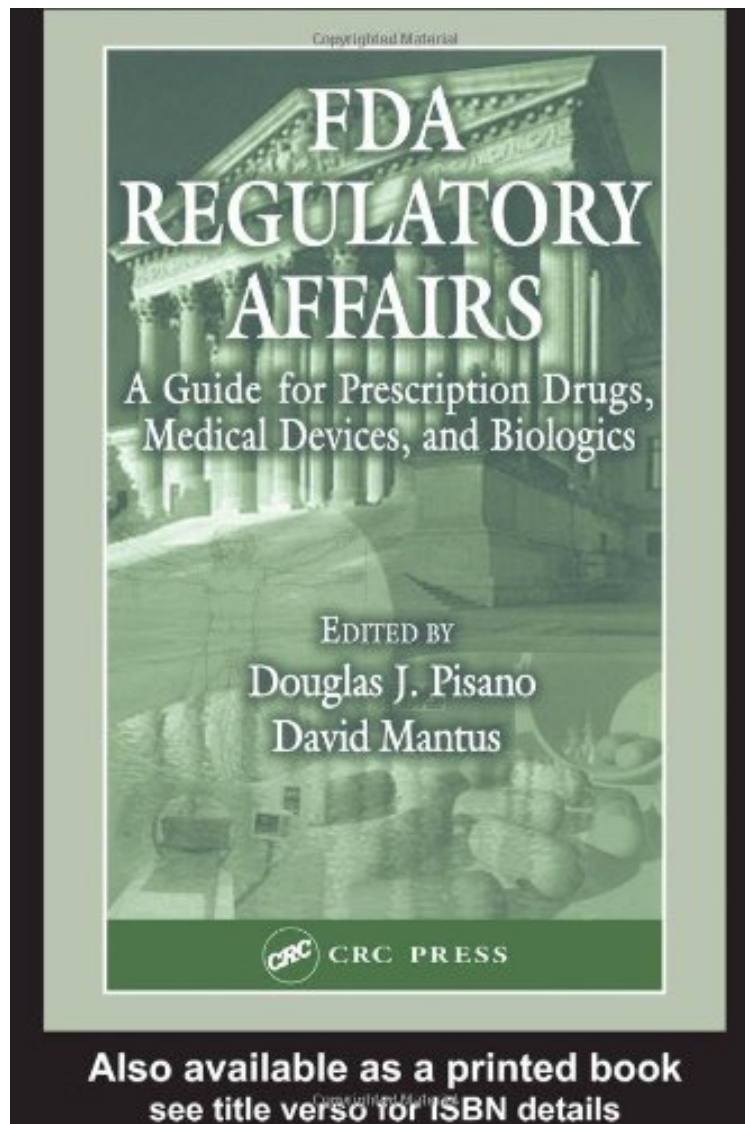


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FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics

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From CRC Press : FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics
before purchasing it in order to gage whether or not it would be worth my time, and all praised FDA Regulatory
Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics:

13 of 14 people found the following review helpful. Doesn't adequately cover medical device regulationBy T. F.

Hurley

Mostly this book covers (perhaps adequately) FDA regulation of the development and approval process of new drugs. These new drugs are (by and large) developed by huge drug companies who doubtless employ teams of lawyers in connection with their FDA submissions and regulatory compliance, and it is quite likely that nearly all involved in that process with such companies would find this to be a "lite" description of FDA drug regulations, and will have little use for this book. (Imagine a beer having only 10 calories, not the 90 or so found in Miller Lite.) Many medical devices, on the other hand, are developed by small companies (such as my employer) and a "layman's level" description (as opposed to a legal treatise) of FDA medical device regulation would be very useful. Since "medical device" is in the title, I figured when buying this book that there would be coverage relating to all FDA regulations pertaining to medical devices. Its why I (or thankfully, my company) bought the book. Ther coverage of medical devices is grossly inadequate. Only a small portion of the book treats (again "litely") FDA medical device regulation, and then it largely covers only the premarket approval process for medical devices and barely mentions (or doesn't even mention--I forget) FDA regulation of the manner in which medical devices may be distributed in the US. Given the relatively high cost of this book, I expected more and was quite disappointed.

8 of 8 people found the following review helpful. Best Available Book for Regulatory Affiars

By H. Grev

Best Available Book for Regulatory Affiars, November 22, 2006

Reviewer: H. Burgoyne (Watertown, MA United States) - See all my reviews

I am currently completing a Masters in Regulatory Affairs and throughout all of my classes, this has been the best source (other than the FDA website, which is most current) pertaining to US reg. affairs. Forget any Parexel books...this one actually has an index, making it easy to find the information you need. Not sure about medical devices, as I do not specialize in them, but for pharmaceuticals and biologics this book is pretty comprehensive. You are not going to get a more "layman's level" interpretation of regulations than this book. Regulations are part of the law, which is never easy to "translate". It is hard to incorporate regulations into a book , as they are constantly being updated, but this book does a pretty good job. I have used the book to develop presentations, study for exams and write papers. If you are interested in US Regulatory Affairs, this book is definitely worth the investment. The price seems high, but is comparable to other books with the same subject matter.

1 of 4 people found the following review helpful. Great resource

By Ryan S. Sanders

This book will not teach you RA, but it will provide you a great reference as an RA professional.

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.