

The book was found

FDA Regulatory Affairs: Third Edition



Synopsis

FDA Regulatory Affairs is a roadmap to prescription drug, biologics, and medical device development in the United States. Written in plain English, the concise and jargon-free text demystifies the inner workings of the US Food and Drug Administration (FDA) and facilitates an understanding of how the agency operates with respect to compliance and product approval, including clinical trial exemptions, fast track status, advisory committee procedures, and more. The Third Edition of this highly successful publication: Examines the harmonization of the US Federal Food, Drug, and Cosmetic Act with international regulations on human drug, biologics and device development, research, manufacturing, and marketing Includes contributions from experts at organizations such as the FDA, National Institutes of Health (NIH), and PAREXEL Focuses on the new drug application (NDA) process, cGMPs, GCPs, quality system compliance, and corresponding documentation requirements Provides updates to the FDA Safety and Innovation Act (FDASIA), incorporating pediatric guidelines and follow-on biologics regulations from the 2012 Prescription Drug User Fee Act (PDUFA) V Explains current FDA inspection processes, enforcement options, and how to handle FDA meetings and required submissions Co-edited by an industry leader (Mantus) and a respected academic (Pisano), FDA Regulatory Affairs, Third Edition delivers a compilation of the selected US laws and regulations as well as a straightforward commentary on the FDA product approval process thatâ™s broadly useful to both business and academia.

Book Information

Hardcover: 400 pages

Publisher: CRC Press; 3 edition (January 23, 2014)

Language: English

ISBN-10: 1841849197

ISBN-13: 978-1841849195

Product Dimensions: 6.3 x 0.8 x 9.1 inches

Shipping Weight: 1.3 pounds (View shipping rates and policies)

Average Customer Review: 4.0 out of 5 starsÂ Â See all reviewsÂ (7 customer reviews)

Best Sellers Rank: #282,920 in Books (See Top 100 in Books) #16 inÂ Books > Medical Books > Pharmacology > Clinical #58 inÂ Books > Textbooks > Medicine & Health Sciences > Reference > Drug Guides #96 inÂ Books > Medical Books > Medicine > Reference > Drug Guides

Customer Reviews

This book has proven, thus far, to be the best reference source I have come across as a student

pursuing a Graduate Certificate in Regulatory Affairs. I would highly recommend this book for all students in a Regulatory Affairs program of study. Wish I would have known about this book when I first started the program.

I was not satisfied by this book. First of all, in the chapters there are many repetitions of the same Topics. For instance, the same concept of GMP is repeated across the different chapters, wasting pages and making the Reader bored. This is because each chapter was written by a different Person. So my understanding is that the Editors failed to harmonize the Contents across the book. Moreover, some Topics like a Medical Device PMA are not deeply discussed, and this is by far the most complex aspect of the regulations that me as buyer I was expecting. Finally, the book does not have Workflows to simplify the understanding as well as Examples. Would have been very useful if, for instance, the authors take the example of a recent Approved drug or device and explain more in Details how to do it. PS: In the book you find much more space on the drugs than for device/biologics. So, be careful of what is your interest.

I was required to purchase this as the assigned textbook for a graduate course. I have not read all of it yet, but have read at least four chapters already. This book contains generally good information; however, it really could have benefited from better editing. It contains numbers of grammatical mistakes and some sections read as if they were first written in another language and then translated into English. The way the chapters have been ordered also strikes me as somewhat illogical. Not the best book I have purchased on this subject.

The book was in good standing and it helped me out on my course, Introductory to Regulatory Affairs for Drugs, Biologics and Medical Devices

[Download to continue reading...](#)

FDA Regulatory Affairs: Third Edition
Third Eye: Awakening Your Third Eye Chakra: Beginner's Guide (Third Eye, Third Eye Chakra, Third Eye Awakening, Chakras)
Third Eye: Third Eye Activation Secrets (Third Eye Awakening, Pineal Gland, Third Eye Chakra, Open Third Eye)
The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices, Second Edition
The Generic Challenge: Understanding Patents, FDA and Pharmaceutical Life-Cycle Management (Fourth Edition)
The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices
The Complete Code of Federal Regulations, Title 21, Food And Drugs, FDA Regulations, 2016
Clinical Trials: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH

Guidelines Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years A Legal Guide for Student Affairs Professionals: (Updated and Adapted from The Law of Higher Education, 4th Edition) Foxfire 5: Ironmaking, Blacksmithing, Flintlock Rifles, Bear Hunting, and Other Affairs of Plain Living (Foxfire (Paperback)) Canadian Men Of Affairs In Cartoon Helping College Students: Developing Essential Support Skills for Student Affairs Practice Reporting the Cuban Revolution: How Castro Manipulated American Journalists (Media and Public Affairs) American intervention in Grenada: The implications of operation "Urgent Fury" (Westview special studies in military affairs) Why Intelligence Fails: Lessons from the Iranian Revolution and the Iraq War (Cornell Studies in Security Affairs) Living Weapons: Biological Warfare and International Security (Cornell Studies in Security Affairs) Foxfire 3: Animal Care, Banjos and Dulcimers, Hide Tanning, Summer and Fall Wild Plant Foods, Butter Churns, Ginseng, and Still More Affairs of Plain Living Foxfire 11: The Old Home Place, Wild Plant Uses, Preserving and Cooking Food, Hunting Stories, Fishing, More Affairs of Plain Living Slaying the Nuclear Dragon: Disarmament Dynamics in the Twenty-First Century (Studies in Security and International Affairs)

[Dmca](#)