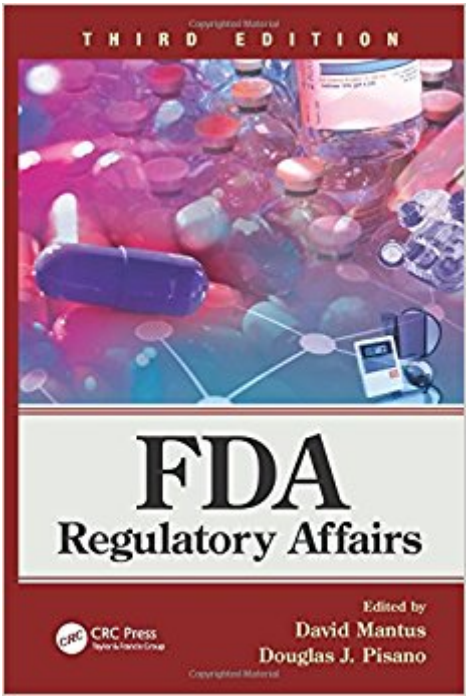
FDA Regulatory Affairs: Third Edition



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 thatÃ¢â ¬â„¢s broadly useful to both business and academia.

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Customer Reviews

"This book covers the myriad of topics related to the development and marketing of all types of drugs and devices regulated by the U.S. Food and Drug Administration. The book discusses not only the relevant regulations, but also the administrative processes that sponsors must deal with in getting their products approved for marketing. ... This book covers many of the important issues in enough depth to answer basic questions related to the components of an IND (investigational new drug) and an NDA (new drug application), as well as IDE (investigational device exemption) and 510k applications. ... This book fulfills a unique need for those seeking a book for a course in drug and device development or for those in the industry who seek information outside of their area of expertise."Ã¢â ¬â ¢Michael R. Jacobs, BS, PharmD, Temple University School of Pharmacy,Ã Â in Doody's Book Reviews

David Mantus worked in the biotechnology and pharmaceutical industry for more than 20 years. He not only served as vice president of regulatory affairs at Cubist Pharmaceuticals but also held various regulatory roles at Sention Inc., Shire Biologics, PAREXEL, the Massachusetts Public Health Laboratory, the Massachusetts College of Pharmacy and Health Sciences, and Procter and Gamble Pharmaceuticals. He received his BS in chemistry from the College of William and Mary, his MS and Ph.D in chemistry from Cornell University, and was a post-doctoral research fellow in biomedical engineering at the University of Washington. He is currently associate professor of pharmaceutical sciences and director, regulatory affairs at MCPHS University in Boston. Douglas J. Pisano received his Ph.D in law, policy, and society from Northeastern University. He has participated on the editorial advisory boards of multiple journals and received the Special Service Award for the Enhancement of Regulatory Education from the Regulatory Affairs Professionals Society. A registered pharmacist and active member of several professional organizations, including the American Association of Colleges of Pharmacy and the Regulatory Affairs Professionals Society, he formerly served as dean of the School of PharmacyÃ¢â ¬â œBoston and is currently professor of pharmacy administration, vice-president of academic affairs, and provost at MCPHS University in Boston.

Absolutely loved the book. I looked at it first in a library and then realized that I must own it. Somebody wrote in his/her review that the material seems to be repetitive. Cannot say this not true, but I found it to be a positive feature. Each chapter is written by a different author(s), so some repetition comes from different people trying to cover their topic and share their perspective on things. It was helpful to me personally, as it gives a better picture of the interplay between various

topics.

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 repetead 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 carefull of what is your interest.

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

This is a great book for FDA RA study and would recommend it.

too pricy for the content of information

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.

Great product and seller!

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