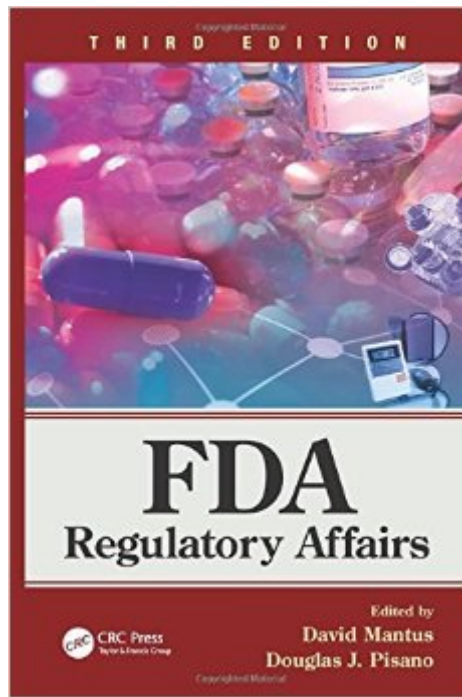


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FDA Regulatory Affairs: Third Edition



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

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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

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Clinical Trials: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH

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