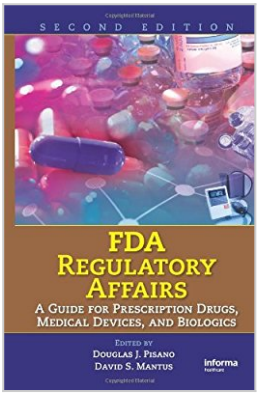

FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics

From CRC Press

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

Examines harmonization of the US Federal Food, Drug, and Cosmetic Act with international regulations as they apply to human drug and device development, research, manufacturing, and marketing. The ***Second Edition*** focuses on the new drug approval process, cGMPs, GCPs, quality system compliance, and corresponding documentation requirements. Written in a jargon-free style, it draws information from a wide range of resources. It demystifies the inner workings of the FDA and facilitates an understanding of how it operates with respect to compliance and product approval.

FDA Regulatory Affairs:

- provides a blueprint to the FDA and drug, biologic, and medical device development
- offers current, real-time information in a simple and concise format
- contains a chapter highlighting the new drug application (NDA) process
- discusses FDA inspection processes and enforcement options
- includes contributions from experts at companies such as Millennium and Genzyme, leading CRO's such as PAREXEL and the Biologics Consulting Group, and the FDA

Three all-new chapters cover:

- clinical trial exemptions
- advisory committees
- provisions for fast track

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

From CRC Press

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

Examines harmonization of the US Federal Food, Drug, and Cosmetic Act with international regulations as they apply to human drug and device development, research, manufacturing, and marketing. The ***Second Edition*** focuses on the new drug approval process, cGMPs, GCPs, quality system compliance, and corresponding documentation requirements. Written in a jargon-free style, it draws information from a wide range of resources. It demystifies the inner workings of the FDA and facilitates an understanding of how it operates with respect to compliance and product approval.

FDA Regulatory Affairs:

- provides a blueprint to the FDA and drug, biologic, and medical device development
- offers current, real-time information in a simple and concise format
- contains a chapter highlighting the new drug application (NDA) process
- discusses FDA inspection processes and enforcement options
- includes contributions from experts at companies such as Millennium and Genzyme, leading CRO's such as PAREXEL and the Biologics Consulting Group, and the FDA

Three all-new chapters cover:

- clinical trial exemptions
- advisory committees
- provisions for fast track

FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics From CRC Press Bibliography

- Sales Rank: #1189633 in Books
- Published on: 2008-08-11
- Original language: English
- Number of items: 1
- Dimensions: 9.50" h x 6.50" w x 1.25" l, 1.70 pounds
- Binding: Hardcover
- 464 pages

Editorial Review

About the Author

DOUGLAS J. PISANO is Dean of the School of Pharmacy and Professor of Pharmacy Administration, Massachusetts College of Pharmacy and Health Sciences, Boston, Massachusetts, USA. Dr. Pisano received his Ph.D. in Law, Policy, and Society at Northeastern University, Boston, Massachusetts, USA. He is an active member of several professional organizations, including the American Association of Colleges of Pharmacy and the American Pharmaceutical Association. A national speaker and invited lecturer, Dr. Pisano was the recipient of the Special Service Award for the Enhancement of Regulatory Education from the Regulatory Affairs Professionals Society in 2000. He has developed several courses and programs at the Massachusetts College of Pharmacy and Health Sciences in such areas as health policy, pharmacy and drug law, and regulatory affairs. Dr. Pisano, along with coeditor Dr. David S. Mantus, is also the editor of the first edition of Informa Healthcare’s FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics.

DAVID S. MANTUS is Vice President of Regulatory Affairs and Program Management, Cubist Pharmaceuticals, Inc., Lexington; Adjunct Professor of Drug Regulatory Affairs, Massachusetts College of Pharmacy and Health Sciences, Boston; and President, C After D Inc., Boston, Massachusetts, USA. Dr. Mantus received his Ph.D. in Chemistry from Cornell University, Ithaca, New York, USA. He is an active member of the Regulatory Affairs Professional Society and the American Chemical Society and is a frequent presenter and lecturer at national conferences on biologics and biotechnology, regulatory affairs, and vaccine development. Dr. Mantus has also served as chairperson for several conferences, including "Outsourcing Regulatory Affairs" and "Vaccine Development for the 21st Century."

Users Review

From reader reviews:

Dione Wicker:

As people who live in the actual modest era should be up-date about what going on or facts even knowledge to make these keep up with the era which can be always change and advance. Some of you maybe will probably update themselves by reading through books. It is a good choice to suit your needs but the problems coming to you actually is you don't know what type you should start with. This FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics is our recommendation to help you keep up with the world. Why, since this book serves what you want and wish in this era.

Debra Daniel:

Hey guys, do you would like to finds a new book to learn? May be the book with the title FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics suitable to you? The book was written by famous writer in this era. The particular book untitled FDA Regulatory Affairs: A Guide for

Prescription Drugs, Medical Devices, and Biologicsis a single of several books that will everyone read now. This kind of book was inspired lots of people in the world. When you read this e-book you will enter the new shape that you ever know ahead of. The author explained their plan in the simple way, thus all of people can easily to understand the core of this e-book. This book will give you a lot of information about this world now. To help you to see the represented of the world on this book.

Pamela Eckert:

The reason? Because this FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics is an unordinary book that the inside of the book waiting for you to snap this but latter it will jolt you with the secret it inside. Reading this book adjacent to it was fantastic author who else write the book in such incredible way makes the content inside of easier to understand, entertaining method but still convey the meaning completely. So , it is good for you for not hesitating having this any longer or you going to regret it. This excellent book will give you a lot of positive aspects than the other book possess such as help improving your proficiency and your critical thinking way. So , still want to hesitate having that book? If I had been you I will go to the e-book store hurriedly.

Heidi Crenshaw:

Playing with family in a very park, coming to see the ocean world or hanging out with close friends is thing that usually you may have done when you have spare time, and then why you don't try factor that really opposite from that. 1 activity that make you not feeling tired but still relaxing, trilling like on roller coaster you are ride on and with addition of knowledge. Even you love FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, you are able to enjoy both. It is great combination right, you still would like to miss it? What kind of hang-out type is it? Oh come on its mind hangout guys. What? Still don't have it, oh come on its identified as reading friends.

Read FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics From CRC Press for online ebook

FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics From CRC Press Free PDF d0wnl0ad, audio books, books to read, good books to read, cheap books, good books, online books, books online, book reviews epub, read books online, books to read online, online library, greatbooks to read, PDF best books to read, top books to read FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics From CRC Press books to read online.

Online FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics From CRC Press ebook PDF download

FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics From CRC Press Doc

FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics From CRC Press Mobipocket

FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics From CRC Press EPub