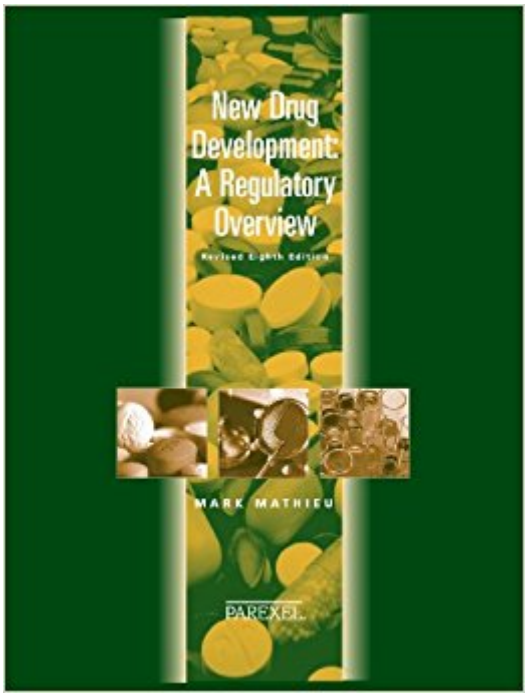
New Drug Development: A Regulatory Overview (New Drug Development (Mathieu))



Synopsis

Go inside the drug development and FDA regulatory process with today's most authoritative and popular reference on the topic. In its all-new 2008 edition, New Drug Development: A Regulatory Overview addresses the most cutting-edge developments redefining how new drugs are developed and regulated today, including:* How the FDA Amendments Act of 2007 will affect everything from drug reviews to postmarketing requirements.* How the CDER's efforts to integrate a culture of drug safety has affected the center's structure and its new drug review and approval processes.* How CDER's much-anticipated January 2008 transition to the eCTD as the only valid esubmission format will affect the FDA's drug submission and review process.* How the FDA and industry are already integrating pharmacogenomics, computer simulation, and other emerging technologies to inform key decisions.* Which drug development strategies are fulfilling their promise and offering optimal returns for industry, given the explosion of accelerated development/approval programs and pilot programs to speed the drug development and review process.Find out why New Drug Development is pharma/biotech's go-to resource for regulatory, clinical, project management, training, and other drug development disciplines navigating the FDA's drug development approval processes.

Book Information

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Customer Reviews

This book provides the most comprehensive and up-to-date analysis of FDA's new drug development process available today. I recommend this well-written book for professionals engaged in the drug development and review process. --Biopharm MagazineThis book is superb! It is the

single best source of information on the drug regulatory system. --Peter Barton Hutt, Covington & Burling

This is a good book, but there are limitations. First, as other have mentioned, no index. Secondly, I bought this book for a class in the winter of 2016. This book was last edited in 2008 and much of it is outdated. 7 years is a long time in the field of regulatory affairs which is ever evolving. Finally, I found some sections within a chapter that were a repeat from other chapters. In summary, not a bad textbook, it just needs to be updated.

I’m doing regulatory intelligence for a client, and this book gave me a lot of great detail about drug development during all the stages, draft guidances and how they’re used, etc (I’m about half way through now).It would be pretty much perfect if it had an index. HUGE downside. I’m combating that by highlighting what I might want to find later and using sticky tabs, but with a textbook this big, it’s very cumbersome to go back and find things. I would really like to go back and find out where draft guidances are referenced, but that’s pretty near impossible. Never even thought to check if the book had one...I just assumed it would!

This is the first textbook that I have used that does NOT have an index at the end. Are you serious? If I have to research a certain topic, I have to use the glossary as a reference yet a certain topic could be discussed in various sections throughout the book so I cant find all the relevant info.

This book needs editing-it does not have an index or a list of abbreviations, and page 154 is repeated on pages 156 and 157. This book is a disaster! It is really hard to use this book to study; the chapters are too long and repetitive; some information is truly unnecessary.

I purchased this book as a required textbook for a Drug Development class in a QA/Regulatory Affairs program. It’s very nicely organized, well written and encompasses a lot of information about all the basics of Regulatory Affair. This is one of those textbooks that I will be keeping for useful reference.

Excellent organization for drug development and evaluation. Vaccines sections are weak and not a focus. Needs revision with changes in FDA processes for review.

Needed the book for class. Good information serves are a fantastic door stop now.

Great book very easy explanation of FDA review and types of submissions involved in drug development process. basically contains top to bottom most information a regulatory person dealing with IND/NDA submission would need.

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