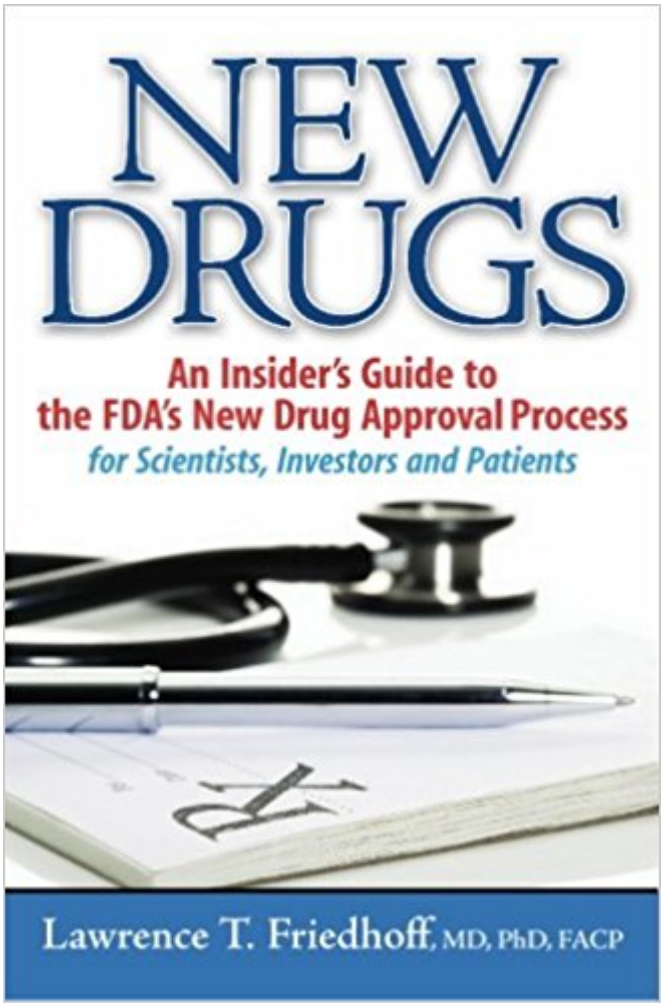
New Drugs: An Insider's Guide To The FDA's New Drug Approval Process For Scientists, Investors And Patients



Synopsis

Drug development, the processes by which a chemical compound becomes a Ã¢â ¬Å“drugÃ¢â ¬Â• and is approved for sale by the FDA and European and Asian regulators, is not for the faint-of-heart or the shortsighted. Designing and monitoring studies, obtaining and analyzing scientific data, and reconciling clinical results against the ethical constraints and regulatory guidelines of government agencies, requires a complex interaction of in-house specialists and academic and commercial consultants worldwide. Scientific, technical, and tactical considerations play out in an environment where a balance must be struck between the often-competing interests of the corporation, its investors, government regulators, and the safety and well being of intended patients. All the while, dwindling patent protections impose an ever-contracting timeframe for success. Written to be accessible to a wide audience, NEW DRUGS provides a thorough, succinct, and practical understanding of these drug-development processes. If youÃ¢â ¬â„¢re involved in the pharmaceutical industry, NEW DRUGS will provide scientific and management tools to increase the likelihood of regulatory approval at each phase of your compoundÃ¢â ¬â„¢s development. If youÃ¢â ¬â„¢re a patient or consumer, NEW DRUGS will enable you to intelligently discuss medications with your health-care provider and empower you to make informed decisions at the pharmacy. If your portfolio, rather than your health, makes you an interested observer of the fortunes of this critical sector of the US economy, NEW DRUGS will help you to decode press releases and annual reports, so that you can recognize and invest in well-run companies with promising products.

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Customer Reviews

"This is an excellent primer on the drug development process that importantly stresses the inter-relationship of studies in each part of the process. I will not only use this book in my course on drug discovery but will also recommend it to faculty interested in translational research." --Anthony Giordano, PhD Assistant Dean of Research and Business Development, Office of Research and Director, Experimental Therapeutics, Feist-Weiller Cancer Center Louisiana State University, Shreveport, LA"Dr. Friedhoff has been a very effective consultant to our firm, and we have profited greatly from his insights. His book, New Drugs, is an eye-opening, inside look at an enormous and very complex sector of the economy, presented in a concise, well-written, and accessible manner. Highly recommended." --Oscar Schafer, Member of "Barron's Roundtable" and Managing Partner of OSS Capital Management, NYC"As the author makes clear, he has learned from many years of drug development. NEW DRUGS really does reveal insider insights that cannot be found in other volumes. This book has been selected for The First Clinical Research Bookshelf." -- Norman M. Goldfarb Managing Director of First Clinical Research LLC

During his 30-year career in pharmaceutical research and development, author Lawrence T. Friedhoff, MD, PhD, FACP has amassed an extraordinary record of industry accomplishments, most notably as the head of the teams that chose, developed, and brought two chemical compounds through regulatory approvals around the world. These new drugs are market Ã¢â ¬Å“blockbusters,Ã¢â ¬Â• each used by millions of patients and each generating well over $1 billion annual revenue worldwide. Dr. Friedhoff's first-hand knowledge of pharmaceutical R&D is extensive and comprehensive: he has held management positions at multi-national corporations developing novel drug compounds, small publicly-traded companies manufacturing generic drugs, start-up ventures, and academic-based research teams writing business plans to obtain venture capital. As an R&D head, he held primary responsibility for choosing drug candidates and preparing comprehensive plans for, as well as managing all phases of, their development, always with an eye towards fulfilling FDA (and often, European and Asian) drug requirements. He has also managed post-FDA-approval activities including collecting and analyzing adverse-event information from consumers, fielding inquiries from patients and healthcare providers, and marketing-related scientific studies. Although the press contains numerous reports of disastrous failed clinical trials, during Dr. Friedhoff's career none of the completed pivotal clinical trials for which he was fully

responsible ever failed and all of his new drug applications (NDAs) submitted to the FDA were approved. Few industry professionals have been able match his achievements.

This isn’t a book to reference when you’re writing an IND. It’s not the book to determine if you need to file a protocol amendment. It’s not the book to help you design Phase III trials. If you want to use this to actually participate in regulatory affairs, you’re out of luck.While Fran Hawthorne’s book is more about the FDA’s interaction with everyone and its eternal balancing act, this book focuses on the POV of someone in industry. There’s a lot of info about the different roles in the business and how these people are motivated and act at every stage of the process. This book is great for people who don’t know anything about regulatory affairs but are part of the drug development process. People often end up cloistered in their fancy offices or lab benches and don’t think about how their work might affect the big picture. This book gives a great overview of that.Also, I think the explicit consideration of ethics was a plus!

This is a book that provides a highly accessible overview of drug approval processes from the perspective of someone who has been there. It is not a technical manual, but rather a narrative on what happens and what needs to happen at each step along the way of a drug’s path to approval. The author drops in many anecdotes on the interpersonal side that I found to be enlightening (such as how to listen to what regulators really mean). I recommend this book for anyone looking to know more, quickly, about this highly complex process

Many books discussing drug development and FDA approval are theoretical, but in this book, Friedhoff gives us a "behind and scenes" view of how it’s really done. The book is a fast read, but full of real-life experiences getting drugs approved. I’d advise anyone involved in drug development or investing to keep this book close by. I think a section on where and how to find drug development investors would be helpful. I give the book 5 stars.Ed SmithPBS-BioTGen

Excellent primer for a better understanding of drug development.I was looking for more information regarding adaptive design and biosimilars

Great book to get an overview of the route of drug approval including the different clinical trial phases required and its components.A must have for people wanting to become MSLs or have just started as an MSL, both inside and outside the US.

Long and repeditive, not what I expected

I feel very excited to find this book. In fact, I view this book as one of the best text books for pharmaceutical industry professionals. It is really in-depth and covers every essential aspect in the new drug development process in a clear and systematic way. Dr. Friedhoff is so skillful in writing that the maze of new drug development and FDA guidelines become so easy to understand and you do not have to be experienced personnel to understand the whole picture. Another thing I appreciate most is that Dr. Friedhoff shares his 30-year professional experience in this book. He not only provides down-to-the-earth but very important information, he also gave us tools to achieve new drug approval. I found all the messages from the book are invaluable. I highly recommend this book.

I great read. It gave a great overview of the drug development process from a Reg Affairs point of view. It provided starting points and in some cases advise for someone who wnats to become an expert. I've been part of new drug development teams and this book provided me with insignt on what goes on up and down the process stream. I loved the book.

New Drugs: An Insider's Guide to the FDA's New Drug Approval Process for Scientists, Investors and Patients Seed-Stage Venture Investing, 2nd Edition: An Insider's Guide to Start-Ups for Scientists, Engineers, and Investors Prescription Drugs: Understanding Drugs and Drug Addiction (Treatment to Recovery and Real Accounts of Ex-Addicts Volume III Ã¢â ¬â œ Prescription Drugs Edition Book 3) Drugs: From Discovery to Approval A Practical Guide to FDA's Food and Drug Law and Regulation, Fifth Edition Clinical Trials, Second Edition: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines Clinical Trials: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines Mastering and Managing the FDA Maze: Medical Device Overview: A Training and Management Desk Reference for Manufacturers Regulated by the Food and Drug Administration The AA Effect & Why You've Never Heard of the FDA-Approved Drugs that Treat Alcoholism (Rethinking Drinking Book 1) Passing on Bypass Using External CounterPulsation : An FDA Cleared Alternative to Treat Heart Disease Without Surgery, Drugs or Angioplasty. SECOND EDITION Hypertension and You: Old Drugs, New Drugs, and the Right Drugs for Your High Blood Pressure New Drugs: Bath Salts, Spice, Salvia, & Designer Drugs (Downside of Drugs) Abusing Over the Counter Drugs: Illicit Uses for Everyday Drugs (Illicit and

Misused Drugs) Percutaneous Absorption: Drugs--Cosmetics--Mechanisms--Methodology: Drugs--Cosmetics--Mechanisms--Methodology, Third Edition, (Drugs and the Pharmaceutical Sciences) Blood-Brain Barrier in Drug Discovery: Optimizing Brain Exposure of CNS Drugs and Minimizing Brain Side Effects for Peripheral Drugs Drugs, Drug Testing, and You (Drug Abuse Prevention Library) I Need Your Love - Is That True?: How to Stop Seeking Love, Approval, and Appreciation and Start Finding Them Instead Drug Addicts- Prescription Pill Drug Abuse: How to Deal With an Addict Adult, Friend, Family Member, Teen or Teenager Who is Addicted to Medications (Prescription Pill Drug Abuse Help) Approval Addiction: Overcoming Your Need to Please Everyone Liked: Whose Approval Are You Living For?