JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 6, No. 4, April 2010 "Can You Handle the Truth?"

"New Drug Development: A Regulatory Overview, 8th Edition"

Mark Mathieu, 2008, 362 pages, PAREXEL, $145

Review by Norman M. Goldfarb

"New Drug Development: A Regulatory Overview, 8th Edition" is the definitive guide through the maze of new drug approval. This edition is updated for the FDA Amendments Act of 2007, CDER's eCTD, "culture of safety," and risk-based GCP compliance programs, emerging technologies like computer simulation, and more. The book discusses CDER's reorganization to better deal with safety issues, adaptive trials, the concept of exploratory IND studies, and the transitions from NDA to eNDA and from CTD to eCTD.

This book has been selected for

The First Clinical Research Bookshelf

Essential reading for clinical research professionals

The challenge of obtaining FDA approval is illustrated by a few statistics for 2006: The rate of clinical holds reached 14% on commercial INDs proposed (43% in the Division of Neurology Products). The NDA Refusal-to-File rate reached 7% (22% in the Division of Pulmonary and Allergy Products).Voluntary complaints regarding clinical investigators, IRBs, sponsors and other entities surged 40% to 352.

The book consists of 16 chapters:

- An Introduction to the U.S. New Drug Approval Process
- Nonclinical Drug Testing
- The IND
- CDER and the IND Review Process
- The Clinical Development of New Drugs
- Good Clinical Practices (GCP)
- The New Drug Application (NDA)
- The NDA Review Process
- The FDA's Priority Review Policy
- Advisory Committees and the Drug Approval Process
- Beyond Approval: Postmarketing Drug Manufacturer Regulatory Responsibilities
- The Supplemental NDA and Postapproval Changes to Marketed Drugs
- The FDA's Orphan Drug Development Program
- CDER's Bioresearch Monitoring Program
- Accelerated Drug Approval/Expanded Access Programs
- The Pediatric Studies Initiative

The book is available in bookstores.

Reviewer

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