Book Reviews

Drugs and the Pharmaceutical Sciences. Volume 100. New Drug Approval Process, 3rd Edition. Edited by Richard A. Guarino. Marcel Dekker, Inc., New York. 1999. xxxiii + 471 pp. 16 × 23.5 cm. ISBN 0-8247-0308-1. $185.00.

Earlier editions of *New Drug Approval Process* have met with general acceptance throughout the pharmaceutical and related industries. The third edition of the book offers many updates along with some additions that the reader will find useful. Because of the wide variations of products that are classified as drugs, the editor has taken steps in the book not to exclude them from consideration when the process of approving a drug or device follows similar regulations. I believe that pharmaceutical professionals, from those in molecular design and drug discovery through those in business development, will find this text a useful road map to understanding the requirements that a drug product must fulfill to achieve approval. In this respect, this book provides guidance.

The book is focused foremost on new molecular entity development and regulations set forth by the FDA and, to a lesser extent, international regulations. From this viewpoint, the book can supplement reading for students preparing to enter a career in the pharmaceutical industry. Particularly useful in this regard is the preface which lists acronyms and initialisms spoken and used by pharmaceutical and regulatory professionals. Other portions, of the book that will be of interest to professionals involved in early stages of the drug development process are the discussions of preformulation and pharmacology prior to entering clinical testing. The book is not, however, a recipe for taking a substance from the laboratory and making a new drug of it. Other areas of assistance in the book include an in-depth discussion of the "applications" needed for filing a drug candidate with the FDA. Here the authors have gone into great detail to annotate and paraphrase the *Code of Federal Regulations*, which is helpful to the reader who is unfamiliar with the language encountered in the regulations. The editor wisely includes sections on effective communication with the FDA.

Almost 50% of the book addresses the clinical phase of product development. While clinical understanding is needed, here the book is perhaps too arrant. The subject of quality assurance is discharged in a paragraph or two and elsewhere in one very short chapter, although this area normally represents one of the greatest impediments to the new drug approval process. I think that the authors could have been more resourceful in providing listings of other textbooks and trade papers in their respective areas, to facilitate the reader's interests. The book does provide bibliographies with footnotes in the chapters. Finally, the book is narrowed by its regulatory considerations, focusing on new drug approvals. Many of the regulatory strategies currently being used by pharmaceutical companies are not discussed in the book. There is discussion of the Rx/OTC switch, and abbreviated new drug applications is presented in description. To the seasoned professional, this comes as a disappointment. Perhaps in the next edition, more attention will be given to this.

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