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Book Review

The Process of New Drug Discovery and Development, 2nd Edition. C. G. Smith and J. T. O'Donnell (Eds.) Informa, Healthcare USA, Inc., New York, NY. 2006

The 2nd edition covers a spectrum of pharmaceutical development activities including drug discovery methods and development strategies. The 1st edition was published over a decade ago and was written by Dr. Smith alone. However, this new edition is more comprehensive with many scientists contributing chapters. New chapters on risk assessment, international harmonization of drug development, dietary supplements, patent law, and entrepreneurial activities have been added. In total, there are approximately 70 contributors to the book with two thirds from the industry, one fifth from the FDA, and the remaining from those contributors who are either independent consultants or from universities.

There is no doubt that the strength of the book arises from the breadth of experiences of the two editors as well as the viewpoint of those in industry and the FDA. To some extent, this book is similar to and reminds the reviewer of Remington's (21st edition), but condensed down to the essentials, for example, what one *really* should know in the large landscape of drug discovery and drug development. Importantly, the essentials come mostly from those in industry and the FDA, so there is very practical and useful information. A weakness of the book is that, except for selected topics mentioned below, material is covered in brevity. For most topics, there are certainly alternative sources that provide more comprehensive information. Nevertheless, this does not diminish the importance of this 2nd edition. The book is an ideal single source on the general topic of drug discovery and development and is very appropriate to be used as a reference material or for training students or new employees.

The book is divided into six sections: Section I, *General Overview* (Chapters 2–3); Section II, *Scientific Discoveries Application in New Drug Development* (Chapters 4–15); Section III, *Standard Drug Development Issues* (Chapters 16–20); Section IV, *Clinical Development* (Chapters 21–24); Section V, *Regulatory and Legal Issues Affecting Drug Development* (Chapters 25–31); and Section VI, *Case Histories* (Chapters 32–35).

Section I, *General Overview*, provides a glimpse of the topics to be covered in the book. Chapter 3 (pp. 16–51) contains general background information that may be best directed to that of first- or second-year pharmacy students or new employees having little experience in drug development. However, information addressing the criteria and selection of dosage forms for clinical development in the form of decision trees is particularly useful.

Section II, *Scientific Discoveries Application in New Drug Development*, covers the topics of combinatorial chemistry, high-throughput screening, pharmacological profiling, antitumor screening, Caco-2 transport screening, metabolomics, pharmacogenetics/pharmacogenomics, safety pharmacology (Chapter 13), nonclinical drug safety assessment (Chapter 14), and genotoxicity testing (Chapter 15). Chapters 13–15 are quite comprehensive and provide very useful information, for example, for those in start-up companies who are heading down this path and who otherwise lack this experience.

Section III, *Standard Drug Development Issues*, covers the topics of animals in biomedical research, new drug substances, pharmacokinetics, compounding, and late-stage process development. Chapters 18 and 19 *Pharmacokinetics* and *Pharmaceutics and Compounding*, respectively, are comprehensive in breadth but cursory in depth.

Section IV, *Clinical Development*, covers the topics of contract research organization, clinical research, and clinical testing issues pertaining to cancer chemotherapy and HIV. Chapter 22, *The Front Lines of Clinical Research: The Industry* by Lori Nesbitt, provides very pertinent information on clinical research, risk-benefit management, and Institutional Review Boards. Chapters 23 and 24 provide points of view on the current and future treatments of cancer and HIV. These chapters are nice overviews on the topic but, except for offering brief comments on clinical trial design, appear somewhat out of place in this section.

Section V, *Regulatory and Legal Issues Affecting Drug Development*, covers the topics of new drug applications, risk-management, and liability in new drug development, markets, and patents. This section, especially, is a must read as it contains a plethora of information and perspectives not easily found or obtained from other sources.

Section VI, *Case Histories*, covers the story of Rituxan, entrepreneurial experiences and advice, an FDA perspective of drug development, and managing R&D uncertainty and risk. These chapters are excellent and a very good read. For any reader, and especially those readers who have more experience in drug development, these chapters may be the highlight of the book.

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