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Book Review

Preclinical Drug Development, Mark C. Rogge and David R. Taft, Eds., Taylor & Francis Group, Florida, 2005, Hardback, 575 pages, ISBN: 1-57444-882-X

Raising a substance from a new chemical entity to marketed pharmaceutical requires the abilities of an entire pharmaceutical company. Even the somewhat bracketed field of preclinical drug development (between drug discovery and clinical trials) involves the expertise and perspiration of a multitude of departments. Each area of expertise is needed to carry the product forward. The editors have gathered experts to write about their area of knowledge, which altogether in this book give the reader an education on preclinical drug development.

This is volume 152 in the useful series "Drugs and the Pharmaceutical Sciences." The book covers a broad range of progressing topics, from the beginning to the end of preclinical drug development. The detail and depth in each chapter is certainly adequate. More extensive coverage of a particular subject can be found in some of the other more narrowly specialized volumes of this practical series. Each chapter is extensively referenced, and points the reader toward additional sources. Therefore, this book is especially welcome to the person requiring an overview of an extensive process, all within one text.

The book has a baker's dozen chapters with two of the chapters written by the editors. The first chapter gives an overview of the field of preclinical development, by editor Rogge. Chapter 2 deals with use of animal toxicology and limits and extent of extrapolation to effects in human. Chapter 3 explores the newer field of producing and utilizing transgenic animals. Chapters 4 and 5 make clear pharmacokinetics/ADME (absorption, distribution, metabolism, and elimination) of small and large molecules, respectively. Chapter 6 outlines modeling and simulation in pharmacokinetics and pharmacodynamics. Chapter 7 teaches the interaction of formulation and route of administration, with emphasis on oral, transdermal, nasal, and pulmonary. Chapter 8, co-authored by editor Taft, focuses on drug transporters and exporters found in the membranes of specific organ systems, especially hepatobiliary, gastrointestinal, renal, and the central nervous system. Chapter 9 assesses alternate ADME methods via pharmaceutical profiling. Chapter 10 evaluates current practices and International Conference on Harmonization guidelines for toxicity. Chapter 11 presents the role of gross and histological pathology of animal tissues in safety and toxicity. Chapter 12 describes the field of toxicogenomics. Finally, Chapter 13 explains how to effectively utilize the entire gathered preclinical database to select human dosing, support efficacy claims, address safety concerns, design drug–drug interaction studies as well as its limitations and predictive value.

The authors come from the largest and also medium size pharmaceutical companies, the FDA, and research universities. The American and also European institution contributors give an international perspective, with an eye to the requirements of the three current largest markets (including Japan).

While an expert in one area will find that chapter straightforward, they will gain clear insight into the workings of their colleagues that they may not have previously appreciated. The book is especially useful as a thorough primer for the beginner. It will be valuable to individuals in the pharmaceutical industry with no formal training who need to quickly understand the many issues to be managed across formulation, delivery, organ specificity, pharmacokinetics, safety, toxicology, and FDA expectations leading to acceptance of the preclinical drug into clinical trials. The experienced manager will also find this book an excellent review of the art of bringing a new chemical entity to first use in humans.

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