A clear, straightforward resource to guide you through preclinical drug development

Following this book's step-by-step guidance, you can successfully initiate and complete critical phases of preclinical drug development. The book serves as a basic, comprehensive reference to prioritizing and optimizing leads, toxicity, pharmacogenomics, modeling, and regulations. This single definitive, easy-to-use resource discusses all the issues that need consideration and provides detailed instructions for current methods and techniques.

Each chapter was written by one or more leading experts in the field. These authors, representing the many disciplines involved in preclinical toxicology screening and testing, give you the tools needed to apply an effective multidisciplinary approach. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.

Among the key topics covered are:

- In vitro mammalian cytogenetics tests
Phototoxicity

Carcinogenicity studies

The pharmacogenomics of personalized medicine

Bridging studies

Toxicogenomics and toxicoproteomics

Each chapter offers a full exploration of problems that may be encountered and their solutions. The authors also set forth the limitations of various methods and techniques used in determining the safety and efficacy of a drug during the preclinical stage.

This is a hands-on guide for pharmaceutical scientists involved in preclinical testing, enabling them to perform and document preclinical safety tests to meet all FDA requirements before clinical trials may begin.

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About the Author

Shayne Cox Gad, PhD, DABT, ATS, is the Principal of Gad Consulting Services. Dr. Gad has more than thirty years of experience as a toxicologist, statistical consultant, manager, and general consultant on research and development in the chemical, consumer product, contract testing, biotechnology, medical device, and pharmaceutical industries. He is the author of twenty-nine books and numerous papers, presentations, and other publications.

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