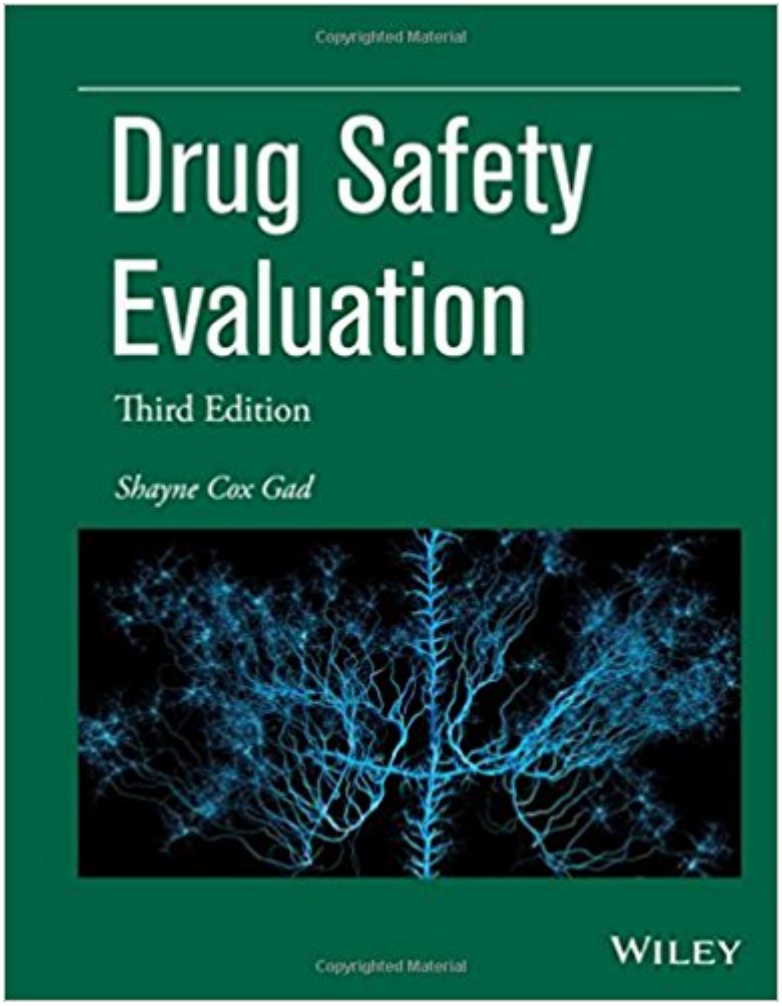
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Drug Safety Evaluation (Pharmaceutical Development Series)



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Synopsis

This practical guide presents a road map for safety assessment as an integral part of the development of new drugs and therapeutics. Helps readers solve scientific, technical, and regulatory issues in preclinical safety assessment and early clinical drug development Explains scientific and philosophical bases for evaluation of specific concerns Ã¢â ¬â œ including local tissue tolerance, target organ toxicity and carcinogenicity, developmental toxicity, immunogenicity, and immunotoxicity Covers the development of new small and large molecules, generics, 505(b)(2) route NDAs, and biosimilars Revises material to reflect new drug products (small synthetic, large proteins and cells, and tissues), harmonized global and national regulations, and new technologies for safety evaluation Adds almost 20% new and thoroughly updates existing content from the last edition

Book Information

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Customer Reviews

"The stated goal of the third edition of Drug Safety Evaluation is to present an all-inclusive practical guide of how the safety of human drugs and biologics are evaluated. One just needs to peruse the table of contents to see that this book provides a comprehensive overview of human drug development as it applies to safety. The content encompasses the regulatory process for small molecules and biologics, and includes detailed descriptions of the toxicological tests that can be conducted and how the results are evaluated"... "Although the content is clearly meant for human

pharma, this book will be useful to those involved in safety evaluations for veterinary drug development. The in-depth explanations of how data are evaluated from toxicity studies conducted for human drug development can be applied to animal drug development. The chapter on statistics in pharmaceutical safety assessment is particularly useful, with assumptions and limitations provided for each of the common statistical tests"..... "This comprehensive book on drug safety evaluation is a welcomed addition to my reference library" (Reviewed by Lesley C. Rausch-Derra, DVM, MS, Scout Bio Inc, Kansas City, Mo 15th June 2017)

The definitive safety guide to all aspects of the drug development processThe third edition of Drug Safety Evaluation continues and expands on the comprehensive resource its predecessors offered Ã¢â ¬â œ an all-inclusive, practical guide for those who are responsible for ensuring the safety of drugs and biologics for patients, for health care providers, for those involved in the manufacture of medicinal products, and for all those who need to understand how the safety of these products is evaluated.In the new edition, changes and updates reflect the many changes in the scope of products (small synthetic, large protein moieties and cells and tissues), harmonized global and national regulatory requirements, the therapeutic development process, and available technologies to identify and evaluate the relevance of potential patient risks. They address specific approaches to evaluating hazards, including problems that are encountered and their solutions. Drawing upon over 39 years of experience, author Shayne Gad explains the scientific and philosophical bases for evaluating specific concerns (e.g., carcinogenicity, developmental toxicity, immunogenicity and immunotoxicity) to provide both understanding and guidance for approaching new problems.Individual chapters address not only the general cases for safety evaluation of small and large molecules, but also all the significant major sub-cases: imaging agents, dermal and inhalation route drugs, vaccines, and gene-therapy products. Among the wide variety of topics covered are:Data MiningAcute toxicity testing in pharmaceutical safety evaluation Genotoxicity Safety assessment of inhalant drugs Immunotoxicology in pharmaceutical development Evaluation of human tolerance and safety in clinical trials Statistics Impurity assessment and qualification QSAR and in vitro alternative methods

It is thorough and flows logically.

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