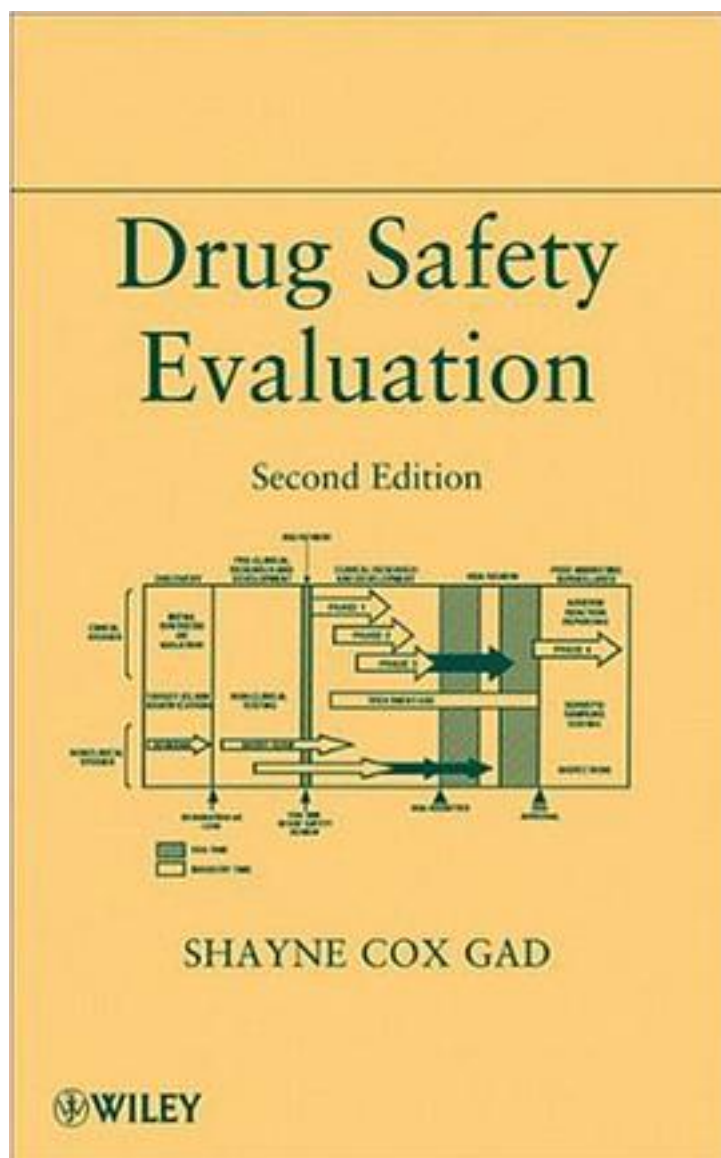


Drug Safety Evaluation



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Drug Safety Evaluation Second Edition Shayne Cox Gad The updated and expanded safety guide to all aspects of the drug development process Drug Safety Evaluation, Second Edition presents 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. This Second Edition has been extensively revised and expanded to respond to the many changes in regulatory requirements as well as pharmaceutical and technological developments. Drawing upon more than twenty years of experience, author Shayne Gad explains the scientific and philosophical bases for evaluating specific concerns (e.g., cardiovascular safety, immunogenicity, carcinogenicity, development toxicity, etc.) 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: Acute toxicity testing in pharmaceutical safety evaluation Genotoxicity Safety assessment of inhalant drugs Immunotoxicology in pharmaceutical development Large animal studies Evaluation of human tolerance and safety in clinical trials More pertinent and practical than ever to the industry, Drug Safety Evaluation, Second Edition provides a road map for safety assessment as an integral part of the development of new drugs and therapeutics.

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