Updated and expanded safety guide to all aspects of the drug development process

This latest edition presents is 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.

It 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:

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