Safety Pharmacology in Pharmaceutical Development: Approval and Post Marketing Surveillance, Second Edition

Shayne C. Gad

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Safety pharmacology is the evaluation and study of the pharmacological effects of a potential drug that are unrelated to the desired therapeutic effect. These effects often present a hazard—particularly in individuals with compromised or limited organ system functions.

Safety Pharmacology in Pharmaceutical Development: Approval and Post Marketing Surveillance, Second Edition covers safety pharmacology from the regulatory requirements down to the studies that must be done to justify them. Using the author's more than 30 years of direct experience, the book incorporates tricks and practical insights for making studies work and understanding why they fail.

The second edition includes current regulations, including USFDA and those from Europe and Japan. Presenting a clear description of what is needed and why for supporting drug development, the book focuses on updated test methods, interpretation, and science. It covers the core and supplemental batteries of test procedures and how to do them and provides an overview of available facilities and contract organizations for performing studies.

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