Integrated Cardiac Safety. Assessment Methodologies for Noncardiac Drugs in Discovery, Development, and Postmarketing Surveillance

Description:
A new, more effective approach for screening drugs for adverse cardiac effects

In recent years, more drugs have been withdrawn from the market for cardiac safety than for any other reason, underscoring the need for better methods and strategies to screen drugs for adverse cardiac effects. Integrated cardiac safety, this book's central tenet, sets forth an effective strategy that enables researchers in drug discovery and development to better assess the cardiac safety of drugs. It entails the use and integration of the methodologies used to assess cardiac safety during the full life cycle of drug development from discovery and design through to postmarketing surveillance. Moreover, the integrated cardiac safety approach demonstrates the benefit of integrating proarrhythmic, generalized, and behavioral cardiac safety issues rather than treating them separately.

This book deals with drugs that are not indicated for cardiac diseases or conditions. It begins with an introduction to cardiac safety assessment and the biology of adverse drug interactions. Following sections on cardiac function and cardiac pathophysiology and disease, the authors guide readers through the assessment process during discovery, preapproval (including QT/QTc trials), and postmarketing surveillance. The book concludes with chapters on medication errors and an examination of future trends in drug safety.

"Turner and Durham's book is well organized and comprehensive, providing both historical and prospective viewpoints. It provides practical information on drug safety throughout life cycle development, from molecular biology to postmarketing surveillance. It will be an invaluable source of information for those who want to learn about this area, as well as for basic scientists, clinical investigators, physicians, and regulators currently wrestling with the diverse challenges of cardiac safety." â??Peter K. S. Siegl, PhD, Siegl Pharma Consulting LLC

"At a moment in health care history when public policy and the practice of medicine are on a collision course and meta–analysis madness threatens to derail twenty–first–century drug development, Turner and Durham strive to return us to the right path, the Critical Path, brightly lit by practical advice and sound science. This is a timely and important book." â??Peter J. Pitts, PhD, President, Center for Medicine in the Public Interest, and former Associate Commissioner, FDA

"Professors Turner and Durham provide a forward–looking guide to medication safety issues relevant to all classes of pharmaceuticals. And their guidance could not be more timely. The public and policymakers are increasingly focused on safety issues at both the development and postmarketing stages. The authors provide a synthesis of medication safety issues that is comprehensive, accessible, and that speaks to a wide range of health care professionals. Integrated Cardiac Safety is an important, and welcome, work." â??Jay Campbell, JD, RPh, Executive Director, North Carolina Board of Pharmacy

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