

1. Record Nr.	UNINA9910254496803321
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Titolo	Cardiovascular Safety in Drug Development and Therapeutic Use [[electronic resource]] : New Methodologies and Evolving Regulatory Landscapes // by J. Rick Turner, Dilip R. Karnad, Snehal Kothari
Pubbl/distr/stampa	Cham : , : Springer International Publishing : , : Imprint : Adis, , 2017
ISBN	3-319-40347-8
Edizione	[1st ed. 2017.]
Descrizione fisica	1 online resource (XXVI, 333 p. 2 illus. in color.)
Disciplina	353.998
Soggetti	Pharmacy Cardiology Drug Safety and Pharmacovigilance
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Nota di bibliografia	Includes bibliographical references at the end of each chapters.
Nota di contenuto	The Central Importance of Cardiovascular Safety in Contemporary New Drug Development -- The Biological Basis of Drug Responses -- Cardiovascular Structure, Function, Pathophysiology, & Disease -- The Current Regulatory Landscape -- The "Comprehensive In Vitro Proarrhythmia Assay" Initiative -- The "Early ECG Assessment" Initiative -- The "Submission of Extended Digital ECG Data" Initiative -- Meta-analysis and Meta-methodology -- Current Regulatory Landscapes and their Potential Evolution -- Off-target Blood Pressure Responses to Non-cardiovascular Drugs -- Oncology Drug Development and Therapeutics: Cardiotoxicity Considerations -- Postmarketing Surveillance -- Regulatory Perspectives on General Drug Safety -- Future Directions in Cardiovascular Safety -- References.
Sommario/riassunto	With the advent of multiple new therapeutic agents for a variety of important diseases has come an increasing realization that many of these drugs can have adverse effects on the heart and vascular system. As this book so elegantly details the mechanisms by which harm occurs are highly complex, many times predictable, but always clinically relevant. Notable experts in the field of cardiovascular medicine, such as Drs. Turner, Karnad, and Kothari, have turned their attention to this thorny problem, and begun to dissect the diverse mechanisms by which

cardiac harm can occur with a variety of non-cardiac drugs. This is no easy task, given the complexity of the diseases we treat, and the wide spectrum of new therapies we seek to apply. However, it is an issue with which all health care providers must become familiar in order to prescribe appropriate therapy while safeguarding patients against avoidable and life-threatening cardiac adverse effects. This compendium represents the state-of-the-art in the evolving field of cardiac safety and is vital reading for those interested in developing new chemical entities, as well as those who prescribe them and monitor patients for their hazard. As such, I recommend this book as essential reading for students, scientists, and health care providers at all levels of training. Peter R. Kowey, MD, FACC, FAHA, FHRS Lankenau Institute for Medical Research & Thomas Jefferson University.
