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## PREFACE

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It is generally easy to define the efficacy of a new therapeutic agent. However, what is even more difficult and more challenging yet more important is to define its safety when administered to millions of patients with multi-faceted diseases, co-morbidities, sensitivities and concomitant medications. The commonest cause of new drug discontinuations, cause for disapproval from marketing and removal from the market after approval is a drug's effect on cardiac repolarization which is essentially identified by increasing the duration of the QTc interval duration on the standard 12-lead electrocardiogram (ECG).

*Cardiac Safety of Noncardiac Drugs: Practical Guidelines for Clinical Research and Drug Development* is designed to present the current preclinical, clinical, and regulatory principles to assess the cardiac safety of new drugs based primarily on their effects on the ECG. Practical guidance to define cardiac safety at all stages of clinical research and drug development are featured and discussed by internationally recognized experts with academic, industrial, and regulatory experience. Each chapter contains the best available evidence, the author's personal opinions, areas of controversy, and future trends. Although some of the areas are highly specialized, this book has been designed for a broad audience ranging from medical and graduate students to clinical nurses, clinical trial coordinators, safety officers, data managers, statisticians, regulatory authorities, clinicians, and scientists.

The book is organized in a practical and easy to assimilate manner, with each chapter focusing on a particular aspect of cardiac safety. Part I contains an historical overview from a clinical and regulatory prospective. Part II is devoted to preclinical and pharmacogenomic aspects of cardiac safety in clinical research and drug development. Part III includes clinical methodologies and technical aspects of assessing cardiac safety of investigational drugs with the main focus on cardiac repolarization, especially as defined by the duration of the QTc interval. Part IV provides a comprehensive review of the application of electrocardiology in clinical research, including fundamentals of ECG interpretation in clinical trials, cardiac safety assessment in all phases of drug development, statistical analysis plans for ECG data obtained in formal clinical trials, and practical interpretation of the results. Finally, Part V presents a broad spectrum of domestic and international regulatory aspects in assessing the cardiac safety in clinical research and drug development.



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The editors of *Cardiac Safety of Noncardiac Drugs* wish to recognize the significant contribution made by all of the contributing authors. The book is the result of a collaboration that has brought together the skills and perspectives of researchers, scientists, and clinicians. Finally, we hope that the book will become a primary reference for drug developers in all therapeutic areas as well as academicians consulting in this arena.

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