CONTENTS

Dedication .................................................................................................................................... v
Preface ......................................................................................................................................... vii
Contributors .............................................................................................................................. xi

Part I. Introduction
Chapter 1. Cardiac Safety of Noncardiac Drugs:
    Historical Recollections ............................................................... 3
    Raymond John Lipicky

Part II. Preclinical and Pharmacogenomic Cardiac Safety Evaluations
Chapter 2. Molecular Physiology of Ion Channels That Control Cardiac Repolarization ........... 13
    Jeanne M. Nerbonne and Robert S. Kass
Chapter 3. Cellular, Molecular, and Pharmacologic Mechanisms Underlying Drug-Induced
    Cardiac Arrhythmogenesis ...................................................... 37
    Charles Antzelevitch
Chapter 4. hERG Assay, QT Liability, and Sudden Cardiac Death ................ 67
    Arthur M. Brown
Chapter 5. Pharmacogenomics in Drug Development:
    When and How to Apply ............................................................ 83
    Richard Judson and Arthur J. Moss

Part III. Clinical Methodologies and Technical Aspects of Assessing Cardiac Safety of
Investigational Drugs: Focus on Cardiac Repolarization
Chapter 6. Assessment of Ventricular Repolarization
    From Body-Surface ECGs in Humans ..................................... 107
    Jean-Philippe Couderc and Wojciech Zareba
Chapter 7. ECG Acquisition and Signal Processing:
    12-Lead ECG Acquisition ........................................................ 131
    Justin L. Mortara
Chapter 8. Digital 12-Lead Holter vs Standard Resting Supine
    Electrocardiogram for the Assessment of Drug-Induced QTc
    Prolongation: Assessment by Different Recording and
    Measurement Methods ............................................................... 147
    Nenad Sarapa
Chapter 9. Holter Monitoring for QT: The RR Bin Method in Depth .......... 167
    Fabio Badilini and Pierre Maison-Blanche
## Part IV. Application of Electrocardiology in Clinical Research

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Title</th>
<th>Author(s)</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Fundamentals of ECG Interpretation in Clinical Research and Cardiac Safety Assessment</td>
<td>Ihor Gussak, Robert Kleiman, and Jeffrey S. Litwin</td>
<td>189</td>
</tr>
<tr>
<td>11</td>
<td>Design and Conduct of the Thorough Phase I ECG Trial for New Bioactive Drugs</td>
<td>Joel Morganroth</td>
<td>205</td>
</tr>
<tr>
<td>12</td>
<td>Use of ECGs in Support of Cardiac Safety in Phase II and III Clinical Trials</td>
<td>Martin P. Bedigian</td>
<td>223</td>
</tr>
<tr>
<td>13</td>
<td>Cardiac Arrhythmia Assessment in Phase IV Clinical Studies</td>
<td>Gerald A. Faich and Annette Stemhagen</td>
<td>229</td>
</tr>
<tr>
<td>14</td>
<td>Statistical Analysis Plans for ECG Data: Controlling the Intrinsic and Extrinsic Variability in QT Data</td>
<td>Alan S. Hollister and Timothy H Montague</td>
<td>239</td>
</tr>
<tr>
<td>15</td>
<td>Interpretation of Clinical ECG Data: Understanding the Risk From Non-Antiarrhythmic Drugs</td>
<td>Rashmi R. Shah</td>
<td>259</td>
</tr>
</tbody>
</table>

## Part V. Regulatory Considerations

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Title</th>
<th>Author(s)</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>The FDA's Digital ECG Initiative and Its Impact on Clinical Trials</td>
<td>Barry D. Brown</td>
<td>301</td>
</tr>
<tr>
<td>17</td>
<td>Quality Control and Quality Assurance for Core ECG Laboratories</td>
<td>Amy M. Annand-Furlong</td>
<td>329</td>
</tr>
</tbody>
</table>

Index ........................................................................................................................... 355
Cardiac Safety of Noncardiac Drugs
Practical Guidelines for Clinical Research and Drug Development
Morganroth, J.; Gussak, I. (Eds.)
2005, XII, 362 p., Hardcover
ISBN: 978-1-58829-515-6
A product of Humana Press