Pharmacokinetics in Drug Development
Volume 2: Regulatory and Development Paradigms

Peter L. Bonate PhD, FCP (ILEX™ Oncology, Inc.)
Danny R. Howard PhD (Aventis Pharmaceuticals, Inc.)

Table of Contents

Preface v
List of Contributors vii

Part 1 Drug Development and Regulatory Issues
Chapter 1 Drug Development: A Rational Approach 3
Ene I. Ette, Varun Garg, and Andrew Jayaraj

Chapter 2 Experimental Design Considerations in Pharmacokinetic Studies 37
Jenny Y. Chien

Steven L. Bramer and Suresh Mallikaarjun

Chapter 4 Role of Toxicology and Toxicokinetics in Drug Development 87
Richard E. Long

Chapter 5 Bioanalysis in a Regulated Environment 105
Anthony J. Destefano and Ray Takigiku

Chapter 6 Role of Preclinical Pharmacokinetics in Drug Development 127
Chandrasekhar Natarajan and Shashank Rohatagi

Chapter 7 Pharmacokinetic/Pharmacodynamic Knowledge Discovery and Creation During Drug Development 163
Paul Williams, Christopher Godfrey, Amit Roy, Hui-May Chu, and Ene I. Ette

Chapter 8 Regulatory Aspects of Clinical Pharmacokinetic Studies 203
Patrick K. Noonan, Edward A. Kelly, Theodore J. Jaworski, and Loren L. Miller

Chapter 9 Regulatory Review of Pharmacokinetic Studies 229
Michael J. Fossler

Chapter 10 Regulatory Perspectives on Clinical Trial Simulations 243
He Sun, Emmanuel O. Fadiran, Ene I. Ette, and Lawrence J. Lesko

Chapter 11 Nuances of Drug Metabolism and Pharmacokinetic Requirements for Package Submission to Japanese Regulatory Authorities 265
James R. Woodworth and Robert R. Fike

Part 2 Special Topics
Chapter 1 Drug Development in Oncology 281
Andreas Kovar and Bernd Meibohm
Chapter 2 Development of Chiral Compounds
Peter J. Van Ess and Joseph Fleishaker

Chapter 3 Development of Controlled-release Products
Nishit B. Modi and Suneel K. Gupta

Chapter 4 Development Considerations for Biological Drugs
Danny R. Howard

Chapter 5 Pharmacokinetics in Ocular Drug Development
Dale Yu

Chapter 6 Development of Parenteral Dosage Forms
David Young and Dakshina Chilukuri

Chapter 7 Development of Transdermal Products
Dario N. Carrara and Gabriel Porto

Index