Contents

Preface to the First Edition ix
Preface to the Second Edition xi
About the Editors xiii
Contributors xv

SECTION I: OVERVIEW OF PHARMACEUTICAL MEDICINE 1

1 The Practice and Practitioners of Pharmaceutical Medicine 3
   Anthony W. Fox

2 Pharmaceutical Medicine as a Medical Specialty 7
   Michael D. Young and Peter D. Stonier

3 Clinical Research Education and Training for Biopharmaceutical Staff 25
   Peter Marks

SECTION II: DRUG DISCOVERY AND DEVELOPMENT 41

4 Drug Discovery: Design and Serendipity 43
   Ronald R. Cobb and Leslie J. Molony

5 Pharmaceutics 51
   Anthony W. Fox

6 Nonclinical Toxicology 63
   Frederick Reno

7 Informed Consent 75
   Anthony W. Fox

8 Phase I: The First Opportunity for Extrapolation from Animal 79
   Data to Human Exposure
   Stephen H. Curry, Dennis McCarthy, Helen H. DeCory, Matthew Marler
   and Johan Gabrielsson

9 Phase II and Phase III Clinical Studies 101
   Anthony W. Fox

10 Phase IV Drug Development: Post-Marketing Studies 119
   Lisa R. Johnson-Pratt
11 Site Management
Barry Miskin

12 Good Clinical Practices
Wendy Bohaychuk and Graham Ball

13 Quality Assurance, Quality Control and Audit
Rita Hattemer-Apostel

14 The Unique Role of Over-the-Counter Medicine
Paul Starkey

SECTION III: SPECIAL POPULATIONS AND REQUIRED SPECIAL STUDIES

15 Drug Research in Older Patients
Lionel D. Edwards

16 Drug Development Research in Women
Lionel D. Edwards

17 Clinical Research in Children
Lionel D. Edwards

18 Racial and Ethnic Issues in Drug Registration

19 Hepatic and Renal Failure
Anthony W. Fox

20 Drug Interactions
Anthony W. Fox and Anne-Ruth van Troostenburg de Bruyn

21 Orphan Drugs
Bert Spilker

SECTION IV: APPLIED ASPECTS OF DRUG DEVELOPMENT

22 Biotechnology Products and Development
David A. Shapiro and Anthony W. Fox

23 Pharmacoeconomics: Economic and Humanistic Outcomes
Raymond J. Townsend, Jane T. Osterhaus and J. Gregory Boyer

24 Pharmacoepidemiology and the Pharmaceutical Physician
Hugh H. Tilson

25 Statistical Principles and Application in Biopharmaceutical Research
Dan Anbar

26 Data Management
T.Y. Lee and Michael Minor
27 Patient Compliance: Pharmionics, a New Discipline
Jean-Michel Métry

28 Monitoring Drug Concentrations in Clinical Practice
Anthony W. Fox

29 Generics
J.D. Gabriel Lopez and J.D. Thomas Hoxie

30 Complementary Medicines
Anthony W. Fox

SECTION V: DRUG REGULATION

31 United States Regulations
William Kennedy

32 Special US Regulatory Procedures: Emergency and Compassionate INDs and Accelerated Product Approvals
Anthony W. Fox

33 The Development of Human Medicines Control in Europe from Classical Times to the Year 2000
John P. Griffin

34 Medicines Regulation in the European Union
Anne-Ruth van Troostenburg de Bruyn and Giuliana Tabusso

35 Japanese Regulations
Etienne Labbé

36 Drug Registration and Pricing in the Middle East
Edda Freidank-Mueschenbornfs

SECTION VI: MEDICAL SERVICES

37 Medical Affairs
Gregory P. Geba

38 Drug Labeling
Anthony W. Fox

39 Drug Surveillance
Howard J. Dreskin and Win M. Castle

40 Data Mining
Mirza I. Rahman and Omar H. Dabbous

41 Risk Management in Product Approval and Marketing
Anthony W. Fox
42 Publishing Clinical Studies
Anthony W. Fox

43 Organizing and Planning Local, Regional, National and International Meetings and Conferences
Zofia Dziewanowska and Linda Packard

44 Drug Withdrawals from the Market – Causes and Consequences
Ronald D. Mann

SECTION VII: LEGAL AND ETHICAL ASPECTS OF PHARMACEUTICAL MEDICINE

45 Introduction to Bioethics for Pharmaceutical Professionals
Andrew J. Fletcher

46 Pharmaceutical Medicine and the Law
Sarah Croft and Timothy Pratt

47 Pharmaceutical Product Liability
Han W. Choi and Howard B. Yeon

48 Patents
Gabriel Lopez

49 Fraud and Misconduct in Clinical Research
Jane Barrett

SECTION VIII: BUSINESS ASPECTS

50 The Multinational Corporations: Cultural Challenges, the Legal/Regulatory Framework and the Medico-commercial Environment
R. Drucker and R. Graham Hughes

51 Advertising and Marketing
Jonathan Belsey

52 Middle East, India, China and the Far East: Pharmaceutical Medicine in the East
Gamal Hammad

53 Financial Aspects of Clinical Trials
R.G. Hughes and N. Turner

54 Outsourcing Clinical Drug Development Activities to Contract Research Organizations (CROs): Critical Success Factors
John R. Vogel

55 The Impact of Managed Care on the US Pharmaceutical Industry
Robert J. Chaponis, Christine Hanson-Divers, and Marilyn J. Wells

Appendix: Useful Internet Links

Index