Contents

Contributors, vii
The editors, x
Acknowledgements, xiii
List of abbreviations, xiv
Preface, xix

Part I Research and development, 1

1 Discovery of new medicines, 3
   Yves J. Ribeill

2 Pharmaceutical development, 32
   Michael Gamlen and Paul Cummings

3 Preclinical safety testing, 42
   Lutz Müller and Elisabeth Husar

4 Exploratory development, 82
   John Posner

5 Clinical pharmacokinetics, 113
   Paul Rolan and Valéria Molnár

6 Biological therapeutics, 132
   Peter Lloyd and Jennifer Sims

7 Objectives and design of clinical trials, 143
   John Posner and Steve Warrington

8 Conduct of clinical trials: Good Clinical Practice, 155
   Kate L.R. Darwin

9 Medical statistics, 189
   Andrew P. Grieve

10 Development of medicines: full development, 219
    Peter D. Stonier

11 Pharmacovigilance, 235
    Stephen F. Hobbiger, Bina Patel and Elizabeth Swain

12 Vaccines, 254
    John Beadle

13 Drugs for cancer, 270
    James Spicer and Johann De Bono

14 Ethics of human experimentation, 286
    Jane Barrett

15 Drug development in paediatrics and neonatology, 295
    Nazakat M. Merchant and Denis V. Azzopardi

16 Due diligence and the role of the pharmaceutical physician, 306
    Geoffrey R. Barker

Part II Regulation, 317

17 A history of drug regulation in the UK, 319
    John P. Griffin

18 The Clinical Trials Directive, 347
    Fergus Sweeney and Agnès Saint Raymond

19 Human medicinal products in the European Union: Regulations, Directives and structures, 360
    Agnès Saint Raymond and Anthony J. Humphreys

20 Human medicinal products in the European Union: Procedures, 379
    Agnès Saint Raymond and Anthony J. Humphreys

21 European regulation of medical devices, 418
    Shuna Mason
Contents

22 Paediatric regulation, 435
Heike Rabe and Agnès Saint-Raymond

23 Technical requirements for registration of pharmaceuticals for human use: The ICH process, 447
Dean W.G. Harron

24 The regulation of drug products by the US Food and Drug Administration, 461
Peter Barton Hutt

25 The US FDA in the drug development, evaluation and approval process, 501
Richard N. Spivey, Judith K. Jones, William Wardell and William W. Vodra

26 Future prospects of the pharmaceutical industry and its regulation in the USA, 518
Richard N. Spivey, William W. Vodra, Judith K. Jones and William Wardell

27 Regulatory and clinical trial systems in Japan, 537
Mamiko Satake and Natsuko Hosoda

28 The regulation of therapeutic products in Australia, 554
Elizabeth de Somer, Deborah Monk and Janice Hirshorn

31 The supply of unlicensed medicines for individual patient use, 610
Ian Dodds-Smith and Ewan Townsend

32 Legal and ethical issues relating to medicinal products, 632
Nick Beckett, Sarah Hanson and Shuna Mason

33 Medical marketing, 653
David B. Galloway and Bensita M.V. Thottakam

34 Information and promotion, 670
Charles De Wet

35 Economics of health care, 692
Carole A. Bradley and Jane R. Griffin

36 Controls on NHS medicines prescribing and expenditure in the UK (a historical perspective) with some international comparisons, 707
John P. Griffin and Geoffrey R. Barker

37 Pharmaceutical medicine in the emerging markets, 728
Nadarajah Sreeharan, Jennie A. Sykes and Richard B. Nieman

38 Biosimilars, 744
Raymond A. Huml and John Posner

Appendix 1 Declaration of Helsinki, 751
Appendix 2 Agreements and Guidelines for Implementation of Clinical Trials, 755
Appendix 4 PharmaTrain Syllabus 2010, 783

Part III Health care marketplace, 587

29 An Introduction to life cycle management of medicines, 589
David Gillen

30 Availability of medicines online and counterfeit medicines, 597
Ruth Diazaraque and David Gillen

Index, 788