Table of Contents

Part I: Research and development.

Introduction: the development of pharmaceutical medicine as a specialty (Susan Bews and Huw Jones).
1 Discovery of new medicines (Anand S Dutta).
2 Pharmaceutical development (Gavin Halbert).
3 Preclinical safety testing (Lutz Mueller and David J Tweets).
4 Exploratory development (John Posner).
5 Clinical pharmacokinetics (Paul Rolan and Valeria Rolan).
6 Purpose and design of clinical trials (Roger A Yates and Steve Warrington).
7 Conduct of clinical trials: good clinical practice (Roger A Yates and Steve Warrington).
8 Medical statistics (Andrew P Grieve).
9 Development of medicines: full development (Alan G Davies and Peter D Stonier).

Part II: Medical department issues.

10 The medical department (Peter D Stonier).
11 Medical marketing (David Galloway).
12 Information and promotion (Charles de Wet).
13 The supply of unlicensed medicines for particular patient use (Ian Dodds-Smith, Amanda Wearing and John O'Grady).
14 Ethics of human experimentation (Duncan Vere).
15 Legal and ethical issues relating to medicinal products (David Marks, Nick Beckett, Sarah Hanson and Shuna Mason).
16 The safety of medical products (A. Peter Fletcher and Susan Shaw).

Part III: Regulatory aspects.

17 History of drug regulation in the United Kingdom (John P Griffin and Rashmi R Shah).
18 Regulation of human medicinal products in the European Union (John P Griffin and Rashmi R Shah).
19 Paediatric regulation (Heike Rabe).
20 European regulation of medical devices (Christopher JS Hodges).
21 Technical requirements for registration of pharmaceuticals for human use: the ICH process (Dean W G Harron).
22 The regulation of drug products by the United States Food and Drug Administration (Peter Barton Hutt).
23 The US FDA in the drug development, evaluation and approval process (Richard N Spivey, Judith K Jones, William Wardell and William Vodra).
25 Regulatory and clinical trial systems in Japan (Yuichi Kubo).
26 The regulation of therapeutic products in Australia (Janice Hirshon and Deborah Monk).
27 Pharmaceutical medicine in emerging markets (N. Shreeharan).
Part IV: Pharmacoeconomic and other issues.

28 Economics of healthcare (Carole Bradley-Kennedy and Jane R Griffin).

29 Controls on NHS medicines prescribing and expenditure in the UK (a historical perspective) with some international comparisons (John P Griffin and Jane R Griffin).

30 Due diligence and the pharmaceutical physician (Geoff Barker).

Appendix 1 Declaration of Helsinki.

Appendix 2 Code of Practice for the Pharmaceutical Industry.

Appendix 3 Guidelines and Documentation for Implementation of Clinical Trials.