

# TABLE OF CONTENTS – Drug Safety Evaluation, 4th Edition

## PREFACE

## ABOUT THE AUTHORS

1 The Drug Development Process and The Global Pharmaceutical Marketplace

2 Regulation of Human Pharmaceutical Safety: Routes To Human Use and Market

3 Data Mining: Sources of Information For Consideration In Study And Program Design and In Safety Evaluation

4 Electronic Records, Reporting, and Submission: eCTD and Send

5 Screens in Safety and Hazard Assessment

6 Formulations, Routes, and Dosage Regimens

7 Mechanisms And End Points Of Drug Toxicity

8 Pilot Toxicity Testing In Drug Safety Evaluation: MTD and DRF

9 Repeat-Dose Toxicity Studies

10 Genotoxicity

11 QSAR Tools For Drug Safety

12 Toxicogenomics

13 Immunotoxicology In Drug Development

14 Nonrodent Animal Studies

15 Developmental And Reproductive Toxicity Testing

16 Carcinogenicity Studies

17 Histopathology and Clinical Pathology In Nonclinical Pharmaceutical Safety Assessment

18 Irritation And Local Tissue Tolerance In Pharmaceutical Safety Assessment

19 Pharmacokinetics And Toxicokinetics In Drug Safety Evaluation

20 Safety Pharmacology

- 21 Special Concerns For The Preclinical Evaluation Of Biotechnology Products
  - 22 Safety Assessment of Inhalant Drugs And Dermal Route Drugs
  - 23 Special Case Products: Imaging Agents
  - 24 Special Case Products: Drugs For Treatment Of Cancer
  - 25 Pediatric Product Safety Assessment (2006 Guidance, Including Juvenile And Pediatric Toxicology)
  - 26 Use Of Imaging, Imaging Agents, And Radiopharmaceuticals In Nonclinical Toxicology
  - 27 Occupational Toxicology In The Pharmaceutical Industry
  - 28 Strategy and Phasing For Nonclinical Drug Safety Evaluation In The Discovery and Development of Pharmaceuticals
  - 29 The Application of In Vitro Techniques In Drug Safety Assessment
  - 30 Evaluation Of Human Tolerance And Safety In Clinical Trials: Phase I And Beyond
  - 31 Postmarketing Safety Evaluation: Monitoring, Assessing, And Reporting of Adverse Drug Responses (ADRs)
  - 32 Statistics In Pharmaceutical Safety Assessment
  - 33 Combination Products: Drugs and Devices
  - 34 Qualification Of Impurities, Degradants, Residual Solvents, Metals, and Leachables in Pharmaceuticals
  - 35 Tissue, Cell, and Gene Therapy
  - 36 Adverse Outcome Pathways in Drug Safety Assessment
- Appendix A: Selected Regulatory and Toxicological Acronyms
- Appendix B: Definition Of Terms And Lexicon of "Clinical" Observations in Nonclinical (Animal) Studies
- Appendix C: Notable Regulatory Internet Addresses
- Appendix D: Glossary Of Terms Used in The Clinical Evaluation of Therapeutic Agents
- Appendix E: Common Vehicles For The Nonclinical Evaluation of Therapeutic Agents
- Appendix F: Global Directory of Contract Toxicology Labs. **INDEX**