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Nota di contenuto	Cover; Title page; Copyright page; Contents; Contributors; Foreword; 1: Introduction: Updated from Second Edition; Background; Diagnosing Adverse Drug Reactions; Current Methods of Pharmacovigilance; Hypothesis-Generating Methods; Spontaneous Adverse Drug Reaction Reporting; Prescription-Event Monitoring; Other Hypothesis-Generating Methods; Hypothesis-Testing Methods; Conclusion; References; 2: History of Pharmacovigilance; Early History of Drug Safety; Recent History; Pre-1962; Turning Point: The Federal Food, Drug and Cosmetics Act; Gradual Increase in Regulatory Authority Tectonic Shift: Thalidomide Post-Thalidomide Evolution of Regulation; United States of America; United Kingdom; Germany; Scandinavia; Japan; World Health Organization; France; Special Issues in Pharmacovigilance; Examples of Drugs that were Withdrawn from the Market; Bendectin; Thalidomide: Today's Approved Uses;

Pharmacovigilance is Not Just for Regulators; References; Part I: The Regulatory Basis of Pharmacovigilance; 3: Legal Basis: European Union; Introduction; Reorganization of the European Union Regulatory System Obligations of being a Marketing Authorization Holder and being Granted a Marketing Authorization Signal Detection and Risk Management; Reporting Requirements; Transparency and Communication; Pharmacovigilance Enforcement; Further Information about Proposed New Legislation and Guidelines; 4: Ethical Oversight, Consent, and Confidentiality; Introduction; Practical Implications of Ethical Oversight; The Privacy and Security of Health Data; The Linkage of Electronic Health Data; The Conduct of Scientifically Sound Studies; Ethical Oversight and Privacy Law and Resulting Dilemmas; The Common Rule State Laws The Health Insurance Portability and Accountability Act; Dilemmas Arising from the Health Insurance Portability and Accountability Act; Directions for Future Ethical Oversight and Privacy Provisions; References; 5: Pharmacovigilance-Related Topics at the Level of the International Conference on Harmonisation¹; Introduction; The International Conference on Harmonisation Step Process; ICH Step 1: Development of Draft Consensus ICH Guideline or Recommendations; ICH Step 2: Confirmation of Six Party Consensus; ICH Step 3: Regulatory Consultation ICH Step 4: Adoption of Tripartite ICH Guideline or Recommendations ICH Step 5: Implementation of ICH Guideline or Recommendations; Pharmacovigilance-Related International Conference on Harmonisation Topics; Topic ICH-E2A: Clinical Safety Data Management - Definitions and Standards for Expedited Reporting; ICH-E2D Topic: Post-Approval Safety Management - Definitions and Standards for Expedited Reporting; ICH-E2B Topic: Clinical Safety Data Management - Data Elements for Transmission of Individual Case Safety Reports ICH-E2C Topic: Clinical Safety Data Management - Periodic Benefit-Risk Evaluation Report (PBRER)

Sommario/riassunto

Mann's Pharmacovigilance is the definitive reference for the science of detection, assessment, understanding and prevention of the adverse effects of medicines, including vaccines and biologics. Pharmacovigilance is increasingly important in improving drug safety for patients and reducing risk within the practice of pharmaceutical medicine. This new third edition covers the regulatory basis and the practice of pharmacovigilance and spontaneous adverse event reporting throughout the world. It examines signal detection and analysis, including the use of population-based data
