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Nota di contenuto	Stephens' Detection of New Adverse Drug Reactions Fifth Edition; Contents; Foreword; Preface; List of Contributors; 1 Introduction; Mercury; Introduction to pharmacovigilance; The history of pharmacovigilance; Under-reporting of adverse drug reactions; Incidence of adverse drug reactions; The financial cost of adverse drug reactions; Preventability of adverse drug reactions; Risk-benefit ratio; The changing risks with new drugs; Expression of risk; The risks we are prepared to take; Definitions; Classification of adverse drug reactions; Adverse reaction profile Adverse events in a patient's lifeSymptoms in healthy persons; Adverse reactions to placebo; Infectiousness of adverse drug reactions; Herbal medicines; Some final food for thought; References; Further reading; 2 Adverse Drug Reactions and Interactions: Mechanisms, Risk Factors, Detection, Management and Prevention; Introduction; Classification of adverse drug reactions; Risk factors for type A adverse reactions; Risk

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ConclusionsReferences; 3 Toxicology and Adverse Drug Reactions; Introduction; Toxicity testing; Drug development; Data interpretation and risk assessment; Adverse drug reactions detected after authorization; Examples of toxicological investigation of adverse drug reactions; Conclusions; Acknowledgements; References; 4 Clinical Trials: Collection of Safety Data and Establishing the Adverse Drug Reaction Profile; Introduction; Adverse events; Final analysis of data; Inadequate reporting of safety data from clinical trials; Conclusions; Future aspirations; Acknowledgements; References
5 Clinical Laboratory Safety Data in Drug StudiesIntroduction; Factors that influence interpretation of clinical laboratory data; Sample collection procedure; Analytical variation; Reference ranges; Intra-individual biological variation; Safety testing in drug development; Test selection; Exclusion criteria and 'panic levels'; Harmonization of data from different laboratories; Data analysis and presentation; Conclusion; References; 6 Statistics: Analysis and Presentation of Safety Data; Introduction and background; Analysis and presentation of data from trials
Measures that take time into accountStatistical tests utilizing time since start of treatment; Combining data from several trials: meta-analysis; Analysis and presentation of data from observational studies; Use of statistical methods for signal detection with spontaneous reports; Summary and conclusions; Acknowledgements; References; 7 Causality and Correlation in Pharmacovigilance; Introduction and historical background; The notions of necessary and sufficient causes; Factors to be considered in causality assessment; Methods for causality assessment; When to assess causality
Assessing causality from multiple information sources: the Bradford-Hill criteria

Sommario/riassunto

A key text for all those involved in pharmacovigilance. Detection of new adverse drug reactions is fundamental to the protection of patients from harm that may occur as a result of medication. This book explores the methods used to investigate new adverse drug reactions, discussing all elements from the scientific background and animal toxicology through to worldwide regulatory and ethical issues. Stephens' Detection of New Adverse Drug Reactions provides comprehensive and up-to-date coverage of material fundamentally important to all those active in the field, whether they w