

Χαρακτηριστικά:

- Presents **vital, easy-to-read, cutting-edge information** on patient safety, the pharmacology regulatory landscape, and the current and future use of digital technologies
- Provides **up-to-date coverage of hot topics in the field**, including pharmacodynamic and safety precision medicine, immunogenicity, vaccine hesitancy and safety, genetic toxicology, and adverse events
- Contains **new chapters** on pre-clinical safety assessment, pharmacogenetics, first-in human trials, product aggregate safety assessment, data monitoring committees, and more
- Offers new and expanded coverage of pharmacovigilance in early pre-clinical drug development through post-marketing surveillance, as well as a **blueprint for training** future pharmacovigilance professionals
- Includes **real-world case studies** to ensure content is relevant and applicable to everyday practice
- Discusses **a range of topics across disciplines** and how they relate to pharmacovigilance, including behavioral science, patient perspectives, and risk communication
- **An eBook version is included with purchase.** The eBook allows you to access all of the text, figures and references, with the ability to search, customize your content, make notes and highlights, and have content read aloud. Additional digital ancillary content may publish up to 6 weeks following the publication date

Περιεχόμενα:

SECTION 1 THE REGULATORY ENVIRONMENT AND THE PHARMACOVIGILANCE QUALITY SYSTEM

1. Does Regulation Drive Science or Does Science Drive Regulation?

SECTION 2 PRECLINICAL SAFETY ASSESSMENT

2. Absorption, Distribution, Metabolism and Excretion, Pharmacokinetics, and Safety Pharmacology

3. Preclinical Safety Assessment : General and Genetic Toxicology

4. Pharmacogenetics

SECTION 3 FIRST-IN-HUMAN TRIALS

5. Safety Planning for First-in-Human Trials

6. Pharmacokinetic and Pharmacodynamic Considerations in Safety Evaluation

SECTION 4 SAFETY ASSESSMENT IN CLINICAL TRIALS

7. Safety Monitoring in Clinical Trials

8. Introduction to Quantitative Methods and Visual Analytics in Drug Safety Data in Clinical Trials

9. Product Aggregate Safety Assessment

10. Data Monitoring Committees

SECTION 5 SIGNAL AND RISK MANAGEMENT

- 11. Methods of Signal Detection and Signal Management
- 12. Causality Assessment
- 13. Examples of Adverse Drug Reactions: Drug-Induced Liver Injury, Renal, Skin, Immune-Mediated Events, and Major Adverse Cardiac Events
- 14. Internal Safety Advisory Groups
- 15. Benefit–Risk Management

SECTION 6 ROLE OF EPIDEMIOLOGY AND REALWORLD EVIDENCE

- 16. Role of Epidemiology and Pharmacoepidemiology in the Biopharmaceutical Industry
- 17. Real-World Pharmacoepidemiology Studies

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- 21. Vaccine Pharmacovigilance
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- 23. Medical Device Safety Oversight and Surveillance

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- 24. Information Technology in Pharmacovigilance: Current State and Future Directions
- 25. The Future of Pharmacovigilance