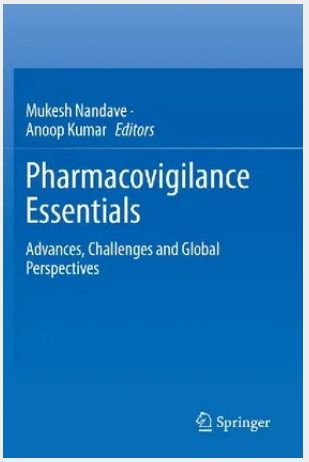
Nandave / Kumar

Pharmacovigilance Essentials

Advances, Challenges and Global Perspectives



The book explores the field of pharmacovigilance, its historical context, along with its critical role in ensuring the safety of medications across the world. From its foundational principles to cutting-edge advancements and future challenges, this book provides a thorough understanding of the field's intricacies. The book begins by establishing the fundamentals of pharmacovigilance, emphasizing its significance in monitoring, detecting, assessing, and preventing adverse drug reactions (ADRs) that occur during the use of medications. Delving into the history of pharmacovigilance and regulatory actions, the book traces the evolution of the field, highlighting significant milestones and the establishment of regulatory frameworks that govern medication safety. It explores the pivotal role of regulatory authorities in developing guidelines, regulations, and policies to safeguard public health. A significant aspect covered in the book is the processing of ADRs, providing insights into the steps involved in handling and evaluating ADR reports. The book also addresses specialized areas within pharmacovigilance, including vaccine safety surveillance, herbovigilance (monitoring the safety of herbal medicines), materiovigilance (monitoring the safety of medical devices), and hemovigilance (ensuring the safety of blood products). Additionally, the book explores the role of pharmacogenetics in pharmacovigilance, highlighting how genetic factors influence individual responses to medications and how this knowledge can be integrated into safety monitoring and risk assessment. This book also covers databases used in pharmacovigilance across the globe, aggregate reporting and pharmacovigilance systems in EU and non-EU countries, and the role of artificial intelligence.

Finally, it emphasizes the need for continuous improvement, vigilance, and proactive measures to adapt to the changing healthcare landscape and address emerging safety concerns. The book serves as acomprehensive guide for healthcare professionals, researchers, regulators, and policymakers involved in pharmacovigilance.

Chapter 1_ Introduction to Pharmacovigilance.- Chapter 2_ History of Pharmacovigilance and Regulatory Actions.- Chapter 3_ Databases Used in Pharmacovigilance Across the Globe.- Chapter 4_ Processing of ADRs.- Chapter 5_ Signal Detection and Aggregate Reporting.- Chapter 6_ Reporting of ADRs across the globe.- Chapter 7_ Pharmacovigilance System in India. - Chapter 8_ Pharmacovigilance System in EU.- Chapter 9_ Pharmacovigilance System in USA.- Chapter 10_ Pharmacovigilance System in non-EU Countries.- Chapter 11_ Vaccine Safety Surveillance.- Chapter 12_ Herbovigilance.- Chapter 13_ Materiovigilance.- Chapter 14_ Hemovigilance.- Chapter 15_ Role of Pharmacogenetics in Pharmacovigilance.- Chapter 16_ Signal Detection and Assessment in Pharmacovigilance.- Chapter 17_ Role of Artificial Intelligence in Pharmacovigilance.- Chapter 18_ Current Challenges and Future Perspectives.

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