

1. Record Nr.	UNINA9910853988703321
Autore	Nandave Mukesh
Titolo	Pharmacovigilance Essentials : Advances, Challenges and Global Perspectives
Pubbl/distr/stampa	Springer Nature, 2024 Singapore : , : Springer Singapore Pte. Limited, , 2024 ©2024
ISBN	981-9989-49-3
Edizione	[1st ed.]
Descrizione fisica	1 online resource (478 pages)
Altri autori (Persone)	KumarAnoop
Disciplina	363.19463
Soggetti	Pharmacovigilance Drug Monitoring Adverse Drug Reaction Reporting Systems
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Nota di contenuto	Intro -- Foreword -- Preface -- Contents -- Editors and Contributors -- About the Editors -- Contributors -- Abbreviations -- 1: Introduction to Pharmacovigilance -- 1.1 Introduction -- 1.2 Needs and Objectives of Pharmacovigilance -- 1.2.1 Needs -- 1.2.2 Objectives -- 1.3 Pharmacovigilance in Drug Development -- 1.4 Classification -- 1.4.1 Vaccine Vigilance -- 1.4.2 Herbovigilance -- 1.4.3 Materiovigilance -- 1.4.4 Hemovigilance -- 1.5 Case Reporting -- 1.5.1 The "4 Ws" of Case Reporting -- 1.5.2 Issues and Possible Solutions in Reporting -- 1.6 Causality Assessment (CA) -- 1.6.1 Purpose of Causality Assessment -- 1.6.2 Tools -- 1.6.3 Measures Taken by Regulatory Bodies -- 1.6.4 Challenges -- 1.7 Management of ADRs -- 1.8 Conclusion -- References -- 2: History of Pharmacovigilance -- 2.1 Introduction -- 2.2 Historical Background -- 2.3 Development of Pharmacovigilance in the USA -- 2.3.1 Sulfanilamide Tragedy -- 2.3.2 Regulatory Action Taken After Sulfanilamide Tragedy -- 2.3.2.1 Federal Food, Drug, and Cosmetic Act (FD&C Act) -- 2.3.3 Thalidomide Disaster -- 2.3.4 Regulatory Actions Taken After the Thalidomide Tragedy -- 2.3.4.1 Kefauver Harris Amendment -- 2.3.4.2 FDA 3-Segment Study Designs

-- 2.3.4.3 International Drug Monitoring Programme -- 2.3.4.4 Drug Efficacy Safety Implementation Programme -- 2.3.4.5 Prescription Drug User Fee Act (PDUFA) -- 2.3.4.6 MedWatch -- 2.3.4.7 US FDA Modernization Act (FDAMA) -- 2.3.4.8 USFDA Amendment of 2007 -- 2.3.4.9 Purple Book -- 2.4 Development of Pharmacovigilance in Europe -- 2.4.1 Thalidomide Disaster -- 2.4.2 Regulatory Action Taken After the Thalidomide Disaster -- 2.4.2.1 Committee for Safety of Drugs -- 2.4.2.2 EC Directive 65/65 -- 2.4.2.3 European Medicines Agency -- 2.4.3 Theralizumab (TGN1412) Tragedy.

2.4.4 Regulatory Action Was Taken After the TGN1412 Tragedy -- 2.5 Development of Pharmacovigilance in India -- 2.6 Development of Pharmacovigilance in Non-European Countries -- 2.6.1 Pharmacovigilance in Korea -- 2.6.2 Pharmacovigilance in China -- 2.7 Some Recent Tragedies -- 2.7.1 Heparin Contamination -- 2.7.2 Counterfeit Avastin -- 2.7.3 Ranitidine Tragedy -- 2.7.4 Digene Recall -- 2.8 Conclusion -- References -- 3: Databases Used in Pharmacovigilance Across the Globe -- 3.1 Introduction -- 3.2 Databases Used in Pharmacovigilance -- 3.3 National Pharmacovigilance Databases Used by the Different Countries -- 3.3.1 VigiBase -- 3.3.1.1 Advantages -- 3.3.1.2 Limitations -- 3.3.2 EudraVigilance -- 3.3.2.1 Advantages -- 3.3.2.2 Limitations -- 3.3.3 FDA Adverse Event Reporting System (FAERS) -- 3.3.3.1 Advantages -- 3.3.3.2 Limitations -- 3.3.4 Indicator-Based Pharmacovigilance Assessment Tool (IPAT) -- 3.3.4.1 Advantages -- 3.3.4.2 Limitations -- 3.3.5 Database of Adverse Event Notifications (DAEN) -- 3.3.5.1 Advantages -- 3.3.5.2 Limitations -- 3.3.6 Canada Vigilance Adverse Reaction Online Database -- 3.3.6.1 Advantages -- 3.3.6.2 Limitations -- 3.3.7 The Korea Adverse Event Reporting System (KAERS) -- 3.3.7.1 Advantages -- 3.3.7.2 Limitations -- 3.4 Commercially Used Pharmacovigilance Database -- 3.4.1 AB Cube: Safety Easy -- 3.4.1.1 Characteristics of AB Cube: Safety Easy -- 3.4.2 Oracle: Argus Safety Database -- 3.4.2.1 Characteristics of AB Cube: Safety Easy -- 3.4.3 Aris Global: ARISg/LifeSphere Safety -- 3.4.3.1 Characteristics of Aris Global: ARISg/LifeSphere Safety -- 3.4.4 Ennov Pharmacovigilance Suite -- 3.4.4.1 Characteristics of Ennov Pharmacovigilance Suite -- 3.4.5 BaseCon -- 3.4.5.1 Characteristics of BaseCon -- 3.5 Conclusion -- References -- 4: Processing of ADRs.

4.1 Processing of ADRs -- 4.2 Collection of ADRs -- 4.3 Processing of Adverse Drug Reactions (ADRs) -- 4.3.1 Case Identification and Collection -- 4.3.2 Data Entry -- 4.3.3 Quality Checks -- 4.3.4 Individual Case Safety Reports (ICSRs) Creation -- 4.3.5 Signal Detection and Analysis -- 4.3.6 Signal Evaluation and Refinement -- 4.3.7 Reporting to Regulatory Authorities -- 4.3.8 Risk Communication and Management -- 4.3.9 Continuous Monitoring and Assessment -- 4.4 Reporting of ADRs in India -- 4.4.1 Reporting Requirements -- 4.4.2 Where to File a Report -- 4.4.3 How to File a Report -- 4.4.4 To Whom Report is Submitted -- 4.5 Selection of Database -- 4.6 Validity of ADRs -- 4.6.1 Validity of ADRS Form -- 4.6.2 Seriousness of ADRs -- 4.7 Triage of Case -- 4.7.1 The Triage Procedure Is Described in Detail Below -- 4.8 Listedness of Cases -- 4.8.1 Categories of Listedness -- 4.9 Medical Coding -- 4.9.1 Most Commonly Used Medical Dictionaries -- 4.9.2 Medical Dictionary for Regulatory Activities (MedDRA) -- 4.9.3 MedDRA Employs a Hierarchical Framework Comprising Five Primary Tiers -- 4.9.3.1 System-Organ Class (SOC) -- 4.9.3.2 High-Level Group Term (HLGT) -- 4.9.3.3 High-Level Term (HLT) -- 4.9.3.4 Preferred Term (PT) -- 4.9.3.5 Lowest Level Term (LLT) -- 4.9.3.6 Advantage -- 4.9.4 Standardized MedDRA Queries (SMQs) -- 4.9.4.1 Advantages -- 4.9.5

WHODRUG Global -- 4.9.5.1 Advantages -- 4.9.6 World Health Organization Adverse Reactions Terminology (WHO-ART) -- 4.9.6.1 Structure of WHO-ART -- 4.9.6.2 Advantages -- 4.9.7 WHO-DDE: World Health Organization Drug Dictionary Enhanced -- 4.9.7.1 Codes Serve the Purpose of Distinguishing Distinct Characteristics of a Product -- 4.9.7.2 Improved Accuracy and Reporting of Clinical Trial and Safety Data.

4.9.7.3 On-Going Expansion Encompassing More Products, Countries and Services -- 4.9.7.4 Related UMC Drug Dictionary Offerings -- 4.9.7.5 Advantages -- 4.9.8 COSTART: Coding Symbols for Thesaurus of Adverse Reaction Terms -- 4.9.8.1 Overview of COSTART -- 4.9.8.2 Advantages -- 4.9.9 ICD-9-CM: International Classification of Disease, Ninth Revision, Clinical Modification -- 4.9.9.1 Development and Purpose -- 4.9.9.2 Structure and Coding System -- 4.9.9.3 Utilization in Healthcare -- 4.9.9.4 Advantages -- 4.9.10 WHO Herbal Dictionary (WHO-HD) -- 4.9.10.1 Advantages -- 4.10 Causality Assessment System -- 4.10.1 Principles of Causality Assessment -- 4.10.2 Basic Standards for Causality -- 4.10.3 Causality Assessment Determination Methods -- 4.10.3.1 Clinical Judgment/Global Introspection -- 4.10.3.2 WHO UPSALA Monitoring Centre (UMC) Method -- 4.10.4 Algorithmic Methods -- 4.10.4.1 Naranjo Scale -- 4.10.5 Probabilistic Method -- 4.10.5.1 Bayesian Method -- 4.10.5.2 Bayes' Theorem -- 4.10.5.3 Bayesian Methods in PV -- 4.11 Conclusion -- References -- 5: Aggregate Reporting -- 5.1 Introduction -- 5.2 Importance -- 5.2.1 Patient Safety -- 5.2.2 Signal Detection -- 5.2.3 Risk Management -- 5.2.4 Regulatory Compliance -- 5.2.5 Decision-Making -- 5.2.6 Public Health Monitoring -- 5.2.7 Long-Term Safety Assessment -- 5.2.8 Communication with Healthcare Professionals -- 5.2.9 Research and Development -- 5.2.10 Global Monitoring -- 5.3 Types of Aggregate Reporting -- 5.3.1 Periodic Safety Update Report (PSUR) -- 5.3.2 Periodic Adverse Drug Experience Report (PADER) -- 5.3.3 Periodic Benefit Risk Evaluation Report (PBRER) -- 5.3.4 Development Safety Updates Report (DSUR) -- 5.4 Significance -- 5.5 Challenges -- 5.5.1 Data Quality -- 5.5.2 Appropriateness -- 5.5.3 Signal Detection and Evaluation. 5.5.4 Regulatory Acquiescence -- 5.5.5 Risk Minimization and Management -- 5.5.6 Resource Allocation -- 5.5.7 Communication and Collaboration -- 5.5.8 Updating Safety Databases -- 5.6 Conclusion -- References -- 6: Reporting of ADRs Across the Globe: India, USA, EU, and Non-EU -- 6.1 Introduction -- 6.2 Overview of ADR Reporting -- 6.2.1 Definition and Importance of ADR Reporting -- 6.2.2 Objectives and Benefits of ADR Reporting -- 6.3 ADR Reporting in India -- 6.3.1 Regulatory Framework and Authorities -- 6.3.2 Structure of ADR Reporting System -- 6.3.3 Challenges and Improvements -- 6.4 ADR Reporting in the United States -- 6.4.1 Regulatory Framework and Authorities -- 6.4.2 Structure of ADR Reporting System -- 6.4.3 Challenges and Improvements -- 6.5 ADR Reporting in the European Union -- 6.5.1 Regulatory Framework and Authorities -- 6.5.2 Structure of ADR Reporting System -- 6.5.3 Challenges and Improvements -- 6.6 ADR Reporting in the Non-European Union -- 6.6.1 Regulatory Framework and Authorities -- 6.6.2 Structure of ADR Reporting System -- 6.6.3 Challenges and Improvements -- 6.7 Comparative Analysis and Lessons Learned -- 6.8 Case Studies or Examples of ADR Reporting in India, US, EU, and Non-EU -- 6.9 Future Perspectives and Recommendations -- 6.9.1 Advancements in ADR Reporting Technology -- 6.10 Collaboration and Information Sharing Among Regions -- 6.11 Recommendations for Enhancing ADR Reporting Globally -- 6.12

Conclusion -- References -- 7: Pharmacovigilance System in India --
7.1 Introduction -- 7.1.1 History of Pharmacovigilance System in India
-- 7.2 Advantages of Pharmacovigilance System in India -- 7.3
National Pharmacovigilance Programme -- 7.3.1 Peripheral
Pharmacovigilance Centers -- 7.3.2 Regional Pharmacovigilance
Centers -- 7.3.3 Zonal Pharmacovigilance Centers.
7.4 Pharmacovigilance Programme of India (PvPI).
