GOOD PHARMACOVIGILANCE PRACTICE GUIDE READ ONLY

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Good Pharmacovigilance Practice Guide Introduction

Good Pharmacovigilance Practice Guide

Pharmacovigilance is the science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medications, biological products, herbalism and traditional medicines with a view to identifying hazards and preventing harm to patients.

Pharmacovigilance Medical Writing

Pharmacovigilance Medical Writing covers the preparation of pharmacovigilance documents for all stages of the drug development process (i.e. from clinical development through to applications for marketing authorisations to the post-marketing stage). For each document, the book presents a review of the regulatory framework that governs the content of the document, followed by practical guidance (e.g. scheduling, source data, department/functions involved in document preparation/review, appropriate timelines and planning activities), ending with a generic model document compliant with the current guidelines, which can be modified to meet specific company and product requirements.

Guidance for Industry

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems. This introductory guide is designed to aid the rapid understanding of the key principles of pharmacovigilance. Packed full of examples illustrating drug safety issues it not only covers the processes involved, but the regulatory aspects and ethical and societal considerations of pharmacovigilance. Covering the basics step-by-step, this book is perfect for beginners and is essential reading for those new to drug safety departments and pharmaceutical medicine students. The second edition is thoroughly revised and updated throughout and includes a new chapter on clinical aspects of pharmacovigilance.

An Introduction to Pharmacovigilance

Efforts to control atmospheric accumulations of greenhouse gases that threaten to heat up the planet are in their infancy. Although the IMF is not an environmental organization, environmental issues matter for the organization's mission when they have major implications for macroeconomic performance and fiscal policy. Climate change clearly passes both these tests. This volume provides practical guidelines for the design of fiscal policies (carbon taxes and emissions trading systems with allowance auctions) to reduce greenhouse gases. Not only are these instruments potentially the most effective at exploiting emission reduction opportunities in the near and longer term, but they can also generate for many countries a valuable new source of government revenue. The chapters, written by leading experts, explain the case for fiscal policies over other approaches; how these policies can be implemented; reasonable levels for emissions prices; policies for the forest sector; appropriate polic

Good Clinical Practice Guide

This brand-new book offers a reference guide to understanding and applying the rules for properly conducting clinical trials to meet the international quality standard – Good Clinical Practice – provided by the International Conference on Harmonization (ICH). The work offers an updated perspective on the clinical research landscape within the context of the clinical trial regulatory frameworks in Europe and the USA. In addition to providing a historical review and a detailed definition of GPC regulations, it includes step-by-step explanations of all the requirements that researchers should bear in mind when designing and performing new trials. Further topics covered include: ethics of clinical research; the drug development process and evolution of regulations; investigator and sponsor responsibilities; and clinical trial protocols. Written by clinicians for clinicians, the book represents a valuable read also for researchers, pharmacists and all professionals involved in applications to the ethic committees, whose approval is required for new clinical studies.

Quick Guide to Good Clinical Practice

In recent years public expectations for rapid identification and prompt management of emerging drug safety issues have grown swiftly. Over a similar timeframe, the move from paper-based adverse event reporting systems to electronic capture and rapid transmission of data has resulted in the accrual of substantial datasets capable of complex analysis and querying by industry, regulators and other public health organizations. These two drivers have created a fertile environment for pharmacovigilance scientists, information technologists and statistical experts, working together, to deliver novel approaches to detect signals from these extensive and quickly growing datasets, and to manage them appropriately. In following this exciting story, this report looks at the practical consequences of these developments for pharmacovigilance practitioners. The report provides a comprehensive resource for those considering how to strengthen their pharmacovigilance systems and practices, and to give practical advice. But the report does not specify instant solutions. These will inevitably be situation specific and require careful consideration taking into account local needs. However, the CIOMS Working Group VIII is convinced that the combination of methods and a clear policy on the management of signals will strengthen current systems. Finally, in looking ahead, the report anticipates a number of ongoing developments, including techniques with wider applicability to other data forms than individual case reports. The ultimate test for pharmacovigilance systems is the demonstration of public health benefit and it is this test which signal detection methodologies need to meet if the expectations of all stakeholders are to be fulfilled.

Practical Aspects of Signal Detection in Pharmacovigilance

This book is open access under a CC BY 4.0 license. The book presents the results of an in-depth comparative study assessing the implementation of the EU Pharmacovigilance Directive in six EU Member States. By going beyond legal transposition and instead focusing on practical implementation, this study aims to close a gap in EU compliance research. Based on qualitative interviews with relevant actors in Germany, Poland, Portugal, France, Finland and the UK, the authors identify perceived challenges and best-practices, issue recommendations, and thereby contribute to a better understanding of the factors that incentivize or impede the practical implementation of EU law at the national level.

ESSENTIAL PHARMACOVIGILANCE.

Risk management of medicines is a wide and rapidly evolving concept and practice, following a medicine throughout its lifecycle, from first administration in humans through clinical studies and then marketing in the patient population at large. Previous reports from CIOMS I - VIII provided practical guidance in some essential components of risk management such as terminology and reporting of adverse drug reactions, management of safety information from clinical trials, and safety signal detection. Beyond the detection, identification, and characterization of risk, \"risk minimization\" is used as an umbrella term for the

prevention or mitigation of an undesirable outcome. Risk management always includes tools for \"routine risk minimization\" such as product information, the format depending on the jurisdiction, to inform the patient and the prescriber, all of which serve to prevent or mitigate adverse effects. Until this current CIOMS IX document, limited guidance has been available on how to determine which risks need \"additional risk minimization,\" select the appropriate tools, apply and implement such tools globally and locally, and measure if they are effective and valuable. Included in the report is a CIOMS framework for the evaluation of effectiveness of risk minimization, a discussion of future trends and developments, an annex specifically addressing vaccines, and examples from real life.

Pharmacovigilance in the European Union

This User’s Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. For the purposes of this guide, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure. The User’s Guide was created by researchers affiliated with AHRQ’s Effective Health Care Program, particularly those who participated in AHRQ’s DEcIDE (Developing Evidence to Inform Decisions About Effectiveness) program. Chapters were subject to multiple internal and external independent reviews.

Practical Approaches to Risk Minimisation for Medicinal Products

Completely revised and updated, the Manual of Drug Safety and Pharmacovigilance, Second Edition is a how-to manual for those working in the fields of drug safety, clinical research, pharmacuetucal, regulatory affairs, government and legal professions. This comprehensive and practical guide discusses the theory and the practicalities of drug safety (also known as pharmacovigilance) and side effects, as well as providing essential information on drug safety and regulations, including: recognizing, monitoring, reporting, and cataloging serious adverse drug reactions. The Manual of Drug Safety and Pharmacovigilance, Second Edition teaches the ins and outs of drug safety in the industry, hospitals, FDA, and other health agencies both in the US and around the world, and presents critical information about what is done when confronted with a drug safety problem.

Registries for Evaluating Patient Outcomes

Part of \"RPS Pharmacy Business Administration Series\

Cobert's Manual of Drug Safety and Pharmacovigilance

In spite of recent progress in the harmonization of terminology and processes affecting work on the clinical safety of medicines consensus is needed on standards for many difficult aspects of day-to-day pharmacovigilance that continue to pose problems for both the pharmaceutical industry and drug regulators. The CIOMS V Working Group has generated proposals for pragmatic approaches to dealing with such issues as: classification and handling of individual safety case reports from a variety of sources (spontaneous consumer reports solicited reports literature the Internet observational studies and secondary data bases

disease and other registries regulatory ADR databases and licensor-licensee interactions); new approaches to case management and regulatory reporting practices (proper clinical evaluation of cases incidental vs other events patient and reporter identifiability seriousness criteria expectedness criteria case follow-up criteria and the role and structure of case narratives); improvements and efficiencies in the format content and reporting of periodic safety update reports (PSURs) (including results of an industry survey on PSUR workloads and practices; proposals for high case volume and long time-period reports simplification of certain PSURs summary bridging reports addendum reports license renewal reports for EU and Japan dealing with old products and other technical details); determination and use of population exposure (denominator) data (sources of data and a guide to analytical approaches for a variety of circumstances).The Group has also taken stock of the current state of expedited and periodic clinical safety reporting requirements around the world with summary data on regulations from more than 60 countries. Recommendations are made for enhancing the harmonization steps already taken as a result of previous CIOMS publications and the ICH process. In addition to dealing with unfinished and unresolved issues from previous CIOMS initiatives the report covers many emerging topics such as those involving new technologies. Its 20 Appendices provide a wealth of detailed explanations and reference information. It is the most comprehensive and recent treatment of difficult pharmacovigilance issues affecting the working practices and systems of drug safety and other pharmaceutical professionals.

Principles of Good Clinical Practice

Completely revised and updated, Cobert's Manual of Drug Safety and Pharmacovigilance, Third Edition, is a how-to manual for those working in the fields of drug safety, clinical research, pharmacology, regulatory affairs, risk management, quality/compliance, and in government and legal professions.This comprehensive and practical guide discusses the theory and the practicalities of drug safety (also known as pharmacovigilance), and provides essential information on drug safety and regulations in the United States, Europe Union, and more, including: recognizing, monitoring, reporting, and cataloging serious adverse drug reactions.Cobert's Manual of Drug Safety and Pharmacovigilance, Third Edition, teaches the daily practice of drug safety in industry, hospitals, the FDA and other health agencies — both in the United States and around the world — and provides critical information about what to do when confronted with a drug safety problem.

A Guide to GCP for Clinical Data Management

Quality Assurance of Aseptic Preparation Services Standards Handbook (also known as the Yellow Guide) provides standards for unlicensed aseptic preparation in the UK, as well as practical information to aid implementation of the standards. The handbook delivers essential standards in a practical way and in a format that will be useful for pharmacy management, staff working in aseptic preparation units and those whose role it is to audit the services. The accompanying support resources help with understanding the complexities of relevant topics including microbiology, radiopharmaceuticals, advanced therapy medicinal products, technical (quality) agreements and capacity planning. All the standards have been revised and updated for this 5th edition. The text is produced on behalf of the Royal Pharmaceutical Society (RPS) and the NHS Pharmaceutical Quality Assurance Committee. New in this edition: Replaces the 4th edition standards and forms the basis for an ongoing audit program in the NHS Many new and revised standards Greater emphasis on Pharmaceutical Quality Systems; the responsibilities of pharmacy management, Chief Pharmacists (or equivalent), has been expanded in line with developments in Good Manufacturing Practice Reformatted into 2 parts: standards and support resources. This is a new collaboration between the RPS and NHS. Since the previous edition the RPS has become the professional body for pharmacists and pharmaceutical scientists. RPS launched these standards as part of a library of professional standards and a programme of work to create standards for all areas of pharmacy. The Handbook is essential for pharmacists, hospital pharmacy management and technical services teams, and auditors of unlicensed NHS hospital pharmacy aseptic preparation services in the UK, pharmacists and regulators. The text is used to inform standards used in several other countries.

Current Challenges in Pharmacovigilance

The long awaited second edition of Principles and Practice of Pharmaceutical Medicine provides an invaluable guide to all areas of drug development and medical aspects of marketing. The title has been extensively revised and expanded to include the latest regulatory and scientific developments. New chapters include: European Regulations Ethics of Pharmaceutical Medicine Licensing and Due Diligence Pharmacogenomics Encompassing the entire spectrum of pharmaceutical medicine, it is the most up-to-date international guide currently available. Review of the first edition: “This book was a joy to read and a joy to review. All pharmaceutical physicians should have a copy on their bookshelves, all pharmaceutical companies should have copies in their libraries.” —BRITISH ASSOCIATION OF PHARMACEUTICAL PHYSICIANS

Cobert's Manual Of Drug Safety And Pharmacovigilance (Third Edition)

Written by experts in the field of pharmacovigilance and patient safety, this concise resource provides a succinct, easy-to-digest overview of an increasingly critical area of medical safety. Drs. Thao Doan, Fabio Lievano, Mondira Bhattacharya, and Linda Scarazzini provide essential information for health care professionals, clinical researchers, and regulators who need a comprehensive, up-to-date source of information on the principles and practice of pharmacovigilance.

Quality Assurance of Aseptic Preparation Services

At the core of this book lies the question how to approach medicines, risks and communication as a researcher - or anybody planning and evaluating a communication intervention, or wanting to understand communication events in private and the media. With a view to tackle current shortcomings of communication systems and processes for improved implementation, patient satisfaction and health outcomes, a multilayered approach is presented. This combines multiple data types and methods to obtain a wider and deeper understanding of the major parties and their interactions, as well as the healthcare, social and political contexts of information flows, how they interfere and which impact they have. Illustrated with real life experiences of safety concerns with medicines, worldwide active experts discuss the methods and contributions their disciplines can offer. With considerations on terminologies, tabulated overviews on communication types and outcomes, a patient-centred vision and plain language for non-medical readers, the book creates a platform for multidisciplinary collaborations amongst researchers as well as practitioners from communications, healthcare, the social sciences and pharmacovigilance. Importantly, it advocates for an active role of patients and highlights the achievements and aspirations of patient organisations. Finally, the book suggests establishing an inclusive discipline of humanities and epidemiology of medicinal product risk communication to realise full research potential. The authors are driven by the curiosity for communication as the most human behaviour, and as good health is amongst the basic human needs, medicinal product risk communication is an exciting research field of high global relevance.

Principles and Practice of Pharmaceutical Medicine

This open access book is a unique resource for health professionals who are interested in understanding the philosophical foundations of their daily practice. It provides tools for untangling the motivations and rationality behind the way medicine and healthcare is studied, evaluated and practiced. In particular, it illustrates the impact that thinking about causation, complexity and evidence has on the clinical encounter. The book shows how medicine is grounded in philosophical assumptions that could at least be challenged. By engaging with ideas that have shaped the medical profession, clinicians are empowered to actively take part in setting the premises for their own practice and knowledge development. Written in an engaging and accessible style, with contributions from experienced clinicians, this book presents a new philosophical framework that takes causal complexity, individual variation and medical uniqueness as default expectations for health and illness.

Pharmacovigilance: A Practical Approach

Civil Society Organizations (CSOs) can make a vital contribution to public health and health systems but harnessing their potential is complex in a Europe where government-CSO relations vary so profoundly. This study is intended to outline some of the challenges and assist policy-makers in furthering their understanding of the part CSOs can play in tandem and alongside government. To this end it analyses existing evidence and draws on a set of seven thematic chapters and six mini case studies. They examine experiences from Austria Bosnia-Herzegovina Belgium Cyprus Finland Germany Malta the Netherlands Poland the Russian Federation Slovenia Turkey and the European Union and make use of a single assessment framework to understand the diverse contexts in which CSOs operate. The evidence shows that CSOs are ubiquitous varied and beneficial and the topics covered in this study reflect such diversity of aims and means: anti-tobacco advocacy food banks refugee health HIV/AIDS prevention and cure and social partnership. CSOs make a substantial contribution to public health and health systems with regards to policy development service delivery and governance. This includes evidence provision advocacy mobilization consensus building provision of medical services and of services related to the social determinants of health standard setting self-regulation and fostering social partnership. However in order to engage successfully with CSOs governments do need to make use of adequate tools and create contexts conducive to collaboration. To guide policy-makers working with CSOs through such complications and help avoid some potential pitfalls the book outlines a practical framework for such collaboration. This suggests identifying key CSOs in a given area; clarifying why there should be engagement with civil society; being realistic as to what CSOs can or will achieve; and an understanding of how CSOs can be helped to deliver.

Communicating about Risks and Safe Use of Medicines

This is thirty-fifth edition of Martindale, which provides reliable, and evaluated information on drugs and medicines used throughout the world. It contains encyclopaedic facts about drugs and medicines, with: 5,500 drug monographs; 128,000 preparations; 40,700 reference citations; 10,900 manufacturers. There are synopses of disease treatments which enables identification of medicines, the local equivalent and the manufacturer. It also Includes herbals, diagnostic agents, radiopharmaceuticals, pharmaceutical excipients, toxins, and poisons as well as drugs and medicines. Based on published information and extensively referenced

Rules and Guidance for Pharmaceutical Manufacturers and Distributors (Orange Guide) 2022

In the European Union (EU), its Member States and the United Kingdom (UK) post-Brexit, as elsewhere, the marketing of pharmaceuticals is subject to an ever more complex web of legislation and regulation, resulting from the intense scrutiny necessary to ensure such essential products are not only efficacious but also safe. This useful volume lays out this system with extraordinary clarity and logic. Adopting a Europe-wide perspective on the law governing pharmaceuticals, expert authors from the law firm Bird & Bird LLP map the life cycle of a medicinal product or medical device from development to clinical trials to product launch and ongoing pharmacovigilance, offering comprehensive and unambiguous guidance at every stage. Following a brief overview of how the exit from the EU by the UK currently affects the regulatory regime, as well as an introductory overview focusing on the regulatory framework for pharmaceuticals in Europe – from its underlying rationales to the relevant committees and agencies – each of the following twenty-one incisive chapters examines a particular process or subject. Among the many topics and issues covered from both an EU and UK perspective are the following: clinical trials; stages and standards for creating a product dossier; obtaining a marketing authorisation; how and when an abridged marketing authorisation procedure can be used; criteria for conditional marketing authorisations; generic products and ‘essential similarity’; paediatric use and the requisite additional trials; orphan medicinal products; biologicals and ‘biosimilars’; homeopathic, herbal and similar medicines; medical devices; pandemics, epidemics and vaccines; pharmacovigilance;

parallel trade; advertising; and relevant competition law, intellectual property rights and data protection regulation. In addition, sample forms and URLs for the most important reference materials are included. Pharmaceutical lawyers and regulatory advisers, both in-house and in private practice, will welcome this unique book. It offers immeasurable value for all who need to understand the process of bringing a medicinal product or medical device to market and the continuing rights and obligations.

Rethinking Causality, Complexity and Evidence for the Unique Patient

At any point in the drug development process, systematic reviews and meta-analysis can provide important information to guide the future path of the development program and any actions that might be needed in the post-marketing setting. This report gives the rationale for why and when a meta-analysis should be considered, all in the context of regulatory decision-making, and the tasks, data collection, and analyses that need to be carried out to inform those decisions. There is increasing demand by decision-makers in health care, the bio-pharmaceutical industry, and society at large to have access to the best available evidence on benefits and risks of medicinal products. The best strategy will take an overview of all the evidence and where it is possible and sensible, combine the evidence and summarize the results. For efficacy, the outcomes generally use the same or very similar predefined events for each of the trials to be included. Most regulatory guidance and many Cochrane Collaboration reviews have usually given more attention to assessment of benefits, while issues around combining evidence on harms have not been as well-covered. However, the (inevitably) unplanned nature of the data on safety makes the process more difficult. Combining evidence on adverse events (AEs), where these were not the focus of the original studies, is more challenging than combining evidence on pre-specified benefits. This focus on AEs represents the main contribution of the current CIOMS X report. The goal of the CIOMS X report is to provide principles on appropriate application of meta-analysis in assessing safety of pharmaceutical products to inform regulatory decision-making. This report is about meta-analysis in this narrow area, but the present report should also provide conceptually helpful points to consider for a wider range of applications, such as vaccines, medical devices, veterinary medicines or even products that are combinations of medicinal products and medical devices. Although some of the content of this report describes highly technical statistical concepts and methods (in particular Chapter 4), the ambition of the working group has been to make it comprehensible to non-statisticians for its use in clinical epidemiology and regulatory science. To that end, Chapters 3 and 4, which contain the main technical statistical aspects of the appropriate design, analysis and reporting of a meta-analysis of safety data are followed by Chapter 5 with a thought process for evaluating the findings of a meta-analysis and how to communicate these.

Civil Society and Health

Veterinary Pharmacovigilance: Adverse Reactions to Veterinary Medicinal Products is an in-depth examination of veterinary pharmacovigilance, looking at the scientific methodologies involved, the role of regulatory agencies and legislation, and the underpinning science. Edited by a renowned expert with over 20 years of experience in the field, it draws together the expertise of authors from around the world.

Martindale

This User’s Guide is a resource for investigators and stakeholders who develop and review observational comparative effectiveness research protocols. It explains how to (1) identify key considerations and best practices for research design; (2) build a protocol based on these standards and best practices; and (3) judge the adequacy and completeness of a protocol. Eleven chapters cover all aspects of research design, including: developing study objectives, defining and refining study questions, addressing the heterogeneity of treatment effect, characterizing exposure, selecting a comparator, defining and measuring outcomes, and identifying optimal data sources. Checklists of guidance and key considerations for protocols are provided at the end of each chapter. The User’s Guide was created by researchers affiliated with AHRQ’s Effective Health Care Program, particularly those who participated in AHRQ’s DEcIDE (Developing Evidence to Inform Decisions

About Effectiveness) program. Chapters were subject to multiple internal and external independent reviews. More more information, please consult the Agency website: www.effectivehealthcare.ahrq.gov)

Guide to EU and UK Pharmaceutical Regulatory Law

Available now to FDA-regulated organizations, this manual allows facility managers to look at their operation's regulatory compliance through the eyes of the government. Because this is the primary reference manual used by FDA personnel to conduct field investigation activities, you can feel confident you are preparing appropriate planning or action. This manual includes revised instructions regarding the release of information and covers FDA's policies and expectations on a comprehensive range of topics: FDA's authority to enter and inspect, inspection notification, detailed inspection procedures, recall monitoring, inspecting import procedures, computerized data requests, federal/state inspection relationships, discussions with management regarding privileged information, seizure and prosecution, HACCP, bioengineered food, dietary supplements, cosmetics, bioterrorism, and product disposition. The manual also includes a directory of Office of Regulatory Affairs offices and divisions.

The Extent of Population Exposure to Assess Clinical Safety

Drug Safety Data: How to Analyze, Summarize and Interpret to Determine Risk was selected for The First Clinical Research Bookshelf - Essential reading for clinical research professionals by the Journal of Clinical Research Best Practices. Drug Safety Data: How to Analyze, Summarize and Interpret to Determine Risk provides drug safety/pharmacovogilance professionals, pharmaceutical and clinical research scientists, statisticians, programmers, medical writers, and technicians with an accessible, practical framework for the analysis, summary and interpretation of drug safety data. The only guide of its kind, Drug Safety Data: How to Analyze, Summarize and Interpret to Determine Risk is an invaluable reference for pre- and post-marketing risk assessment. With decades of pharmaceutical research and drug safety expertise, authors Dr. Klepper and Dr. Cobert discuss how quality planning, safety training, and data standardization result in significant cost, time, and resource savings. Through illustrative, step-by-step instruction, Drug Safety Data: How to Analyze, Summarize and Interpret to Determine Risk is the definitive guide to drug safety data analysis and reporting. Key features include: * Step-by-step instruction on how to analyze, summarize and interpret safety data for mandatory governmental safety reports * Pragmatic tips...and mistakes to avoid * Simple explanations of what safety data are collected, and what the data mean * Practical approaches to determining a drug effect and understanding its clinical significance * Guidance for determining risk throughout the lifecycle of a drug, biologic or nutraceutical * Examples of user-friendly data displays that enhance safety signal identification * Ways to improve data quality and reduce the time, resources and costs involved in mandatory safety reporting * Relevant material for the required training of drug safety/pharmacovigilance professionals * SPECIAL FEATURE: Actual examples of an Integrated Analysis of Safety (IAS) -used in the preparation of the Integrated Summary of Safety (ISS) and the Summary of Clinical Safety (SCS) reports -, and the Periodic Safety Update Report (PSUR)

Evidence Synthesis and Meta-analysis for Drug Safety

This guide offers a practical step-by-step approach and algorithm to aid immunization professionals and decision-makers in determining the best course of action if additional vaccine safety data is needed. The guide provides a structured process for evaluating whether significant knowledge gaps exist, whether passive safety surveillance is adequate, and if not, methods for and practical aspects of conducting active vaccine safety surveillance. The guide also includes an essential vaccine information source list for evaluating the extent of data resources and several case studies for review. With more vaccine solutions available and opportunities for earlier availability of new vaccine products in resource-limited countries (e.g. vaccines against rotavirus, human papillomavirus or pneumococci) as well as new products that address diseases endemic in those countries only (e.g. malaria, dengue among others), generating reliable data about specific safety concerns is becoming a priority for all countries. This CIOMS publication--more than any other in

recent history--has focused on the special needs of the country level organizations responsible for developing strategies and implementing new vaccination programs into resource-limited environments.

Veterinary Pharmacovigilance

For adults. There is a pressing need for methodologically sound RCTs to confirm whether such interventions are helpful and, if so, for whom.

Developing a Protocol for Observational Comparative Effectiveness Research: A User's Guide

Medical Product Regulatory Affairs Hands-on guide through the jungle of medical regulatory affairs for every professional involved in bringing new products to market Based on a module prepared by the authors for an MSc course offered by the University of Limerick, Ireland, Medical Product Regulatory Affairs is a comprehensive and practical guide on how pharmaceutical and medical devices are regulated within the major global markets. The Second Edition builds on the success of the first with an even wider scope and full coverage of new EU regulations on the safe use of medical devices. Following a look at drug development, complete sections are devoted to national and EU regulatory issues, manufacturing license application and retention, and regulation in the USA. Other topics dealt with include CDER, CBER and marketing and manufacturing licenses, the ICH process and Good Laboratory/Clinical/ Manufacturing Practices. Medical Product Regulatory Affairs includes information on: Aims and structure of regulation, covering purpose and principles of regulation, national and EU legislative processes, and pharmacopeia Regulatory strategy, covering product development and manufacturing, market vigilance, quality assurance systems, personnel, and documentation Drug discovery and development, covering prescription status, physical properties, therapeutic use, and drug discovery, development, and delivery Non-clinical studies, covering non-clinical study objectives and timing, pharmacological and pharmacodynamic studies, and bioavailability and bioequivalence Clinical trials, covering trial protocol, monitoring of trials, trial master files, and FDA communications The wide coverage of different product types and the main global markets makes Medical Product Regulatory Affairs ideal for training courses on regulatory affairs in academia and industry. It is also a valuable reference for pharmacologists, bioengineers, pharma engineers, and students in pharmacy to familiarize themselves with the topic.

Guidelines for Preparing Core Clinical-safety Information on Drugs

The purpose of this document is to present the case for the importance of pharmacovigilance, to record its growth and potential as a significant discipline within medical science, and to describe its impact on patient welfare and public health.

FDA Investigations Operations Manual

Consumer and environmental protection depend on the careful regulation of all classes of chemicals. Toxicology is the key science used to evaluate safety and so underpins regulatory decisions on chemicals. With the growing body of EU legislation involved in chemical regulation, there is a concomitant need to understand the toxicological principles underlying safety assessments. Regulatory Toxicology in the European Union is the first book to cover regulatory toxicology specifically in Europe. It addresses the need for a wider understanding of the principles of regulatory toxicology and their application and presents the relationship between toxicology and legislative processes in regulating chemical commodities across Europe. This title has a broad scope, covering historical and current chemical regulation in Europe, the role of European agencies and institutions, and also the use of toxicology data for important classes of chemicals, including human and veterinary medicines, animal feed and food additives, biocides, pesticides and nanomaterials. This book is therefore extremely pertinent and timely in the toxicology field at present. This

book is an essential reference for regulatory authorities, industrialists, academics, undergraduates and postgraduates working within safety and hazards, toxicology, the biological sciences, and the medicinal and pharmaceutical sciences across the European Union.

Drug Safety Data

\"In the new 2016 version of the ethical guidelines, CIOMS provides answers to a number of pressing issues in research ethics. The Council does so by stressing the need for research having scientific and social value, by providing special guidelines for health-related research in low-resource settings, by detailing the provisions for involving vulnerable groups in research and for describing under what conditions biological samples and health-related data can be used for research.\"--Page 4 de la couverture.

CIOMS Guide to Active Vaccine Safety Surveillance

Pharmaceutical manufacturing can be viewed as a supply chain which spans from the production and purchase of the starting and packaging materials through the manufacture of dosage forms until the safe reception of the finished product by the patient. The entire chain comprises of several processes: auditing, materials purchase (procurement), production, storage, distribution, quality control, and quality assurance. The quality standard for pharmaceutical production is ‘current good manufacturing practice (CGMP)’‘, which is applied within the frame of a pharmaceutical quality system (PQS). This implementation, however, requires a scientific approach and has to take into account several elements such as risk assessment, life cycle, patient protection, among other factors. Hence, pharmaceutical manufacturing is a complex subject in terms of regulation, given the technical and managerial requirements. This comprehensive handbook describes CGMP for new professionals who want to understand and apply the elements which build up pharmaceutical quality assurance. The book gives details about basic quality control requirements (such as risk management, quality hazards and management systems, documentation, clean environments, personnel training) and gives guidelines on regulatory aspects. This is an ideal handbook for undergraduates studying pharmaceutical or industrial manufacturing and supply chains as well for entrepreneurs and quality control professionals seeking to learn about CGMP standards and implementing quality assurance systems in the pharmaceutical sector.

Systematic Reviews

This volume, developed by the Observatory together with OECD, provides an overall conceptual framework for understanding and applying strategies aimed at improving quality of care. Crucially, it summarizes available evidence on different quality strategies and provides recommendations for their implementation. This book is intended to help policy-makers to understand concepts of quality and to support them to evaluate single strategies and combinations of strategies.

Medical Product Regulatory Affairs

The Importance of Pharmacovigilance