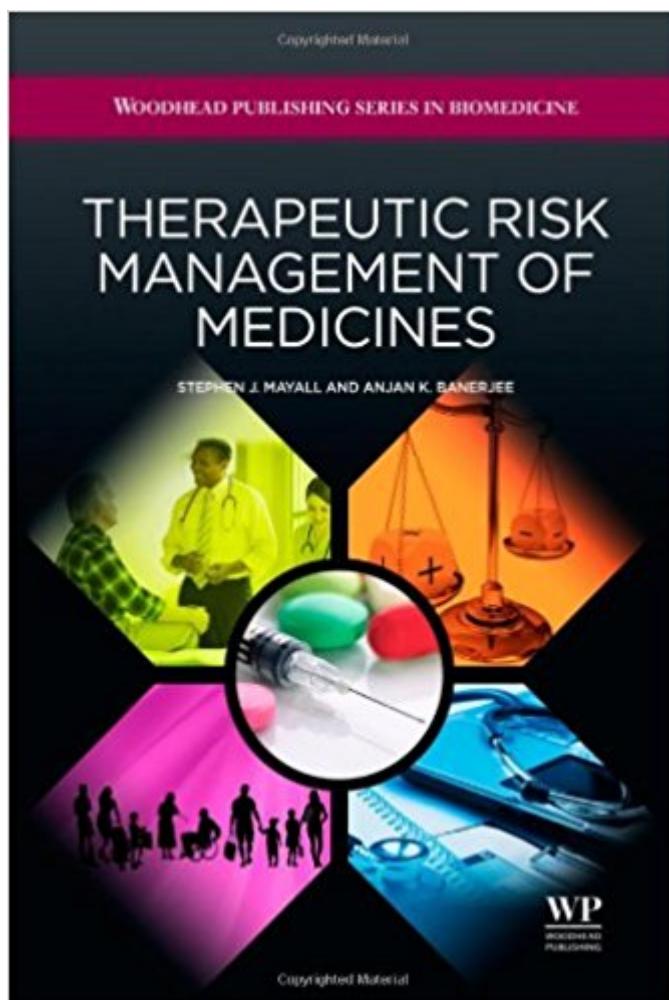


The book was found

Therapeutic Risk Management Of Medicines (Woodhead Publishing Series In Biomedicine)



Synopsis

Therapeutic risk management of medicines is an authoritative and practical guide on developing, implementing and evaluating risk management plans for medicines globally. It explains how to assess risks and benefit-risk balance, design and roll out risk minimisation and pharmacovigilance activities, and interact effectively with key stakeholders. A more systematic approach for managing the risks of medicines arose following a number of high-profile drug safety incidents and a need for better access to effective but potentially risky treatments. Regulatory requirements have evolved rapidly over the past decade. Risk management plans (RMPs) are mandatory for new medicinal products in the EU and a Risk Evaluation and Mitigation Strategy (REMS) is needed for certain drugs in the US. This book is an easy-to-read resource that complements current regulatory guidance, by exploring key areas and practical implications in greater detail. It is structured into chapters encompassing a background to therapeutic risk management, strategies for developing RMPs, implementation of RMPs, and the continuing evolution of the risk management field. The topic is of critical importance not only to the pharmaceutical and biotechnology industries, but also regulators and healthcare policymakers. Some chapters feature contributions from selected industry experts. An up-to-date practical guide on conceiving, designing, and implementing global therapeutic risk management plans for medicines. A number of useful frameworks are presented which add impact to RMPs (Risk Management Plans), together with regional specific information (European Union, United States, and Japan). A comprehensive guide for performing risk management more effectively throughout a product's life-cycle.

Book Information

Series: Woodhead Publishing Series in Biomedicine

Hardcover: 448 pages

Publisher: Woodhead Publishing; 1 edition (March 27, 2014)

Language: English

ISBN-10: 1907568484

ISBN-13: 978-1907568480

Product Dimensions: 6.1 x 0.9 x 9.2 inches

Shipping Weight: 1.7 pounds (View shipping rates and policies)

Average Customer Review: Be the first to review this item

Best Sellers Rank: #716,725 in Books (See Top 100 in Books) #75 in Books > Business & Money > Industries > Pharmaceutical & Biotechnology #77 in Books > Textbooks > Medicine

Customer Reviews

"...a must-have book for those working in the field of therapeutic risk management of medicines...very useful as a training book for new pharmacovigilance officers, but it is also useful for experienced staff" --Drug Safety, 03-Oct-14

Dr Stephen Mayall is a Principal Consultant at Pope Woodhead & Associates. He has over 15 years of consulting and project management experience in the global pharmaceutical industry, and has focused on therapeutic risk management since 2003. Steve has worked on the development and/or implementation of over 40 risk management plans, including EU-RMPs, REMS and development-stage RMPs. These have encompassed a diverse range of therapeutic areas, product types, life-cycle stages and client companies. He has also conducted a variety of other consulting projects for global pharmaceutical and biotechnology companies, covering communications, drug safety, clinical development, strategic marketing and in-licensing topics. This broader experience has provided valuable insights for placing risk management in a wider context within different organisations and healthcare systems. Steve has a Bachelor's degree in natural sciences (biochemistry) from the University of Cambridge, and a PhD in cell biology from University College London. Dr Anjan Swapu Banerjee is Deputy Managing Director (Deputy CEO) of Pope Woodhead & Associates and Head of Development Consulting. He has wide experience of numerous global risk management programmes, is a member of the ENCePP network and has been involved in multiple EU and US regulatory filings, regulatory projects and the design of clinical development programmes. He is also a Faculty member in Regulatory, Drug Safety and Risk Management at the Institute of Biotechnology, Cambridge University. Anjan has over 15 years of experience in global pharmaceuticals, biotech, advanced therapies and devices in clinical development, regulatory, medical affairs and drug safety roles in addition to experience as a Management Consultant at McKinsey & Company. He has spent more than 30 years in healthcare, remaining clinically active as a part-time Honorary Consultant Surgeon at Bedford Hospital NHS Trust. He has completed UK higher medical training in pharmaceutical medicine (as well as general surgery) and has an MSc in pharmacoepidemiology. Anjan is MBBS, DM, MBA, FRCP(Edin), FRCS(Gen), FRCS(Glas), FAcadMEd, FICS, MFPM, FSB.

[Download to continue reading...](#)

Therapeutic Risk Management of Medicines (Woodhead Publishing Series in Biomedicine) An Introduction to Pharmaceutical Sciences: Production, Chemistry, Techniques and Technology (Woodhead Publishing Series in Biomedicine) Handbook of Waste Management and Co-Product Recovery in Food Processing (Woodhead Publishing Series in Food Science, Technology and Nutrition) Stockley's Herbal Medicines Interactions: A Guide to the Interactions of Herbal Medicines KINDLE PUBLISHING: How To Build A Successful Self-Publishing Business With Kindle and Createspace. A Detailed, Step-By-Step Guide To The Entire Process (Kindle Publishing Series Book 1) Forensic Assessment of Violence Risk: A Guide for Risk Assessment and Risk Management Hedging Currency Exposures: Currency Risk Management (Risk Management Series) Strengthening of Reinforced Concrete Structures: Using Externally-Bonded Frp Composites in Structural and Civil Engineering (Woodhead Publishing Series in Civil and Structural Engineering) Structural Dynamics of Earthquake Engineering: Theory and Application Using Mathematica and Matlab (Woodhead Publishing Series in Civil and Structural Engineering) Principles and Applications of Organic Light Emitting Diodes (OLEDs) (Woodhead Publishing Series in Electronic and Optical Materials) Handbook of Organic Materials for Optical and (Opto)Electronic Devices: Properties and Applications (Woodhead Publishing Series in Electronic and Optical Materials) Regulatory Affairs for Biomaterials and Medical Devices (Woodhead Publishing Series in Biomaterials) Advances in Concentrating Solar Thermal Research and Technology (Woodhead Publishing Series in Energy) Advances in Wind Turbine Blade Design and Materials (Woodhead Publishing Series in Energy) Materials for Ultra-Supercritical and Advanced Ultra-Supercritical Power Plants (Woodhead Publishing Series in Energy) Advances in Wrought Magnesium Alloys: Fundamentals of Processing, Properties and Applications (Woodhead Publishing Series in Metals and Surface Engineering) Fracture and Fatigue of Welded Joints and Structures (Woodhead Publishing Series in Welding and Other Joining Technologies) Dental Biomaterials: Imaging, Testing and Modelling (Woodhead Publishing Series in Biomaterials) Ultra-Supercritical Coal Power Plants: Materials, Technologies and Optimisation (Woodhead Publishing Series in Energy) The Coal Handbook: Towards Cleaner Production: Volume 2: Coal Utilisation (Woodhead Publishing Series in Energy)

[Contact Us](#)

[DMCA](#)

[Privacy](#)

FAQ & Help