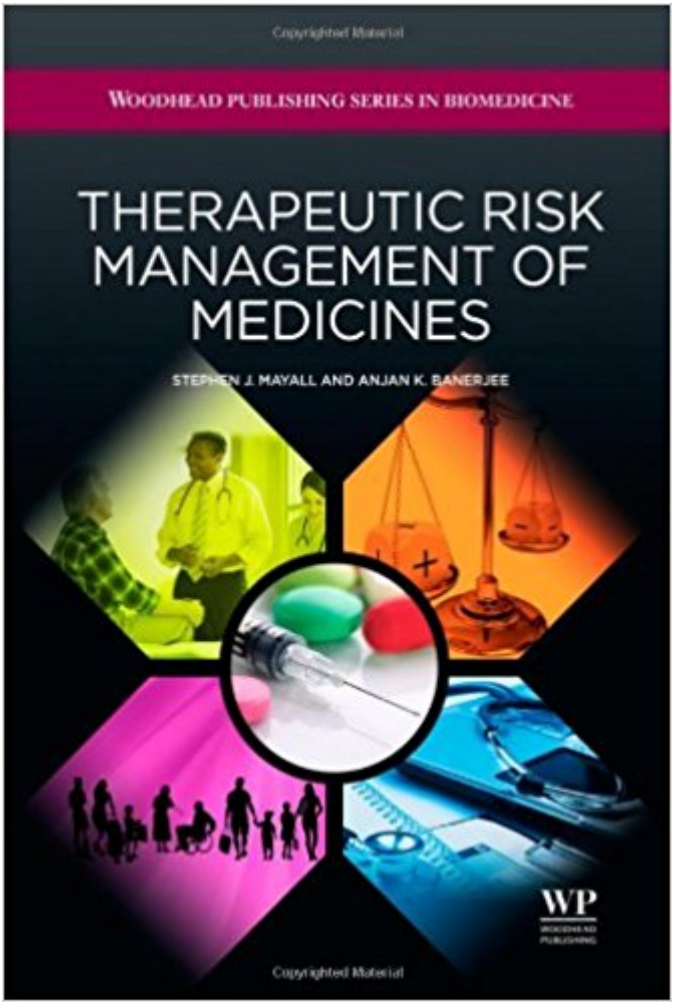
Therapeutic Risk Management Of Medicines (Woodhead Publishing Series In Biomedicine)



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 medicinesA 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)AÃ Â comprehensive guide for performing risk management more effectively throughout a productÃ¢â ¬â„¢s life-cycle

Book Information

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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 staffÃ¢â ¬Â|" --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 BachelorÃ¢â ¬â„¢s degree in natural sciences (biochemistry) from the University of Cambridge, and a PhD in cell biology from University College London.Dr Anjan Ã¢â ¬Å“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.

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