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Therapeutic Risk Management of Medicines (Woodhead Publishing Series in Biomedicine)

Stephen J. Mayall, Anjan Swapu Banerjee

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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

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