

Book Review

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Pharmaceutical Risk Management: Practical Applications

With a foreword by Janet Woodcock, MD

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Given several high-profile recalls in recent years of pharmaceuticals by the US Food and Drug Administration (FDA), the subject of pharmaceutical risk management has become increasingly important. Pharmaceutical risk management refers to manufacturers creating special tools and programs to ensure the safe use of certain high risk products. The FDA's Amendments Act (FDAAA) of 2007 prompted the Food and Drug Law Institute (FDLI) to publish *Pharmaceutical Risk Management: Practical Applications* (2008), a follow up to their 2003 publication, *A Framework for Pharmaceutical Risk Management*. The 2008 edition is a multi-author work written by experienced risk managers who have organized risk management programs as consultants or industry executives; some are alumni of the FDA. It is important to note that this is not a second edition of the 2003 book, but rather an extension of the research and methods presented in the original, with an emphasis on practical applications of risk management principles. The purpose of this publication is to educate pharmaceutical companies, consultants, and other drug industry stakeholders on the new rules for Risk Evaluation and Mitigation strategies (REMS) during pre- and post-marketing drug development.

Pharmaceutical Risk Management: Practical Applications provides the historical context for all

of the recent changes in the FDA's requirements for risk management, which culminated with the FDAAA of 2007. The authors describe the Vioxx® withdrawal from the market and how it ultimately compelled the Institute of Medicine (IOM) to issue its report, *The Future of Drug Safety: Promoting and Protecting the Health of the Public*, which pointed out deficiencies in drug safety in the US and made recommendations for correcting them. Some of these recommendations were incorporated in the FDAAA of 2007, including the expanded ability of the FDA to require a REMS if the agency deems the strategy would be "necessary to ensure that the benefits of the drug outweigh the risks of the drug." The legislation also allows the FDA to require a REMS for a previously approved drug if it "becomes aware of new safety information and makes a determination that such a strategy is necessary to ensure that the benefits of the drug outweigh its risks."

The author/s goes on to address specific elements of a REMS or risk management action plan (RiskMAP). It details the application of risk management to clinical development, regulator approval, clinician acceptance, and outcomes improvement. Incorporating educational interventions into risk management is explored, as is evaluating the performance of risk management plans. The authors conclude with chapters on crisis avoidance and management,

and the legal implications of risk management. An extensive appendix is also provided, including three guidance documents on risk management published by the FDA in 2005, the FDAAA of 2007, a list of products with approved REMS in effect when the FDAAA was passed, and a March 2008 draft of the Prescription Drug User Fee Act (PDUFA) IV: Drug Safety Five-Year Plan.

This FDLI publication on pharmaceutical risk management, when accompanied by *A Framework for Pharmaceutical Risk Management* (2003), acts as an excellent primer for individuals devising or interpreting a REMS or RiskMAP for the FDA, and could also be helpful for devising risk management strategies internally or for other regulatory agencies. The book provides first-hand knowledge from a collection of authors who have extensive training and experience in the field of pharmaceutical risk management. Both manufacturers and the FDA hope that effective risk management programs will protect consumers from future recalls and increase the safety of medications in the US. ■

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