In the Bookstores

An Introduction to Pharmacovigilance (Second Edition)

By Patrick Waller and Mira Harrison-Woolrych
Wiley-Blackwell
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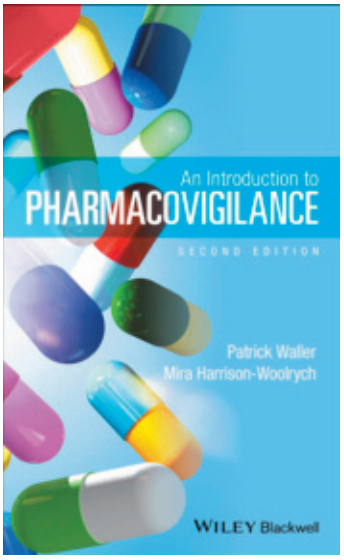

An Introduction to Pharmacovigilance is a compelling read and one that both new and experienced medical writers will find useful for providing a succinct, yet thorough, overview of today's current drug safety requirements. Patrick Waller and Mira Harrison-Woolrych are experts in pharmacovigilance; their wealth of knowledge makes this second edition book a must have on any medical writer's desk and provides a more up-to-date and internationally focused work than its predecessor.

The book is organised into 10 chapters and these are ordered into several topics such as the processes and societal considerations of pharmacovigilance, making it easier to find specific areas of interest to the readers. To open the medical writer's eyes to the importance of drug regulation, Chapter 1 starts at the beginning of modern pharmacovigilance, with thalidomide, and how the terrible consequences of poor safety monitoring led to legislation that was the forebear of what is in place today. From here the authors go on to discuss other more recent drug scandals, from practolol in the 1970s up to pandemrix in 2009, to give a wide-ranging timeline of pharmacovigilance evolution that brings further clarification to how vital drug safety regulations have been put in place to protect patients taking drugs.

Chapter 2 segues into an outline of basic concepts, from adverse drug reactions (ADRs) and their systems of classification to the risk-benefit balance and how to evaluate causality. Chapter 3 offers summaries of the multiple clinical trial phases, followed by safety reporting methods (for example, spontaneous ADR reporting systems and prescription-event monitoring) that are employed by different agencies to further build the profile of a drug once marketed. The overall process of pharmacovigilance is then followed up within Chapter 4, where the authors explain ADR signal detection techniques and their merits, signal evaluation and prioritisation, and the different courses of action that can be implemented. The assumption that all readers would be aware of the statistical methods mentioned in this chapter, such as Bayesian statistics, is a potential weakness, and I personally would have found it beneficial to go into these methods in more depth. However, the overarching messages of this chapter are the importance of communication in pharmacovigilance and the need to assess the adequacy of actions once completed, which are both conveyed excellently.

Chapter 5 reviews how pharmacovigilance procedures are regulated, starting with a focus on the authors' own line of expertise – drug safety within the EU. We are presented with many of the EU's rules and objectives regarding pharmacovigilance, such as the need to increase efficiency and transparency with regard to drug safety to ensure patient welfare whilst on medication. Additional guidelines such as the European Medicines Agency's 12 modules on Good Pharmacovigilance Practices and guidelines on the Summary of Product Characteristics are introduced and described alongside the obligations imposed upon pharmaceutical companies to guarantee that the products they sell and research are fully compliant. The subsections on periodic safety update reports and risk management planning might be of particular interest to medical writers, due to the likelihood of having already worked on these documents or needing to in the future.

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In Chapter 6, the authors continue the theme of pharmacovigilance regulation by reviewing the international coordination that takes place to ensure drug safety is monitored appropriately and that relevant safety information is shared between parties immediately to prevent further worldwide issues. They focus mainly on the larger regulatory bodies relevant to safety, such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the Council for International Organizations of Medical Sciences (CIOMS), and also highlight the role of other types of organisations, including international professional societies, such as the Drug Information Association (DIA). This offers the reader a greater understanding of the huge efforts the healthcare community employs to ensure pharmacovigilance information is collated and shared to reduce patient risks. Chapter 7 then delivers an overview of how pharmacovigilance affects patients on a day-to-day basis, exploring the consequences of ADRs for patients within all walks of life and outlining important ADRs such as gastrointestinal bleeding and agranulocytosis. The rest of the chapter then assesses how work in the clinic can help to limit ADR occurrence. Tasks mentioned include checking up routinely on the well-being of patients who are taking new medication and taking additional care when prescribing to specific patient populations such as the elderly, who are more at risk of ADRs than other populations.

Chapter 8 dissects the ethics of pharmacovigilance, looking specifically at common ethical principles within the pharmaceutical industry (informed consent, privacy/confidentiality), and examining the safeguards that are put in place, such as ethics committees/review boards. The penultimate chapter of *An*

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Introduction to Pharmacovigilance then discusses how pharmacovigilance is expected to evolve, by judging its current limitations and what can and is being done to overcome them. The final chapter recommends where to go next for those interested in learning more by providing a range of books and journals for suggested reading, as well as courses that can be attended and relevant societies that the reader could join.

Overall this book is an interesting read that provides a wealth of knowledge on numerous aspects of pharmacovigilance. As a medical writer with 2 years' experience, I did already have an understanding of some sections, but this book expanded on my awareness and understanding of pharmacovigilance, and it delivered a much broader education on current pharmacovigilance concerns. In particular, I thought the introduction was very effective in stressing the role of pharmacovigilance in healthcare, by examining several drug scandals and determining how each of these in turn has shaped pharmacovigilance. Other chapters, such as those concerning ethics and pharmacovigilance in the clinic, put pharmacovigilance into perspective with regard to everyday living, and these chapters were, in my opinion, especially successful at complementing some of the more information-heavy chapters explaining procedure. Although some of these information-heavy chapters might be a bit of a hard read in one go, they are extremely informative and are a brilliant companion to have with you at your desk when working on a pharmacovigilance project. In general, this is a very useful book that could improve any medical writer's understanding of the state of pharmacovigilance today.

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