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Pharmacovigilance Medical Writing: A Good Practice Guide
by Justina Orleans-Lindsay;
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34.99 GBP. 286 pages.

A useful reference for writing pharmacovigilance documents

Like other areas of medical writing, pharmacovigilance (PV) medical writing has many detailed regulations, guidance documents, and templates associated with it. As such, there is a need for medical writers to be familiar and up-to-date with all that is involved in preparing and writing these important documents.

The author, Justina Orleans-Lindsay, describes her book as an attempt to produce 'a comprehensive manual for all PV documents submitted to regulatory authorities throughout the life-cycle of any given medicinal product…' This is an enormous task as the number of documents that are listed in the overview of the PV documents required in the EU and US regions is large. The initial overview provides us with a side-by-side comparison of the requirements for a clinical trial authorisation and an investigational new drug submission and serves as a useful reminder that, in terms of submission documents, one size still does not fit all. Although the main focus of the book is on PV medical writing in the US and Europe, a summary of the PV requirements for Japan, Canada, Australia, New Zealand, India, Singapore, and Taiwan are provided. In general, these countries follow the International Conference on Harmonisation guidance, format and standards and each is discussed in turn in a chapter entitled 'The rest of the world'. There is also a chapter on dealing with *ad hoc* safety reviews and requests from regulatory authorities.

Most regulatory medical writers are asked to write safety-related material for documents required before and after a submission has been completed. Writers may be expected to write the whole document or contribute small sections ranging from a few lines to a complete patient narrative in a clinical trial, through to writing some or all the sections for an integrated summary of safety or post-marketing update. The chapters of the book are organised across the drug development process: writing for clinical trials, writing for marketing authorisation, and writing risk evaluation and management plans, as well as writing for marketed products and *ad hoc* safety reviews. For many of the documents detailed in the book the author has provided the reader with a generic template containing headings and guidance about the type of information that should be presented under each heading. From a practical view, this makes it easy for a writer to track down the information required for writing specific documents when using this book as a reference text.

The chapter concerning writing for clinical trials provides detailed information on the Development Safety Update Report (DSUR). The evolution of this document is explained and placed in a useful historical context. The scope and general principles of the DSUR are outlined, together with advice on obtaining the relevant sources of data.

PV medical writing for marketing authorisation is a key area and in the chapter dedicated to this activity the author provides much insight into the main components devoted to safety in the Common Technical Document (CTD), the Summary of Clinical Safety (SCS; Module 2.7.4) and two other US-specific documents: the Integrated Summary of Safety (ISS) and the 120-Day Safety Update Report. Useful generic template models are provided for the SCS and ISS documents.

As well as describing the content of the different sections of the SCS and ISS the author proposes a timeline for planning and collating source data as well as listing key reviewers and their responsibilities. This is a useful place to start for those who have not completed these documents before. Her suggested timeline for either document is to allow up to 4 months from planning to finalisation. When a submission is planned for both the US and the EU the relevant summary documents are often completed in tandem, and it is difficult to put an exact timeline in place but depending on the scope and timing of data finalisation, 4 months is probably a minimum.

In the appendices section, there is some detail about the new EU PV legislation which came into

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effect during 2012, and the author points out that for the next few years we are in a 'transition period.' To this end, she has tried to put the new EU legislation in context with a description of the revised EU legislation, and the impact it has had on other documents. For those of us not familiar with all of these changes this is a useful summary and introduction to the new legislation and will be helpful when working through this 'transition period.'

PV medical writing is considered a specialist area of medical writing by many in the medical writing profession. However, the level of involvement of a medical writer in PV medical writing often depends on the size and structure of the company, with many smaller companies requiring the medical writer to play a major part in writing most or all of the documentation. The author refers to PV medical writing 'as a discrete' discipline and separate from what she refers to as 'general medical writing'. For many medical writers this is not the case.

For those of us who consider PV medical writing as another aspect of our regulatory medical writing, there is a need to maintain current knowledge of the guidelines, templates, and requirements through continuous professional development. In my opinion, this book contributes greatly to an ability to maintain CPD in this key area of medical writing and is to be recommended.

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