

## In the Bookstores...

## Useful help and advice for writing regulatory documents



Linda Fossati Wood and MaryAnn Foote, editors: *Targeted Regulatory Writing Techniques: Clinical Documentation for Drugs and Biologics*. Birkhauser, 2008. ISBN 978-3-7643-8361-9. 39.99 GBP, approximately 45.00 euro. 237 pages.

Quite often, in the dialogue section of the EMWA website, people new to regulatory writing ask whether they can access examples of clinical study reports (CSRs) or protocols. Although International Conference on Harmonisation guidelines are available for the content and structure they don't really provide a flavour of what information/data the finished document might contain or what it will actually look like. It is difficult to gain open access to examples of these types of document because, unsurprisingly, they are confidential and not freely available.

This book, which is primarily aimed at the novice medical writer, provides what could be considered the next best thing. Individual chapters deal in detail with protocols, CSRs and investigator brochures (IBs). In each of the dedicated chapters the author provides a suggested outline of sections, describes what the purpose of each individual section is in the document, and the type of data you would expect to find in the section. This information is presented together with examples of in-text table formats. For example, the CSR chapter includes in-text tables for adverse events and serious adverse events and an example table for structuring patient narratives. Other chapters of the book describe the role of integrated summaries of efficacy and safety (ISE and ISS) and the common technical document (CTD). There is also a very useful glossary and list of abbreviations that new writers might be unfamiliar with.

The authors provide the new writer with an introduction to everything they might be unfamiliar with when it comes to being a regulatory medical writer. They set the scene by providing an insight into the regulatory aspect of medical writing and the drug development process. They introduce the concept of source documents (protocols and CSRs) and integrated documents (IB, ISS, ISE, CTD etc) and how they come together to form the clinical submission. The authors also highlight the differences/similarities between the submission requirements of the three main regions: the European Union, Japan and the United States. Strategies for organising and writing the documents to maximise efficiency and consistency are presented and discussed.

They also attempt to provide an insight into best practice for regulatory medical writing. Examples of templates, and style guides as well as check lists for performing quality control on protocols and CSRs are presented in a series of appendices. There are very helpful regulatory writing tips together with insights into the review process and the role

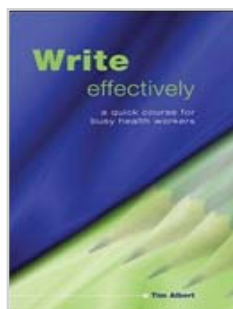
of the medical writer in this process. For those working in a larger company, templates and standard operating procedures will be well established, however this may not be the case for smaller companies or writers setting out on the freelance road. This book could provide you with a very useful starting point if you find yourself in this position.

I liked this book a lot, with the lay out suited to my own style of learning. It is well organised with each chapter building into the bigger picture of the regulatory submission. You can read it from beginning to end, or use it as a reference book to look up specific topics relating to particular documents. Although I think the book is well suited to the novice writer, it would also make a useful reference book for more experienced medical writers who find themselves in need of a quick tutorial, or an equally useful addition to a departmental library if such things still exist!

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## A great overview for the uninitiated medical writer



Tim Albert: *Write effectively—a quick course for busy health workers*. Radcliffe Publishing, 2008. ISBN 978-1-846191350 (paperback) 21.95 GBP, approximately 25.00 euro. pages 140.

Being relatively new to medical writing, *Write effectively* gave me a fantastic overview on what makes an effective healthcare writer; having said this, I think it could apply equally to most types of writing as the basic rules given follow a common sense approach. The book describes the kind of logical things that seem quite obvious for a writer to know, yet could so often get overlooked when starting a piece of writing from fresh.

The book is divided into 10 'sessions' that aim to teach effective writing of any sort of document relating to health such as articles, reports, applications, protocols, policy statements and even e-mails. Examples of the session titles are *putting together a plan, writing the first draft—and enjoying it!, rewriting—ask the big five questions, and getting others to help (not hinder)*. An exercise is given at the end of each session to help cement the learning. This allows readers to put what they have learnt into practice by focusing on a piece of writing they are currently working on and applying the rules to this. Thus the interactive element ensures that this book does not simply involve masses of reading, and so holds the reader's interest.

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Then there is an ‘after-sales service’ that acts a little like revision notes that you can come back to after a month or so. These notes address the same initial questions to ensure you have not deviated too far from the basic writing rules. There is a section at the end with very handy lists such as commonly misspelt words, useful grammatical terms and avoiding clichés. This makes *Write effectively* a useful reference book that is handy to keep close by for those moments when you simply can’t think of a non-cheesy alternative version for something.

There is a very informative section on what effective writing actually is. Little did I know, but this is not about how well a piece flows or how interesting it is. Nor is it about how concisely it has been written or if it contains all the correct information. Effective writing is, quite simply, about getting your message across to your target audience. Get this right and the rest will follow; and this is precisely what this book aims to teach.

Of course everybody has their own preferred style of writing and long-standing, seasoned professional writers will no doubt have their own tried-and-tested methods. But I think this book offers a very comprehensive overview for newcomers such as myself. Hatching a thorough plan before commencing the writing process is an invaluable tip that could save a great deal of time. It forces you to think about the overall structure of the piece and who the message is directed towards.

Once a plan has been written and the background research done, a suggested, yet somewhat daunting writing method is to hide all materials far out of reach, not to refer to them again, and simply write, write, write for 10 minutes solid without reading anything back until the following day. The idea behind this is not to be seduced by adding superfluous information just because it is sat there in front of you—the things you remember will be the really important points.

One part I found of particular relevance was the author’s views on political correctness. Albert’s advice, when writing a first draft, is not to worry too much about political correctness, but instead to write a ‘private’ draft and then rewrite it by removing/rewording anything that could needlessly offend your audience. The danger with thinking about this too thoroughly before beginning a piece is that we often worry unnecessarily about offending people and end up saying too little. I rather like the thought of taking this more relaxed approach!

There is an adequate but not exhaustive index. With 136 pages the book is a good length for busy health workers as the title suggests. All in all, I would recommend *Write effectively* as a great kick-off point for the uninitiated medical writer.

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**Acknowledgements  
then and now**

Acknowledgements have existed for over 500 years, but as Roberts (2003)<sup>1</sup> interestingly reports, the common practice of acknowledging among 16<sup>th</sup> and 17<sup>th</sup> century authors was not to recognize any intellectual contribution (as is most frequently the case today), but to thank financial benefactors or to endear authors to potential patrons. This form of acknowledgments was called an “impensis” which, in Latin, means ‘at the expense of.’

Another type of acknowledgement these early authors quite frequently resorted to was what Roberts calls a ‘a prudent bow’ to the official body, religious or secular, that licensed the printing of the book. That form was known as ‘imprimatur’, Latin for ‘let it be printed’. Later, for strategic reasons and for underlining academic network dependence and belonging, Acknowledgements started flourishing in academic writing and publishing, from doctoral dissertations to scientific research articles.

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<sup>1</sup> Roberts, S. (2003) On acknowledgments, the Inquisition was easier. *New York Times*, November 27<sup>th</sup>

## Definitions box

**Strong/weak**

These adjectives are often applied to drugs or their effects, but are effectively worthless in this sense as they cannot be expressed numerically. A more useful term is *potency*, which expresses the amount of drug needed to produce a given effect—a potent drug produces its effects at low doses (or concentrations), whereas an *impotent* drug produces the same effects at high doses (or concentrations). Sometimes the term *strong* is used in a way that implies that the drug in question has a high propensity to cause unwanted effects (*side effects* or *adverse effects*). There is no place in science for terms which imply properties but which cannot be measured or expressed numerically. For such drugs the term *non-selective* may be more useful, although low selectivity does not necessarily mean that the side effects of the drug are undesirable or adverse.

However, the adjective *strong* can be usefully applied to some properties of drugs, notably *affinity*. It is perfectly reasonable to describe a drug as having *strong* affinity for a particular receptor, although it would probably be better to write *high* affinity. This is because it is possible to express affinity numerically.

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