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Strategic Scientific and Medical Writing: The Road to Success

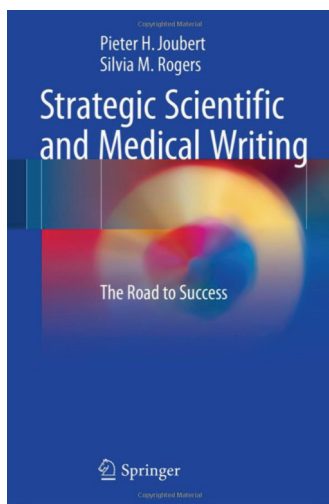
By **Pieter H. Joubert**
and **Silvia M. Rogers**

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In *Strategic Scientific and Medical Writing: The Road to Success*, Pieter Joubert and Silvia Rogers describe how to identify the target audience, construct key messages, and recognise the

desired outcome of your document to make your writing more successful. This book is divided into 15 chapters, with the first six chapters providing general advice to medical writers on topics ranging from contacting regulatory authorities to scientific misconduct. The latter chapters focus on specific document types which are commonly authored by medical writers, including investigator's brochures (IBs), the common technical document (CTD), clinical study reports (CSRs), and protocols. This book is aimed at a range of professions and roles within the medical and academic fields.

Chapter 1 introduces the reader to the importance of understanding your target audience: anticipating their level of understanding, considering what the desired outcome of the document is (e.g. acceptance of a publication or approval of a CTD for marketing by a regulatory agency), and recognising the need to familiarise yourself with the relevant regulatory guidelines. The authors introduce a number of different documents that are discussed in later chapters.

Chapter 2 discusses the importance of early contact with regulatory authorities to help speed up the drug development process. Discussing manufacturing formulation and new drug candidate testing early on can help prevent delays downstream. For example, in the US, pre-IND (Investigational New Drug) meetings have seen clinical development time shorten by 3 years or more. Early communication can also lead to tailor-made review and approval procedures such as Fast Track and Breakthrough Therapy (for drugs used to treat serious conditions with unmet

needs), Priority Review (for drugs expected to provide significant advancement in medical care), and Accelerated Approval (for drugs used to treat serious conditions where less effective treatments are available). In these situations the approval is based on intermediate clinical endpoints followed by additional trials performed after approval to confirm the benefit.

Chapter 3 looks at written communication in

academic settings, including scientific papers, master's and doctoral theses, laboratory reports, research proposals, and grant applications. This chapter provides suggested structures for the reports and advice on how to communicate the content effectively. For those working in an academic setting, this chapter may be of particular interest. Chapters 4 and 5 look at language issues for both native and non-native English speakers, such as avoiding the use of colloquial terms and jargon, choice of tense, active and passive writing, essential and non-essential clauses, and the need for experienced translators. Chapter 6 discusses scientific misconduct and Chapters 7 and 8 discuss key statistical concepts and tables and graphs, respectively.

By far the most informative chapters for medical writers are in the latter part of this book. Chapter 9 introduces the reader to the International Council for Harmonisation (ICH) guidelines that provide the structure for documents submitted when applying for approval of new medicines. ICH guidelines cover four categories: quality, efficacy, safety, and multidisciplinary. Application of these guidelines should result in consistency between documents and a more positive outcome (e.g. a high-quality, clear description of the study in a CSR, approval of a CTD by a regulatory authority, or acceptance of a manuscript by a journal). However, the authors highlight the fact that the ICH guidelines are there to guide and that they may not cover all situations; in some cases, deviations from the guidelines may be required. Although this chapter provides a nice overview of the

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guidelines, no one guideline is discussed in detail and the reader is required to consult the ICH website if further information is required.

In Chapter 10, the authors discuss the importance of updating the IB. The IB is a living compilation of an investigational product's nonclinical and clinical data. It not only provides the investigator with necessary background information such as the dosing rationale, but also provides the reference safety information for a product in development. The IB is an important document during the regulatory approval of a trial and submission to ethics committees. This chapter highlights the importance of keeping the IB succinct and clear by the removal of unnecessary nonclinical data when advancements are made in the clinical development. This makes the document easier to read and facilitates the transfer of key messages, thereby safeguarding the safety of subjects, and allows clinicians to form unbiased and independent benefit-risk decisions. Notable parts of this chapter include useful links to the ICH guidelines and a summary of content to be included in an IB that gives the writer a structure to follow. The different emphasis that the EMA, US FDA, and ICH have on the IB is also discussed, with the ICH and EMA viewing the IB as a Good Clinical Practice document to inform the investigator and the FDA seeing the IB as part of the IND application with a stronger emphasis on safety. This chapter also discusses the key messages of the IB and reiterates the common theme of the book, which is to know your audience and adapt your writing accordingly.

Chapter 11 describes the initiation of clinical programmes. Broadly speaking, European countries require a clinical trial application (CTA) and the US requires an IND application in addition to the IB. Chapter 11 goes further to describe the various components of the IND application and CTA. The authors highlight that information in an application should include (but not be limited to) the current knowledge of the drug, rationale

for the indication, and medical need for the drug; show an acceptable benefit-risk ratio; have sufficient nonclinical data to identify a safe starting dose and a maximum dose; and list clearly the safety parameters to be monitored. This chapter presents summaries of the CTA and IND application succinctly in tabular format and provides useful web links for further reading. Although the title of this chapter includes the Investigational Medicinal Product Dossier (IMPD), I feel this chapter would benefit from more discussion of the IMPD, as its content is relatively unfamiliar when compared to more commonly authored medical writing documents such as CSRs and IBs. As in Chapter 9, readers may need to use the web links to find out more, but the chapter does provide a useful basis to work from.

Chapter 12 discusses the key components of the CTD including information on efficacy, safety, and quality. The CTD provides a format for applications to register new drugs. The chapter describes how it consists of five modules split into three main components: Module 1 – Administrative Information; Module 2 – Summaries of the Quality from Nonclinical and

Clinical Data; and Modules 3, 4, and 5, which include the nonclinical and clinical data referenced in Module 2. This chapter focuses primarily on Modules 2.4 and 2.5 (nonclinical and clinical overviews) and provides some very useful information on length, content, structure, emphasis, common mistakes, and relevant links to guidance. The authors also highlight the ultimate purpose, which is to obtain marketing approval.

Chapter 13 looks at study protocols, with a focus on the rationale, objectives, study populations, and study design. The second half of this chapter provides a brief summary of CSRs and abbreviated CSRs, emphasising that regulatory authorities are the audience and that the key messages must be clearly reported. Although much of the information in this chapter may be known to experienced medical writers, I think it provides a useful refresher, with tips on planning, template guidance, and links to guidance on ethics, informed consent, and abbreviated reports.

The book concludes with Chapters 14 and 15, which look at scientific papers and publication strategy, respectively. These chapters complement

each other and provide useful information about planning a paper, selecting the right journal, and the timing of submission.

Overall, this book provides insight into the themes of knowing the purpose of the document you are writing, knowing your audience, and adapting to their requirements. I feel this book covers some lesser known medical writing documents as well as providing useful advice on more commonly encountered documents such as CSRs and protocols. Each chapter complements the others and the reader gets a good understanding of how the various documents interlink. I would recommend this book as a good basis to learn from; however, due to the nature of the guidelines and the documents described, a comprehensive discussion of each falls beyond the scope of this book and readers should be prepared to follow the suggested links to discover more detail.

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