Foreword

This book describes the authors' standard or 'best' practices used in writing regulated clinical documents for the drug and biologics industry. The fundamental premise of this book is that the end (documents submitted to a health authority) is dependent on the beginning (the planning and strategy that go into organizing written documentation). Each regulatory document inherently exists within a constellation of related documents. This book attempts to show the relationships between and among these documents and suggests strategies for organizing and writing these documents to maximize efficiency while developing clear and concise text. At all times, and irrespective of applicable laws and guidelines, good communication skills and a sense of balance are essential to adequately, accurately, and clearly describe a product's characteristics. At no time should the reader perceive these suggestions to be the only viable solution to writing regulatory documents nor should the reader expect that these suggestions guarantee product success.

The audience for this book is the novice medical writer, or those who would like to explore or enhance regulatory-writing skills. We assume the reader will have a basic understanding of written communication, but little experience in applying this skill to the task of regulatory writing. Extensive knowledge of science, clinical medicine, mathematics, or regulatory affairs law is not required to use the best practices described in this book.

The scope of this book is regulatory writing of clinical documents and clinical sections of regulatory submissions for drugs and biologics during premarketing stages of product development. This type of writing is described within the context of a regulated environment for Europe, Japan, and the United States. Because the editors and chapter authors are most experienced with writing documents for the United States regulatory authorities, these documents are the primary focus of this book. The exception is Chapter 12 (Clinical trial procedures and approval processes in Japan), with a focus on the regulatory requirements in Japan. Many other regions of the world also require regulated clinical documents but discussion is not within the scope of this book.

Regulatory writing techniques also are used for medical devices, for nonclinical and manufacturing writing, and during the postmarketing phase of development, but these documents are outside the scope of this book. The list of documents included here is meant to represent those documents that are most frequently written by a regulatory writer. The list is by no means exhaustive, as many additional documents may be required based on product-specific characteristics or global region.

It should be noted that the opinions expressed by chapter authors may not necessarily reflect the opinions of the editors. We have taken due diligence to ensure that all information is current and correct, but we are not responsible for errors, omissions, or commissions. Discussion of a product is not endorsement for its use.

We hope that you enjoy the book and that it helps you in clarifying your thinking as you prepare your regulatory submissions.

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