Targeted Regulatory Writing Techniques: Clinical Documents for Drugs and Biologics

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Chapter 1

Developing a target

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Introduction

Finis origine pendet (The end depends on the beginning)
Attributed to Roman poet Manlius

Regulatory writing is an integral part of the health-product development process. Most nations have a governmental authority (also called a regulatory agency) responsible for determining whether a drug or biologic is sufficiently safe to allow commercial distribution. The product's manufacturer must provide written documentation to this regulatory agency (called a submission) making an argument for safety and efficacy of the product. The regulatory agency, if it approves of the data and the claims, will file the submission and grant marketing approval. Regulatory writing is the discipline responsible for development of these regulatory documents.

Regulatory writing is important to companies that wish to market and sell their healthcare products and also is important to the general public that uses these products. Clear, concise text that communicates corporate goals and satisfies local and international regulatory requirements is critical to successful and rapid product approval for commercial distribution. Most importantly, an accurate and clear characterization of a product's safety and efficacy is an essential part of medical care.

Standard methods, also called 'best practices,' have been used by the authors of this book to write regulated clinical documents for the drug and biologics industry. The point of these best practices is to plan for the end (documents submitted to a health authority), by developing a document strategy at the beginning. The authors

attempt to show the relationships between and among these documents, and they suggest strategies for organizing and writing these documents to maximize efficiency while developing clear and concise text.

Best practices in regulatory writing are described in terms of five tasks:

- Developing a target: Determining which document(s) is needed based on five steps: classification of the product, the geographic region in which the product will be marketed, the stage of development, the intended content, and bringing these 4 steps together to determine the document(s) to be written (Chapter 1, Developing a target).
- Using a writing toolkit: Selecting and using general principles of regulatory writing (Chapter 2, Regulatory writing tips); templates and styles (Chapter 3, Templates and style guides); and developing procedures for document review (Chapter 4, Document review).
- Writing source documents: Writing the documents that form the basis for all integrated documents and submissions (Chapter 5, Protocols; Chapter 6, Clinical study reports).
- Writing integrated documents: Writing documents that integrate and summarize information from source documents (Chapter 7, Investigator's brochures; Chapter 8, Investigational medicinal products dossier; Chapter 9, Integrated summaries of safety and efficacy; Chapter 10, Informed consent forms).
- Writing submissions: Putting the source and integrated documents together (Chapter 11, Global submissions: The common technical document; Chapter 12, Clinical trial procedures and approval processes in Japan; Chapter 13, Region-specific submissions: United States of America).

Unlike many types of writing, regulatory writing is not a solitary task. All regulated documents described in this book are the result of collaboration with a team and as such reflect the cross-disciplinary efforts and expertise of the team members. The specific functional areas included on each development team vary by company and document, and occasionally by product. We suggest that team members should be included during development, with the caveat that not all are always required for each area and the best teams may be flexible, comprising members from additional functional areas .

The first step in regulatory writing is to ascertain which document needs to be written and should be determined in collaboration with clinical and regulatory staff. The writer should have sufficient knowledge to understand the context within which the document will be written. Determining the document to be written requires categorization of products using the following steps:

- Step 1: Product classification: Is it a drug, biologic, medical device, or combination product?
- Step 2: Geographic region: Will the application be submitted in Europe, Japan, or the United States, the three major regions that drive regulatory documentation? Or will it be submitted to another region of the world?
- Step 3: Stage of product development: Is the product currently being sold (also called marketed) or is it in premarketing development?
- Step 4: Source or integrated document: How many studies are being described? A source document describes one study, an integrated document describes more than one study (often with an integrated analysis of data across two or more studies) or may cross company departments.
- Step 5: Developing a target: using information from the first four steps, the document(s) required is evident.

Side bar: Lessons learned

It is impossible to overstate the importance of this type of rudimentary planning, which intuitively would be the logical first step when embarking on a project with such scope and impact. The editors sadly can attest to problems encountered when upfront planning for a regulatory submission was inadequate. While many submission team members may balk at the time spent in planning what documents are needed, who will write each document, how documents will be reviewed and changes agreed on, and other planning details, experience has shown us that detailed planning saves time. The maxim is every day off market for a good product is a loss of US$1 million; this statistic alone should bolster the writer's (and the team's) efforts for planning.

Step 1: Product classification

Although regulatory writers are not responsible for determining whether an investigational product is a drug, biologic, or medical device, an understanding of the distinction between drugs and biologics and medical devices is important because of the difference in documents.

Drugs

Drugs (also called pharmaceuticals) are chemical entities that affect metabolism. The European Medicines Agency (EMEA) in Europe, the Ministry of Health, Labour and Welfare (MHLW) in Japan, and the United States Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) regulate drug