Targeted Regulatory Writing Techniques. Clinical Documents for Drugs and Biologics,
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Chapter 2
Regulatory writing tips

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Introduction

The discipline of regulatory writing is a combination of language, science or engineering, and law as applied to corporate objectives. General principles of good writing, particularly those pertaining to summarization of complex data, are certainly relevant to regulatory writing but are beyond the scope of this book. However, several strategies for focusing text are particularly helpful to the regulatory writer.

The goal of regulatory writing is to produce documents for submission to health authorities that are:

- Scientifically and editorially accurate
- Reflective of regulatory strategy and corporate goals
- In compliance with all applicable regulations and guidelines
- Clearly worded with respect to main messages

Several general rules of good writing and graphic design apply to regulatory writing for all submissions irrespective of submission type or region for intended submission. Understanding your intended audience and effectively using concepts such as visual logic, logical flow of content, and streamlining are essential to any well-written document. Management of global submissions is important and some suggestions are also included on this topic.

Audience characteristics

Consideration for your audience is of prime importance with any communication. The people who review regulated documents are generally scientists, clinicians,

or engineers and most are highly educated. They are charged with protecting the safety of the general population, and most take their jobs and the attendant responsibilities seriously. You may, however, also assume they do not (understandably) have great familiarity with your product, may be rushed and overworked, may not speak English as a first language, and job training may have been brief. Therefore, the utmost in care must be taken to communicate simply and effectively. With this in mind, consider the following principles of regulatory writing as you write:

- Organization and navigation tools: Logical flow is essential to understanding information, and tools such as a table of contents are essential to finding information.
- Brevity: Focus on the key messages; too many details may actually obscure the point you are making.
- Conciseness: Summarize information to focus on relevant points.
- Clarity: Short, simple sentences convey complex messages well.
- Accuracy: Check the facts you are writing about.

General regulatory writing concepts

Visual logic

Many regulatory writing concepts are based on graphic design principles as applied to text and are intended to help your reader navigate through the text. A few of these principles are [1]:

Readers respond to a consistent page structure	Order, consistency, and simplicity constitute 'elegance' in design, as they reduce the reader's work. Templates establish design.
We search for "differences"	We have an evolutionary advantage in that we see differences in the environment. Bulleted or numbered lists, and bolded text exploit this advantage.
Visual stimulation keeps the reader awake	A pleasant appearance, coupled with visual interest, can draw the reader through the text and reduce the effort of reading. Use of tables, figures, and graphs provide visual interest and can help clarify a complex message.

Space attracts the eye	Good design requires that not all space be filled. White space can frame your message. Appropriate use of white space, a ragged right margin, and bulleted or numbered lists all help to make your messages stand out.

Side bar: Lessons learned

While the data are paramount to any regulatory submission, clean and clear writing is paramount to getting your message across. Regulatory writers will certainly meet resistance from some team members when they, the writers, begin to edit the submission. In our experience, few people will question statistical data, and most will admit to rudimentary knowledge of complex statistics; however, almost everyone fancies him or herself a writer. It is important for the writer to establish a good rapport with the rest of the team and to explain that if he/she finds the document difficult to read and comprehend, perhaps a regulatory reviewer will have similar problems.

The rule should be that the writer does not change concepts or conclusions without detailed discussion with the science-author but that editing for clarity and readability, formatting to eliminate brick walls, and formatting to increase visual logic are acceptable tasks for the regulatory writer. In our experience, initial resistance and skepticism can be replaced by eager anticipation of the writer's skills in this area if handled with sensitivity. Team members do not appreciate a 'schoolmarm' approach to their writing!

Logical flow and levels of detail

Conceptually, all submissions are pyramids, with a top-level summary at the apex (generally the cover letter, usually written by regulatory affairs), and text that gradually expands details as it moves toward the bottom of the pyramid. Therefore, the reader is first introduced to the product through a cover letter (that represents a high-level summary and therefore has the fewest details), and all subsequent text gradually expands on that summary information (all the way to the individual data points, which represent the greatest level of detail).

Document requirements for each level of this pyramid are defined individually by the three regions, by product category, by submission type, and even within companies, but a few general writing principles will help guide the writer. Each section of a submission and each document should begin with an introduction or executive summary (the top-level summary) that sets the stage for information to be discussed in the section and should include, as appropriate:

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