

"Targeted Regulatory Writing Techniques: Clinical Documents for Drugs and Biologics"

Linda Fossati Wood and MaryAnn Foote, editors, 2008, 237 pages, Birkhäuser, \$79.95

Review by Norman M. Goldfarb

"Targeted Regulatory Writing Techniques: Clinical Documents for Drugs and Biologics" is a detailed, practical and comprehensive guide for the entire process, from start through signatures, in the U.S., Europe and Japan. The six primary document types are discussed. The book includes a wealth of information for the novice medical writer. For the experienced writer, it probably offers at least a few valuable insights and tools.

This book has been selected for
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Essential reading for clinical research professionals

Some tips adapted from the book include the following:

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

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

Document templates assure consistency and support quality. There are two types: Instructional templates include written instructions and formatting styles. Property templates, also known as style templates, appear as blank pages. They contain formatting styles, e.g., for title, headings and tables. (A ninth-generation, cut-and-paste site questionnaire is a primitive template that has probably accumulated errors along the way.)

Documents for submission to multiple regulatory authorities should be formatted to fit on both U.S. letter paper and the A4 paper popular in Europe. A text area of 9.25" X 6" (23.5 X 15.24 cm) fits both sizes of paper and allows room for headers and footers.

Different people should review different parts of a clinical study report. For example, the statistician should verify that the methods section correctly describes the statistical methods, the text agrees with tables and statistical results, the correct version of statistical tables has been used, and references to statistical tables and listings are correct.

All-hands round-table meetings in windowless rooms to review collected comments on large documents are torture according to most international definitions. The only questions are how long the torture will continue, whether the task will be completed, and whether the results justify the agony. To maximize the results and minimize the pain, the meeting should focus on the important issues in an organized and tightly managed manner. Style and grammatical comments should be handled by the writer outside the meeting.

The ICH E3 Guideline for clinical study reports contains a detailed table of contents that has been misconstrued as the only acceptable organization. Unfortunately, it does not work well with some products. First-level section headings should be in the specified order, but second-level headings can be moved around in the interest of logic and clear communication.

The book consists of 13 chapters:

- Developing a target
- Regulatory writing tips
- Templates and style guides
- Document review
- Protocols
- Clinical study reports
- Investigator's brochures
- Investigational medicinal products dossier
- Integrated summaries of safety and efficacy
- Informed consent forms
- Global submissions: The common technical document
- Clinical trial procedures and approval processes in Japan
- Region-specific submissions: United States of America

Fourteen appendices include samples and forms.

The book is available in bookstores.

Reviewer

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