IND Submissions: A Primer

Reviewed by Amy N. Grant

IND Submissions: A Primer is reminiscent of the Betty Crocker cookbook with tabs for easy reference. You can go right to what you need to “cook up” a particular submission, and the book stays open while you read and work. This book contains everything needed for submission of an Investigational New Drug application, including examples of forms already filled out, content templates to start the submission, cover letters and even a CD-ROM with electronic examples. Best of all, the author has a sense of humor and has a way of making dry material easy to read and remember. For example, a section on FDA Form 1571 is titled, “Original, Original, Who has the Original?” (Chapter 5, p. 32). And, each chapter contains concise definitions, glossaries and practical tips that usually are only learned on the job. Overall, the book is designed with readers in mind.

The 62 chapters of the book cover the original IND submission plus the submissions needed to support the IND once it is filed. The information is well organized and concise, including the applicable regulations and guidance documents for all the supporting submissions, the contents of the submissions, the source of the information, how to write the submission and then how to publish/submit it. The text includes references to the International Conference on Harmonisation (ICH) related to FDA regulations. The book will be helpful both to people new to the IND process and seasoned professionals who need a refresher.

The author provides insights from hands-on experience as a regulatory affairs professional combined with her university teaching experience. For example, topics within the chapters include: timing of submissions in the development program, whether routine or special, plus submission triggers; the difference between submissions for drugs and biologics; and tips for filing plus different perspectives on how filing can be done. When applicable, examples are provided from previous filings (from FDA’s website), case studies and content templates to start the submissions.

Special features within the text include:
- how CMC requirements change over the phases of an investigation
- exercises at the end of several chapters to help the professional “reverse engineer” an IND from an approved label to get writing experience
- tables listing types of submissions

In the introduction, the author states that the book “is a first attempt,” “there may be some omissions or errors,” and feedback is welcomed. In the next edition, the author might consider adding a template for End of Phase 1 (EOP1) meetings and information on priority review. This book has the potential to be to regulatory what Bert Spilker’s book, Guide to Clinical Trials, is to clinical. Meredith Brown-Tuttle’s IND Submissions: A Primer could evolve with the needs of the industry and become a standard reference textbook for all those working with INDs.

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