IND Submissions: A Primer

Meredith Brown-Tuttle, RAC
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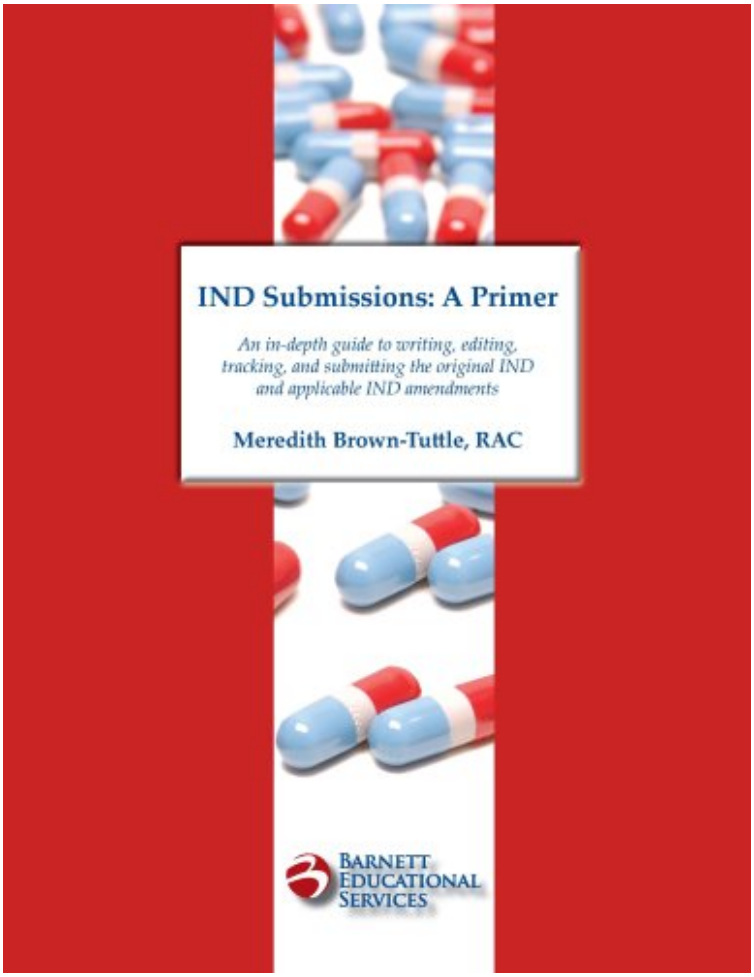

#860647 in Books Parexel Intl Corp 2009-02-27Original language:English .0 x .0 x .0l, Binding: Ring-bound530 pages | File size: 72.Mb

Meredith Brown-Tuttle, RAC : IND Submissions: A Primer before purchasing it in order to gage whether or not it would be worth my time, and all praised IND Submissions: A Primer:

0 of 0 people found the following review helpful. Five StarsBy Dudley SmithWell organized.0 of 0 people found the following review helpful. Excellent reference book for IND submissionsBy Dmitry KryndushkinI am a regulatory professional and I am using this book for my work in a biotech company. It provides a comprehensive overview of the submission process. It also contains working examples on the separate CD disk.5 of 5 people found the following review helpful. A good reference book for regulatory professionalsBy S. PandyaI came across "IND Submission: A Primer" as a text book for a class taught by the author, Meredith Brown-Tuttle. Since taking the class the red book has become my favorite reference book.A Primer is a step by step guide that covers a wide range of topics for IND submissions, starting from style guides, submission planning to publishing. IND submission process starts with a pre IND meeting with the FDA. The writing and compilation of various sections of the IND follows. There is also a

section on writing amendments to an IND. Each step includes a list of guidance documents and regulations. The book also walks you through the steps involved in IND review at the FDA in anticipation of questions and queries from the FDA.The red spiral bound book comes with a CD filled with templates for preparing a submission in CTD as well as traditional formats.By using the IND as the main focus of the book, the author has managed to cover topics that can be useful as reference for writing a host of regulatory documents.

IND Submissions: A Primer provides a hands-on approach that teaches regulatory professionals novice and veteran alike to work with the regulations, guidance documents, content templates, contributing authors, and style guides necessary to write an IND. The book s writing tips show regulatory professionals how to produce a range of U.S. drug and biologics submissions that comply with the requirements and are also clear to read. Included with the book is a CD filled with electronic examples. IND Submissions: A Primer is the only comprehensive IND manual of its kind. This 600-page, spiral-bound, hardcover book is easy to use, providing step-by-step instructions on how to plan, write, and submit regulatory documents. Each chapter (62 in total) is divided by easy-to-read tabs. It is the ideal resource for new professionals entering the field, a useful training guide, and a valuable reference for the experienced professional. Specific topics include: * Regulations and guidance document references. * Overview and background of why the submission is required. * Structure of the submission itself. * Details on who should contribute to the submission. * Where to pull, re-use, or start as a basis for information needed in a submission. * Tips and lessons learned from the author's experience. * Different perspectives on how a submission can be approached. * Applicable FDA Form 1571 information for each submission. * Paper publishing tips. * Electronic CTD publishing sections for each submission, where applicable. * Real life examples taken from the press and approved NDAs when available. * Electronic examples and content templates to utilize so that an RA professional can begin immediately working on a submission.

About the AuthorMeredith Brown-Tuttle, RAC, is a regulatory consultant whose background incorporates all aspects of drug, device, and biologics development including clinical research, data management, medical writing, and regulatory affairs. She served for six years on the Board of Editors for the Regulatory Affairs Professional Society s journal, Focus, and has published numerous articles, edited books and book chapters, and presented at professional meetings on a variety of clinical research and regulatory topics. Ms. Brown-Tuttle also teaches about regulatory submissions, intelligence, strategy, and agency interactions for the Regulatory Affairs Certificate program at UC Santa Cruz.