



IND Submissions: A Primer

By Meredith Brown-Tuttle, RAC

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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.

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Editorial Review

About the Author

Meredith 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.

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