by a due diligence team from a potential buyer. Since this book is designed as a monograph with case studies, it would make a useful companion volume to a previous book by the same author, *Introduction to the Due Diligence Process*, published in 2010.

Review of *IND Submissions: A Primer*

Brown-Tuttle M. *IND Submissions: A Primer*. Needham, MA: Barnett International; 2009. 530 pages plus CD-ROM.

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The subtitle of this book is "An in-depth guide to writing, editing, tracking, and submitting the original IND and applicable IND amendments." This book is a clear and thorough guide to the preparation, writing, publishing, submission, and monitoring of documents that FDA requires drug sponsors to submit. Although the title and subtitle focus on IND submissions, in fact the book covers in depth a few other types of FDA submissions as well, such as orphan drug applications and FDA meeting requests.

The book is set up like a training manual for those who are entering regulatory affairs for drug products, and it is a good one. It would be useful as a textbook for a regulatory affairs course or to study for certification. Although it is very basic, it might also be useful as a desk reference for a regulatory affairs department for a quick look at an applicable chapter when a quick answer is needed.

Topics include all aspects of INDs, including administrative aspects of submissions (creating style guides and templates; tips on writing and coordinating writing by a group; FDA forms), paper and electronic submissions, tracking submissions, managing references, CTD format, electronic document management systems, FDA meetings, dispute resolution, expanded use INDs, exploratory INDs, IND amendments, protocols, transfers of obligations, investigator's brochures, safety reports, fast-track designation, responding to clinical holds, special protocol assessments, statistical analysis plans, filing at clinicaltrials.gov, CMC issues, orphan drug issues, USAN and proprietary name development, inactivating and reactivating an IND, and drug master files.

The book does not seem to miss any IND-related topics, and everything I read was very accurate and also easy to read. The organization of the book is roughly along the lines of how one would go about initiating and maintaining an IND. However, surprisingly many introductory concepts are not introduced until chapters 22, 26, and 27.

This is a sizable book, with 530 pages of relatively large dimensions (approximately 11" × 12"). It has a plastic spiral binding, but that is mounted within an attractive solid hardcover backing. The spiral binding appears intended to allow readers to remove the spiral-bound pages from the hard cover so that pages can be turned back on the spiral. Each of the 62 chapters is marked with a thick-tabbed divider with each topic clearly marked on the tab, which is extremely convenient and makes its use as a reference tool easier, particularly since the book lacks an index. Its 33-page detailed table of contents partially compensates for this as well.

One of the most impressive aspects of this book is the accompanying CD-ROM, containing template documents, arranged by chapter, for 54 of the chapters. With artificial "samples" of FDA meeting requests, completed FDA forms, etc, as well as a sample style guide and examples of the types of letters that FDA sends to drug sponsors, this CD-ROM collection could be worthwhile for any new regulatory affairs department to obtain.

There is no information about author Meredith Brown-Tuttle in the book. A quick search on the Internet reveals that she has been active in regulatory affairs as a consultant and at a number of consulting firms over the years, was on the Board of Editors at the Regulatory Affairs Professionals Society (RAPS) for many years, and teaches regulatory affairs at the University of California, Santa Cruz.

Review of *Clinical Trial Design: Bayesian and Frequentist Adaptive Methods*

Yin G. *Clinical Trial Design: Bayesian and Frequentist Adaptive Methods*. Hoboken, NY: John Wiley & Sons; 2012. 336 pages.

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The escalating costs of conducting clinical trials coupled with the increasing likelihood of late-stage failure has led the pharmaceutical industry to re-examine the drug development process. As a result, a great deal of recent attention has focused on adaptive clinical trial designs.[1] In contrast to traditional clinical trials that employ fixed sample sizes and constant treatment allocation probabilities, adaptive designs utilize data from the ongoing trial to modify various features of the study.[2] For example, these adaptations could allow for early termination of a study in cases where the drug under investigation is particularly efficacious, or for those instances when there is little hope of showing both a clinically and statistically