JOURNAL OF CLINICAL RESEARCH BEST PRACTICES
Vol. 12, No. 7, July 2015 "Happy Trials to You"

"Medical Device Development: Regulation and Law, 3rd Edition"

Jonathan S. Kahan, 2014, 619 pages, Barnett, $195

Review by Norman M. Goldfarb

"Medical Device Development: Regulation and Law, 3rd Edition" is the essential handbook for medical device professionals. Indeed, one can question the *bona fides* of a medical device regulatory expert who has not read the book or who does not, at least, keep a copy handy for reference.

This book has been selected for

The First Clinical Research Bookshelf
Essential reading for clinical research professionals

The book is written in a practical and straightforward manner, as illustrated by this excerpt from the section on blinding (masking):

> Unlike similar studies for pharmaceuticals and other FDA-regulated products, double-blind and sometimes even single-blind medical device trials are difficult to perform. To a large extent, the ability to blind the patient or the physician to the treatment assignment depends on the type of control treatment chosen. If the device is used externally (e.g., laser, ultrasound, injection), blinding may be much easier to accomplish when convincing sham devices are used in the control group. Blinding may be possible for studies of implanted devices, with a sham procedure or an approved implantable device with the same indications for use, where patients are unable to observe the implantation procedure (e.g., implantation performed under general anesthesia). When the control treatment is drug therapy or traditional surgery, blinding is usually impossible. Third-party blinding was developed for just such situations, so that the evaluation of patient outcome is independent of knowledge of the treatment. In some cases, even third-party blinding is difficult, particularly when the patient bears obvious physical signs or symptoms of treatment (e.g., surgical scar). When a study is blinded, it is possible that FDA will require that the study design include an assessment of blinding effectiveness by asking the subjects and/or investigators blinded to the group assignment at the end of the study to indicate which treatment group they thought they were in and why.
>
> If a trial is not blinded, there is a potential for bias in the assessment of outcome measures. Patient reporting of symptoms, side effects, or the ability to perform tasks are, for example, susceptible to bias. Therefore, CDRH perceives a real potential for bias in unblinded studies that employ subjective response variables, which are often difficult to measure and are subject to varying interpretation. The blinding in the study design should thus be discussed with FDA at the presubmission stage. If possible, objective endpoints are usually preferable to subject-reported outcomes, and clinical staff should use a standardized script for follow-up questions asked of study participants.

The book includes 16 chapters:

- The Framework for Regulation of Medical Devices
- The 501(k) Premarket Notification Process
- Device Modifications Requiring a 510(k) Notice
- FDA Regulation of Medical Device Software

- The Investigational Device Exemption Application: Overview of the IDE Process and Humanitarian Devices
- Medical Device Clinical Studies
- The Premarket Approval Application
- Review of a Premarket Approval Application
- PMA Supplements
- Medical Device Reclassification
- The Regulation of In Vitro Diagnostics
- The Quality System Regulation
- Compliance
- Medical Device Exports and Imports
- Product Jurisdiction and the Regulation of Combination Products
- Working Well with the FDA

An extensive medical device glossary follows the last chapter.

The book is available at bookstores.

Reviewer

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.