JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 3, No. 8, August 2007 "Can You Handle the Truth?"

"How to Work with the FDA, Second Edition"

Wayne L. Pines, Editor, 2003, 250 pages, FDLI, $129.00

Review by Norman M. Goldfarb

"How to Work with the FDA, Second Edition" is required reading for anyone who interacts with the FDA, and should probably be mandatory for FDA personnel as well. The book is a detailed, nuts-and-bolts guide to working effectively with the FDA. It includes 28 essays on different aspects of the relationship, ranging from "How to Get your Drug Product Approved" to "Persuading FDA to Your Position" to "Tips on FDA Etiquette: Field Offices vs. Headquarters."

This book has been selected for

The First Clinical Research Bookshelf

Essential reading for clinical research professionals

Much of the advice in the book is common sense, so perhaps common sense may not be as common as one might expect. Professional competence, good communications, and courtesy go a long way in working with the FDA. The more interesting challenges arise when these characteristics appear to be lacking on the FDA's side of the table. Many such challenges are due to misunderstandings about what the FDA expects, the FDA's culture, the specifics of the situation, and the luck of the draw.

FDA has 10,000 employees scattered across 40 buildings in the Washington, DC area plus field offices, regulating products that range from oncology vaccines to chicken feed. Regulations and guidances are deliberately designed to maximize the FDA's flexibility. The FDA must satisfy multiple constituencies, with conflicting and changing priorities. Exceptional circumstances are unexceptional. Without long experience working with the FDA, it can be hard to discern whether a problem is due to a deficiency in your application, an internal policy dispute within the FDA, a bad experience the FDA officer had last month in a similar situation, or unintentionally insulting an investigator by calling him an inspector.

Working with the FDA is a question of balance. You want to include information the FDA considers important in applications and letters, but you do not you want to pile on excess detail. You want to exercise your rights, but not game the system. You want to ask questions, but not waste their time by asking too many questions. You want to keep relevant FDA personnel informed, but you don't want to go over peoples' heads. You want to accommodate the FDA's requests, but you do not want to roll over for every unreasonable demand. This book provides invaluable advice from experts in this balancing act.

The book is available at http://www.fdli.org

Reviewer

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