Drug Development and Industrial Pharmacy, 23(8), 855-856 (1997)

Book Reviews

Good Manufacturing Practices for Pharmaceuticals—A Plan for Total Quality Control Sidney H. Willig and James R. Stoker, Fourth edition, revised and expanded. Marcel Dekker, 1997 520 pages. Hard cover. $99.75.

The purchase of this book is very strongly recommended for any organization or individual with professional interest in the design, manufacture, evaluation, or regulatory approval of pharmaceuticals. It provides an authoritative and easy-to-follow review of CGMP regulations which quite properly includes reference to ICH developments.

The style is clear and simple (but not simplistic), and the comments are helpful and generally above reproach. Because of the reviewer's involvement as an expert witness, in the Barr case he takes issue with the statement on page 140:

> "While many of the rulings from Judge Wolin make scientific sense, it does seem inappropriate that they are universally applied by FDA as requirements for CGMP compliance."

Although I would agree that it would be preferable to formally update CGMP regulations by publication of drafts of proposed changes, rather than rely on action by federal courts, I believe that if aspects of Judge Wolin's rulings do indeed make scientific sense, they should be universally applied—at least within the U.S. It is my firm opinion that much of Judge Wolin's superbly crafted decision does make eminently acceptable good scientific sense. However, this is a relatively small point. I find that the book generally incorporates most helpful and valid comments. Thus, I recommend pages 150 through 152 for a useful exposition of bracketing and matrixing. The authors prudently recommend that, for the present time at least, the FDA should be contacted before embarking on this practice.

I confidently predict that this book will be widely and successfully used as a reference book for scientists and persons in regulatory affairs groups in industry, academia, and government.

C. T. Rhodes

Clinical Research in Pharmaceutical Development edited by Barry Bleidt and Michael Montagne, Marcel Dekker, 1996 $135.

The authors attempt to cover an enormous amount of material in this book. For the most part, in the subjects covered, there is no more than a brief overview of the processes involved. The chapter on pharmacokinetics for example spans a mere fifteen pages and is just a scratch on the surface of that subject. However a book written on such a vast area can only aim to touch upon what is a complicated and involved process.

The authors claim they are highlighting the changes in clinical research and drug development since the early 80's. This is a rapidly changing and evolving area and so it is surprising that some chapters contain very few, if any, up-to-date references. In light of this claim one would expect the chapter on drug discovery to relate to

the process as it is today rather than the process as it used to be.

However, the book is written in a style that is very readable and for those people with a very limited knowledge of the clinical research process it may provide a little insight.

Kimberley A. Jackson