

**Biopharmaceutical Statistics for Drug Development.** Statistics: Textbooks and Monographs Series, Volume 86. Edited by K. E. Peacor. Marcel Dekker, New York, 1988. xii + 640 pp. 17 × 25 cm. ISBN 0-8247-7798-0. \$125.00.

This book contains 14 chapters by a total of 22 authors; it covers applications of statistics in pharmaceutical research and development, both clinical and laboratory. It is an applied book; there is little development of the many equations that appear. Most of the authors supply very good citations for the methods they discuss. The quality of the references list in each chapter varies with the diligence of the authors, but in most of the chapters the references are representative and as recent as 1986. Many data sets to illustrate the methods are included.

The book is organized by area of application rather than by type of statistic, but a very good index makes it easy to find statistical topics of interest. This book invites comparison with an earlier volume in this series, Volume 36, *Statistics in the Pharmaceutical Industry*. The present volume is a much larger book, and in general contains much more statistical meat. A few of the chapters are largely expository in nature, but they may be useful for giving perspective to readers not familiar with the drug development process. Overall, it is a very useful book; it has enough statistical content to be valuable in graduate seminars. I think many scientists, including statisticians, will find it a useful reference work.

I was particularly pleased with the material on categorical data, both in the chapter by Koch and Edwards and in other chapters. Again, the index made it easy to find this material. As with most books of this type the chapters are uneven and the coverage not complete. The most obvious omission is a chapter on pharmacokinetic and pharmacodynamic modeling, although some mention is made of these topics by several authors. An additional useful chapter would deal with computational problems. Several authors make reference to computer programs, and one chapter includes SAS code for a special problem. With the proliferation of computer programs, material on computational software, especially for microprocessors, would be welcome.

One caveat for an otherwise impressive book: Was the first word of the title really necessary? "Nonparametric statistics" I know, and also "robust statistics", but what is "biopharmaceutical statistics"?

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**Hard Capsules, Development and Technology.** Edited by K. Ridgway. The Pharmaceutical Press, London, UK, 1987. 320 pp. 25.3 × 19.4 cm. ISBN 0-85369-159-2. \$90.00.

*Hard Capsules* fills a long-standing gap in the literature of pharmaceutical technology. Beginning with the historical development of capsules, the book attempts to cover all aspects of hard capsule technology, including the manufacture of capsules and their filling, printing, weighing, et cetera, and drug release. Some information on soft gelatin capsules also is included. The book is divided into 13 chap-

ters, of which 12 are authored by three of the four contributing authors. The chapters are well supported by nearly 150 illustrations.

Despite the relatively small number of authors (six different chapters were penned by a single author), there is surprising unevenness among the chapters. Chapter 1 is an interesting, well-researched treatise on capsule history. Chapters 2 and 3 on gelatin properties and manufacture also are especially well done. On the other hand, Chapter 7 on powder characteristics for capsule filling (only five pages in length) is incomplete and too superficial to be of any real value. A large portion of this chapter is devoted to methods of measuring the angle of repose (why?) and a discussion of flow from hoppers; however, these are not related to capsule formulations and weight variation. Other methods of flow assessment that have been related to weight variation in machine-filled capsules, for example Chowhan's compressibility index, are not mentioned. There is no discussion of powder cohesibility and its relationship to the quantitative transfer of plugs and plug mechanical strength. An all too brief discussion of bulk density is not related to the powder beds from which samples are removed. No discussion was made of particle-particle and particle-wall interactions and their relationship to powder retention in dosator nozzles. However, some of these issues are pointed up in Chapter 9 ("The Mechanical Operations of Filling Hard Capsules") and in Chapter 11 ("Capsule Types, Filling Tests, and Formulation"), but without much detail. Chapter 8 on the history of capsule-filling machinery, again only five pages, seems out of place and probably should have been placed in Chapter 1. The discussion of certain outmoded or discontinued equipment in both Chapters 9 and 10 should also have been relegated to Chapter 1, or eliminated. Overall, Chapter 10, on "Capsule-filling Machinery", is comprehensive and generally well done, though no mention is made of the Osaka machine. In Chapter 11, formulation and capsule filling are discussed; however, since this discussion is derived from a survey of reports on instrumented dosator (e.g., Zanasi) filling machines, only that type of machine is considered. Omitted from this chapter was any discussion of formulations for the widely used dosing disk (e.g., Hoffiger and Karg) machines, and no mention was made of the instrumentation of these machines. "Capsule Handling Systems", Chapter 12, is generally well done, and includes a brief discussion of sealing and positive closure methods. Since this is a book written in the UK, the authors can be excused for including only a brief reference to the American problem of tampering. Chapter 13 on "Drug Release from Capsules" is concerned chiefly with *in vitro* drug release. Radiocintigraphic studies on capsule disintegration and bead dispersion are rather briefly mentioned. Although acknowledgment is made of the possible influence of method of filling on drug release, the author has omitted studies based on capsules filled using instrumented filling machines in which the forces involved in plug formation are controlled. Chapter 13 also includes a discussion of drug release from soft gelatin capsules and a brief comment on liquid-filled hard shell capsules.

Omitted from this book altogether is the making and coating of pellets, an area of obvious interest and concern in modern capsule technology. Also, no discussion of mixing effects could be found. Furthermore, greater depth in the area of formulation, including the types and performance of excipients, would have enhanced this book significantly. One

# Hard Capsules Development Technology

**TD Snyder**



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