the shelf of (and also read by) every individual having responsibility in a Quality Control function.

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Pharmacokinetics, 2nd edn., edited by P.G. Welling and F.L.S. Tse, Marcel Dekker, New York, 1995, 528 pp., US$175.00. ISBN 0-8247-9378-1.

The title of this volume does not do its subject matter justice, as it suggests that the book is mainly concerned with methodology to track the concentrations of drug substances in the body. The editors have chosen to place this science within the larger context of drug delivery, and have therefore succeeded in producing a far superior product. The more comprehensive scope of the chapter structure gives the reader a much better appreciation of classical pharmacokinetics, pharmacodynamics, and drug metabolism.

The first chapter (Dexter Goldman) presents the regulatory aspects of the subject matter, and outlines the principles of Good Laboratory Practice regulations as these are applied to pharmacokinetics. The chapter discusses in sufficient length the pertinent sections of 21 CFR 58 which define the regulatory requirements for such work. The author correctly points out that the GLPs have nothing to do with the science and design of pharmacokinetic studies, but are concerned with the prudent management of studies and with the integrity of data. It is his conclusion that compliance is cost-effective, since conduct of work ensures that studies would not be repeated due to insufficient documentation or questionable practices.

The next several chapters present an excellent overveiw of topics which precede the introduction of a drug into the circulatory system. Karen Habucky contributed an overview of the in vitro and in situ methods which can be used to assess the degree of drug absorption. Christopher Rhodes has provided a critical evaluation of the situation which has arisen whereby the science of drug delivery is now strongly influenced by pharmacokinetic principles. His overview is strong, but the strength of this chapter lies in the author's choice to be frank in his opinions and suggestive as to where the field ought to be headed. Vincent Lee follows with a discussion of the particular challenges associated with the delivery of peptides and proteins, focusing on both the preemptive barriers and on the systematic clearance of these drugs. To place a drug at its desired site requires transport across cell membranes, and the topic of membrane transport is addressed by Ernest Wright. The drug delivery section of the book concludes with a contribution by William Banks and Abba Kastin, discussing the blood-brain barrier and the special concerns of peptide drugs.

The next major section of the book begins with a description of the methodology used to model the relationships existing between pharmacokinetics and pharmacodynamics (Meindert Danhof and Jaap Mandema), and provides a particularly strong summary of models relating to the time course of pharmacological effects. Immediately following are chapters oriented toward drug metabolism topics: spatial imaging of radioactivity in animal tissues and organs (Alain Schweitzer), an outline of experimental methods used in studies of drug metabolism (Roger Hayes, William Pool, Michael Sinz, and Thomas Woolf), and the use of hepatic microsomes as in vitro models for drug metabolism (Thomas Kronbach).

Following the drug metabolism section, several reviews of the application of pharmacokinetic principles during various stages of drug development are presented. Peter Welling presents an overview of three approaches where pharmacokinetics could be totally integrated into all phases of the drug discovery and development process, amply discussing the pros and cons of each proposal. Francis Tse follows with a review of the goals and objectives associated with nonclinical pharmacokinetic studies, focusing on support for pharmacology, support for toxicology, prediction of human pharmacokinetics, and the screening of drug formulations. This chapter is followed by an equally detailed summary of the use of pharmacokinetics during the conduct of clinical studies, where Horst Schran and James Jaffe provide a lucid description of exactly what is to be learned during the three phases of clinical development. This section concludes with an exposition of the

variability in pharmokinetics or pharmacodynamics which might be encountered when administering the same drug formulation of differing population groups (Jaap Mandema). Given the current trend at producing studies and data suitable for international filings, this particular chapter is particularly important for those designing such studies.

The volume concludes with chapters covering the bioavailability and bioequivalence of oral extended-release products (Henry Malinowski and James Henderson), and the statisticsl considerations that are associated with bioavailability and bioequivalence studies (Lianng Yuh). This last chapter is refreshingly welcome in that the author presents its subject matter in a fashion intelligible even to non-statisticians!

Owing to its comprehensive approach, this volume should be required reading for any scientist involved in drug development, regardless of discipline. The clarity with which most of the various authors have incorporated in their discussions also suggests that the book would also serve as a useful text for an introductory graduate course in pharmacokinetics and pharmacodynamics.

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