Book Reviews

In Vitro-In Vivo Correlations. David Young, John G. Devane, and Jackie Butler, Eds. Plenum Publishing Corporation, 233 Spring St., New York, NY 10013-1578, 1997. ix, 300 pp., illustrations. $95.00.

This book was compiled from the presentations at a conference entitled "In Vitro-In Vivo Relations Workshop" which was held in September, 1996. Although the purpose of the workshop was to discuss new concepts and methods in the development of in vitro-in vivo relationship for extended release products, many of the case examples presented are relevant also to in vitro-in vivo correlations (IVIVC) for immediate release products. As stated by the editors, the pace of development and application of IVIVC concepts has accelerated within the last 5 years, largely due to the initiatives of the FDA. Nevertheless, the materials presented in this book are very current, perhaps partly due to the fact that many of the presentations at the conference were given by FDA scientists or those working closely with the FDA. In the 25 chapters presented one can find all essential elements of IVIVC, including discussions of considerations arising from the Biopharmaceutics Classification Scheme, appropriate design of dissolution tests, methods for obtaining correlations (deconvolution, convolution, neural networks, population-based methods etc.), non-linear IVIVC, and, last but not least, regulatory aspects.

Particularly interesting is Professor Corrigan's chapter concerning the application of the Biopharmaceutic Classification Scheme to drugs administered in extended release formulations. His ideas are well-thought out and clearly presented - how to handle drugs with varying permeability in the GI tract and how to take into account motility considerations - this chapter is a must for those working in the IVIVC area. A further chapter that this reviewer found especially interesting was Dr. Levane's chapter on the "Impact of IVIVC on Drug Development", which gives a very good overview of where and when IVIVC can expedite the development of new products as well as verify the equivalence of post-approval changes. Lacking in this volume is a specific chapter on physiologically relevant design of dissolution tests for IVIVC. Certain elements, such as the choice of apparatus and pH profile and the need to establish an appropriately discriminatory test are discussed, however none of the authors presents an integrated concept. A few of the chapters, including the one on determination of release mechanisms with confocal microscopy and those containing case examples of immediate release products fall somewhat outside the scope of the book, although they are interesting in their own right.

For the most part the chapters are well-written and scientists with a good general knowledge in the area will be able to follow the theoretical sections without difficulty. The generous illustration of the concepts presented, using case examples, is very helpful in this regard. The only real criticism of the book is that the chapters don't follow any immediately apparent logical order, and as a result one skips back and forth between themes as diverse as the application of neural networks and methods for the analysis of the dissolution results - hardly comfort to those less experienced in the area. Furthermore, many of the basic concepts are assumed by the authors and, since it was not the intent of either the Workshop nor the book to cover immediate release dosage forms, this subject is only superficially addressed. For those wishing to "dig in" to the current issues in IVIVC more deeply, it is recommended that this volume be combined with the recent AAPS Press publication "Scientific Foundations for Regulating Drug Product Quality". Together, the two publications satisfactorily cover the relevant current issues in IVIVC for both immediate release and extended release products.

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A Practical Guide for the Preparation of Specimens for X-Ray Fluorescence and X-Ray Diffraction Analysis. Victor E. Buhrke, Ron Jenkins, and Deane K. Smith, Eds. John Wiley & Sons, Inc., 605 Third Avenue, New York, NY 10158, 1998. xxiv, 333 pp., illustrations. $79.95.

This book represents a much-needed addition to the practical powder x-ray diffraction (PXRD) and x-ray fluorescence (XRF) literature. It is a clearly written, no nonsense guide for virtually every phase of sample preparation including specifics for a wide variety of sample types and preparation equipment with sources.

The first chapter of the book deals implicitly with good laboratory practices (GLP), basic statistics, diffraction, representative sampling and homogenization, particle size reduction, and the artifacts that may be associated with each topic. For the beginning scientist, the tips like "asking the submitter whether a qualitative or quantitative analysis is required" are particularly nice to see. The discussions on representative sampling and the statistical tools for determining required replicates are very timely. The backgrounds on the XRF and, particularly, the PXRD instruments given in their respective chapters are very well done. There is enough depth to understand where sample preparation can contribute artifact without losing sight of the main purpose of the book.

The scope of the sample types that are dealt with is very large, although the reader will notice the almost total absence of pharmaceuticals and most other organics. This work was clearly not aimed at the pharmaceutical community, which is not surprising as it makes up a relatively small part of the x-ray analysis community. (Although one example in XRF was sampling of leaves from a tree which can not represent a much larger community than pharmaceutics.) This was of some concern at first; however, I found the techniques presented and the factors they address to be directly applicable to the vast majority of analytical x-ray problems in pharmaceutics. There is significant treatment of preferred orientation and quantitation in PXRD as well as cautions on inducing phase changes on particle size reduction. The discussion of sample cells and their characteristics is the best I have seen. The XRF sections discuss in

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detail the complications and implications of analyzing light elements. There are many techniques and examples that do not fall into the mainstream of pharmaceutical analysis; however, the majority of pharmaceutical problems are well addressed. The non-pharmaceutical examples are very interesting and instructive and as pharmaceutical use of XRF/PXRD increases these examples may be very relevant.

The book is suitable for new experimentalists as well as for a practical graduate course in x-ray analysis. It has brought together most of the relevant information from the traditional sources (with references) as well as information unique to the authors not found elsewhere. The work has also brought together many anecdotal observations and "tips and tricks" and provided a sound rationale for them. For example, the fact that preferred orientation may be a reproducible phenomenon has probably been observed by most PXRD practitioners but only documented here. This is one of the characteristics that make the book very useful for even the experienced practitioner.

Pharmaceutical scientists may not use all of the information in the book, but it is a long overdue, much-needed reference that may help reduce the time we spend chasing artifacts in our XRF/PXRD data.

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Designer Vaccines: Principles for Successful Prophylaxis. Huw P.A. Hughes and Manuel Campos, Eds. CRC Press, 2000 Corporate Blvd. NW, Boca Raton, FL 33431-9868, 1998. vii, 204 pp., illustrations. $99.95.

The goal of the editors of this book is to promote the use of current immunological knowledge in the rational design of vaccines. They have selected several immunological topics that they believe need to be clearly understood for successful prophylaxis. The topics, which include immunologic memory, costimulatory signals for T and B cells, cytokines as vaccine adjuvants, mucosal immunology, and viral and bacterial vaccine vectors, are presented and discussed by experts in the field. Knowledge of these areas is clearly important to people involved in the development of novel vaccines against infectious agents that have eluded traditional approaches, and improved vaccines with better efficacy and safety than conventional vaccines. While the emphasis of the book is on basic immunological theory, the authors occasionally use examples from human and veterinary medicine to illustrate or support their reasoning.

The chapters are generally succinct and well referenced. Extensive tables of studies of viral and bacterial vectors for the delivery of various vaccine antigens will facilitate finding appropriate references. The main limitation of this book is that certain aspects of immunology that are also relevant to the rational design of vaccines, such as antigen processing and the mechanism of action of non-cytokine adjuvants, are not discussed. Overall, this relatively short book, approximately 200 pages, is a useful addition to the vaccine literature, especially for those investigators who want a quick review or update on immunology as it relates to vaccine development.

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Books Received

Biomaterials and Drug Delivery

Synthetic Biodegradable Polymer Scaffolds. Anthony Atala, David Mooney, Joseph P. Vacanti, and Robert Langer, Eds. Birkhaüser Boston, 160 Imlay St., Brooklyn, NY 11231, 1997. xii, 258 pp., illustrations. $99.00.

Selected Contents

1. Legal issues and FDA regulation of tissue engineering.
2. Drug delivery related to tissue engineering.
3. Tissue engineering of cartilage, bone, liver, and heart valves.

Protein-Based Materials. Kevin McGrath and David Kaplan, Eds. Birkhaüser Boston, 160 Imlay St., Brooklyn, NY 11231, 1997. xx, 429 pp., illustrations. $79.95.

Advances in Polymeric Biomaterials Science. Toshihiro Akaike, Teruo Okano, Mitsuru Akashi, Minoru Terano, and Nobuhiko Yui, Eds. CMC Co., Ltd. Tokyo, Japan, 1997. x, 686 pp., illustrations. 70,000 Japanese Yen.

Handbook of Biodegradable Polymers. Abraham J. Domb, Joseph Kost, and David M. Wiseman, Eds. Harwood Academic Publishers, Amsteldiihk 166, 1st Floor, 1079 LH Amsterdam, The Netherlands, 1997. xvii, 526 pp., illustrations. $155.00.

Materials Chemistry. An Emerging Discipline. Leonard V. Interrante, Lawrence A. Casper, and Arthur B. Ellis, Eds. American Chemical Society, P. O. Box 57136, Washington, DC 20037-0136, 1995. xviii, 570 pp., illustrations. $83.95.

Routes of Medication Administration and New Drug Delivery Systems. Augustine S. Aruna. Global Publishing Network, Inc., P. O. Box 850439, New Orleans, LA 70185-0439, 1997. 79 pp. Paper. $14.00.

Blood Substitutes. New Challenges. Robert M. Winslow, Kim D. Vandegriff, Marcos Intaglietta, Eds. Birkhaüser Boston, 160 Imlay St., Brooklyn, NY 11231, 1996. viii, 208 pp., illustrations. $69.50.

Selected Contents

1. Blood substitute oxygen carriers designed for clinical applications.
2. Biological consequences of cross-linked hemoglobin.
3. Preparation of hemoglobin containing non-phospholipid liposomes.

Computer Modeling

Computer Modeling of Chemical Reactions in Enzymes and Solutions. Arieh Warshel. John Wiley & Sons, Inc., 605 Third Avenue, New York, NY 10158, 1991. xiv, 236 pp., illustrations. Paper. $49.95.

Drugs

Drug Products for Clinical Trials: An International Guide to Formulation, Production, and Quality Control. Donald C. Monkhouse, C. T. Rhodes, Eds. Marcel Dekker, Inc., 270 Madison Ave., New York, NY 10016-0602, 1998. xi, 387 pp., illustrations. $165.00.

Selected Contents

1. Drug discovery considerations.
2. Formulations used in clinical trials and their bioequivalency to marketed products.
3. Formulation design considerations.
4. Clinical supply manufacturing and packaging.
5. Overseas trials and blinding clinical trial supplies.

Drugs of Natural Origin: Economic and Policy Aspects of Discovery, Development, and Marketing. Anthony Artuso, Ph.D. The Pharmaceutical Products Press, An Imprint of the Haworth Press, Inc., 10 Alice Street, Binghamton, NY 13904-1580, 1997. 201 pp., illustrations. Paper. $24.95.

Eicosanoids and Other Bioactive Lipids in Cancer, Inflammation, and Radiation Injury 3. Kenneth V. Honn, Lawrence, J. Marnett, Santosh Nigam, Robert L. Jones, and Patrick Y-K Wong, Eds. Plenum Publishing Corporation, 233 Spring St., New York, NY 10013-1578, 1997. xvi, 599 pp., illustrations. $149.50.

Ways to Successful Strategies in Drug Research and Development. H. Harold Sedlacek, Alice M. Sapienza, Volker Eid. John Wiley & Sons, Inc., 605 Third Avenue, New York, NY 10158, 1997. xiii, 265 pp., illustrations. $90.00.

Caffeine Consumption and Health. Fact and Fallacy. Augustine S. Aruna. Global Publishing Network, Inc., P. O. Box 850439, New Orleans, LA 70185-0439, 1997. 64 pp. Paper. $10.75.

The Integration of Pharmacological and Nonpharmacological Treatments in Drug/Alcohol Addictions. Norman S. Miller, Ed. The Pharmaceutical Products Press. An Imprint of the Haworth Press, Inc., 10 Alice Street, Binghamton, NY 13904-1580, 1997. ix, 122 pp., illustrations. $39.95.

Herbal Remedies. Thomas Brendler, Joerg Gruenwald, Christof Jaenicke, Eds. Deutscher Apotheker Verlag, P. O. Box 101061, D-70009 Stuttgart, Germany, 1997. Illustrations. CD-Rom. $99.00.

Strategies for Organic Drug Synthesis and Design. Daniel Lednicer. John Wiley & Sons, Inc., 605 Third Avenue, New York, NY 10158, 1998. xv, 502 pp., illustrations. $79.95.

Selected Contents

1. Prostaglandins, protease inhibitors, and retinoids.
2. Drugs based on a substituted benzene ring and polycyclic aromatic compounds.
3. Steroids and nonsteroidal estrogens.
4. Drugs based on heterocycles and heterocycles fused to benzene or other heterocyclic rings.

Management

Pharmaceutical Project Management. Tony Kennedy, Ed. Marcel Dekker, Inc., 270 Madison Ave., New York, NY 10016-0602, 1998. viii, 304 pp., illustrations. $125.00.

Selected Contents

1. Strategic project management at the project level and at the portfolio level.
2. Managing an international project team, joint ventures, and contracted clinical research.
3. The development of drug delivery devices.
4. Information technology and future visions of pharmaceutical project management.

Pharmacy and the U. S. Health Care System. Second Edition. Jack E. Fincham, and Albert I. Wertheimer, Eds. The Pharmaceutical Products Press, An Imprint of The Haworth Press, Inc., 10 Alice St., Binghamton, NY 13904-1580, 1998. xxi, 557 pp., illustrations. Paper. $39.95.

Teaching and Learning Strategies in Pharmacy Ethics. Second Edition. The Pharmaceutical Products Press. An Imprint of the Haworth Press, Inc., 10 Alice Street, Binghamton, NY 13904-1580, 1997. xiii, 159 pp.. $39.95.

The Scientist as Consultant. Building New Career Opportunities. Carl J. Sindermann and Thomas K. Sawyer. Plenum Publishing Corporation, 233 Spring St., New York, NY 10013, 1997. xiv, 341 pp. $29.95.

Concurrent Engineering Effectiveness: Integrating Product Development Across Organizations. Mitchell Fleischer and Jeffrey Liker. Hanser Gardner Publications, 6915 Valley Ave., Cincinnati, OH 45244-3029, 1997. viii, 506 pp., illustrations. $49.95.

Pharmacokinetics

Pharmacokinetics: Processes, Mathematics, and Applications Second Edition. Peter G. Welling. American Chemical Society, 1155 Sixteenth St., N.W., Washington, D. C. 20036, 1997. xiv, 393 pp., illustrations. $99.95.

Polymers

Handbook of Industrial Membranes. Keith Scott. Elsevier Science, P. O. Box 211, 1000 AE Amsterdam, The Netherlands, 1997. xii, 912 pp., illustrations. $293.00.

Selected Contents

1. Introduction to membrane separations.
2. Membrane materials, preparation and characterization.
3. Separation of liquid mixtures/pervaporation.
4. Analytical application of membranes.
5. Biotechnology and medical applications.

Plastics Extrusion Technology. 2nd Edition. Friedhelm Hensen, Ed. Hanser Gardner Publications, 6915 Valley Ave., Cincinnati, OH 45244-3029, 1997. xxi, 653 pp., illustrations. $198.00.

Understanding Plastics Packaging Technology. Susan E.M. Selke. Hanser Gardner Publications, 6915 Valley Ave., Cincinnati, OH 45244-3029, 1997. xiv, 206 pp., illustrations. Paper. $34.95.

Supramolecular Chemistry of Anions. Antonio Bianchi, Kristin Bowman-James, and Enrique Garcia-Expã, Eds. John Wiley & Sons, Inc., 605 Third Avenue, New York, NY 10158, 1997. xiv, 461 pp., illustrations. $79.95.

Interpenetrating Polymer Networks. D. Klempner, L. H. Sperling, and L. A. Utracki, Eds. American Chemical Society, P.

O. Box 57136, Washington, DC 20037-0136, 1994. xvi, 638 pp., illustrations. $146.95.

Physical Properties of Polymers. Second Edition. James E. Mark, Adi Eisenberg, William W. Graessley, Leo Mandelkern, Edward T. Samulski, Jack L. Koenig, and George D. Wignall. American Chemical Society, P. O. Box 57136, Washington, DC 20037-0136, 1993. xi, 409pp., illustrations. $47.95.

Statistics

SPC for Short Run Manufacturing. Leonard A. Doty. Hanser Gardner Publications, 6915 Valley Ave., Cincinnati, OH 45244-3029, 1997. v, 148 pp., illustrations. Paper. $34.95.

Understanding Design of Experiments. R. J. Del Vecchio. Hanser Gardner Publications, 6915 Valley Ave., Cincinnati, OH 45244-3029, 1997. xii, 175 pp., illustrations. Paper. $34.95.

Design and Analysis of Animal Studies Pharmaceutical Development. Shein-Chung Chow and Jen-Pei Liu, Eds. Marcel Dekker, Inc., 270 Madison Ave., New York, NY 10016-0602, 1998. x, 407 pp., illustrated. $175.00.

Surfaces and Interfaces

Particle and Surface Characterisation Methods. R. H. Müller and W. Mehnert, Eds. medpharm Scientific Publishers, Birkenwaldstr. 44, D-70191 Stuttgart, Germany, 1997. xi, 280 pp., illustrations. DM/sFr 62.

Interfacial Engineering for Optimized Properties. Clyde L. Briant, C. Barry Carter, and Ernest L. Hall, Eds. Materials Research Society, 9800 McKnight Road, Pittsburgh, PA 15237, 1997. xiv, 510 pp., illustrations. $75.00.

Atomic Resolution Microscopy of Surfaces and Interfaces. David J. Smith, Ed. Materials Research Society, 9800 McKnight Road, Pittsburgh, PA 15237, 1997. ix, 282 pp., illustrations. $71.00.

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