AAPS Update

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November 2005

New Title from AAPS Press

Methods for Structural Analysis of Protein Pharmaceuticals

Edited by Wim Jiskoot and Daan Crommelin, Utrecht University.

This book is Volume 3 of the *Biotechnology: Pharmaceutical Aspects* series from AAPS Press.

This edition discusses the various techniques used to study the structural aspects of proteins, including, among others, spectroscopic techniques (e.g., fluorescence, circular dichroism, infrared, and Raman spectroscopy), light scattering techniques, separation techniques (e.g., liquid chromatography, capillary electrophoresis, and analytical ultracentrifugation), and mass spectrometry, calorimetric, and immunochemical techniques.

Various leaders from academia and industry have contributed to *Methods for Structural Analysis of Protein Pharmaceuticals*. The result is a comprehensive volume for anyone in academia or industry interested in protein pharmaceuticals.

As you can see, this new release from AAPS Press would be an important addition to your reference library. Call (703) 243-2800 to place your order. And be sure you visit **www.aapspharmaceutica.com/publications/press/index.asp** to learn about other AAPS Press publications.

List Price: $188.00; AAPS Member price: $150.00

Current Titles from AAPS Press

Pharmacokinetics in Drug Development: Clinical Study Design and Analysis (Volume 1)

Edited by Peter Bonate, *Ilex Oncology*
Danny Howard, *Aventis Pharmaceuticals, Inc.*

Clinical Study Design and Analysis (Volume 1) discusses the role pharmacokinetics plays in selected clinical study designs. Included are first-time-in-man studies, biopharmaceutical, and special population studies. The chapters are written to provide the reader with a familiarity for scientific and operational considerations, and to provide insight into the authors' practical experiences conducting these studies. Volume 1 also discusses the application of pharmacokinetic analysis techniques to drug development—from noncompartmental analysis and interspecies scaling to deconvolution and clinical trial simulation. Volume 1 closes with a discussion on the analysis of clinical safety data in pharmacokinetic studies.

List Price: $175.00, AAPS Member $140.00

Pharmacokinetics in Drug Development: Regulatory and Development Paradigms (Volume 2)

Edited by Peter Bonate, *Ilex Oncology*
Danny Howard, *Aventis Pharmaceuticals, Inc.*

In Volume 2, the authors' attentions turn toward key regulatory and development paradigms where pharmacokinetics supplements decision-making during drug development. Pharmacokinetics' association with toxicologic assessments, bioanalysis targets and objectives, and application in preclinical programs are discussed. General discussions for rational development and knowledge discovery schemes are presented. Specific areas of recent regulatory interest are reviewed for exposure - response relationships, and detailed overviews of regulatory considerations and review are presented for pharmacokinetic studies and clinical trial simulations. Also included in Volume 2 are reviews of topics of special development consideration for pharmacokinetics - oncology, controlled release, transdermal, ocular, parenteral, chiral, and biologic products.

List Price: $150.00, AAPS Member $120.00

Pharmaceutical Profiling in Drug Discovery for Lead Selection

Edited by Ronald T. Borchardt, *University of Kansas*
Edward H. Kerns, *Wyeth Research*
Christopher A. Lipinski, *Pfizer Global R & D (retired)*
Dhiren R. Thakker, *University of North Carolina*
Binghe Wang, *Georgia State University*

Volume 1 of the AAPS Press series, *Biotechnology: Pharmaceutical Aspects*. Based on a 2003 AAPS workshop of the same name, Pharmaceutical Profiling in Drug Discovery for Lead Selection emphasizes the importance of accuracy in the prediction, measurement, and application of physiochemical and ADME properties, not only to guarantee successful lead selection in "hit-to-lead" research but also to avoid the common pitfalls that arise when property information is lacking. Its contributors include highly experienced leaders from both industry and academia, with specialization in advanced methods for *in silico*, physico-chemical, permeability, *in vitro*, and

Continued

ADME, as well as in medicinal chemistry applications on pharmaceutical property information. This book is the first volume of the *Biotechnology—Pharmaceutical Aspects series*.

List Price: $185.00; AAPS Member price: $148.00

Lyophilization of Biopharmaceuticals

Edited by Henry R. Costantino, *Nastech/ Pharmaceutical Company, Inc.*
Michael J. Pikal, *University of Connecticut*

Volume 2 of the AAPS Press series, *Biotechnology: Pharmaceutical Aspects*. This edition covers the important topic of freeze-drying of biopharmaceuticals. The book starts by discussing lyophilization equipment and validation. Next, stresses involved in lyophilization are reviewed. Other important areas included in this volume are transport phenomena, physics of glassy materials, and process design and control. Formulation development and lyophilization cycle development are likewise reviewed.

Also included is a relevant and comprehensive presentation of FDA-approved biopharmaceutical products and their excipients. Attention is given to the characterization of protein and peptide powders by commonly used solid-state methods. These methods facilitate formulation development in a rational fashion to address the various solid-state degradation mechanisms, which are also reviewed in a separate chapter. Additional chapters which should provide timely relevant reviews treat lyophilization of liposomes, lyophilization of nucleic acids, spray freeze drying, and the use of dried enzymes as nonaqueous catalysts.

Various leaders from academia and industry have contributed to *Lyophilization of Biopharmaceuticals*. The result is a comprehensive volume for anyone in academia or industry interested in formulation of peptide and protein drugs in the lyophilized state.

List Price: $195.00, AAPS Member $156.00

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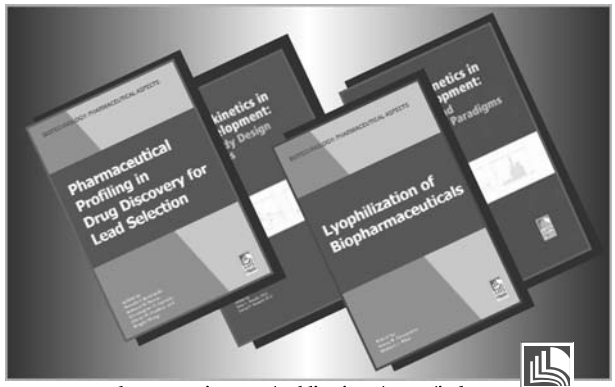

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AAPS Distance Learning

AAPS Distance Learning is pleased to announce the addition of two new on-demand webcasts produced from sessions conducted at the 2004 AAPS Annual Meeting and Exposition in Baltimore:

- Symposium on Biopharmics Consideration in Early Product Development (160 minutes)
- Symposium on New Techniques in Formulation of Lipid-Based Oral Dosage Forms (153 minutes)

As always, AAPS Distance Learning webcasts are available 24/7, and include the original audio lectures synchronized to the PowerPoint™ slides. Each session is split into small segments, so you need not commit a large chunk of time at once to any given event. Our webcasts represent a great opportunity to catch up on what you might have missed at the AAPS Annual Meeting and Exposition.

For complete details on all of our 46 currently available webcasts, please visit **www.aapspharmaceutica.com/DL** (today!)

Upcoming AAPS Meetings

Log onto **www.aapspharmaceutica.com/meetings** for details.

▶January 22-27, 2006
AAPS 41st Annual Pharmaceutical Technologies Conference–Oral Controlled Release Development and Technology
The Thayer Hotel, West Point, NY

▶June 18-21, 2006
2006 AAPS National Biotechnology Conference
2006 AAPS National Biotechnology Conference
John B. Hynes Veteran's Memorial Convention Center, Boston, MA

▶November 9, 2006
2006 AAPS Annual Meeting and Exposition
San Antonio Convention Center, San Antonio, TX

Coming in the Spring 2006
AAPS Conference on Critical Issues in Discovering Quality Clinical Candidates to be held in the Mid-Atlantic Area.
Date and location to be announced.
Stay tuned visit:
www.aapspharmaceutica.com/meetings

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