

AAPS Update

AAPS—YOUR FORMULA FOR SUCCESS!

September 2004

New Titles from AAPS Press!

Pharmaceutical Profiling in Drug Discovery for Lead Selection

Author(s): 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 physicochemical 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*, physicochemical, permeability, *in vitro*, and ADME, as well as in medicinal chemistry applications on pharmaceutical property information. This book is the first volume of the *Biotechnology: Pharmaceutical Aspects* series.

Suggested List Price: \$185
AAPS Member Price: \$148

Lyophilization of Biopharmaceuticals

Author(s): Henry R. Costantino, Nasteck 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 non-aqueous 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.

Suggested List Price: \$195
AAPS Member Price: \$156

You'll want to order your copies now to assure immediate delivery. Call, 703-243-2800 to place your order.

AAPS - NIDA Symposium Frontiers in Science: Drug Addiction—From Basic Research to Therapies

September 9 - 11, 2004
National Institutes of
Health Campus
Natcher Auditorium,
Bethesda, MD
Co-Sponsored with NIDA



Drug addiction is a major societal problem today, with staggering costs incurred by the individual and society as a whole. Progress at the basic science level has been impressive, but treatment of addiction remains a daunting challenge. On the other hand, insights into neurobiological mechanisms underlying addiction have spurred novel treatments of related disorders, such as neurodegeneration and pain. This conference will focus on the translation of fundamental addiction research to a variety of treatments, bringing together scientists in molecular biology, genetics, and neuroscience with researchers in pharmacogenetics, pharmaceutical chemistry, drug targeting and development, and quantitative therapeutics. Participation by scientists from industry will serve to highlight new therapies currently under commercial development. For more information, please go to www.aapspharmaceutica.com/frontiers.

Continued

AAPS Workshop: Optimization of Drug Like Properties During Lead Optimization

September 19-22, 2004

Hilton Parsippany
Parsippany, NJ

Co-Sponsored with The Society of Toxicology, ACS—Medicinal Chemistry Division, ACS—North Jersey Section, ASCPT, ISSX and EUFEPS

Drug discovery and development is an increasingly difficult and expensive undertaking. One difficulty is that drug candidates have a high rate of failure during discovery and development. One reason for this failure is the lack of drug-like properties of candidate compounds. In development, inadequate properties result in insufficient bioavailability and pharmacokinetics performance, and in discovery they result in inadequate and/or improper evaluation of the biological activity. As a consequence, potentially useful drug candidates may be discarded prematurely or too much time may be spent on biological activity of drug candidates that are not likely to result in efficacious therapeutic agents. This workshop will contribute to the field by focusing on procedures for prediction, measurement, and application of compound properties to actively optimize lead candidate performance. For more information, please go to www.aapspharmaceutica.com/leadopt.

AAPS Workshop on Specifications for Biotechnology and Biological Products

October 6-8, 2004

Marriott Metro Center
Washington, DC

This workshop should be the first in a series of activities to address the process of setting specifications for biologics and biotechnology products. Carefully planned discussion should surround the fundamentals of setting specifications, and not particular solutions to identified issues. Thus, the goal of this workshop will not be to amend current practices, but to recommend an overall and comprehensive process from scratch. In addition to mapping the process of setting specifications, small interactive break out sessions will be used to identify product specific elements and explore in depth additional approaches to specific issues related to setting specifications. For more information, please go to

www.aapspharmaceutica.com/specifications.

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AAPS Update

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- ▶ Interact with your scientific peers
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- ▶ Mentoring Program

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- ▶ Scholarships/Grants/Travelships
- ▶ AAPS Career Center
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▶ September 9-11, 2004

AAPS-NIDA Symposium Frontiers in Science: Drug Addiction-From Basic Research to Therapies

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National Institutes of Health Campus, Natcher Auditorium
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▶ September 19-22, 2004

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Co-Sponsored with The Society of Toxicology, ACS Medicinal Chemistry Division, ACS North Jersey Section, SCPT, ISSX and EUFEPS

Hilton Parsippany, Parsippany, NJ

▶ October 6-8, 2004

AAPS Workshop on Specifications for Biotechnology and Biological Products

Marriott Metro Center, Washington DC

▶ November 5-6, 2004

AAPS Workshop on Clinical Biomarkers in Drug Development: Efficacy Assessment, Pharmacokinetics and Pharmacodynamics and Regulatory Insights

Co-Sponsored with ACCP

Holiday Inn Inner Harbor, Baltimore, MD

▶ November 7-11, 2004

2004 AAPS Annual Meeting and Exposition
Baltimore Convention Center, Baltimore, MD

▶ February 3-5, 2005

AAPS Workshop on Getting the Dose Right
Crystal Gateway Marriott, Arlington, VA

▶ June 5-8, 2005

2005 AAPS National Biotechnology Conference
San Francisco Marriott, San Francisco, CA



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