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AAPS Update

AAPS—YOUR FORMULA FOR SUCCESS!

August 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,
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 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.

Calling All Authors!

AAPS has launched a new book program called AAPS Press. Whether you're an established author, or a recently minted Ph.D. with research to discuss, send AAPS Press your manuscript and AAPS Press will share it with the world.

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To learn more about this groundbreaking book program contact the AAPS Director of Publications, Victor Van Beuren at 703-248-4760 or **VanBeurenV@aaps.org**.

AAPS Pharmaceutical Technologies Summer Conference: Optimizing the Global Clinical Supplies Process

August 15-20, 2004
Hilton Philadelphia/Cherry Hill
Cherry Hill, NJ

Goals and Objectives:

The goal of the conference is a comprehensive presentation of the requirements for global clinical supplies development. The objective is to address individual cGMP requirements for the USA, Canada, EU and Japan; for most dosage forms/delivery systems, including oral, parenteral and topically applied, large and small molecule; requirements for specifications,

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methods and criteria; requirements for selection of resources; the new FDA System Based Risk Assessment; and methods and electronic systems for accelerating the clinical supplies/development process, facilitating cGMP and regulatory requirements, and metrics for assessment. The conference will also address specific ways to accelerate the process.

The conference will NOT address the processes of developing dosage forms or nor provide training in analytical and QA techniques. It is assumed that each participant has access to CROs or internal resources for these tasks.For more information, please go to **www.aapspharmaceutica.com/meetings**

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

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

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 neurosciences 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**.

AAPS Workshop: Optimization of Drug Like Properties During Lead Optimization

September 19-22, 2004
Hilton Parsippany
Parsippany, NJ

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 bioavailabilty 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/meetings**.

Have an Idea for a Meeting?

To submit a proposal for a workshop or themed meeting, use the submission form at **www.aapspharmaceutica.com/meetings/meeting_proposal.asp**.

Upcoming AAPS Meetings

Log onto **www.aapspharmaceutica.com/meetings** for the latest meeting and registration details.

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▶September 19-22, 2004
AAPS Workshop on Optimization of Drug Like Properties During Lead Optimization
Hilton Parsippany, Parsippany, NJ

▶October 6-8, 2004
AAPS Workshop on Specifications for Biotechnology and Biological Products
Marriott Metro Center, Washington DC

▶November 7-11, 2004
2004 AAPS Annual Meeting and Exposition
Baltimore Convention Center, Baltimore, MD

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