

AAPS Connection

American Association of Pharmaceutical Scientists

March 2012

2012 AAPS National Biotechnology Conference

May 21–23, 2012
Sheraton San Diego Hotel and Marina, San Diego

Overview

Come join us for the 2012 AAPS National Biotechnology Conference! The scientific programming will feature 19 symposia, 17 roundtables and mini-symposia, eight sunrise sessions, three short courses, two workshops and one brand new advanced immunogenicity training course. All sessions are planned around the following themes: Antibody Drug Conjugates, Bioanalysis, Biosimilar/Biobetters, Biotherapeutics Drug Development, Biotherapeutics Drug Discovery, Biotherapeutics Pharmaceutical Sciences, Drug Delivery (Noninvasive and Minimally Non-invasive), Innovative Drug Delivery, Translational Research, and Vaccines. Sessions will also cover diverse topics, such as Diversity and Complexity of Vaccine Manufacturing, Scale Up and Tech Transfer Strategies, Applications of Multiscale Systems Pharmacology, and Advancements in Novel Small Protein Therapeutic Modalities.

For information visit www.aaps.org/nationalbiotech.

AAPS Biotechnology 101

Fundamentals of Biotherapeutics Development eLearning Series

AAPS is pleased to announce the release of a brand new online training course, AAPS Biotechnology 101. This comprehensive, multi-module course was developed for those interested in learning more about the field of biologic development and to fill training gaps. This series offers

- lectures by leading experts from industry and academia,

- convenient self-paced learning,
- coverage of the current state of biotherapeutics, and
- practical perspectives from practicing scientists.

This brand new training course was developed for

- professionals seeking to expand their knowledge to include biopharmaceuticals and
- college students and faculty members seeking to augment their training in biotechnology.

For more information visit www.aaps.org/BT101.

2012 AAPS National Biotechnology Awards

The AAPS awards program provides a wonderful opportunity for scientists and graduate students to be recognized and honored for their valuable contributions to the pharmaceutical sciences. Nominate your colleagues for one of the prestigious awards to be presented by AAPS at the 2012 National Biotechnology Conference, May 21–23, San Diego.

Innovation in Biotechnology Awards Sponsored by Genentech

This award is intended to recognize and promote the achievements of individuals who demonstrate innovation in the area of biotechnology. The award is open to individuals who submit an abstract to the 2012 AAPS National Biotechnology Conference. Applicants do not need to be an AAPS member. Each winner selected will receive a cash award of \$500, a plaque, and a complimentary registration to the 2012 National Biotechnology Conference. In addition, travel expenses will be reimbursed (maximum \$1,000 domestic/\$1,500 international) following the meeting.

For more information visit www.aaps.org.

Excellence in Ligand Binding Assays Sponsored by EMD Millipore

This award is designed to recognize excellence in ligand binding assays within the pharmaceutical sciences. The award will promote the science and technology of ligand binding assays. Selection will be made based on the submitted abstracts and summaries of those individuals judged by the committee to have provided the most outstanding contributions in ligand binding assays within the pharmaceutical sciences. Any abstract that is submitted to the BIOTEC section for the National Biotechnology Conference and employs ligand binding assay technology will be given consideration for the award. The primary presenting author will be awarded \$1,000, a plaque, and complimentary registration to the 2012 National Biotechnology Conference.

For more information visit www.aaps.org.

Biotechnology Graduate Student Symposium Award Sponsored by Eli Lilly & Co

This award is designed to recognize excellence in graduate education in the fields of pharmaceutical biotechnology. Students will be selected to participate in the symposium by the AAPS Selection Committee on the basis of abstracts submitted to the committee. On the basis of submitted abstracts and summaries, students will be selected to present their research during the Graduate Symposium at the 2012 AAPS National Biotechnology Conference. Selection will be made on the basis of those students judged by the committee to have provided the most outstanding contributions in the above fields through their graduate research. Each student selected will receive a cash award of \$250 and a complimentary registration to the 2012 National Biotechnology Conference. In addition, travel expenses will be reimbursed (maximum \$1,000 domestic/\$1,500 international) following the meeting.

For more information Visit www.aaps.org.

AAPS Workshop on Lipid-Based Delivery for Improving Drug Absorption: Mechanistic Understanding and Practical Approaches

April 23–24, 2012
Sheraton Inner Harbor Hotel, Baltimore

Goals and Objectives

This workshop will update the participants on the present state-of-the-art of lipid-based drug delivery.

The use of lipid-based drug delivery systems (LBDDS) for oral delivery is increasing, both as a result of the increasing number of poorly soluble drugs in development and the recent success of lipid-based systems for the delivery of peptides and proteins.

The workshop will be divided into four parts focusing on the concepts and principles of LBDDS, predictive tools for development of LBDDS, practical approaches to formulate LBDDS, and the use of lipids to increase drug permeability.

For more information visit www.aaps.org/Lipids.

AAPS Workshop on Formulation Strategies for Nonparenteral Drug Delivery of Biotherapeutics

May 19–20, 2012
Sheraton San Diego Hotel and Marina, San Diego

Goals and Objectives

Unfavorable physiochemical and pharmacokinetic properties of therapeutic peptides, proteins, and nucleic acids represent unique challenges for the development of safe and efficacious medications intended for human use. Inherent instability, combined with the macromolecular nature of this class of biotherapeutics, most often translates into preparation of lyophilized parenteral formulations. Since parenteral administration bypasses important protective barriers of the body, manufacturers have to comply with the highest FDA standards associated with parenteral drug delivery systems. This limits the use of formulation excipients and significantly increases the cost of goods. Furthermore, patients do not prefer parenteral dosage forms, as they are invasive and less suitable for self-administration. Over the past decade, novel scientific concepts have been explored to develop nonparenteral formulations for biotherapeutics that produce acceptable therapeutic efficacy. The primary objective of the workshop is to highlight promising approaches that have emerged from these efforts (e.g., oral, nasal, and pulmonary delivery systems) and successfully entered clinical development.

For more information visit www.aaps.org/Formulation.

AAPS Workshop on Clinical Pharmacology and ADME Biotherapeutic Proteins

May 19–20, 2012

Sheraton San Diego Hotel and Marina, San Diego

Summary/Description

This workshop will provide the current best practices in clinical pharmacology of biotherapeutic proteins by experts from industry, academia, and regulatory colleagues who will discuss challenges we are facing. The emphasis will be on monoclonal antibodies and antibody-drug conjugates and will cover topics such as FIH study design, QT assessment, pharmacokinetic characterization, bioanalytical assays, therapeutic protein-drug interactions, QT risk assessment, and immunogenicity testing. Additionally, traditional clinical pharmacology aspects, including special populations (paediatrics, hepatic and renal impairment) and ADME characterization, will be reviewed, along with regulatory expectations in this area.

For more information visit www.aaps.org/ClinPharm.

Upcoming AAPS Meetings

Log onto www.aaps.org/meetings for details.

- **April 23-24, 2012**
AAPS Workshop on Lipid-Based Delivery for Improving Drug Absorption: Mechanistic Understanding and Practical Approaches
Sheraton Inner Harbor Hotel, Baltimore
- **May 19-20, 2012**
AAPS Workshop on Formulation Strategies for Nonparenteral Drug Delivery of Biotherapeutics
Sheraton San Diego Hotel and Marina, San Diego
- **May 19-20, 2012**
AAPS Workshop on Clinical Pharmacology and ADME Biotherapeutic Proteins
Sheraton San Diego Hotel and Marina, San Diego
- **May 19-20, 2012**
Immunogenicity Training Course II—Advanced Topics in Evaluation of the Immunogenicity of Biotherapeutics
Sheraton San Diego Hotel and Marina, San Diego
- **May 21-23, 2012**
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