

AAPS Connection

American Association of Pharmaceutical Scientists

February 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/NBC.

AAPS Biotechnology 101

Fundamentals of Biotherapeutics Development eLearning Series

AAPS is pleased to announce the release of a brand new online training course, Biotechnology 101. This

comprehensive, multimodule 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.

47th Annual Pharmaceutical Technologies Arden Conference: Nanoscience in Pharmaceuticals: Translating Fundamental Understanding to Practical Application in Drug and Device Development

March 11–14, 2012
The Thayer Hotel, West Point, N.Y.

The unique physicochemical properties of materials on the nanoscale introduce certain challenges into most aspects of pharmaceutical R&D. For example, the ADMET properties of compounds administered as nanoparticles are very different from the same molecules dosed using macro- and microparticulate systems for reasons directly attributable to their size and surface chemistry. Fundamental understanding of the chemistry

and engineering of nanomaterials and nanoparticles and relation to their *in vitro/in vivo* performance, along with manufacturing and toxicity considerations, is critical to their wider acceptance and applications in drug and device development. Promising scientific strategies and approaches such as those that combine disease diagnosis with therapy (nanotheragnostics) and delivery systems for small molecules and macromolecules are progressing from bench to clinic to commercialization with the potential to profoundly affect human health. Particular emphasis will be placed on establishing and distinguishing among what is being accomplished now based on marketed products and what is feasible based on drugs and devices and combinations thereof in clinical and preclinical development. Emerging nanotherapeutics and nanodevices based on early preclinical data will be included in the discussion. There are safety concerns on the interaction of nanomaterials and nanoparticles with the human body. Other areas of concern and future development are nanoparticle pharmacokinetics, formulation, and process development and manufacturing. Quality control and regulatory aspects of nanopharmaceuticals will be highlighted throughout the conference and specifically discussed towards the end in a regulatory roundtable.

For more information visit www.aaps.org/Arden2012.

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 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/meetingsfor details.

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- **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

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