

AAPS Connection

American Association of Pharmaceutical Scientists

November 2010

Get Connected through the AAPS Online Career Center!



AAPS has relaunched our interactive job board—the AAPS Online Career Center! The AAPS Online Career Center focuses on pharmaceutical companies and professionals, and offers jobseekers and employers an easy-to-use and highly targeted resource for online employment connections.

Employers may post jobs online, search for qualified candidates based on specific job criteria, and create online résumé agents to email candidates daily. They also benefit from the enhanced online reporting feature which provides job activity statistics.

For jobseekers, the Online Career Center provides a free service that connects candidates to employers and jobs in the pharmaceutical sciences industry. Registered jobseekers may post résumés, browse available jobs based on specific criteria, archive up to 100 jobs for future viewing or résumé submission, and create search agents for email job notifications.

As an added benefit, registered employers and job seekers also gain access to the National Healthcare Career Network (NHCN), a group of more than 200 top healthcare associations and professional organizations, including the American Hospital Association, the American Academy of Pediatrics, and the Association of American Medical Colleges.

AAPS's alliance with NHCN increases jobseekers' reach to a large database of industry-specific résumés and job postings, providing more control over career advancement to jobseekers and a "one-stop shop" for employers to find quality candidates.

As a companion to the AAPS Online Career Center, AAPS also offers an onsite career fair at many of its program offerings.

To access the AAPS Online Career Center, please visit <http://careers.aaps.org>.

2011 Arden Conference: Pharmaceutical Development of Biologics: Fundamentals, Challenges, and Recent Advances

March 6–10, 2011
Thayer Hotel
West Point, NY, USA

Background

Biopharmaceuticals continue to represent the fastest growing segment of the global pharmaceutical industry. High throughput cell line selection and protein variants production have notably shortened discovery time and lead identification cycle for biologic drug development. Biologics are generally not amenable to oral route delivery due to their intrinsic molecular properties. Injectable dosage forms have therefore become the common choice for initial commercial development. However, injections are invasive, and patient perception is generally less than pleasant, resulting in dosing compliance and market acceptability issues. In addition, competitions from biosimilars (biogenerics) have increasingly become a reality. Consequently, development of various sustained release formulations and non-invasive delivery technologies have been a main focus of product enhancement and life-cycle management for many innovator biopharmaceuticals. The primary goal is generally to reduce injection frequencies as well as possibly improve safety and efficacy profiles at the same time. As regulatory guidelines for biologics are not as well established as for small-molecule drugs, regulatory paths for development and approval of biologics are often more challenging.

Goals and Objectives

This program is designed to provide a comprehensive review of biologic drug development, commonly encountered issues, challenges, and recent advances in bioprocess, formulation, delivery, and manufacturing technologies. Detailed presentations will cover four development areas: biological drug substance and preformulation; formulation, delivery, and process development; analytical technologies and PAT; and regulatory landscape and biosimilars. Each topic will include lectures from experts in the field followed by interactive group discussions and case studies in which the audience is strongly encouraged to participate. Attendees are also encouraged to bring practical examples of issues and problems encountered at work for discussion and thought exchange, including success stories as well as lessons learned.

For more information, please visit www.aapspharmaceutica.com/ardenconference.

AAPS Workshop on Drug Transporters in ADME: From the Bench to the Bedside

March 14–16, 2011
Bethesda North Marriott & Conference Center
Bethesda, MD, USA

Background

The area of drug transport continues to evolve rapidly, including advances in understanding the role of transport in drug absorption, distribution, and excretion, as well as toxicity and disease; improvements in clinical translation of in vitro and preclinical transport studies; and increased regulatory expectations for understanding transport interactions (2010 EmEA draft DDI guidance and 2010 ITC whitepaper). For the past decade, the AAPS Workshop on Drug Transport has been the only recurring North American meeting dedicated to discussion of advances in this field, and has a consistent record of relevance to pharmaceutical scientists. The 2011 workshop will continue to provide a venue for focused interactions with drug transport experts and thought leaders.

Objectives

The recognition of the influence of membrane transporters on drug disposition has driven a surge in drug transport-related research activities within the pharmaceutical sciences. Although considerable progress has been made over the past 15 years, the field of drug transport continues to evolve, particularly with respect to clinical translation of in vitro/preclinical data (2010 EmEA draft DDI guidance and 2010 ITC whitepaper), understanding systemic/tissue exposure implications, toxicity/disease pathogenesis, targeting transport for drug delivery, and interplay with metabolism. The AAPS Workshop on Drug Transport aims to continue on the success of this meeting previously held in 2003, 2005, 2007, and 2009, and to provide an opportunity for pharmaceutical scientists to exchange ideas about the cutting-edge science in this field.

Key Areas of Focus

- ▶ Update on most recent developments in the field
- ▶ In vitro-to-in vivo and preclinical-to-clinical translation of transport data
- ▶ Implications of the ITC whitepaper and revised EmEA draft DDI guidance to drug development
- ▶ Transport strategies for drug discovery
- ▶ The role of drug transporters in toxicity/disease
- ▶ Transporters as determinants of drug exposure and targeting transporters as drug carriers
- ▶ Interplay between metabolism and transport
- ▶ Incorporation of transport into in silico, PBPK, and PK/PD models
- ▶ Current understanding of clinical implications of transporter polymorphisms

For more information, please visit
www.aapspharmaceutica.com/drugtrans.

AAPS eLearning
Check out our upcoming and
archived webinars!
www.aapspharmaceutica.com/webinars



Emerging Oral Delivery Strategies and Technologies to Enable Biopharmaceutical Performance of BCS II, III and IV Molecules

April 2011

Goals and Objectives

For small molecules, approximately 60–70% of NMEs are BCS II and IV, and there is increasing need for drug delivery technologies to enable the development of “drug-like” molecules in a timely and cost-effective manner. Proper biopharmaceutical and ADMET properties along with adequate selectivity and potency minimize subsequent failure risks and increase the chance that the most promising leads are advanced to development candidates. In the case of macromolecules (BCS III), intestinal permeability and metabolism are still the major barriers to overcome with no commercial product on the market despite significant advancements over the last two decades. Proper selection and evaluation of a suitable drug delivery technology using proper in vitro/in vivo methodologies by considering the physicochemical and biopharmaceutical properties of the molecule/macromolecule is critical to the overall drug discovery and development strategy and success. This feature will be highlighted throughout the workshop and introduced by two keynote talks on new paradigms in drug discovery and development and emerging drug delivery technologies. It will then cover the following three areas, the first on general drug development principles and considerations and the other two on specific drug delivery technologies and case studies: physicochemical and biopharmaceutical properties and evaluation tools, lipid-based systems and solid dispersions, and prodrugs and nanoparticles.

For more information, please visit
www.aapspharmaceutica.com/oraldelivery.

Upcoming AAPS Meetings

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

▶ March 6 - 10, 2011

2011 Arden Conference
Thayer Hotel, West Point, NY, USA

▶ March 14-16, 2011

AAPS Workshop on Drug Transporters in ADME
Bethesda N. Marriott & Conference Center, Bethesda, MD, USA

▶ April 2011

AAPS Workshop on Emerging Oral Delivery Strategies and Technologies to Enable Biopharmaceutical Performance of BCS II, III and IV Molecules
Location TBD

▶ May 14 - 15, 2010

AAPS Workshop on Delivery and Disposition of Biotherapeutics across the Blood Brain Barrier
Hilton San Francisco Union Square, San Francisco, CA, USA

▶ May 16-18, 2011

2011 AAPS National Biotechnology Conference
Hilton San Francisco Union Square, San Francisco, CA, USA



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