

AAPS Update

AAPS — YOUR FORMULA FOR SUCCESS!

May 2008

2008 AAPS National Biotechnology Conference

June 22–25, 2008
Metro Toronto Convention Centre
Toronto, Canada
Co-sponsored with BIOTECCanada



AAPS is pleased to announce that the 2008 AAPS National Biotechnology Conference will take place June 22–25, 2008, at the Metro Toronto Convention Centre in Toronto, Canada. Attendees can enjoy a week of pharmaceutical biotechnology programming at the 2008 AAPS National Biotechnology Conference.

Participants can join in three days of conference programming consisting of a Plenary Session, Symposia, Roundtables and Sunrise Sessions. Some of the sessions that encompass the full program include Plant-based Biologics, Storage and Shipment of Biologics, Quality by Design, Inhibitors, Immunogenicity and Gene Therapy. The conference concludes by offering attendees the opportunity to attend one of four AAPS sponsored short courses, all of which are certain to engage your interest.

This conference will also feature a fully operational Career Center, including job postings, a résumé database, and interview facilities. Additionally, a full Exposition Hall will be hosting major companies. The call for papers submission has been released; check the NBC website, www.aapspharmaceutica.com/nationalbiotech, for further details regarding topics and submission deadlines.

If you have any questions about the program or registration procedures, please contact the AAPS office, (703) 2432800, or, send an email to meetings@aaps.org.

The 2008 AAPS National Biotechnology Conference is designed to provide a complete educational event allowing each and every attendee the ability to customize their experience. Biotechnology is the cutting edge and AAPS is there with you.

The online preliminary program now available at: www.aapspharmaceutica.com/meetings/biotech/bt08/prelim

Have an idea for a Meeting? AAPS wants to hear from you.

To submit an idea, go to www.aapspharmaceutica.com/meetings, and click on the "Submit an idea" button
Email meetings@aaps.org for more information

www.aapspharmaceutica.com/meetings

AAPS Workshop on Drug Discovery Strategies and Critical Issues for Clinical Candidates

May 19–21, 2008
South San Francisco Conference Center,
San Francisco, CA
Co-sponsored with EUFEP and SOT

Goals and Objectives:

The Strategies for Preclinical Drug Discovery and Delivery Interface Workshop is intended to introduce those people who are less familiar with pre-clinical evaluations, which lead to drug-like molecules, an opportunity to get introduced to those disciplines prior to the main meeting.

The discovery and development of quality drug leads and clinical candidates, which will eventually become novel drugs to address un-met medical needs, remains a significant challenge to pharmaceutical scientists. It is increasingly clear that integration of drug-like properties into the early stages of drug discovery is advantageous to efficient and effective drug development. This meeting will examine the critical issues of compound selection and quality, safety, pharmacokinetics and formulation. Symposia and speakers will be selected to enhance our collective knowledge on the discovery and development of novel lead molecules that have drug-like properties and can lead to clinical development candidates. Key areas of focus will include state-of-the-art techniques to mine SAR to identify promising lead compounds, study drug-like properties, screen for early safety concerns, and novel approaches to early formulation. The meeting will target academic and industrial scientists from the following disciplines: discovery medicinal chemists and biologists, DMPK and toxicology scientists and formulation scientists. This conference on Drug Discovery Strategies will provide a forum for pharmaceutical scientists to exchange ideas on the state-of-the-art techniques to study drug discovery, enhance knowledge about the relative importance of drug-like properties, and provide an opportunity to learn of the cutting edge science in this area through seminars by invited speakers. For more information, please visit: www.aapspharmaceutica.com/DDS

Biomarker Assay Development and Validation: Challenges and Creative Solutions Associate with Emerging Biomarker Assays

November 15–16, 2008
Georgia World Congress Center, Atlanta GA

The goal of this workshop/training course is to initiate discussions on the current concepts for the qualification and

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validation of biomarker assays and the application of these concepts to non-conventional (non-ELISA based) biomarker assays. This workshop/training course will include two sessions: the first session will take the form of a biomarker assay development and validation tutorial, providing in-depth training on the fit-for-purpose method development and validation approach advocated in the 2006 White Paper (Lee, *et al.*). Specific topics will include biomarker nomenclature, an overview of various biomarker methods types, a comparison of biomarker, PK and clinical diagnostic assays, and an overview of general approaches as well as specific case studies to illustrate best practices for biomarker assay development. In addition, common issues encountered in biomarker assays such as selection of the reference standard curve and appropriate QC materials, fit-for-purpose assay acceptance criteria, and the pros and cons of utilizing commercial assay kits will also be discussed. The second session will focus on development and validation challenges and creative solutions associated with less-conventional biomarker assay platforms such as qRT-PCR, Flow Cytometry, ELISPOT, Cell Search, and various multiplex platforms such as Luminex, Meso Scale Discovery (MSD) and LC/MS. Both sessions will rely heavily on real life case study examples to illustrate the concepts of fit-for-purpose biomarker method development and validation, and successful implementation of biomarker efforts in drug development.

AAPS Section News — Implementation has begun!

AAPS Members will need to examine and make decisions around how to affiliate with the available AAPS Sections. AAPS Members can now fully affiliate with up to two AAPS Sections of their main interest and do not have to make the choice of which should be their primary and secondary sections. AAPS Members wishing to affiliate with more than two AAPS Sections will be charged \$5.00 for each additional affiliated AAPS Section.

AAPS now has nine Sections available for AAPS Members:

- ▶ **Analysis and Pharmaceutical Quality Section**—provides a forum for the exchange of information pertaining to analytical techniques, regulatory and compendial issues, and assurance of quality.
- ▶ **Biotechnology Section**—enables individuals from multiple scientific disciplines to address issues, share information and experimental findings, and provide education for research, development, and commercialization of new biopharmaceuticals.
- ▶ **Clinical Pharmacology and Translational Research Section**—provides the clinical research dimension within the comprehensive range of pharmaceutical sciences and is concerned with issues related to the clinical use of pharmaceuticals.
- ▶ **Drug Design and Discovery Section**—encourages the generation of knowledge concerning the chemistry, biochemistry, and pharmacological actions of synthetic and naturally occurring medicinal agents.

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▶ **NEW—Formulation Design & Development Section**—unites multiple scientific disciplines in order to share experimental results, consider new formulation and dosage form technologies, and discuss issues and concerns regarding the design and development of formulations/drug products for small molecules.

▶ **NEW—Manufacturing Science & Engineering Section**—composed of scientists and engineers interested and involved in the application and advancement of science and technology to the manufacture of pharmaceutical and pharmaceutical-related products.

▶ **Pharmacokinetics, Pharmacodynamics and Drug Metabolism Section**—provides a forum to examine issues related to the biopharmaceutics, pharmacokinetics, pharmacodynamics, drug metabolism and transport of pharmaceutical products and therapies.

▶ **NEW—Physical Pharmacy & Biopharmaceutics Section**—focuses on a quantitative understanding of the intrinsic properties of the small drug molecule and the interacting biological system, enabling the selection of developable drug candidates and the identification of potential strategies for optimal drug delivery.

▶ **Regulatory Sciences Section**—analyses information on product performance, addresses issues regarding drug law and resultant regulations, and promotes science-based regulations to help drug regulatory agencies protect public health and safety.

For more information, please visit:

www.aapspharmaceutica.com/inside/Sections

Members can re-affiliate immediately. View your current profile and make any adjustments at: www.aapspharmaceutica.com

If you have any questions, please contact our Member Relations Specialists at: membership@aaps.org or call (877) 998-AAPS (2277)

Upcoming AAPS Meetings

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

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2008 AAPS Annual Meeting and Exposition
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