

AAPS Update

AAPS—YOUR FORMULA FOR SUCCESS!

September 2008

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

November 15–16, 2008

Georgia World Congress Center, Atlanta GA

The goal of this workshop is to initiate discussions on the current concepts for the qualification and validation of biomarker assays and the application of these concepts to non-conventional (non-ELISA based) biomarker assays. This workshop 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.

Please visit www.aapspharmaceutica.com/Biomarkers for more information.

2008 AAPS Annual Meeting and Exposition

November 16–20, 2008

Georgia World Congress Center, Atlanta GA

AAPS expects nearly 9,500 attendees representing dozens of countries at the 2008 AAPS Annual Meeting and Exposition. This is a prime opportunity for you to showcase your research; network with your colleagues doing similar work; and contact possible employers and clients.

As you know, the AAPS Annual Meeting and Exposition is the premier educational event in the pharmaceutical sciences that represents multiple disciplines from the global community. AAPS offers you the diverse programming you demand, while maintaining the high quality and depth you have come to expect. Block out your calendars now for November 16–20, 2008 so you don't miss a single day of the AAPS Annual Meeting and Exposition.

Please visit www.aapspharmaceutica.com/annualmeeting for more information.

AAPS Section News

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.
- ▶ Formulation Design and 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.
- ▶ Manufacturing Science and 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 pharmaceutically 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.
- ▶ Physical Pharmacy and 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
- ▶ AAPS 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)

AAPS Membership Offers Numerous Benefits

AAPS can help you stay informed and connected, as you move your career forward and save money.

Stay Informed

- ▶ Sections
- ▶ Focus groups
- ▶ Discussion groups
- ▶ Student center
- ▶ AAPS meetings, workshops, and short courses
- ▶ AAPS press and publications
- ▶ A portfolio of scientific journals
- ▶ AAPS newsmagazine
- ▶ Key links

Networking Opportunities

- ▶ Make new professional contacts
- ▶ Interact with your scientific peers
- ▶ AAPS membership directory
- ▶ Mentoring program

Career Advancement

- ▶ Awards programs/peer recognition
- ▶ Scholarships/grants/travelships

- ▶ AAPS career center
- ▶ AAPS online job listings

Money Saving Opportunities

- ▶ Registration discounts at AAPS scientific workshops, short courses, and meetings
- ▶ Enjoy special savings on journal subscriptions and AAPS press publications
- ▶ AAPS job listings
- ▶ Twenty-five percent off all Springer book purchases

Upcoming AAPS Meetings

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

▶ November 15-16, 2008

AAPS 2008 Workshop on Biomarker Assay Development and Validation: Challenges and Creative Solutions
Associated with Emerging Biomarker Assays
Georgia World Congress Center, Atlanta, GA

▶ November 15-16, 2008

AAPS 2008 Workshop on Pharmacogenetics in Individualized Medicine: Methods, Regulatory and Clinical Applications
Co-sponsored with FIP
Georgia World Congress Center, Atlanta, GA

▶ November 15-16, 2008

CRS/AAPS 2008 Workshop for Critical Variables in the *In Vitro* and *In Vivo* Performance of Parenteral Sustained Release Products
Georgia World Congress Center, Atlanta, GA

▶ November 16-20, 2008

2008 AAPS Annual Meeting and Exposition
Georgia World Congress Center, Atlanta, GA

▶ February 1-6, 2009

AAPS 2009 Arden Conference "Sterile Alternatives to Oral Modified Release—Critical Issues in Design, Development and Manufacture"
The Thayer Hotel, West Point, NY

▶ Spring, 2009

AAPS 2009 Workshop on Utilization of Process Modeling and Advanced Process Control in QbD based Drug Development and Manufacturing
Washington, D.C. Metro Area

▶ May, 2009

AAPS 2009 Workshop on Physical Pharmacy and Biopharmaceutics
Mid-Atlantic Region

▶ February/March, 2009

AAPS 2009 Workshop on CMC Aspects for the eCTD: Learning from Challenges, Embracing Opportunities and Developing Strategic Solutions
Washington, D.C. Metro Area

