

AAPS Connection

American Association of Pharmaceutical Scientists

May 2009

AAPS e.Learning Webinars at no cost to you!

AAPS periodically hosts successful webinars, each serving hundreds of members and non members alike from all over the world. So mark your calendars for these upcoming live events, free of charge!

Tuesday, May 12, 2009
12:30 p.m.–2:00 p.m. EDT

Characterization of Solids by Thermal Methods

Presented by Yuchuan Gong, Ph.D., Abbott
Moderated by Ping Gao, Ph.D., Abbott
Sponsored by AstraZeneca—Organized by the AAPS
PPB Section.

Wednesday, May 27, 2009
12:30 p.m.–2:00 p.m. EDT

Linking Drug Effects to Target Site Concentrations by Microdialysis—PART 2

Presented by Drs. Ralph Clinkers, William Couet, and Hartmut Derendorf.
Moderated by Elizabeth de Lange, Ph.D.,
Leiden/Amsterdam Center for Drug Research
Sponsored by AstraZeneca and organized by the AAPS
PPDM Section.

To get all the information about upcoming and archived webinars, please read our up-to-date list of webinars at:
www.aapspharmaceutica.com/webinars



AAPS Workshop on Translational Biomarkers for Accelerating Drug Development: from Preclinical to Clinical

May 6–7, 2009
Sheraton Inner Harbor Hotel, Baltimore, MD
Co-sponsored with ACCP

Workshop Goals

The Biomarker market will reach \$2.5 billion by 2012 according to an April, 2008 article in R&D Directions. Biomarkers are being discovered and used for drug target discovery as well as decision-making during development, and are also being used clinically for disease diagnosis and treatment. The FDA has published its Critical Path Initiative and is working with experts from the academicians and industry to facilitate biomarker qualification for drug development and clinical application. In short, biomarkers are an important area for drug development and disease treatment.

The objectives of this workshop are:

- ▶ Provide pharmaceutical scientists, academicians and regulatory scientists with a dialogue opportunity and educational highlights of biomarkers application in drug development and disease diagnosis/prognosis and treatment;
- ▶ provide an overview of how biomarkers are being utilized in drug discovery, translating preclinical lead to clinical trials, and for bedside applications;
- ▶ provide an educational opportunity for understanding how biomarkers are used pre-clinically and clinically and the challenges for translating preclinical biomarkers to clinical application;
- ▶ use various diseases, including cancers, dyslipidemia, osteoporosis, and organ transplantation, as examples to illustrate recent success and challenges ahead in application of biomarker to drug development and disease treatment;
- ▶ cover biomarkers from genomics to proteomics to imaging, and showcase the diversity and breadth of biomarkers application in drug development;
- ▶ enable the attendees to take away the message of how biomarkers could be interpreted mechanistically with mathematics for analyzing the exposure/response relationship to guide treatments for better clinical outcomes; and
- ▶ update the regulatory perspectives concerning biomarker qualifications.

Posters will be available at this workshop.

For more information, please visit:

www.aapspharmaceutica.com/TranslationalBiomarkers

AAPS Workshop on Evolving Science and Technology in Physical Pharmacy and Biopharmaceutics

May 13–14, 2009

Baltimore Hilton Hotel, Baltimore, MD

Co-sponsored with FDA and USP

Goals and Objectives

- ▶ describe physicochemical characterization of drug substance properties including solubility and stability;
- ▶ reiterate understanding and practice for solid polymorphism evaluation, salt selection, co-crystals consideration, and powder characterization;
- ▶ present assessment of permeability and transporters *in vitro* and *in vivo*; and
- ▶ discuss oral drug absorption prediction and impact of formulation, dissolution and food effect on bioavailability.

For more information, please visit:

www.aapspharmaceutica.com/PhysicalPharmacy

AAPS Workshop on The 21st Century Bioanalytical Laboratory: Maximizing Quality and Efficiency Through Innovation

June 20–21, 2009

Washington State Convention and Trade Center Seattle, WA

Co-sponsored with ALA

Goals and Objectives

A common theme throughout drug development is to “do more with less” and reduce the cost of drug development. One way to obtain more results with fewer resources and reduced costs is to be more efficient. The 21st century ligand binding assay laboratories must harness potential synergies between technology platforms, innovative optimization approaches, robotics, software programs, LIMS and electronic lab notebooks. The current consensus is that most ligand binding assay laboratories have not achieved the level of efficiency that is possible. Some of the reasons for this lack of efficiency include: dependence on manual processes, lack of instrument and system integration, reliance on paper, and lack of functionality by the LIMS. Many companies are building efficiencies and integrated systems within their own bioanalytical laboratories using similar but individualized approaches. Yet the commonality of the challenges and approaches to addressing issues of inefficiency in individual ligand binding labs suggests opportunities to develop more

widely accessible technologies. The purpose of this workshop will be to provide a vision of the ideal 21st century laboratory. In order to build the vision, we will outline the challenges and unique aspects of LBA laboratory processes and workflow and provide examples of successful components that, if combined, would create the ideal laboratory.

For more information, please visit:

www.aapspharmaceutica.com/21stCentury

Upcoming AAPS Meetings

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

▶ May 6-7, 2009

AAPS Workshop on Translational Biomarkers for Accelerating Drug Development: From Preclinical to Clinical
Co-sponsored with ACCP
Sheraton Inner Harbor Hotel, Baltimore, MD

▶ May 13-14, 2009

AAPS Workshop on Evolving Science and Technology in Physical Pharmacy and Biopharmaceutics
Co-sponsored with FDA and USP
Baltimore Hilton Hotel, Baltimore, MD

▶ June 20-21, 2009

AAPS Workshop on The 21st Century Bioanalytical Laboratory: Maximizing Quality and Efficiency Through Innovation
Co-sponsored with ALA
Washington State Convention and Trade Ctr., Seattle, WA

▶ June 21-24, 2009

AAPS 2009 National Biotechnology Conference
Washington State Convention and Trade Ctr., Seattle, WA

▶ June 25-26, 2009

LBABFG Immunogenicity LBA Training Course
Washington State Convention and Trade Ctr., Seattle, WA

▶ September 24-25, 2009

AAPS Workshop on Current Trends in Stability–Challenges with Today’s New Products
Washington, D.C. Metro Area

▶ November 7, 2009

AAPS Workshop on Quantitative Model-based Drug Development in Drug Discovery and Translational Research
Los Angeles, CA

▶ November 7-8, 2009

CRS/AAPS Workshop on Development and Regulatory Challenges for Controlled Release Formulations
Los Angeles Convention Center, Los Angeles, CA

▶ November 8-12, 2009

AAPS 2009 Annual Meeting and Exposition
Los Angeles Convention Center, Los Angeles, CA

