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AAPS Connection

American Association of Pharmaceutical Scientists September 2011

2011 AAPS Annual Meeting and Exposition Keynote Speaker


Janet Woodcock, M.D

Janet Woodcock, M.D., is the Director of the Center for Drug Evaluation and Research at FDA. She previously served as FDA Deputy Commissioner and Chief Medical Officer.

Dr. Woodcock has led many cross-Agency initiatives while at FDA. She introduced the concept of pharmaceutical risk management in 2000 as a new approach to drug safety. She has led the "Pharmaceutical Quality for the 21st Century Initiative" since 2002. This effort, to modernize pharmaceutical manufacturing and its regulation through the application of modern science and quality management techniques, has been highly successful in meeting its objectives. She has spearheaded an initiative on pharmacogenomics that has led to unprecedented agency-industry interactions on pharmacogenomics use in drug development. In 2004, she introduced FDA's "Critical Path" initiative to improve the scientific basis for medical product development. Most recently, she launched the "Safety First" and "Safe Use" initiatives that are designed to improve drug safety management within and outside the FDA, respectively.

Prior to joining CDER, Dr. Woodcock was director of the Office of Therapeutics Research and Review, Center for Biologics Evaluation and Research (CBER), where she oversaw approval of the first biotechnology-based treatments for multiple sclerosis and cystic fibrosis. She also served as Acting Deputy Director of CBER for several years.

Dr. Woodcock received her M.D. from Northwestern University Medical School in 1977. She received her undergraduate degree from Bucknell University. She has held teaching appointments at Pennsylvania State University and the University of California at San Francisco. She has also received three HHS Secretary's Distinguished Service Awards, the HHS Asian-Pacific Network achievement award (2001), and six FDA Commissioner's Special Citations. She has authored over 60 publications.

Coming This Autumn: AAPS Website Redesign

After almost two years of data gathering, analysis, surveying AAPS members, usability studies, testing, and hard work, the AAPS website is gearing up for its latest redesign.

Some of the new features AAPS members will enjoy include

- a brand new look and feel
- collaborative areas for section groups, student chapters, focus groups, and discussion groups
- member self-service area to facilitate managing member accounts and registering for events
- improved searching capability
- RSS feeds
- more members-only content

Conduct a Targeted Job Search with AAPS Online Career Center!

Your profession isn't for everyone, and we don't think your job board should be either. The AAPS Online Career Center, a member of the National Healthcare Network (NHCN), is dedicated to the pharmaceutical science industry and its professionals. We provide access to some of the best, high-profile, niche job openings locally and nationwide, from the industry's leading companies and affiliates.

The AAPS Online Career Center virtual search agent will act as your headhunter to find the openings that best suit your specific career goals. Our application process is easy, free and confidential, so you can post with confidence. You've worked hard to get where you are—now allow the AAPS Online Career Center to help make it easier to get where you're going.

Visit the AAPS Online Career Center at **http://careers.aaps.org**.

AAPS Workshop on the Role of Pharmacogenomics (PGx) in Reducing Adverse Drug Reactions (ADRs)

October 22–23, 2011
Walter E. Washington Convention Center
Washington, D.C.
Co-sponsored with FDA

The goals of the workshop are to

- provide an overview of new developments in the area of PGx that are related to ADRs,
- discuss the process of identifying genetic/genomic factors that might play a role in reducing drug-associated adverse events,
- discuss how PGx can be used in regulatory decision making,
- assess the clinical utility of genetic/genomic tests, and
- apply PGx in drug development and in clinical decisionmaking.

Preliminary programs posted at
www.aapspharmaceutica.com/PGxADRs.

AAPS Workshop on Facilitating Oral Product Development and Reducing Regulatory Burden through Novel Approaches to Assess Bioavailability/ Bioequivalence

October 22–23, 2011
Walter E. Washington Convention Center
Washington, D.C.
Co-sponsored with FDA and EUFEPS

During this workshop, we will

- provide a forum to discuss approaches to consider drug biopharmaceutic data in product development;
- discuss strategies and techniques to reduce resources expended on BA/BE assessments;
- review and discuss the industrial and regulatory experience and perspective on using the Biopharmaceutics Classification System (BCS) guidance and *In Vitro-In Vivo* Correlation (IVIVC) guidance for regulatory applications;
- discuss current issues in bioequivalence of oral products, including highly variable drugs and drugs needing early exposure evaluation (e.g. some modifiedrelease);
- provide a forum to discuss formulation development case studies (*e.g.* pediatric formulations).

Preliminary programs posted at
www.aapspharmaceutica.com/oralproduct.

AAPS Workshop on Pharmaceutical Stability—Scientific and Regulatory Considerations for Global Drug Development and Commercialization

October 22–23, 2011
Walter E. Washington Convention Center
Washington, D.C.
Co-sponsored with CHPA, GPhA, USP

The meeting will provide participants with the current scientific approaches, industry best practices and global regulatory trends to

- design stability strategies to develop drug substances and drug products to meet diverse global regulatory requirements;
- apply Quality by Design approaches for optimum stability-indicating methods, validations, and stability protocols;
- predict and identify stability-related problems during drug product development;
- understand unique stability challenges and solutions for biopharmaceutical products.

Preliminary programs posted at
www.aapspharmaceutica.com/stability.

Upcoming AAPS Meetings

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

- **October 22-23, 2011**
  AAPS Workshop on Facilitating Oral Product Development and Reducing Regulatory Burden through Novel Appoaches to Assess Boavailability/Bioequivalence
  Walter E. Washington Convention Center, Washington, D.C.
- **October 22-23, 2011**
  AAPS Workshop on the Role of Pharmacogenomics (PGx) in Reducing Adverse Drug Reactions (ADRs)
  Walter E. Washington Convention Center, Washington, D.C.
- **October 22-23, 2011**
  AAPS Workshop on Pharmaceutical Stability—Scientific and Regulatory Considerations for Global Drug Development and Commercialization
  Walter E. Washington Convention Center, Washington, D.C.
- **October 23-27, 2011**
  25th AAPS Annual Meeting and Exposition
  Walter E. Washington Convention Center, Washington, D.C.
- **March 11-14, 2012**
  47th Annual Pharmaceutical Technologies Arden House Conference Nanoscience in Pharmaceuticals: Translating Fundamental Understanding to Practical Application in Drug and Device Development
  The Thayer Hotel,West Point, NY
- **May 21-23, 2012**
  2012 AAPS National Biotechnology Conference
  Sheraton San Diego Hotel and Marina, San Diego, CA