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AAPS Connection

American Association of Pharmaceutical Scientists August 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, which is designed 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 and the HHS Asian-Pacific Network achievement award (2001) and six FDA Commissioner's Special Citations. She has authored over 60 publications.

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

October 22–23, 2011
Walter E. Washington Convention Center
Washington, D.C.

Goals and Objectives

This workshop will feature current issues in oral biopharmaceutics in product development and oral bioequivalence. Emphasis will be placed upon best product development practices and Quality-by-Design (QbD) implementation, including early QbD or formulation design, as well as novel

approaches to assess bioequivalence. Over-arching themes include reduction in regulatory burden and international regulatory harmonization.

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 modified-release; and
- provide a forum to discuss formulation development case studies, e.g., pediatric formulations.

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

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.

Goals and Objectives

Adverse drug reactions (ADRs) have been reported to be the fourth leading cause of death in the USA. They are also responsible for up to 12% of hospital admissions, and the associated costs may exceed $177 billion annually in the USA alone. The causes for ADRs are many and include product defects, medication errors, and differences in drug exposure. The ADRs caused by drug exposure are believed to be responsible for ~60% to 90% of adverse events. Pharmacogenomics has helped us to understand some of the factors responsible for ADRs caused by high exposures and factors associated with the mechanism-of-action of the drug. The reasons underlying some ADRs are not understood and are termed "unavoidable" or "idiosyncratic". Recently, some examples have surfaced where genetic markers identified patients at risk for serious, often life-threatening, ADRs before administration of drugs. Thus, pharmacogenomics holds great promise in identifying individuals at risk of developing an ADR and assists in the determination of the appropriate dose for the individuals. Identification of the genetic/genomic risk factors begins at the bench and culminates in the use of the genetic/genomic test for individualized medicine (dose selection, drug selection or patient selection).

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

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.

Goals and Objectives

The meeting will provide participants with an overview of 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; and
- understand unique stability challenges and solutions for biopharmaceutical products.

Stability of a pharmaceutical product throughout shelf-life is an integral component of a product's Quality Target Product Profile (QTPP). Pharmaceutical scientists face enormous challenges in developing increasingly complex new products that have to meet diverse stability requirements for global registration. Stability evaluation of these products using limited resources and reduced cost and within aggressive timelines requires best scientific practices and creative approaches, while meeting complex regulations across the globe. The workshop will bring together scientists and regulators to discuss best scientific approaches, current industry practices, global regulations, and their impact on drug development and commercialization.

For more information, please visit
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 Approaches to Assess Bioavailability/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**
  2011 AAPS Annual Meeting and Exposition
  Walter E. Washington Convention Center
  Washington, D.C.