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AAPS Connection

American Association of Pharmaceutical Scientists May 2011

Celebrate with AAPS in 2011!

AAPS will celebrate its 25th anniversary in 2011! AAPS has spent the past 25 years offering timely educational programming and professional development opportunities to pharmaceutical scientists. AAPS will commemorate its 25th year by recognizing the ways the organization has developed science and impacted health. Upcoming issues of the *AAPS Newsmagazine* will include articles featuring profiles of AAPS founders, AAPS past presidents, and members from diverse disciplines. AAPS will also highlight significant events in the pharmaceutical sciences and present AAPS's impact in the field during the past 25 years. Plus, we'll look ahead to what the future may have in store for the pharmaceutical sciences. There will be other exciting events throughout the year, all culminating at the AAPS 25th Anniversary Celebration at the 2011 AAPS Annual Meeting and Exposition in Washington, D.C.

For more information please visit **aapspharmaceutica.com/annualmeeting**.

Network through AAPS Online Career Center!

Networking is an essential part of any successful job search, and the AAPS Online Career Center makes it easier with the "email to a friend" feature. Perhaps you know someone at a company you're targeting, or maybe you'd like to assist someone who's looking for a job. With the AAPS Online Career Center, you could find a great job for yourself or see something that would be perfect for someone else. The AAPS Online Career Center makes it easy to pass that tip to a friend. Visit our website today at **http://careers.aaps.org** to view available openings.

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., USA

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/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**.

2011 AAPS Annual Meeting and Exposition

October 23–27, 2011
Walter E. Washington Convention Center
Washington, D.C., USA

The 2011 Annual Meeting Programming Committee met in early January to select and schedule the scientific program for the 2011 AAPS Annual Meeting and Exposition. All sections were represented at the meeting in order to collaborate on the final program which will feature 31 symposia, 35 roundtables and mini-symposia, 15 sunrise sessions and 6 short courses. All sessions are planned around the following themes:

- Bioequivalence
- Biopharmaceutics Classification System (BCS)
- Combination Products
- Modified Release
- Nanotechnology
- Quality by Design
- Systems Analysis

Sessions will also cover diverse topics such as clinical supply chain, transporters, regulatory challenges in emerging markets, modeling, genotoxic impurities and hot melt extrusion.

Full details on the program will be available in the Preliminary Program which will be launched in early May.

2011 AAPS Annual Meeting and Exposition KEYNOTE SPEAKER

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). There 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.