Pharm Res (2011) 28:1442–1444
DOI 10.1007/s11095-011-0466-x

AAPS Connection

American Association of Pharmaceutical Scientists June 2011

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.

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 ADRs. 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 assist 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).

A keynote lecture will introduce the concept of utilizing PGx to reduce ADRs. The process of identifying and confirming the genetic/genomic biomarkers that can help reduce ADRs will be highlighted throughout the workshop with case studies.

The workshop objectives and benefits to the attendees include a) learning about new developments in the area of PGx that are related to ADRs, b) understanding the process of identifying genetic/genomic factors that might play a role in reducing drug-associated adverse events, c) learning how PGx can be used in regulatory decision making, d) comprehending the clinical utility of the genetic/genomic tests, and e) applying PGx in drug development and in clinical decision-making.

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, at reduced costs, and within aggressive timelines requires the best scientific practices and creative approaches, while meeting complex regulations across the globe. The workshop will bring together scientists and regulators to discuss the best scientific approaches, current industry practices, global regulations, and their impact on drug development and commercialization. The workshop will benefit pharmaceutical scientists and managers with responsibility for a variety of functions related to drug development and commercialization, including analytical development, formulation development, stability evaluation, quality control and regulatory affairs.

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

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▶ **October 23-27, 2011**
2011 AAPS Annual Meeting and Exposition
Walter E. Washington Convention Center
Washington, D.C.