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AAPS Connection

American Association of Pharmaceutical Scientists December 2013

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For more information visit **www.aaps.org/jobs** or email the AAPS Senior Marketing Specialist Kevin Folk at FolkK@aaps.org.

Be Recognized by Your Peers at the AAPS National Biotechnology Conference

The AAPS awards program provides a wonderful opportunity for scientists and graduate students to be recognized and honored for their valuable contributions to the pharmaceutical sciences. Please view the 2014 awards and travelships offered at our National Biotechnology Conference, and nominate your colleagues today.

Award nomination material can be found at www.aaps.org/NBCAwards.

AAPS Fellows Webinar

AAPS has a strong commitment to the recognition of select AAPS members through their designation as Fellow.

AAPS will be hosting a 1-hour webinar on **Wednesday, December 11, 2013, 1:00 pm (Eastern Standard Time).** The webinar will describe how to develop a nomination package according to the Fellows Process outlined by the Fellows Committee. The nominator is responsible for assembling and submitting the completed nomination package, which must be received by the AAPS Office on **Friday**, **March 14, 2014.**

For more information, visit www.aaps.org/About_AAPS/Fellows.

Workshop on Quantitative Bioanalytical Methods Validation and Implementation: The 2013 Revised FDA Guidance

Cosponsored by FDA
December 3–5, 2013
Hilton Baltimore, Baltimore, MD

AAPS Regular Member SAVINGS
AAPS members save $420.00 at early registration.

The draft revision to the U.S. Food and Drug Administration (FDA) Guidance on Bioanalytical Method Validation has the potential to have a significant impact on the bioanalytical community and thereby all pharmaceutical and biotechnology companies and the contract research organizations (CROs) that support them. Four previous conferences (1990, 2000, 2006, and 2007) between the American Association of Pharmaceutical Scientists (AAPS) and FDA were very successful. Starting in 1990, the first meeting established a dialogue between industry and agency that was then enhanced in the subsequent meetings. The bioanalytical and scientific needs that intersected with regulatory compliance and patient safety were freely discussed and debated to produce best practices and influence the FDA in finalizing the first guidance in 2001. Subsequent AAPS/FDA meetings resulted in white papers that have served as de facto guidance to the industry. The FDA has released a draft revision of its 2001 guidance to incorporate the recent advances in bioanalysis in September 2013.

Goals and Objectives

- To provide a forum for open discussion between industry and the agency around FDA's 2013 draft revision to the Bioanalytical Method Validation Guidance.
- To permit science-based industry perspectives to align and harmonize around the new proposals.
- To understand the implications and reasoning behind the revisions and new aspects of the guidance.
- To provide global industry input to FDA.

For more information visit www.aaps.org/BMV.

Read the revised FDA draft guidance at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM368107.pdf.

49th AAPS Arden Conference: Development of Pediatric Formulations: Challenges and Opportunities

February 24–26, 2014
USP Meetings Center
Rockville, MD

AAPS Regular Member SAVINGS
AAPS members save $425.00 at early registration.

The need for pediatric pharmaceutical formulations has been growing rapidly in recent years as a result of the recognition that children are often underserved by ad hoc compounding of adult formulations and increased regulatory incentives. Pediatric drug products can be challenging to develop due to their unique requirements and limitations.

Examples of these challenges include:

- Effects of growth and development on drug ADME
- Poorly soluble drugs with incomplete absorption
- Safety concerns of commonly used excipients in pediatric patients
- Taste evaluation and masking
- Age-appropriate dosage forms and flexible dosing
- Combination drug products for pediatric patients.

In order to address the increasing need of developing innovative age-appropriate pediatric products, also driven by regulatory requirements, the pharmaceutical industry is committed to meeting pediatric patients' needs.

Goals and Objectives

- Present current state-of-art technologies suitable for pediatric drug products.
- Review technical issues, including flexibility of dose titration, ease of administration and swallowing, palatability, solution stability, microbial challenges, dosing and measuring devices, considerations of a multi-phase and/or multi-use product, and packaging.
- Discuss practical development strategies to facilitate the selection of pediatric dosage forms for clinical trials and commercial manufacturing.
- Discuss special considerations and issues unique to pediatric products from the regulatory agency perspective (US FDA and the EMEA).
- Initiate a flow diagram/guideline for pediatric formulations development.

For more information visit www.aaps.org/Arden.

AAPS Connection **December 2013**
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