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AAPS Connection

American Association of Pharmaceutical Scientists July 2009

AAPS eLearning Announces a New Product Release!

The Ligand Binding Assay Training Program on DVD-ROM

Recorded at the 2008 AAPS National Biotechnology Conference in Atlanta, this is a menu-driven, interactive course on DVD-ROM data disc containing 13 h of video (synchronized PowerPoint slides with audio lecture), printable pdf files for each presenter, and mp3 audio files for transfer to your favorite digital audio player. On-screen instructions for each menu selection; no complicated manual needed!

Complete details at: **www.aapspharmaceutica.com/LBA**

AAPS Workshop on Current Trends in Stability—Challenges with Today's New Products

September 24–25, 2009
Gaylord National Resort and Convention Center
National Harbor, MD

The role of stability in today's pharmaceutical development process and ongoing manufacturing environment is increasingly complex. Development, Quality, and Regulatory scientists are faced with many challenges including how to develop methodologies that predict stability, the assessment of stability for increasingly complex drug products, the role of QbD as applied to stability, diverse regulations in worldwide markets, and the continuous pressure to reduce costs.

This workshop will bring together scientists and regulators from around the world to discuss current requirements and best practices to address these challenges:

- Stability strategies and factors in design/formula tion for drug device combinations;
- Regulatory harmonization of worldwide stability requirements—WHO Stability Guideline, Emerging markets, Globalization;
- Stability strategies for proteins, devices, and biotech products including follow-on biologics; and
- Case studies

For more information, please visit:
www.aapspharmaceutica.com/StabilityTrends

AAPS Workshop on Pharmacokinetic/Pharmacodynamic Modeling in Drug Discovery and Translational Research: A Building Block for Quantitative Model-based Drug Development

November 7, 2009
Los Angeles Convention Center
Los Angeles, CA

The area of Preclinical Pharmacokinetic/Pharmacodynamic (PK/PD) Modeling and Simulation is an integral part of quantitative model-based drug development (QMBDD) as it applies to drug discovery; and encompasses a multitude of quantitative approaches to integrate preclinical pharmacology, bio-marker response and safety data toward the selection of the most promising drug targets and the development of the most optimal drug candidates.
This rapidly evolving area has been recognized as critical for pharmaceutical companies to reduce high rates of failures in advancing compounds from the bench to the bedside.

Goals and objectives

- Provide basic education on the concepts and principles of PK/PD modeling and simulation as it applies to drug discovery/preclinical setting, and introduce a range of modeling approaches ranging from empirical to mechanistic models, that can be used to eventually facilitate decision making;
- Use real-time and contemporary case studies from drug discovery to demonstrate how preclinical PK/PD modeling can facilitate knowledge development and decision making during drug discovery;
- Provide practical hands-on training on the key aspects of preclinical PK/PD modeling; topics include PK/PD modeling and simulation for drug target selection, mechanism-based PK/PD modeling for biomarker development, and human dose projection for both small and large molecule (e.g. antibody) compounds; and

- Introduce strategies to overcome challenges associated with the implementation of PK/PD modeling and simulation in drug discovery and development, including silo-structure, interdisciplinary communication and decision-making infrastructure.

For more information, please visit:
www.aapspharmaceutica.com/QMBDD

AAPS Workshop on Special Dosage Forms—What's New with *In Vitro* Drug Release?

November 7–9, 2009
Los Angeles Convention Center
Los Angeles, CA

Dissolution testing is a very important tool in drug development and quality control. Application of dissolution testing has widened to a variety of novel or special dosage forms and is referred as 'drug release' test. The test is used for the biopharmaceutical characterization of the drug product, and as a tool to assure consistent product (batch) quality within a defined set of specification criteria. Ideally, the drug release method should correlate with the *in vivo* performance of the product. However, because of the complexity of the novel dosage form and simplicity of *in vitro* release methodology, it may not be possible to achieve this. Nevertheless, the *in vitro* release methodology should serve to test the key performance of the formulation.

This workshop will present drug release methodologies to evaluate the product performance for special dosage forms, such as, buccal, topical, ophthalmic, inhalation, stent and nanoparticle formulations. It will provide opportunities for the participants to interact with the faculty in panel discussions.

The workshop presentations and discussions should be of interest to scientists working in academia, pharmaceutical industry and regulatory agencies.

CRS/AAPS Workshop on Development and Regulatory Challenges for Controlled Release Formulations

November 7–9, 2009
Los Angeles Convention Center
Los Angeles, CA

Background

In November 2007, AAPS and CRS together held the workshop, Development and Regulatory Challenges for Controlled Release Formulations, which was an enormous success. Workshop attendees, AAPS members, and CRS members have all asked for the next phase of the workshop, and we are pleased to announce that it is coming your way. Watch for more details to come, including how to register.

Goals

For 2009, the workshop will include a combination of FDA and European regulatory perspectives on developing controlled release formulations. There will be speakers participating in open discussions on newly emerging technologies to help individuals understand the challenges in developing the technology of controlled release formulations as well as the regulatory hurdles that these technologies may face. There will also be speakers who are well known experts talking about mature technologies and the associated developmental and regulatory challenges that were encountered along the road to success. We encourage and expect a lively discussion among the attendees, speakers, and regulatory officials that can shed some light on what is expected when working to get a controlled release product to market. The topics were chosen to cover a number of different routes of administration, as each has their own unique challenges. Case studies will be used to demonstrate the speaker's points and engage the attendees.

Upcoming AAPS Meetings

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

▶ **September 24-25, 2009**
AAPS Workshop on Current Trends in Stability—Challenges with Today's New Products
Gaylord National Resort & Convention Center
National Harbor, MD

▶ **November 7, 2009**
AAPS Workshop on Pharmacokinetic/Pharmacodynamic Modeling in Drug Discovery and Translational Research: A Building Block for Quantitative Model-based Drug Development
Los Angeles Convention Center, Los Angeles, CA

▶ **November 7-8, 2009**
AAPS Workshop on Special Dosage Forms—What's New with *In Vitro* Drug Release?
Los Angeles Convention Center, Los Angeles, CA

▶ **November 7-8, 2009**
CRS/AAPS Workshop on Development and Regulatory Challenges for Controlled Release Formulations
Los Angeles Convention Center, Los Angeles, CA

▶ **November 8-12, 2009**
AAPS 2009 Annual Meeting and Exposition
Los Angeles Convention Center, Los Angeles, CA