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AAPS Connection

American Association of Pharmaceutical Scientists March 2015

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50th AAPS Arden Conference: Continuous Manufacturing of Solid Oral Drug Products

Cosponsored by AIChe
March 16–18, 2015
Baltimore Renaissance Harborplace Hotel
Baltimore

The pharmaceutical industry is undergoing great change, and incremental improvement to the decades old batch manufacturing paradigm is no longer sufficient to ensure viability. Fortunately, broad implementation of continuous manufacturing in both API and drug product arenas has great potential to address industry needs. This workshop will provide participants with an up-to-date and in-depth understanding of the benefits, technologies, formulation/process design practices, the degree of uptake within the industry, regulatory considerations and implementation challenges associated with continuous manufacturing for oral solid dosage forms (OSD). Case studies will be used to demonstrate state-of-the-market, gaps, and emerging OSD continuous manufacturing technologies, including automation and measurement systems necessary to integrate equipment in a continuous process train.

For more information, please visit **www.aaps.org/Arden**

AAPS/FDA/USP Joint Workshop Inhalation Biopharmaceutical Product Classification System Development: Challenges and Opportunities

March 16–17, 2015
Baltimore Renaissance Harborplace Hotel
Baltimore

The purpose of this workshop is:

- to determine if an inhalation biopharmaceutical product classification system can be developed for both small molecule and biologic inhaled drug products based on the dose administered and fundamental physico chemical properties of physiological importance.
- to explore and identify the parameters required to establish an in vivo/in vitro correlation for inhaled products and their practical relevance.
- to provide a collaborative, cross-disciplinary forum for scientific discussion.

For more information, please visit **www.aaps.org/Inhalation**

AAPS/ITC Joint Workshop on Drug Transporters in ADME: From the Bench to the Bedside

April 20–22, 2015
Baltimore Renaissance Harborplace Hotel
Baltimore

The joint AAPS/ITC Workshop on Drug Transporters in 2015 will deliver cutting-edge science in a focused and state of the art meeting. Key areas of focus will include:

- transporter tools of the future (e.g. organs-on-a-chip, humanized mouse models and transporter imaging);

- interplay of drug metabolism and transporters;
- state of the art sessions on (i) emerging transporters, (ii) endogenous biomarkers to assess transporter-mediated drug efficacy/toxicity or predict drug-drug interactions, and (iii) quantitative transporter proteomics in translational DMPK;
- hot topics in the translation of transporter data to the clinic;
- prospective transporter substrate modeling; and
- a post-regulatory guidance review of transporter questions.

For more information, please visit **www.aaps.org/Transporters15**

AAPS Workshop on Implementing Biomarkers into Drug Development: Dose Selection to Patient Diagnosis

June 6–7, 2015
San Francisco Marriott Marquis
San Francisco

Held in conjunction with the 2015 AAPS National Biotechnology Conference, the AAPS Workshop on Implementing Biomarkers into Drug Development: Dose Selection to Patient Diagnosis will focus on how biomarkers in drug development can improve cycle times, enhance therapeutic understanding, and identify the correct patient population. In order to achieve these objectives, biomarker implementation must consider proper selection, characterization, implementation, and interpretation. The objective of this workshop is to create a forum for experts in the biomarker field to educate, share best practices, and identify potential risks and challenges in the discipline.

The workshop will be divided into four themes: biomarker selection, analytical characterization, implementation and interpretation. In addition to efficacy and pharmacodynamic biomarkers, the workshop will address key and emerging elements of diagnostic assays.

Goals and Objectives

At the completion of this workshop, participants will have a greater understanding of how biomarkers are applied to the drug development paradigm, the unique aspects of developing a successful biomarker, and the opportunities that biomarkers offer. Each lecture will address specific concepts, definitions, and will highlight specific examples through case studies.

For more information, please visit **www.aaps.org/Biomarkers/**

AAPS Workshop on Challenges of Biologics Stability: From Concepts to Practices

June 6–7, 2015
San Francisco Marriott Marquis
San Francisco

The AAPS Workshop on Challenges of Biologics Stability: From Concepts to Practices will provide a comprehensive summary of stability considerations impacting quality of biologic and large molecules products. Topics will include:

- Working risk assessments into biologics stability design
- What is not in the ICH guidances: Strategies before starting biologics stability studies
- Emerging stability methods for biologics
- Evolving expectations for biologics shipping studies
- In-process hold time studies
- Degradation pathways of mAbs
- Stability studies for antibody-drug conjugates
- Stability studies for biosimilars
- Stability and specification setting strategy for biologics
- Method changes during stability studies

Goals and Objectives

Stability is a key element that has always been on a critical path of the development process for biological products. Adopting the right strategy for stability studies therefore becomes critical for accelerating the development of innovative biologics therapies. The regulatory guidances covering this field have not changed significantly over the past several years. Yet the regulatory expectations have evolved due to several factors. There have been changes in expectations for protein analytical methods in general and therefore on the supportive stability studies. The advent of biosimilars has led to changes in methods toolbox for proteins in general, and the industry continues to learn about the regulatory expectations for biosimilars stability studies. Finally, the increasingly global nature of product manufacturing has increased the need and regulatory expectations for effective, efficient shipping and other auxiliary stability studies.

This workshop is designed to serve as a refresher event to provide information about recent developments in the field of biologics stability for the stability professional, while providing

an overview of the field for the stability professional, who is making the transition from pharmaceuticals to biologics.

This workshop will discuss the foundational aspects of building stability into the development process to enable predictability and provide assurance of safety and efficacy. Innovative methodologies for development of effective stability control strategies will be presented. The workshop will provide participants a forum to discuss a comprehensive array of topics affecting the development of large molecules such as biologics and vaccines. Issues related to shipping studies, photostability and temperature excursions will be explored.

For more information, please visit **www.aaps.org/Biologics/**

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