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AAPS Connection

American Association of Pharmaceutical Scientists May 2015

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2015 AAPS National Biotechnology Conference

June 8–10, 2015
San Francisco Marriott Marquis
San Francisco

The 2015 AAPS National Biotechnology Conference (NBC) will offer five program themes:

- CMC including Formulation, Characterization, Stability and Biomanufacturing
- Research and Discovery
- Clinical Pharmacology, PK/PD and Bioanalytics
- Regulatory
- Biomarkers and Imaging

Visit http://www.aaps.org/NBCRegister/

NBC Plenary Speakers

To view the preliminary program, please visit https://nbc.aapsmeeting.org/

Register today!

Stefan Klein, Ph.D.
Physicist, Author and Essayist

Atul Butte, M.D., Ph.D.
Director, Institute of Computational Health Sciences (ICHS) at the University of California, San Francisco, and Professor of Pediatrics

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/.

AAPS Workshop on Design of Experiments for Bioanalysis and Manufacturing

June 7, 2015
San Francisco Marriott Marquis San Francisco

Held in conjunction with the 2015 AAPS National Biotechnology Conference

Goals and Objectives

The goal of this workshop is for attendees to gain a working knowledge of DOE and its application towards LBAs or process development/manufacturing. By targeting beginning users and separating out attendees based on interest (LBA vs. manufacturing) for two simultaneous break-out sessions, we will be able to focus on fewer case studies, while slowing down the pace of the training and ultimately increase the

confidence that the attendees have in their ability to implement DOE in their laboratory.

Individuals with little to no DOE exposure will be provided with basic DOE-specific concepts, applications in the laboratory, and hands on training. The course will be taught using a "problem-based learning" (PBL) strategy. The first of these problems will be a hands-on experiment that is done during the course so attendees can learn about design, data collection, and data analysis in a model that is easily understood and observed. Following this, a second PBL module will require attendees to perform critical thinking, DOE design, analysis, and interpretation in a more relevant system (optimization of a bioanalytical assay or manufacturing process).

For more information, please visit www.aaps.org/DOE/.