AAPS Connection

American Association of Pharmaceutical Scientists April 2009

AAPS Workshop on Utilization of Process Modeling and Advanced Process Control in QbD based Drug Development and Manufacturing

April 27–28, 2009
Sheraton Inner Harbor Hotel, Baltimore, MD
Co-sponsored with AIChE & SBE, ISPE and FDA

About the workshop

This workshop will bring together scientists and engineers who are recognized experts in process modeling and control with newcomers and regulatory experts in the field to discuss the role of models in QbD based drug development and manufacture. The workshop will consist of invited talks by experts from the pharmaceutical industry, academia, and the FDA. There will also be panel discussions, contributed posters, vendor exhibits and significant time for discussion.

Workshop attendees would be able to:

- ►Gain knowledge about how mechanistic models can be used for process design and scale up;
- ►learn how regression models can be used to define design space and ways to handle the uncertainty associated with design space;
- ►understand how advanced process control models can be applied to consistently deliver quality products;
- ►hear regulatory perspectives on implementation of models in the QbD paradigm; and
- ►gain an understanding of applicability of process systems engineering to drug development.

Posters and exhibits will be available at this workshop.
For more information, please visit:
www.aapspharmaceutica.com/ProcessModeling

AAPS Workshop on Translational Biomarkers for Accelerating Drug Development: from Preclinical to Clinical

May 6–7, 2009
Sheraton Inner Harbor Hotel, Baltimore, MD
Co-sponsored with ACCP

Workshop Goals

The Biomarker market will reach $2.5 billion by 2012 according to an April, 2008 article in R&D Directions. Biomarkers are being discovered and used for drug target discovery as well as decision-making during development, and are also being used clinically for disease diagnosis and treatment. The FDA has published its Critical Path Initiative and is working with experts from the academians and industry to facilitate biomarker qualification for drug development and clinical application. In short, biomarkers are an important area for drug development and disease treatment.

The objectives of this workshop are:

- ►Provide pharmaceutical scientists, academicians and regulatory scientists with a dialogue opportunity and educational highlights of biomarkers application in drug development and disease diagnosis/prognosis and treatment;
- ►provide an overview of how biomarkers are being utilized in drug discovery, translating preclinical lead to clinical trials, and for bedside applications;
- ►provide an educational opportunity for understanding how biomarkers are used pre-clinically and clinically and the challenges for translating preclinical biomarkers to clinical application;
- ►use various diseases, including cancers, dyslipidemia, osteroporosis, and organ transplantation, as examples to illustrate recent success and challenges ahead in application of biomarker to drug development and disease treatment;
- ►cover biomarkers from genomics to proteomics to maging, and showcase the diversity and breadth of biomarkers application in drug development;
- ►biomarkers could be interpreted mechanistically with mathematics for analyzing the exposure/response relationship to guide treatments for better clinical outcomes; and

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- update the regulatory perspectives concerning biomarker qualifications.

Posters will be available at this workshop.
For more information, please visit:
www.aapspharmaceutica.com/TranslationalBiomarkers

AAPS Workshop on Evolving Science and Technology in Physical Pharmacy and Biopharmaceutics

May 13–14, 2009
Baltimore Hilton Hotel, Baltimore, MD
Co-sponsored with FDA

Goals and Objectives

- describe physicochemical characterization of drug substance properties including solubility and stability;
- reiterate understanding and practice for solid polymorphism evaluation, salt selection, co-crystals consideration, and powder characterization;
- present assessment of permeability and transporters *in vitro* and *in vivo*; and
- discuss oral drug absorption prediction and impact of formulation, dissolution and food effect on bioavailability.

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

AAPS Workshop on The 21st Century Bioanalytical Laboratory: Maximizing Quality and Efficiency Through Innovation

June 20–21, 2009
Washington State Convention and Trade Center
Seattle, WA
Co-sponsored with ALA

Goals and Objectives

A common theme throughout drug development is to "do more with less" and reduce the cost of drug development. One way to obtain more results with fewer resources and reduced costs is to be more efficient. The 21st century ligand binding assay laboratories must harness potential synergies between technology platforms, innovative optimization approaches, robotics, software programs, LIMS and electronic lab notebooks. The current consensus is that most ligand binding assay laboratories have not achieved the level of efficiency that is possible. Some of the reasons for this lack of efficiency include: dependence on manual processes, lack of instrument and system integration, reliance on paper, and lack of functionality by the LIMS. Many companies are building efficiencies and integrated systems within their own bioanalytical laboratories using similar but individualized approaches. Yet the commonality of the challenges and approaches to addressing issues of inefficiency in individual ligand binding labs suggests opportunities to develop more widely accessible technologies. The purpose of this workshop will be to provide a vision of the ideal 21st century laboratory. In order to build the vision, we will outline the challenges and unique aspects of LBA laboratory processes and workflow and provide examples of successful components that, if combined, would create the ideal laboratory.

For more information, please visit:
www.aapspharmaceutica.com/21stCentury