

AAPS Connection

American Association of Pharmaceutical Scientists

March 2009

AAPS Workshop on Strategic Management of CMC Dossiers in the eCTD Format: What CMC Professionals Need to Know Now!

March 10-11, 2009

Sheraton Inner Harbor Hotel, Baltimore, MD

Co-sponsored by DIA and RS supported programming

Goals and objectives

By the end of the meeting participants should have a better understanding of:

- ▶ The benefits and flexibility of the eCTD submission process for managing quality data and agency commitments throughout the product lifecycle;
- ▶ available global and regional eCTD guidances and their current interpretations related to chemistry, manufacturing and controls for regulatory processes;
- ▶ authoring and dossier assembly strategies for developing robust quality modules of eCTD submissions that enable efficient lifecycle processes; and
- ▶ current, pending and future opportunities and challenges in managing the quality modules of the eCTD submission process throughout a product lifecycle.

For more information, please visit:

<http://www.aapspharmaceutica.com/CMCAspects>

AAPS Workshop on Scientific and Technological Advances in the Use of Lipid-based Drug Delivery Systems for Bioavailability Enhancement and Tissue Targeting

March 10-11, 2009

Sheraton Inner Harbor Hotel, Baltimore, MD

Goals and objectives

- ▶ realizing and maximizing the drug delivery potential of lipids and lipid-based formulations;

- ▶ addressing fundamental and practical aspects of lipid-based systems;
- ▶ expanding knowledge on the physicochemical and biopharmaceutical aspects of lipids;
- ▶ resuscitating failing drug candidates due to poor solubility, membrane permeability and absorption;
- ▶ maximizing value of drug reformulations and product line extensions; and
- ▶ dealing with regulatory and strategic product development perspectives on lipid systems.

For more information, please visit:

<http://www.aapspharmaceutica.com/Lipids>

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

March 29-April 1, 2009

Sheraton Inner Harbor Hotel, Baltimore, MD

Goals and objectives

Membrane transporters can have a significant impact on the absorption, distribution, metabolism and excretion (ADME) of a drug. Transporters can be an effective barrier to drug exposure, be the rate determining step in the uptake and/or excretion of a compound or metabolite, and be a cause of drug-drug interactions when transporter activity is induced or inhibited. The recognition of the influence of membrane transporters on drug disposition is driving a surge in drug transport-related research activities within the drug metabolism and pharmaceutical sciences. These activities include identifying and cloning the major drug transporter genes; determining the impact of genetic polymorphisms on plasma pharmacokinetics; elucidating the mechanisms regulating gene and protein expression; examining the structure- activity relationship of transporter substrates; and developing assays to support pharmaceutical profiling in drug discovery and development. This workshop on Drug Transporters will provide a forum for academic and industrial pharmaceutical scientists to exchange ideas on the state-of-the-art techniques to study drug transport and uptake, enhance knowledge about mechanisms of drug transport, and provide an

opportunity to learn of the cutting edge science in this area through seminars by invited speakers and focused breakout sessions.

Key areas of focus will include:

- ▶ New, state-of-the-art models for investigation of drug transporters and application of these models to address basic research questions;
- ▶ applications of pharmacokinetic modeling and simulation with drug transporter data; and
- ▶ the role of drug transporters in the areas of toxicology and disease.

For more information, please visit:

<http://www.aapspharmaceutica.com/DrugTransportersADME>

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, Baltimore, MD

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:

<http://www.aapspharmaceutica.com/ProcessModeling>

Upcoming AAPS Meetings

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

▶ March 10-11, 2009

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▶ April 27-28, 2009

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

Sheraton Inner Harbor Hotel, Baltimore, MD

▶ May 6-7, 2009

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

Sheraton Inner Harbor Hotel, Baltimore, MD

▶ May 13-14, 2009

AAPS Workshop on Physical Pharmacy and Biopharmaceutics

Baltimore Hilton Hotel, Baltimore, MD

▶ June 20-21, 2009

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

Washington State Convention and Trade Center, Seattle, WA

▶ June 21-24, 2009

AAPS 2009 National Biotechnology Conference
Washington State Convention and Trade Center, Seattle, WA

