

AAPS Connection

American Association of Pharmaceutical Scientists

June 2009

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AAPS National Biotechnology Conference

June 21–24, 2009
Washington State Convention and Trade Center, Seattle, WA



The Online Preliminary Program is Open!

Go to www.aapspharmaceutica.com/nationalbiotech and explore this new fully Interactive PDF from NxtBook! You can easily navigate, search, print, or save the Preliminary Program to your computer.

The 2009 AAPS National Biotechnology Conference is designed to provide a complete educational event allowing each and every attendee the ability to customize their experience with the goal of advancing health through innovations on biotherapeutics.

Find everything you could want in pharmaceutical biotechnology programming in Seattle. Attendees can join in three full days of conference programming where you are invited to participate in a variety of topics including sessions on Drug-drug Interactions, Protein Engineering, Drug Product Manufacturing, Computation Modeling, Translational Research of Biotherapeutics, and QbD.

The conference concludes by offering participants the opportunity to attend one of three AAPS sponsored short courses, all of which are certain to engage your interest. We encourage your participation in this event by submitting an abstract of your work for presentation in Seattle.

We look forward to your participation in the 2009 AAPS National Biotechnology Conference.

AAPS Workshop on The Twenty-First 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 twenty-first 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 twenty-first 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

AAPS Workshop on Methods for Detecting and Characterizing Sub-visible Particulates

June 21, 2009

Washington State Convention and Trade Center
Seattle, WA

Background Information

Recently a great deal of attention has been focused on the possible impact of particulates in biological therapeutics. In particular, it has been recognized that there is a gap in analysis of "so-called" sub-visible particulates <10 µm. While good methods exist for detecting and characterizing the size distributions of very small (<0.1 µm) particulates, there are fewer analogous techniques that provide accurate size distributions for particulates in the 0.1 to 10 µm size range.

Goals and Objectives

The goal of this workshop is to familiarize pharmaceutical researchers with what current and future technologies are available for characterizing sub-visible particulates in formulations. The workshop will include presentations by researchers who have experience with the existing technologies. However, the emphasis of this workshop will be on new technologies. Technical presentations will be provided by instrument manufacturers on how their upcoming offerings will address pharmaceutical industry and FDA concerns. Questions to be addressed for each technology include: What size range is accessible by the method? What is the sensitivity limit? How does the sensitivity of the method vary over the size range? How well are different sized particulates discriminated? What are the solvent requirements/limitations? Manufacturers will be encouraged to provide hands-on demonstrations of their instruments. A round-table will summarize the day's discussion.

Speakers and Topics to include

- ▶ Steven J. Shire, Ph.D.
Genentech, Inc.
- ▶ Current Sub-visible Particle-size Distribution Technologies
Barthélemy Demeule, Ph.D.
University of Geneva and University of Lausanne
- ▶ Coulter Counter Technologies
Matt Rhyner, Ph.D.
Emory University
- ▶ Light Obscuration Methods
Deepak K. Sharma, Ph.D.
Brightwell Technologies Inc.
- ▶ Thomas M. Scherer, Ph.D.
University of Massachusetts

For more information, please visit:

www.aapspharmaceutica.com/sub-visibleparticulates

AAPS Connection

2107 Wilson Blvd., Suite 700, Arlington VA 22201-3042 USA, Ph: +1 703 243-2800

Upcoming AAPS Meetings

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

▶ June 21, 2009

AAPS Workshop on Methods of Detecting and Characterizing Sub-visible Particulates
Washington State Convention and Trade Ctr., Seattle, WA

▶ June 20-21, 2009

AAPS Workshop on The 21st Century Bioanalytical Laboratory: Maximizing Quality and Efficiency Through Innovation
Co-sponsored with ALA
Washington State Convention and Trade Ctr., Seattle, WA

▶ June 21-24, 2009

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

▶ June 25-26, 2009

LBABFG Immunogenicity LBA Training Course
Washington State Convention and Trade Ctr., Seattle, WA

▶ 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

