

AAPS Update

AAPS—YOUR FORMULA FOR SUCCESS!



May 2006



Co-sponsored with **FDA** & **SOCIETY for BIOLOGICAL ENGINEERING**
An AICHE Technological Community

June 18-21, 2006

John B. Hynes Veterans Memorial Convention Center, Boston, MA

The AAPS 2006 National Biotechnology Conference will feature:

- ▶ Open Forums
- ▶ Posters (submissions by 2/14/06)
- ▶ Exhibits
- ▶ Career Center
- ▶ Advertising and Sponsorship Opportunities
- ▶ Plenary Session
- ▶ Symposia
- ▶ Roundtables
- ▶ Short Courses

Advanced registration and additional registration fees are required for the following sessions:

- ▶ Training Course: Development and Validation of Quantitative Ligand Binding Assays
- ▶ Biotech Open Forum: Protein Aggregation Methodology
- ▶ APQ-BIOTECH Open Forum: Therapeutically Equivalent Biologics—Current Issues and Perspectives of 'Biogenerics'
- ▶ PPDM Open Forum: Implementing FDA's Critical Path Initiative: Is This a 'Big Dig' Challenge for Biotech Development?
- ▶ Short Course on Pharmaceutical Perspective of Synthetic and Hybrid Vectors Based Nucleic Acid Therapeutics
- ▶ Short Course on Special Topics in Neutralizing Antibody Assay Development

For up-to-date information log onto www.aapspharmaceutica.com/nationalbiotech

Special Discounts—Save up to 15%

Register for the following and become eligible for a reduced combination fee:

AAPS Workshop on Current Trends in Monoclonal Antibody Development and Manufacturing

or

Any of the two *AAPS Short Courses* offered in conjunction with this conference

and

The *2006 AAPS National Biotechnology Conference*

Circle the appropriate fee under the Special Discounts section on the registration form to save up to 15%.

Save Money—Group Registrations are Available

Take advantage of this opportunity to register you and your colleagues for this meeting and save hundreds of dollars! Group registration discounts will be applied as follows:

Three fully paid registrations qualify for one additional complimentary registration.

Five or more fully paid registrations qualify for two additional complimentary registrations.

Registrations must be in groups of three or more paid registrants, from the same organization, and cannot be combined with any additional offer. Group registrations are not valid after May 19, 2006 and are available through online registration only. (No faxed group registrations accepted.) All registrations must be made at the same time to qualify. Group registration not available for exhibitor or one-day registrants.

Register your group online at:
www.aapspharmaceutica.com/nationalbiotech

Travel Information

Discounted rail and airfares are available for attendees traveling to/from this meeting. To take advantage of these discounts please call the official AAPS travel agency, Navigant International, and mention this meeting. You may also contact the airlines directly to take advantage of discounted airfares. Certain restrictions apply and seats are limited.

Navigant International
 Ph: (866) 412-7957 in the US
 Ph: (304) 876-8635 outside the US
 EM: sissel.smith@navigant.com

9:00 am - 5:30 pm, Monday - Thursday
 9:30 am - 4:00 pm, Friday
 Times listed are in Eastern Standard Time (EST)

Go by Rail!

Amtrak
 Ph: (800) 872-7245
 24 Hours, Monday- Sunday
 Fare Code: #X99H-947

AAPS Ligand Binding Assay Training Course: Development and Validation of Ligand Binding Assays to Support Pharmacokinetic Assessments of Biopharmaceuticals

June 17-18, 2006

John B. Hynes Veterans Memorial Convention Center
Boston, MA

The goals of this training course are to provide an intensive learning experience for the basic principles and regulatory (GLP) considerations of ligand binding assays to support the bioanalysis of biopharmaceuticals. Even though this training course will include LBA theory, it will emphasize practical aspects of LBAs to enable attendees to apply learning immediately following the course completion.

Course spans all LBA stages from method conception, through design/optimization, validation and implementation with test samples (pre-clinical through clinical), along with statistical considerations.

This course will cover important aspects of ligand binding assays for application of this technology for quantitative determination of therapeutic proteins and monoclonal antibodies in biological matrices in support of biopharmaceutical development.

- ▶ Module 1: Introduction of biopharmaceuticals
- ▶ Module 2: Basics of macromolecule protein chemistry and immunochemistry for application of ligand binding assay development
- ▶ Module 3: Development and optimization of ligand binding assays to support pharmacokinetic assessment of biopharmaceuticals
- ▶ Module 4: Pre-study and in-study validation of ligand binding assays to support pharmacokinetic assessments of biopharmaceuticals
- ▶ Module 5: Important statistical considerations during the development, validation and implementation of ligand binding assays

AAPS Workshop on Current Trends in Monoclonal Antibody Development and Manufacturing

June 22-23, 2006

John B. Hynes Veterans Memorial Convention Center
Boston, MA

Co-sponsored with FDA and SBE

Monoclonal antibodies represent one of the fastest growing areas of new drug development within the pharmaceutical industry. Several blockbuster products have been approved over the past several years including Rituxan, Remicade, Avastin, Humira, and Herceptin. In addition, over 300 new drugs are currently in clinical trials. With both large, established biotechnology companies and small start-ups involved in the development of this important class of molecules, monoclonal antibodies products will become increasingly prevalent over the next decade. Recently the

regulatory review of monoclonal antibodies has been moved from CBER to the CDER division of the FDA. It is anticipated that CDER will expect a certain minimal amount of data to be provided as more of these products move through the regulatory pipeline. This workshop will provide attendees with an understanding of what is currently being done in the industry to manufacture and release monoclonal antibody products, and what will be required for a successful regulatory submission.

For information on the training course and workshop visit www.aapspharmaceutica.com/nationalbiotech



Visit the AAPS Career Center being held in conjunction with the 2006 AAPS National Biotechnology Conference.

To help you maximize your use of the center, contact:

Chris Reed, Career Center Manager

Ph: (703) 248-4744 or EM: careercenter@aaps.org

The AAPS Press Room welcomes all professional journalists and science writers during the AAPS 2006 National Biotechnology Conference.

For press registration information, contact:

Sarah Pfeiffer, Communications Specialist

Ph: (703) 248-4744 or EM: PfeifferS@aaps.org

Upcoming AAPS Meetings

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

▶ June 17-18, 2006

AAPS Ligand Binding Assay Training Course: Development and Validation of Ligand Binding Assays to Support Pharmacokinetic Assessments of Biopharmaceuticals
John B. Hynes Veterans Memorial Convention Center, Boston, MA

▶ June 18-21, 2006

AAPS 2006 National Biotechnology Conference
Co-sponsored with FDA and SBE
John B. Hynes Veterans Memorial Convention Center, Boston, MA



▶ June 22-23, 2006

AAPS Workshop on Current Trends in Monoclonal Antibody Development and Manufacturing
Co-sponsored with FDA and SBE
John B. Hynes Veterans Memorial Convention Center, Boston, MA

▶ October 27-29, 2006

2nd Joint AAPS/AAVPT/CRS Workshop on Collaboration in Research and Development of Veterinary Pharmaceuticals
Henry B. Gonzalez Convention Center, San Antonio, TX

▶ October 28, 2006

AAPS Workshop on Application of Ion Chromatography in Pharmaceutical Drug Analysis
Henry B. Gonzalez Convention Center, San Antonio, TX

▶ October 29-November 2, 2006

2006 AAPS Annual Meeting and Exposition
Henry B. Gonzalez Convention Center, San Antonio, TX

