AAPS Update 1401

## **AAPS Update**

AAPS—YOUR FORMULA FOR SUCCESS!



June 2006



#### **Co-sponsored with**



June 18-21, 2006 John B. Hynes Veterans Memorial Convention Center, Boston, MA

The AAPS 2006 National Biotechnology Conference will feature:

- Open Forums
- Posters
- N D 1 1 1 1
- **►** Exhibits
- Career Center
- ▶Plenary Session
- **▶**Symposia
- **▶**Roundtables
- ►Short Courses
- ► Advertising and Sponsorship Opportunities

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

#### AAPS Announces Dr. Burt Adelman, Dr. Kevin Eggan, and Dr. Ian Wilmut as Plenary Speakers for 2006 National Biotechnology Conference

Dr. Burt Adelman, M.D, is currently Executive Vice President, Development at Biogen Idee, Cambridge, Massachusetts. Dr. Adelman has led development and regulatory efforts for four currently marketed drugs: ANGIOMAX®, AVONEX®, AMEVIVE®, and TYSABRI®. Prior to joining Biogen, Dr. Adelman was Associate

Professor of Medicine, Medical College of Virginia, and Chief of the Hematology Service, Hunter Homes McGuire Department of Veteran's Affairs Medical Center.

Dr. Eggan is assistant professor of molecular and cellular biology at Harvard University. Dr. Eggan's work at the Harvard Stem Cell Institute, with developmental biologist Doug Melton, hopes to generate embryonic stem cells that match individual patients. To do this, he will use a technique called somatic cell nuclear transfer – more commonly referred to as cloning.

Ian Wilmut is the leader of the team that produced Dolly, the first animal to develop after nuclear transfer from an adult cell. His research has all be concerned with understanding gametes and embryos. His Ph.D. degree was awarded in 1971 for research on the Deep Freeze Preservation of Boar Semen and subsequent research in Cambridge led to the birth of the first calf from a frozen embryo—Frosty. At present, Professor Wilmut is in the Department of Gene function and Development at Roslin Institute. Later this year he will move to the University of Edinburgh, Division of Reproductive and Developmental Sciences.

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

# 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.

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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.

## 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

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

At the AAPS Career Center conference attendees can:

- ► Submit résumés online and onsite
- ► Interview with potential employers
- ▶ Browse job boards
- ▶ Network with exhibiting companies
- ▶ Get information on the upcoming 2006 AAPS Career Center to be held with the AAPS Annual Meeting and Exposition in San Antonio, TX

For more information on the Career Center, please contact:

Ms. Chris Reed, Career Center Manager

Ph: (703) 248-4773

EM: careercenter@aaps.org

### What does your AAPS Member Record Say?



Check the member only section at aapspharmaceutica.com TODAY to find out.

Help us stay in touch with you by verifying your contact and demographic information.

You will need your member ID number and password to log on.

If you have forgotten either, please click "Forget your ID or Password:" on the main page of the site or call us toll free at (877) 998-AAPS.

After you log in click "Change your Membership Information" and help AAPS stay in touch with you.

#### **Upcoming AAPS Meetings**

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

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#### ▶ September, 11-12, 2006

AAPS Workshop on Real World Applications of PAT and QbD in Drug Process Development and Approval Hyatt Crystal City, Arlington, VA

#### ▶September, 13-14, 2006

AAPS Workshop Challenges in Developing Fixed-dose Combination Oral Solid Dose Products Hyatt Crystal City, Arlington, VA

#### ▶0ctober 27-29, 2006

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

#### ▶0ctober 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



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