AAPS Update

AAPS—YOUR FORMULA FOR SUCCESS!

20th Anniversary aaps
Celebrating Volunteers and Successful Careers
American Association of Pharmaceutical Scientists

March 2006

New for 2006! AAPS Workshop Clustering

AAPS is now offering clustered workshops. Workshops are being clustered with our two Annual Meetings, as well as several other times during the year. Workshops attached to the AAPS National Biotechnology Conference and the AAPS Annual Meeting and Exposition will be limited to a maximum of two workshops.

The first AAPS Clustered Workshops are being held May 1–3, 2006 at the Hyatt Crystal City, Arlington, VA.

AAPS Workshop on Dissolution Testing for the 21st Century: Linking Critical Quality Attributes and Critical Process Parameters to Clinically Relevant Dissolution Method/Specification

AAPS/FDA Third Bioanalytical Workshop on Quantitative Bioanalytical Methods Validation and Implementation: Best Practices for Chromatographic and Ligand Binding Assays

AAPS Workshop on Ensuring the Supply of Qualified Pharmaceutical Scientist Specialists in Product Development and Related Technologies that Meet Current and Future Needs

Please visit **www.aapspharmaceutica.com/meetings** for more information.

AAPS Conference on Critical Issues in Discovering Quality Clinical Candidates

April 24–26, 2006
Hyatt Regency Philadelphia
Philadelphia, PA

Pharmaceutical companies continue to be challenged by hurdles imposed by the properties of compounds. Discovery teams regularly face issues with safety, pharmacokinetics, compound quality, formulation, and bioassay reliability. This meeting will examine these critical issues. Industry scientists will provide insights in understanding these critical issues, assessing them, and successful solutions they have implemented. Academic speakers will review the fundamentals of the issues and current technologies. Medicinal chemists will discuss strategies for structural modifications to improve compound properties. This workshop brings together a multidisciplinary ensemble of leaders in the field of drug-like properties in drug discovery for a program of quality presentations. The meeting is targeted to be beneficial to an audience that includes the following:

▶discovery chemistry and biology scientists,
▶scientists who provide property data and consultation for discovery colleagues, and
▶AAPS members who wish to better understand the property challenges faced by discovery colleagues.

The format promotes discussion among the presenters and audience for a wide exploration of critical issues and solutions. Participants will gain insight on property challenges, technologies, methods, and strategies that can impact their own institution's success.

For more information, please visit
www.aapspharmaceutica.com/criticalissues

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.

Cruse spans all LBA stages from method conception, through design/optimization, validation and implementation with test samples (preclinical 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 is 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

Continued

▶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 aasays

For more information, please visit
www.aapspharmaceutica.com/nationalbiotech

2006 National Biotechnology Conference

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

Co-sponsored with FDA and SBE

The 2006 National Biotechnology Conference will feature:

▶Open Forums
▶Plenary Session
▶Posters
▶Symposia
▶Exhibits
▶Roundtables
▶Career Center
▶Short Courses
▶Advertising and Sponsorship Opportunities

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

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 more information, please visit **www.aapspharmaceutica.com/monoclonal**

Upcoming AAPS Meetings

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

▶April 24-26, 2006
AAPS Conference on Critical Issues in Discovering Quality Clinical Candidates
Hyatt Regency Philadelphia

▶May 1-3, 2006
AAPS Workshop on Dissolution Testing for the 21st Century Linking: Clinical Quality Attributes and Critical Process Parameters to Clinically Relevant Dissolution Method Specification
Hyatt Crystal City, Arlington, VA

▶May 1-3, 2006
AAPS/FDA Third Bioanalytical Workshop on Quantitative Bioanalytical Methods Validation and Implementation: Best Practices for Chromatographic and Ligand Binding Assays
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▶May 1-2, 2006
Ensuring the Supply of Qualified Pharmaceutical Scientist Specialists in Product Development and Related Technologies That Meet Current and Future Needs
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▶October 29-November 2, 2006
2006 AAPS Annual Meeting and Exposition
San Antonio Convention Center, San Antonio, TX

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