

AAPS Connection

American Association of Pharmaceutical Scientists

April 2010

Development of Ligand Binding Analytical Methods to Support Immunogenicity Testing: Theoretical to Practical Considerations

May 15–16, 2010
Hilton San Francisco Union Square
San Francisco, CA, USA

Goals and Objectives

The focus of this course is on the development and validation of analytical methods required for the detection and characterization of the anti-drug antibodies present in pre-clinical and clinical samples. The participants should gain familiarity with the following:

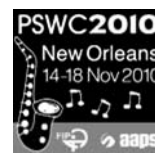
- ▶ basic principles of the immune response as it is involved in the development of antibodies to biotherapeutic agents;
- ▶ analytical methods used in the detection, measurement and characterization of the anti-drug antibody response;
- ▶ regulatory perspective on immunogenicity of biotherapeutics and regulatory expectations for pre- and post-licensing; and
- ▶ challenges in the development and validation of analytical methods for quantitative vs. detection, approaches and platforms, sensitivity, background, specificity, positive controls, detection reagents, normal serum pools, titrating strategies, effect of circulating drug and cut-off models and statistical analysis to determine assay cut-off, and characterization of anti-drug antibodies.

In addition, case studies will be used to illustrate safety issues, methods development, interpretation of study data, and examples of statistical models for cut-off and assay design.

For more information, please visit:
www.aapspharmaceutica.com/immunogenicity.

Improving Global Health Through Advances in Pharmaceutical Sciences

November 14–18, 2010
New Orleans Convention Center
New Orleans, LA, USA



Every three to four years, the International Pharmaceutical Federation (FIP) organizes a Pharmaceutical Sciences World Congress (PSWC). The PSWC series alternates among the American, Asian, and European continents. In 2010, the PSWC is scheduled to be held on the North American continent.

Each year, the American Association of Pharmaceutical Scientists (AAPS) organizes the AAPS Annual Meeting and Exposition.

In 2010, FIP and AAPS have agreed to hold the PSWC and the Annual Meeting together in New Orleans, Louisiana, USA from 14–18 November. FIP and AAPS also agree that the objective of this joint meeting is for the education and benefit of the members of each organization and the constituencies that they represent. The programming, exposition, and other events have been planned to provide maximum educational opportunities.

The joint meeting includes the following:

- ▶ A forum for exchange of ideas and information about the sciences which the organizations represent.
- ▶ Continuing professional development of the individual members and related professionals.
- ▶ An introduction of the latest technological advances.

The scientific theme is: Improving Global Health Through Advances in Pharmaceutical Sciences. PSWC 2010 Committee Structure—The Scientific Programming Committee is geographically balanced with members from the Americas, Asia, and Europe.

Mario L. Rocci Jr., Ph.D. (USA), Congress Chair

Ho-Leung Fung, Ph.D. (USA), Scientific Program Chair

Mitsuru Hashida, Ph.D. (Japan), Asia Scientific Program Committee Chair

Geoffrey T. Tucker, Ph.D. (UK), Europe Scientific Program Committee Chair

Robert G. Bell, Ph.D. (USA), Americas Scientific Program Committee Chair

For more information, please visit:
www.pswc2010.org.

Call for Papers

Put your world-class scientific knowledge on the world stage at PSWC2010 in New Orleans, where cultures will cross and minds will meet to advance pharmaceutical sciences. Be part of the excitement surrounding this worldwide effort.

**Contributed Paper Abstract Final Submission Deadline:
May 12, 2010**

The site opened on January 29, 2010 for Contributed Paper abstract submissions and will remain open until the final submission deadline of May 12, 2010. Final status notification will be sent via email on June 18, 2010.

To submit abstracts please visit:
www.pswc2010.org/abstracts.

AAPS Workshop on Strategies to Address Therapeutic Protein Drug Interactions During Clinical Development

May 15, 2010
Hilton San Francisco Union Square
San Francisco, CA

Goals and Objectives

To arrive at an industry/regulatory consensus on Drug-Drug Interactions (TPDI) strategy for therapeutic proteins in combinations with small and large molecules. The objectives of this short course will be four-fold:

- ▶ In-depth review of reported and documented TPDI for small/therapeutic protein combinations in the context of clinical relevance.
- ▶ Discussion of case studies, study designs, acceptance criteria to assess PK and PD-based TPDI in clinical studies.
- ▶ Review of a science-driven, risk-based approach to assessing the potential for TPDI.
- ▶ Roundtable discussion with an industry and regulatory representative of the topic to arrive at a science-driven, risk-based approach for assessing the potential for TPDI.

Therapeutic proteins, such as monoclonal antibodies and cytokines/cytokine modulators, are increasingly being combined with small molecules and/or other therapeutic proteins. Limited scientific and drug development TPDI experience is available for these drug combinations. However, following round table discussions and symposia with industry, academic and regulatory participation, a few important main themes have emerged: molecule type, target, indication, and, disease biology. Recent reports

also suggest that regulation of CYP450 in inflammatory indications and use of cytokines, cytokine modulators, immunosuppressant-containing combinations in inflammatory indications can also be a potential concern. Such combinations need to be considered on a case-by-case basis, particularly when combined with narrow therapeutic index drugs. The potential for TPDI for monoclonal antibody and small molecule drug combinations appears to be low because of a lack of overlap in clearance pathways.

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

Upcoming AAPS Meetings

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

▶ May 15, 2010

AAPS Workshop on Strategies to Address Therapeutic Protein Drug Interactions (TPDI) during Clinical Development
Hilton San Francisco Union Square, San Francisco, CA, USA

▶ May 15-16, 2010

Development of Ligand Binding Analytical Methods to Support Immunogenicity Testing: Theoretical to Practical Considerations
Hilton San Francisco Union Square, San Francisco, CA, USA

▶ May 16-19, 2010

2010 AAPS National Biotechnology Conference
Hilton San Francisco Union Square, San Francisco, CA, USA

▶ September 13-14, 2010

AAPS Workshop on Recent Advances in Controlled Release and Non-invasive Drug Delivery of Biopharmaceuticals
Venue TBD, Baltimore, MD, USA

▶ September 2010

AAPS Workshop on Advances and Opportunities in Drug Product Manufacturing
Location TBD

▶ November 13-14, 2010

AAPS Workshop on Contemporary Challenges and Advances Impacting the Development of Veterinary Pharmaceuticals
Ernest N. Morial Convention Center, New Orleans, LA, USA

▶ November 13-14, 2010

AAPS Workshop on Harmonization of Regulatory Approaches for Evaluating Therapeutic Equivalence and Interchangeability of Multisource and Complex Drug Products
Ernest N. Morial Convention Center, New Orleans, LA, USA

▶ November 14-18, 2010

FIP Pharmaceutical Sciences World Congress 2010 in association with the AAPS Annual Meeting and Exposition
Ernest N. Morial Convention Center, New Orleans, LA, USA

▶ May 15-18, 2011

2011 AAPS National Biotechnology Conference
Hilton San Francisco Union Square, San Francisco, CA, USA



AAPS Connection

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

April 2010