Pharmaceutical Research, Vol. 27, No. 1, January 2010 (© 2009)
DOI: 10.1007/s11095-009-9996-x

AAPS Connection

American Association of Pharmaceutical Scientists January 2010

45th Annual Pharmaceutical Technologies Arden Conference: Formulation Strategies for Poorly Soluble Drugs

February 2–5, 2010
The Thayer Hotel
West Point, NY

Goals and Objectives

The solubility behavior of drugs remains one of the most challenging aspects in formulation development. This program will provide fundamental understandings and the latest updates on solubility enhancement technologies.

Day one of the program will focus on drug solubility in terms of BCS, alteration and prediction. Day two of the program is designed to provide in-depth review on liquid formulations. Day three of the program will focus on solid formulations. Day four of the program will cover enabling technologies for solubility enhancement, such as supercritical fluid processing, spray drying and hot melt extrusion freeze drying. The final day will be devoted to QbD from both industrial and regulatory perspectives. Case studies and workshops will also be provided every day to engage participation from the attendees.

The topics will be covered by experts in the field followed by in-depth panel discussions and case studies in which participants will be eager to participate. Attendees are encouraged to bring examples of current problems from their laboratories to share past successes and failures with other participants.

For more information, please visit **www.aapspharmaceutica.com/ardenconference**.

Improving Global Health Through Advances in Pharmaceutical Sciences

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 should be for the education and benefit of the members of each organization and the constituencies that they represent. The programming, exposition, and other events will be planned to provide maximum educational opportunities.

The joint meeting will include 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 will re-open 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.

Contributed paper abstracts with the following primary topics will be considered:

- Drug Design and Discovery
- Drug Delivery—Biopharmaceutics
- Drug Delivery—Pharmaceutical Technologies (Small Molecule)
- Large Molecule Product Development Strategies
- Analytical Methodology
- Pharmacokinetics/Pharmacodynamics
- Clinical Pharmacology and Translational Research
- Biomarkers
- Manufacturing
- Regulatory Affairs

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

AAPS Workshop on Strategies to Address Drug-Drug Interactions of Therapeutic Proteins 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 (DDI) strategy for therapeutic proteins in combinations with small and large molecules, the objectives of this short course will be fourfold:

- In-depth review of reported and documented DDIs 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 DDI in clinical studies.
- Review of a risk-based approach to assessing the potential for DDI.
- Roundtable discussion with an industry and regulatory representative on the topic to arrive at a science-driven, risk-based approach for assessing the potential for DDIs.

Therapeutic proteins, such as monoclonal antibodies and cytokines/cytokine antagonists, are increasingly being combined with small molecules and/or other therapeutic proteins. Limited scientific and drug development DDI experience is available for these drug combinations. However, following round table discussions and symposia with industry and regulatory participation, a few important main themes have emerged: molecule type, target, indication and MOA, and disease biology. Recent reports also suggest that regulation of CYP450 in inflammatory indications and use of cytokine, anticytokine mAb, 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 ratio drugs. Furthermore, the potential for DDI for monoclonal antibody and small molecule drug combinations appears to be minimal and low because of a lack of overlap in clearance pathways.

For more information, please visit **www.aapspharmaceutica.com/DDI**.

Upcoming AAPS Meetings

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

▶ February 1-5, 2010
45th Annual Pharmaceutical Technologies Arden Conference: Formulation Strategies for Poorly Soluble Drugs
The Thayer Hotel, West Point, NY

▶ May 15, 2010
AAPS Workshop on Strategies to Address Drug-Drug Interactions (DDI) of Therapeutic Proteins during Clinical Development
Hilton San Francisco Union Square, San Francisco, CA

▶ May 16-19, 2010
2010 AAPS National Biotechnology Conference
Hilton San Francisco Union Square, San Francisco, CA

▶ November 14-18, 2010
FIP Pharmaceutical Sciences World Congress 2010 in association with the AAPS Annual Meeting and Exposition
New Orleans Convention Center, Louisiana, USA

▶ May 15-18, 2011
2011 AAPS National Biotechnology Conference
Hilton San Francisco Union Square, San Francisco, CA

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