AAPS Update

AAPS — YOUR FORMULA FOR SUCCESS!

March 2008

2008 AAPS National Biotechnology Conference

June 22–25, 2008
Metro Toronto Convention Centre
Toronto, Canada

AAPS is pleased to announce that the 2008 AAPS National Biotechnology Conference will take place June 22–25, 2008, at the Metro Toronto Convention Centre in Toronto, Canada. Attendees can enjoy a week of pharmaceutical biotechnology programming at the 2008 AAPS National Biotechnology Conference.

Participants can join in three days of conference program- ming consisting of a Plenary Session, Symposia, Roundtables and Sunrise Sessions. Some of the sessions that encompass the full program include Plant-based Biologics, Storage and Shipment of Biologics, Quality by Design, Inhibitors, Immunogenicity and Gene Therapy. The conference concludes by offering attendees the opportunity to attend one of four AAPS sponsored short courses, all of which are certain to engage you interest.

This conference will also feature a fully operational Career Center, including job postings, a résumé database, and interview facilities. Additionally, a full Exposition Hall will be hosting major companies. The call for papers submission has been released; check the NBC website, **www.aapspharmaceutica.com/nationalbiotech**, for fur- ther details regarding topics and submission deadlines.

If you have any questions about the program or registra- tion procedures, please contact the AAPS office, (703) 243–2800, or, you can send an email to **meetings@aaps.org**.

The 2008 AAPS National Biotechnology Conference is designed to provide a complete educational event allowing each and every attendee the ability to customize their experience. Biotechnology is the cutting edge and AAPS is there with you.

AAPS Workshop on Drug Discovery Strategies and Critical Issues for Clinical Candidates

May 19–21, 2008
South San Francisco Conference Center, San Francisco, CA

Goals and Objectives

The Strategies for Preclinical Drug Discovery and Delivery Interface Workshop is intended to introduce those people who are less familiar with pre-clinical evaluations, which lead to drug-like molecules, an opportunity to get introduced to those disciplines prior to the main meeting.

The discovery and development of quality drug leads and clinical candidates, which will eventually become novel drugs to address un- met medical needs, remains a significant challenge to pharmaceutical scientists. It is increasingly clear that integration of drug-like properties into the early stages of drug discovery is advantageous to efficient and effective drug development. This meeting will examine the critical issues of compound selection and quality, safety, pharmacokinetics and formulation. Symposia and speakers will be selected to enhance our collec- tive knowledge on the discovery and development of novel lead molecules that have drug-like properties and can lead to clinical development candidates. Key areas of focus will include state-of-the-art techniques to mine SAR to identify promising lead compounds, study drug-like properties, screen for early safety concerns, and novel approaches to early formulation. The meeting will target academic and industrial scientists from the following disciplines: discovery medicinal chemists and biologists, DMPK and toxicol- ogy scientists and formulation scientists. This conference on Drug Discovery Strategies will provide a forum for pharmaceutical scientists to exchange ideas on the state-of-the-art techniques to study drug discovery, enhance knowledge about the relative importance of drug-like properties, and provide an opportu- nity to learn of the cutting edge science in this area through seminars by invited speakers.

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

AAPS Workshop on Role of Dissolution on QbD and Drug Product Life Cycle

April 28–30, 2008
The Hyatt Regency Crystal City, Arlington, VA

Background

Dissolution testing continues to be one of the critical tests that support drug and product development through commercialization. There is a need to better understand the objectives behind the dissolution test and the role it plays during different stages of product development. QbD concepts and science-based risk assessment (ICHQ8–10) require industry and regulatory agencies to re-examine the current approaches to dissolution method develop- ment. In this emerging context of QbD, dissolution may serve as a more important role in some cases; while in others, if other critical parameters are more relevant, dissolution may not be needed as a test. This workshop is aimed at exploring the dissolution test in QbD environ- ment in the 21st century.

Continued

This workshop will scientifically evaluate the objectives of dissolution testing through the various stages of product development, i.e. pre-clinical stage to Phase IV and beyond. Case studies and best practices to maximize the value of the dissolution test using science-based assessment will be presented. Strategies to enhance *IVIVC/IVIVR* and biorelevance of the dissolution test by proper selection of test conditions will be presented. The role of dissolution in assessing drug release from novel or modified release dosage forms that may require non- or modified compendial methods will be considered.

The scientific basis for using surrogate tests such as disintegration and API solubilization along with leading edge methodologies to evaluate product performance will be examined. The impact of alternate methods in building a knowledge space to enhance the Quality by Design (QbD) approach for varying dosage forms will be highlighted.

Goals and Objectives

At this workshop we will:

- explore Quality by Design (QbD) as it applies to dissolution testing;
- demonstrate why dissolution testing methods and specifications are clinically relevant *(IVIVC/IVIVR)*;
- explain the role of dissolution in assessing drug release from novel and modified release dosage forms;
- show the relevance of dissolution through various stages of product development;
- highlight other diagnostics which may complement the dissolution test; and
- illustrate recent advances in dissolution technology.

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

AAPS MemberNet

The ability to "network" profession- ally is one of the primary benefits of AAPS Membership. In order to enhance AAPS Members' ability to network, AAPS is pleased to offer the AAPS MemberNet, a virtual networking environment that in many ways repli- cates the face-to-face networking at meetings while providing a rich set of online tools that are available around the clock!

Join the community of scientists by completing your profile and searching for colleagues with similar interests and experiences. Take a moment to see how AAPS MemberNet can keep you connected.

For more information visit
www.aapspharmaceutica.com/MemberNet

Upcoming AAPS Meetings

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

▶April 28-29, 2008
AAPS Workshop to Discuss Design, Endpoints and Analyses to Discern Symptomatic and Disease Modifying Drug Effects for the Treatment of Parkinson's Disease
Hyatt Regency Crystal City, Arlington, VA

▶April 28-30, 2008
AAPS Workshop on Role of Dissolution on QbD and Drug Product Life Cycle
Hyatt Regency Crystal City, Arlington, VA

▶May 19-21, 2008
AAPS Workshop on Drug Discovery Strategies and Critical Issues for Clinical Candidates
South San Francisco Conference Center, San Francisco, CA

▶June 22-25, 2008
2008 AAPS National Biotechnology Conference
Metro Toronto Convention Centre, Toronto, Canada

▶November 16-20, 2008
2008 AAPS Annual Meeting and Exposition
Georgia World Congress Center, Atlanta, GA

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