AAPS Update

AAPS–YOUR FORMULA FOR SUCCESS!

October 2005

Plan Now for the 2005 AAPS Annual Meeting and Exposition

Ron Reagan
Keynote speaker

November 6–10, 2005
Gaylord Opryland Resort &
Convention Center Nashville
Nashville, Tennessee

Plan ahead to join over 9,000 pharmaceutical scientists from every corner of the globe who will be promoting breakthrough research and technologies, networking with colleagues, and improving their professional edge at the 2005 AAPS Annual Meeting and Exposition.

Visit **www.aapspharmaceutica.com** for details on this year's exciting meeting.
More than 550 companies are expected to showcase the latest equipment, technical developments, publications and other services for the pharmaceutical scientist. Find both new and current suppliers of the equipment, services, and techniques you need for your most pressing needs. An exhibit guide will be available on site for all attendees and will feature detailed descriptions of exhibiting company's contact information, products and services, plus an index of the companies by product category. This guide to the exposition will also serve as a valuable reference after the meeting.

The Keynote Speaker for the 2005 AAPS Annual Meeting and Exposition is Ron Reagan.

Since his father's death from Alzheimer's in June of 2004, Reagan has been speaking out on the subject of stem cell research, advocates increased research, and federal funding. He spoke at the 2004 Democratic National Convention on the issue.

For more information on the 2005 AAPS Annual Meeting and Exposition, please visit
www.aapspharmaceutica.com/annualmeeting/

Career Center at the AAPS Annual Meeting and Exposition

November 6–9, 2005
Gaylord Opryland Resort &
Convention Center Nashville
Nashville, Tennessee

Join us Sunday, November 6 at the reception to celebrate the opening of the 2005 AAPS Annual Meeting Career Center.

Network with Top Recruiting Companies

Reception begins at 2:00 pm in Delta Ballroom A at the Gaylord Opryland Resort & Convention Center Nashville.

The AAPS Career Center offers these services:

- résumé/CV submission online and onsite
- interview with top companies
- browse job boards
- network with recruiting companies
- attend career counseling sessions and professional development events

...all in one setting.

Employers/Recruiters Contact
Ms. Chris Reed, Career Services Manager
(703) 248–4773,
ReedC@aaps.org

Job Seekers Contact
Career Services Specialist
(703) 248–4771,
CareerCenter@aaps.org

Visit our website at
www.aapspharmaceutica.com/careercenter

Funded by grants from

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Save Hundreds of Dollars
Register for the Annual Meeting in groups $$$$$$$$

Take advantage of this opportunity to register you and your colleagues for this meeting and save hundreds of dollars! Group registration discounts will be available as follows:

- Three fully paid registrations qualify for one additional complimentary registration
- Five or more fully paid registrations qualify for two additional complimentary registrations

Registration must be in groups of four or more, from the same organization and cannot be combined with any additional offer. Group registrations are not valid after September 30, 2005 and are available through online registration only. All registrations must be made at the same time to qualify. Group registration fee is not available for exhibitor or one-day registrants.

Registration is now open at **www.aapspharmaceutica.com/annualmeeting**

Continued

AAPS Workshop on Pharmaceutical Quality Assessment—A Science and Risk-Based CMC Approach in the 21st Century

Co-sponsored with FDA and ISPE

October 5–7, 2005
Bethesda North Marriott
North Bethesda, Maryland

Consistent with the cGMPs for the 21st Century Initiative, FDA is establishing a modern, risk-based pharmaceutical quality assessment system to replace the current chemistry, manufacturing, and controls (CMC) review system. The new quality assessment system is intended to facilitate innovation and continuous improvement throughout the product lifecycle; provide regulatory flexibility for specification setting and post-approval changes based on scientific knowledge and understanding of product and process by applying quality-by-design principles; and to expedite the review of drug applications without compromising the high quality of drugs in the United States. Plenary sessions will present scientific and technical challenges to provide the framework for discussions in the breakout sessions. Breakout sessions will serve as the forum for FDA to seek input from the public in understanding the pros and cons of the various aspects and in identifying alternative approaches to achieve the desired state. Specifically, the workshop will:

- explore and evaluate all facets of the new pharmaceutical quality assessment system;
- define what is meant by a risk-based system and how to establish criteria to identify and measure risk associated with the development and manufacturing of pharmaceutical drug products;
- assess the roles and value of pharmaceutical development information, quality overall summary, and integrated review/inspection functions in the new paradigm;
- examine the kind of amount, and extent of data in future CMC submissions and its value in making science-based regulatory decisions;
- develop appropriate strategies to submit and to assess critical manufacturing science information to facilitate PAT, and to encourage innovation in pharmaceutical manufacturing;
- determine how to set product specifications in the new paradigm based on recommendations and findings of PQRI Workshop (March 2005); and
- identify the roles of industry and FDA to facilitate continuous product and process improvement.

For more information and to register, please visit **www.aapspharmaceutica.com/cmc**

AAPS Workshop on Microdialysis Principles, Application and Regulatory Perspectives

Co-sponsored with FDA

November 4–5, 2005
Gaylord Opryland Resort & Convention Center Nashville, Nashville, Tennessee

Although most biochemical and pharmacological events take place in the tissue, diagnostic and therapeutic decisions in medical practice are based generally on levels of drugs and/or endogenous molecules in the blood. Microdialysis is a catheter-based sampling method that enables *in vivo* measurement of tissue chemistry in humans. The technique is minimally invasive and is feasible in virtually every human organ. It is currently being used to monitor brain ischemia and metabolic control, transdermal drug distribution and pharmacokinetics, and is set to become a standard tool in drug monitoring and development in the future.

Goals and Objectives

This workshop aims to give an overview of the principles and techniques of microdialysis and its application in clinical research and drug development. In addition, there will be discussion as to the potential general utility of microdialysis from regulatory perspectives. Upon completion, participants will be able to:

- discuss the basic principles of microdialysis.
- describe how microdialysis is used to measure tissue concentrations of endogenous and exogenous compounds (e.g., drugs and their metabolites).
- describe how microdialysis is used to investigate the tissue penetration of drugs into a variety of tissues in animals and humans *in vivo*.
- describe how microdialysis can be used to provide data in support of therapeutic safety and efficacy trials.

For more information and to register, please visit **www.aapspharmaceutica.com/microdialysis**

Upcoming AAPS Meetings

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

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