

# AAPS Update

AAPS—YOUR FORMULA FOR SUCCESS

July 2005

## New Title from AAPS Press



### Methods for Structural Analysis of Protein Pharmaceuticals

Edited by Wim Jiskoot and Daan Crommelin, Utrecht University.

This book is Volume 3 of the *Biotechnology: Pharmaceutical Aspects* series from AAPS Press.

This edition discusses the various techniques used to study the structural aspects of proteins, including, among others, spectroscopic techniques (e.g., fluorescence, circular dichroism, infrared, and Raman spectroscopy), light scattering techniques, separation techniques (e.g., liquid chromatography, capillary electrophoresis, and analytical ultracentrifugation), and mass spectrometry, calorimetric, and immunochemical techniques.

Various leaders from academia and industry have contributed to *Methods for Structural Analysis of Protein Pharmaceuticals*. The result is a comprehensive volume for anyone in academia or industry interested in protein pharmaceuticals.

As you can see, this new release from AAPS Press would be an important addition to your reference library. Call (703) 243-2800 to place your order, and be sure you visit [www.aapspharmaceutica.com/publications/press/index.asp](http://www.aapspharmaceutica.com/publications/press/index.asp) to learn about other AAPS Press publications.

**List Price: \$188.00; AAPS Member price: \$150.00**

## AAPS Workshop on Integrated Roadmap to Biomarkers for Drug Development—Method Validation and Qualification

September 8–9, 2005  
Doubletree Hotel and Executive Meeting Center  
Rockville, Maryland

The FDA has identified biomarkers as one of the tool kits in the recent Critical Path document. However, there is a gap in translating the biomarkers knowledge and

technologies from discovery into preclinical and clinical phases. AAPS will take the leadership role of providing the forum for discussion in developing workable roadmaps for sound scientific and statistical bases of evidential drug development using biomarkers. This will be accomplished with the critical involvement and support of other organizations such as ACCP, PhRMA, FDA, and NIH.

### Goals and Objectives

Biomarkers are increasingly used in drug development to aid scientific and clinical decisions regarding the progress of candidate and marketed therapeutics. Early implementation of biomarker strategies holds the promise of reducing costs and time to market as drugs proceed through increasingly costly and complex clinical development programs. AAPS conducted a biomarker workshop in 2003 on “Method Validation and Measurement of Biomarkers in Nonclinical and Clinical Samples in Drug Development,” and another in 2004 on “Clinical Biomarkers in Drug Development: Efficacy Assessment, PK/PD and Regulatory Insight.” The 2003 workshop addressed key issues on the method validation and implementations with follow-up actions in work groups to discuss and build consensus resolving the issues into a practical “Fit-for-Purpose” process for method development, validation, and assay implementation. The 2004 workshop included discussions on the evaluation process of clinical qualification and the FDA Exposure-Response Guidance. The processes of assay validation and qualification are intertwined and must be integrated for successful applications of biomarkers.

This workshop will

- ▶ Present an overall view of integrated roadmaps to biomarker applications;
- ▶ Discuss biomarker applications based on “Fit-for-Purpose” assay development and validation and appropriate data interpretation and correlation during clinical qualification;
- ▶ Discuss issues and build consensus leading to the successful use of biomarkers for preclinical and clinical phases; and
- ▶ Discuss the issues surrounding the development of a successful collaboration model.

For more information and to register, please visit [www.aapspharmaceutica.com/meetings](http://www.aapspharmaceutica.com/meetings)

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## AAPS Workshop on Microdialysis Principles, Application, and Regulatory Perspectives

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*; and
- ▶ 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/meetings](http://www.aapspharmaceutica.com/meetings)

## Plan Now for the 2005 AAPS Annual Meeting and Exposition

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

Plan ahead to join over 7,500 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.

More than 575 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.

Visit [www.aapspharmaceutica.com](http://www.aapspharmaceutica.com) for details on this year's exciting meeting.

### Register for AAPS Annual Meeting and Exposition as a Group and Save Hundreds of Dollars

**T**ake 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

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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.

**Note:** Group registration fee is not available for exhibitor or one-day registrants.

Registration is now open at [www.aapspharmaceutica.com/annualmeeting](http://www.aapspharmaceutica.com/annualmeeting)

### Upcoming AAPS Meetings

Log onto [www.aapspharmaceutica.com/meetings](http://www.aapspharmaceutica.com/meetings) for details.

#### ▶ September 8–9, 2005

AAPS Workshop on Integrated Roadmap to Biomarkers for Drug Development—Method Validation and Qualification  
Doubletree Hotel and Executive Meeting Center  
Rockville, MD

#### ▶ October 5–7, 2005

AAPS Workshop on Pharmaceutical Quality Assessment—A Science and Risk-based CMC Approval in the 21<sup>st</sup> Century  
Co-sponsored with FDA and ISPE  
Bethesda North Marriott  
North Bethesda, MD

#### ▶ November 4–5, 2005

AAPS Workshop on Microdialysis Principles, Application, and Regulatory Perspectives  
Gaylord Opryland Resort & Convention Center Nashville  
Nashville, TN

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