AAPS Update

AAPS—YOUR FORMULA FOR SUCCESS!

September 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** to learn about other AAPS Press publications.

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

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 and to 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.

Goals and Objectives

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, 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/meetings**

Continued

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*.
- 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**

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** for details on this year's exciting meeting.

Upcoming AAPS Meetings

Log onto **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 21st 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

▶November 6-10, 2005
2005 AAPS Annual Meeting and Exposition
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