Association News and Announcements

AAPS THIRD ANNUAL MEETING AND EXPOSITION

October 29–November 3, 1988, Marriott's Orlando World Center, Orlando, Florida

In an effort to bring you up-to-date on the symposia scheduled for the Third Annual Meeting in Orlando, the next two issues of Pharmaceutical Research *will feature information about the symposia and short courses that was unavailable at the time of printing of the AAPS Preliminary Program.*

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Unique Intravenous Formulation Approaches for Poorly Water Soluble Compounds (Short Course). This short course was arranged by Barbara J. Floy, Ph.D. Poorly water soluble compounds offer unique formulation problems when intravenous administration is desired. Although organic solvents may enhance solubility, the extent of solubilization may not be sufficient for the dose desired. Organic solvents may also be unsuitable due to unacceptable toxicity or irritation. This course will explore alternative formulation methods for intravenous delivery of poorly water soluble compounds. These methods include microparticulate suspensions, emulsions, and techniques incorporating lyophilization. Additionally, stability and sterility considerations for these formulations will be discussed. This course will be valuable to anyone interested in parenteral formulation development and, in particular those working with problematic compounds. *Emulsions:* Michael J. Groves, Ph.D., University of Illinois at Chicago, *Microsphere Suspensions:* Dr. Robert Morris, Eli Lilly & Company. *Lyophilization Techniques:* Larry A. Gatlin, Ph.D., Glaxo Pharmaceuticals. *Cycoldextrin Complexation:* Josef Pitha, Ph.D., NIH/National Institute on Aging. *Case Studies:* Dr. James Craddock, National Cancer Institute.

Analysis and Control of Biotechnology Products (APQ/BIOTECH Symposium). This Symposium was arranged by Fran Bogdansky, Ph.D., and Edward Smith, Ph.D. This session will examine analysis and control issues uniquely related to biotechnology products as well as those issues that are of concern for all drug products but which require special considerations when applied to recombinant proteins and monoclonal antibodies. Emphasis will be placed on the selection and design of tests suitable for assuring product identity, strength, quality, and purity. Specifically, the session will address testing for adventitious agents and product-specific contaminants such as polynucleotides and antigenic substances, chromatographic assay methods, and cell culture and other biological potency tests. Consideration will also be given to process validation studies as a necessary component for controlling the impurity profile in biotechnology products. *Practical Considerations for the Regulation of Biotechnology Products:* Robert W. Kozak, Ph.D., Food and Drug Administration. *Purity of Biotechnology Products from an Industrial Perspective:* Robert L. Garnick, Ph.D., Genentech, Inc. *Contamination Detection in Cell Lines and Products:* Forrest H. Anthony, M.D., Ph.D., Quality Biologics. *Cell Culture Assays for Determining Potency of Biotechnology Products:* Lewis H. Lambert, M.A., XOMA Corporation. *Selected Aspects of Process Validation for Biological Products Produced by Cell Culture Techniques:* Anthony Lubiniecki, Ph.D., Genentech, Inc.

Pharmaceutical Development of Peptides and Proteins (BIOTECH Symposium). This symposium was arranged by Bobbe Ferraiolo, Ph.D., Carol Gloff, Ph.D., and Zachary Yim, Ph.D. As peptides and proteins move from discovery research into product development, a new set of challenges arises. Special considerations are required for biotechnology-derived products in the areas of pharmacology, toxicology, pharmacokinetics, assay development, formulations, and drug delivery. For example, efficacy and toxicology studies of proteins pose particular problems when the pharmacologic effects are species-specific. Analysis of proteins commonly involves either immunoassay or bioassay, with all of the problems inherent in these techniques. Bioavailability by nonconventional routes requires special considerations when assessing protein drug delivery. The solution to these problems involves new *in vitro* and *in vivo* techniques, innovative methods of analysis and novel drug delivery systems. This symposium will address some of the issues raised in the preclinical development of peptides and proteins. *Analysis of Processes Causing Thermal Inactivation of Proteins:* Tim J. Ahern, Ph.D., Genetics Institute. *Analytical Challenges for Protein Delivery Development:* Por-Hsiung Lai, Ph.D., Centocor Inc. *Novel Drug Delivery Systems for Proteins and Peptides:* Yuan-Yuan Chiu, Ph.D., Food and Drug Administration. *Preclinical Evaluation of Hematopoietic Growth Factors:* Robert Donahue, V.M.D., Genetics Institute. *Recombinant Tissue Plasminogen Activator Prevents Intra-Abdominal Adhesion Formation.* Marge Mohler, Ph.D., Genentech, Inc. *Circulating Growth Hormone Binding Proteins:* Gerhard Baumann, M.D., Northwestern University Medical School. *Pharmacokinetic/Pharmacodynamic Aspects of Peptides and Proteins:* Robert J. Wills, Ph.D., Hoffmann-La Roche. *Toxicology of Recombinant Human Erythropoietin, A New Protein Pharmaceutical:* Lynn Anderson, D.V.M., Amgen.

Cell Culture (PDD Symposium). This symposium was arranged by Denise Pretzer, Ph.D., and Robert E. Stratford, Jr., Ph.D. Improvement of drug delivery depends on a thorough understanding of the transport process at the cellular level, and cell culture is rapidly emerging as a tool for elucidating these processes. This symposium will present a critical assessment of the subject with emphasis on techniques, current and potential applications, drawbacks, and areas

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where additional study is needed. Examples will include intestinal, buccal, nasal, dermal, renal, and brain capillary endothelial cell cultures. *Introduction:* Robert E. Stratford, Jr., Ph.D., Eli Lilly & Company. *Overview of Cell Culture in Drug Delivery Research:* Ronald T. Borchardt, Ph.D., The University of Kansas. *Techniques of Establishing and Maintaining Cells in Culture:* Mary Pat Moyer, Ph.D., University of Texas Health Sciences Center. *Transepithelial Transport in Renal Cell Culture:* James M. Mullin, Ph.D., Lankenau Medical Research Center. *Transepithelial Transport in Brain Capillary Endothelial Cell Culture:* Kenneth L. Audus, Ph.D., The University of Kansas. *Cell Culture Models of Intestinal Epithelium:* Glynn Wilson, Ph.D., CIBA-GEIGY Pharmaceuticals UK. *Buccal Epithelial Cell Culture:* Christopher A. Squier, Ph.D., The University of Iowa. *Nasal and Tracheal Epithelial Cell Cultures:* Richard C. Boucher, M.D., The University of North Carolina at Chapel Hill. *Keratinocyte Cell Culture:* Charles S. Harmon, Ph.D., Pfizer Central Research.

Physicochemical Means of Improving Skin Permeation (PDD Symposium in two parts November 1–2). This symposium was arranged by Gary W. Cleary, Pharm.D., Ph.D., and Mario A. Gonzalez, Ph.D. Systemic drug administration via the skin is an active area of pharmaceutical research. This symposium will critically examine the principles, potential, and limitations of several means designed to render skin more permeable. These include the use of prodrugs, chemical enhancers, iontophoresis, and ultrasound. *Physicochemical Opportunities to Breach the Skin Barrier:* Carl C. Peck, M.D., Food and Drug Administration. *Iontophoresis as an Enhancement Mechanism:* Theoretical—Ronald R. Burnette, Ph.D., University of Wisconsin; Applications—John Sanderson, Ph.D., Schering Research, Miami; Applications—Yie W. Chien, Ph.D., Rutgers University. *Pro-Drugs as a Route to Enhanced Transdermal Delivery:* Bradley D. Anderson, Ph.D., University of Utah. *Chemical Enhancement of Transdermal Flux:* Tamie Kurihara-Bergstrom, Ph.D., CIBA-GEIGY Corporation. *Ultrasound Enhanced Transdermal Drug Delivery:* Robert S. Langer, Ph.D., Massachusetts Institute of Technology. *NDA Viewpoint:* Jerome P. Skelly, Ph.D., Food and Drug Administration. *ANDA Viewpoint:* Shrikant V Dighe, Ph.D., Food and Drug Administration. *Toxicity Requirements:* Judy Weissenger, Ph.D., Food and Drug Administration.

Kinetics of Drug Action: Role in Drug Product Development and Evaluation (PPDM Symposium). This symposium was arranged by William Gillespie, Ph.D., and Salomon Stavchansky, Ph.D. The goal of this symposium is to summarize the state of the art in pharmacodynamics analysis and to identify what role pharmacodynamics can and should play in drug product development and evaluation. A number of recent advances have been made in theory and methodology of pharmacodynamic analysis. Compartmental modeling has been successfully extended into the realm of pharmacodynamics via the effect compartment approach. More general noncompartmental approaches have been developed with further advances expected. The combination of new technology and investigator ingenuity has provided a variety of new methods for the measurement of drug actions. This is particulary true for the new generation of novel drug delivery systems and high potency drugs. Targeted drug delivery systems by design confuse the relationship between drug concentrations and pharmacologic response; any meaningful measures of their value must be related to the time courses of the effects they induce. Extremely high potency drugs result in plasma concentrations which are very difficult to measure, thereby precluding conventional pharmacokinetic investigations and bioavailability assessment. Pharmacodynamic evaluations may provide the means for overcoming such problems. *Pharmacodynamic Considerations in Skin Drug Product Development/An FDA Perspective:* Carl C. Peck, M.D., Food and Drug Administration. *Animal Models for Clinically Relevant Pharmacodynamic Studies:* Gerhard Levy, Pharm. D., State University of New York at Buffalo. *Effect Measures: A Substitute for an Adjunct to Drug Concentrations:* Patricia D. Kroboth, Ph.D., University of Pittsburgh. *Pharmacodynamics in New Drug Development/An Industrial Perspective:* Wayne A. Colburn, Ph.D., Warner Lambert/Parke Davis. *Pharmacodynamic Studies: The Good, the Bad and the Ugly:* Randall J. Erb, Ph.D., Phyto Dynamics, Inc. *System Analysis in Pharmacodynamics/Alternatives to Compartmental Analysis:* William Gillespie, Ph.D., The University of Texas at Austin. *Panel Discussion.*

CALENDAR OF EVENTS

The Second Symposium on Frontiers of Pharmacokinetics and Pharmacodynamics will be held in Little Rock, Arkansas on October 12–14, 1988. For further information, contact: Dr. David Young, School of Pharmacy, University of Maryland, Baltimore, Maryland 21201, Telephone (301) 328-6576.