Association News and Announcements

HIGHLIGHTS OF THE AMERICAN ASSOCIATION OF PHARMACEUTICAL SCIENTISTS 1ST NATIONAL MEETING AND PREMIERE EXPOSITION[1]

November 2–6, 1986, Washington Hilton Hotel, Washington, D.C.

Friday and Saturday, October 31–November 1, 1986

Workshop: *Principles and Practices of* In Vitro *Percutaneous Penetration Studies as Relates to Bioavailability and Bioequivalence* [Co-sponsored by AAPS, FDA, University of California. The purpose of the workshop is to recommend guidelines for the performance of *in vitro* penetration procedures to be used in the characterization of topical dosage forms. There are several decades of experience with this *in vitro* technology; as a general observation, many laboratories have chosen to improvise technology and methodology. The workshop will provide insight into the scientific basis and validation of this technology so as to provide more relevant evaluation. *Introduction:* Opening Remarks [J. Goyan (UCSF), C. Evans (FDA), J. Skelly (FDA)], Objectives [V. Shah (FDA)], Historical Perspectives [R. Stoughton (UCSD)]. *Skin and Alternative Membranes:* Human Skin: Different Anatomic Sites, Cadaver vs. Surgical [G. Flynn (U. Michigan)], Species (Human vs. Animal) [R. Wester (UCSF)], Storage Conditions [W. Riefenrath (LAIR)], Metabolism [J. Kao (SKF)], Preparative Technique [F. Marzulli (NAS/NRC)], Alternative Membranes [Y. Chien (Rutgers)], Horizontal Method [H. Schaeffer (CIRD)]. *Apparatus:* Design [R. Scott (ICI)], Static Cell Design (T. Franz (Hoffmann-LaRoche)], Flow-Through Cell Design [R. Bronough (FDA)], Perfusates [R. Bronough (FDA)], Temperature [T. Spencer (S. C. Johnson)]. *Procedures:* (1) Finite Dosing vs. Steady State [B. Barry (Bradford U., England)], (2) Volatility [T. Spencer (S. C. Johnson)], (3) Washing Procedures [T. Mathias (NIOSH-Cincinnati)], (4) Statistics [S. Glantz (UCSF)], (5) Kinetic Analysis [J. Hadgraft (U. Wales, UK)], (6) Bioavailability Assessment [R. Guy (UCSF)], (7) Pharmacology/Toxicology [H. Maibach (UCSF)], (8) An Industrial Approach [B. Poulsen (Syntex), Utilization of Skin Penetration Technology [J. Shaw (Alza)]. **Workshop:** *Principles and Practices of* In Vitro *Percutaneous Penetration Studies as Relates to Bioavailability and Bioequivalence* (Continued). (1) Round-table discussion. (2) Recommendation. (3) Where do we go? What should be/needs to be done?

Sunday, November 2, 1986

Project Management: A Key to More Successful Research **(Short Course I).** This short course will present the essential elements of Project Management, focusing on the common elements which must be present in any organization in order to make Project Management effective. The short course will discuss the process which should be undertaken in order to implement Project Management in a pharmaceutical research environment without having an unfavorable impact upon creativity, innovation, and synergism. This short course will be presented by Dr. Ira Bitz, a certified management consultant. *Animal Health Care: Drug Products and Delivery Systems* **(Short Course II).** This short course will encompass the modern aspects of formulation and product development for the animal health industry. Emphasis will be placed on the use of controlled release systems in optimizing animal drug delivery. (Speakers to be announced.) **Welcoming Reception**—Sponsored by FMC Corporation.

Monday, November 3, 1986

Experimental and Clinical Toxicokinetics: **Symposium** (Co-Sponsored by PPDM and FDA). Toxicokinetic studies are an increasingly important component of drug safety evaluation. There is growing recognition of toxic effects caused by chronic exposure to drugs, to environmental chemicals and/or to their metabolites. Recent technological advances constitute important contributions to toxicokinetic studies, which have led to a more effective preclinical test in animals and the earlier detection of toxicity through clinical use in humans. The purpose of this symposium is to discuss recent advances in toxicokinetics, and its role in support of safety studies in animals and man. Toxicokinetics—An Overview [S. Kaplan (Am. Cyanamid)], [A. Yacobi (Am. Cyanamid]. Application of Toxicokinetics in Drug Safety Evaluation [F. dela Iglesia (Parke-Davis)]. FDA Perspective [V. Glocklin (FDA)]. Some Pharmacodynamic Aspects of Toxicokinetics [G. Levy (SUNY at Buffalo)]. Gastrointestinal Toxicity—Absorption and Metabolism Considerations [K. Rozman (U. Kansas)]. The Role of Biotransformation in Toxicity—N-Oxidation of Xenobiotics [A. Cho (UCLA)]. Pharmacokinetics and Adverse Reactions—An Overview [L. Lemberger (Lilly Research Labs.)]. Facts and Flaws in the Use of Pharmacokinetic Parameters to Predict Efficacy and Toxicity [L. Benet (UCSF)]. Toxicokinetics of Antibiotics [J. Schentag (SUNY at Buffalo)]. Concentration—Effect Relationships for Methotrexate—Toxicity and Efficacy [W.

[1] Specific titles are subject to change.

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Evans (U. Tenn)]. Role of Active Metabolites in Drug Responsiveness and Toxicity in Man [G. Wilkinson (Vanderbilt U.)]. Role of Pharmacokinetics in Drug Evaluation—Safety Related Issues [R. Temple (FDA)]. *Biotechnology in Drug Discovery, Therapeutics, and Pharmaceutical Research*—**Symposium** (PDD/PT/MNPC). Recent research advances in the structural elucidation of numerous natural peptides, in understanding their role in several physiological processes, and in their production using biotechnological techniques have stimulated research that aims at establishing peptides and proteins in therapy. This symposium provides an in-depth examination on several broad issues relating to the impact of biotechnology in drug discovery, therapeutics, and pharmaceutical research. These include (a) delivery challenges such as strategies to improve peptide absorption, to modify immunogenicity, and to detect toxicological manifestations, (b) delivery approaches such as those based on erodible and nonerodible polymers, implants, infusion pumps, liposomes and emulsions, and (c) practical considerations such as design of new proteins and production of peptides, formulation considerations, use of monoclonal antibodies in drug delivery, and changes in production processes demanded by peptide and protein drugs. Introduction [V. Lee (USC)]. Chemical Strategies to Improve Peptide Absorption [J. Samanen (SK&F)]. Penetration Enhancers: Mechanisms, Applications, and Limitations [E. Cooper (Alcon)]. Approaches to Modify Immunogenicity of Peptides and Proteins [A. Abuchowski (ENZON)]. Toxicological Manifestations Unique to Peptides and Proteins [B. Marafino (Cetus)]. *Institutional Life Beyond DRGs: Some Possible Impacts on New Product Development and Marketing*—**Symposium** (ESAS). This seminar will focus on the changing health-care delivery system and the probable impact on new product development and marketing. Reporting requirements of state health data commissions, pharmacy preferred provider organizations, and intelligent computer systems tracking the process of care in hospitals will be presented. Implications of these significant changes on new product development and marketing will be discussed. Pharmacy Preferred Provider Organizations and Outpatient Drug Consumption [L. Strandberg (Oregon State)]. State Health Data Commissions [F. Miller (Denver Technology)]. Intelligent Computer Systems [C. Jacobs (Mediqual Systems)]. Implications for New Product Development and Marketing [L. Weaver (PMA)]. *Product Development Problems and Their Resolutions*—**Symposium** (PT). This symposium has been planned to illustrate the typical problems which occur during formulation and scale-up of various pharmaceutical dosage forms and the means to resolve them. Often these problems require specially designed experiments and the application of more fundamental physiochemical principles. Speakers with extensive knowledge in several specific product categories will present some of their experiences relative to identification of problems, means of solving them, and illustrate actual experiences. Product groups include solids, aerosols, sterile products, liquids and semisolid dosage forms. Sterile Products [J. Portnoff (Merck)]. Aerosols [A. Cutie (A&M Schwartz College of Phy.)]. Solids [E. Rudnic (Schering)]. Liquids and Semisolids [L. Pena (Upjohn)]. AQM Workshop. ESAS/PDD/PPDM Posters and Exhibits. AQM, MNPC, and PT Podium Sessions. Professional Placement Center.

Tuesday, November 4, 1986

Topical Corticosteroids in Health and Disease—**Symposium** (Co-Sponsored by PPDM and the Biopharmaceutics Division of FDA). This is the first symposium of the dermatopharmaceutics section of PPDM. It will provide an insight into the utilization of corticosteroids in dermatologic diseases. Corticosteroids provided a miracle class of drugs that revolutionized clinical dermatology and provided a cure or marked amelioration for many millions of dermatitis sufferers. Many interdisciplinary teams including pharmacologists, pharmaceutical chemists, dermatologists, toxicologists, and related scientists have delved deeply into the mechanisms involved in this critical dermatologic area. The symposium speakers will dissect three decades of experience to define not only present knowledge but also to define pathways for future improvements. Introduction [H. Maibach (UCSF), B. Barry (Bradford U.)]. Biotransformation of Steroids in Skin [J. Kao (SKF)]. Human Models for Evaluation of Efficacy and Toxicity [H. Maibach (UCSF)]. Dermatopharmacokinetics, Part I—*In Vitro* [H. Schaeffer (CIRD)]. Dermatopharmacokinetics, Part II—*In Vivo* [R. Guy (UCSF), H. Maibach (UCSF), R. Wester (UCSF)]. Lessons Learned from Vasoconstriction [R. Stoughton (UCSD)]. Pharmaceutics [B. Poulsen (Syntex)]. Open Forum for Interested Parties in Dermatopharmacy Subsection "Where Do We Go From Here?" *Biotechnology in Drug Discovery, Therapeutics, and Pharmaceutical Research*—**Symposium** (Continued). See Monday Program for Description. Strategies in Drug Delivery System Design [J. Robinson (U. Wisc.)]. Nonerodible Systems for Peptides and Proteins [R. Langer (MIT)]. Implants [D. Elsberry (Medtronics)]. Infusion Pumps [D. Winchell (Baxter-Travenol)]. Erodible Systems for Peptides and Proteins [J. Kohn (Rutgers)]. General Applications of Liposomes in Peptide and Protein Delivery [D. Mufson (LTI)]. Delivery of Interferons by Liposomes [D. Eppstein (Syntex)]. Applications of Emulsions in Drug Delivery [S. Frank (Ohio State)]. *Electrochemistry in the Pharmaceutical Sciences*—**Symposium** (AQM). Electrochemistry has been employed extensively for more than 20 years in the analysis of pharmaceutical products. However, in the past, the technique lacked the advantages, reproducibility, accuracy, and convenience of operation of other common techniques routinely employed in pharmaceutical sciences. Recent advances in electronics, computerization, miniaturization, material technology and the availability of commercial instrumentation incorporating these features have helped the scientist to use this technique in several areas. Electrochemical detection in HPLC is routinely employed for analysis at nanogram levels of drugs which are easily electrooxidizable or reducible. In addition, this technique is also used in other nonanalytical applications such as structure elucidation, reaction mechanisms, electrochemical syntheses, understanding of biological processes, drug delivery systems, etc. This symposium, in addition to highlighting these developments, will also show how a combination of this technique, with other techniques such as spectrophotometry, photochemistry, ESR spectroscopy, and flow-injection analysis, in helping to solve a variety of problems. The object of this symposium is to show how the data from electrochemistry can supplement those obtained from other techniques in gaining fundamental

knowledge in the pharmaceutical sciences. Introduction [G. Padmanabhan (CIBA)]. Electrochemistry and HPLC-EC Overview [P. Kissenger (Purdue)]. Electrochemistry in the Understanding of Biological Processes [G. Dryhurst (U. Okla.)]. Reaction Mechanisms and Structure Effects [P. Zuman (Clarkson College)]. Electrochemistry in Metabolism and Xenobotics [D. Radzik (Lederle)]. Electrochemistry and Electron Spin Resonance Spectra of Certain Antitumor Agents [P. Gutierrez (U. MD)]. In Vivo Electrochemistry [R. Wightman (Indiana U.)]. Photo-Electro Chemistry in Pharmaceutical Analysis [K. Bratin (Pfizer)]. Red-Ox Concepts in Novel Experimental Drug Delivery Systems [N. Bodor (U. Florida)]. Electrochemical Immuno-Analysis [W. Heineman (U. Cincinnati)]. Electrochemical Synthesis of Pharmaceuticals [D. Hall (Eli Lilly)]. Electrochemistry in Pharmaceutical Analysis [M. Brooks (Merck)]. Spectroelectrochemistry of Oxidation Products of Pharmaceuticals [R. McCreery (Ohio State)]. *Application of Population Pharmacokinetics to Drug Development and Utilization*—**Symposium** (Co-Sponsored by the American College of Clinical Pharmacists, FDA, and PPDM). The estimation of population pharmacokinetic parameters has received widespread attention recently in all phases of drug development and utilization. The purpose of this symposium is to (1) provide information regarding the theoretical aspects of population pharmacokinetic analysis, (2) relate practical experiences in various aspects of application using actual clinical data, and (3) provide an open forum for discussion of viewpoints between academia, industry, and regulatory agencies. Pharmacostatistical Modeling—Structural Models [T. Grasela (M. Fillmore Hospital)]. Pharmacostatistical Modeling—Variability [L. Sheiner (UCSF)]. Population Pharmacokinetic Analysis—Interpreting a NONMEM Output [L. Sheiner (UCSF)]. Application of Population Pharmacokinetic Analysis to Large-Scale Clinical Efficacy Trials [E. Antal (Upjohn)]. A Population Pharmacokinetic Profile of Imazodan in Congestive Heart Failure Patients [S. Olson (Parke-Davis)]. PDD and PT Podium Sessions. MNPC/PT, and PPDM Posters and Exhibits. Professional Placement Center. AAPS Recepton/Banquet.

Wednesday, November 5, 1986

Application of Population Pharmacokinetics to New Drug Development and Utilization—**Symposium** (Continued). See Tuesday Program for Description. Application of Population Pharmacokinetic Analysis to Special Populations—Theophylline Pharmacokinetics in Neonates [E. Moore (U. Mich.)]. Estimating Population Dose-Response Curves by NONMEM Analysis of Dose Escalation Studies [N. Sambol (UCSF)]. Detection of Drug-Drug Interaction Using Population Pharmacokinetic Analysis [L. Ereshefsky (U. Texas)]. Application of Pharmacokinetic Population Analysis to Physiologic Models [T. Ludden (U. Texas)]. Panel Discussion: L. Sheiner (UCSF), J. Wagner (U. Mich.), J. Skelly (FDA), G. Wright (A. H. Robins). *Automated Analysis and Inspection of Pharmaceutical Materials*—**Symposium** (AQM). The symposium provides a review of recent advancements in laboratory automation and on-line inspection technology. Papers to be presented will discuss the application of these new tools to pharmaceutical manufacturing, packaging, and laboratory operations. Specific topics include the use of computer expert systems, laboratory robotics, near-infrared reflectance, spectroscopy, on-line chemical sensors, and machine vision. XMIDAS: An Exact Advisory System for Microbiological Laboratories [K. Tsuji (Upjohn)]. Near Infrared Analysis of Pharmaceuticals: Do We Need Another Tool? [E. Ciurczak (Sandoz)]. Application of On-Line Analysis to Pharmaceutical Production [D. Chapman (Upjohn)]. Machine Vision: Application to Pharmaceutical Packaging [R. Shillman (Cognex)]. Robotics [W. Mason (Ortho)]. *Biotechnology in Drug Discovery, Therapeutics, and Pharmaceutical Research*—**Symposium** (Continued). See Monday Program for Description. Biotechnology-Based Diagnostics: Chemistry, Immunology and Applications [M. Becker (Syva Syntex)]. Use of Biotechnology in the Production of Peptides [H. Chan (Syntex)]. Creation of New Proteins by Recombinant DNA Technology [C. Craik (UCSF)]. Practical Formulation Considerations [S. Anik (Syntex)]. Changes in Production Processes Demanded by Peptide and Protein Drugs [Z. Shaked (Cetus)]. *Aqueous Coating Technology*—**Symposium** (PT). Significant changes in coating technology have occurred over the last several years. This has been influenced by the availability of new forms of polymeric coating materials, the impact of environmental regulations, and the high cost of buying and operating solvent recovery equipment. The speakers will address both theoretical and practical considerations relative to the use of aqueous latex materials to both pellets and tablets. Comparisons between different materials, different processing, and different processing machinery will be given. Thermodynamic Model of Aqueous Film Coating [G. Ebey (Thomas Engineering)]. Comparative Evaluation of Water-Based Sustained Release Coatings for Pellet Formulations—Part I [I. Ghebre-Sellassie (Parke-Davis)]. Comparative Evaluation of Water-Based Sustained Release Coatings for Pellet Formulations—Part II [M. Harris (Parke-Davis)]. Evaluation of Various Aqueous Enteric Coating Materials on Tablets [L. Luciano (Upjohn)]. MNPC, PPD, and PT Podium Sessions. AQM, PDD, and PPDM Poster Sessions and Exhibits. Professional Placement Center. AAPS Business Meeting.

Thursday, November 6, 1986

AQM/PDD/PPDM/PT Poster Sessions.

INTERNATIONAL SYMPOSIUM: PROTEINS AND PEPTIDES—A CHALLENGE FOR DRUG DELIVERY

Heidelberg, Sept. 28–Oct. 1, 1986

On the occasion of the 600th anniversary of the Ruprecht-Karls University. Chemistry, pharmacokinetics, formulation of registration of proteins and peptides; eighteen invited speakers from eight countries; conference language: English.

For further information please contact: International Association for Pharmaceutical Technology (A.P.V.), Hefenstr. 23, D-6500 Mainz, West Germany.