

Association News and Announcements

AAPS, FDA JOINT CONFERENCE ON STABILITY GUIDELINES

AAPS and the Food and Drug Administration will be sponsoring a joint Conference on the current Stability Guidelines as they relate to new product approval and marketed product stability testing. The Conference is intended to surface problems which have been experienced by both industry and FDA since the Guidelines have been implemented and, at the same time, propose alternatives which might alleviate these problems while accomplishing the intent of the Guidelines. The Conference will be two days with two sessions each day. Each session will consist of presentations by a panel comprised of representatives from Industry and FDA. In addition, the topics of each session will be open to discussion from the floor to present additional issues and proposals. The subject for the first day will cover: Protocol Design including new product submissions, line extensions, manufacturing site changes, process changes, and marketed product stability. The subject for the second day will be Stability Conditions/Intervals and Their Use including the definition of "room temperature" and the use of accelerated conditions for definition of labelling and projecting shelf life. The Conference will be held in Arlington, Virginia on December 11-12, 1989.

WHAT IS AAPS?

The American Association of Pharmaceutical Scientists (AAPS), was founded to provide pharmaceutical scientists in academia, industry, government and other research institutions with an independent and unified voice. For an application, contact: AAPS, 601 King Street, Alexandria, Virginia 22314-7349; telephone 703-548-3000.

WHAT ARE THE AAPS SECTIONS?

Analysis and Pharmaceutical Quality (APQ)

This section is composed of members whose interests are in the areas of analytical methods development for bulk drug substances as well as drugs in pharmaceutical dosage forms and biological fluids, and methods and procedures for assuring that quality is designed into pharmaceutical products. APQ provides a forum for the exchange of information pertaining to analytical techniques, regulatory and compendial issues, and assurance of quality. By its very nature, APQ is an area which interacts continually with the other disciplines involved in the development and production of pharmaceutical products. Many of its programs and activities are undertaken with other sections of the Association.

Biotechnology (BIOTECH)

This section focuses on issues involved in the discovery, design, development, manufacture, and evaluation of therapeutic and diagnostic agents derived from biotechnology. These issues include stabilization and stability characterization, pharmaceutical analysis, drug delivery, biodisposition, pharmaceutical processing, and regulatory aspects, specific to these new pharmaceutical species. A major focus of this section is on the use of proteins as therapeutic, immunologic, and drug carrier agents.

Economic, Marketing, and Management Sciences (EMMS)

The particular segments of the pharmaceutical sciences included in EMMS are pharmaceutical marketing, economics, health care system management, operations research, marketing research, computer science, public policy, and private and public health care systems administration. Membership in this section affords personal interaction with representatives of many segments of the health care system, including those in the pharmaceutical industry, pharmacy education, the practice of pharmacy, and various public and private health care programs who are researching economic, social and administrative issues. The primary purpose of this section is to facilitate the development, expansion and exchange of scientifically-oriented knowledge relevant to the section's disciplines.

The section's primary functions are (1) to stimulate studies and research on areas of interest, (2) to serve as a forum and conduit for the distribution of this information, (3) to promote and support the intellectual and professional growth of its members, and (4) to act as a knowledge resource to the entire Association for its health care delivery policy and procedural activities. EMMS members receive the *Journal of Pharmaceutical Marketing and Management* as a member benefit.

Medicinal and Natural Products Chemistry (MNPC)

This section is unique among scientific organizations serving medicinal and natural product chemistry by providing a single organization and forum to serve these closely related sciences. The multidisciplinary character of the section and of AAPS encourages productive scientific discourse and relationships between all segments of the basic pharmaceutical sciences. The section is committed to joint symposia with other sections of AAPS.

The goal of the MNPC Section is to stimulate research not only in medicinal and natural product chemistry but also in the related pharmaceutical sciences by providing an atmosphere and opportunities not otherwise available for professional growth and development of its members and of colleagues in other disciplines and sections of AAPS.

Pharmaceutical Technology (PT)

The PT Section is a body of pharmaceutical scientists involved in the application of the principles of pharmaceuticals, engineering and material science to the design, development and production of drug delivery systems. A major focus of the PT Section is on pharmaceutical formulation and manufacturing process technology, with emphasis on improved control of product performance and manufacturing process parameters.

This section serves the needs of its members by providing technical and professional forums for presenting and discussing current developments in these areas of applied research and manufacturing.

This section further seeks to recognize individual achievements in these areas and to foster career growth and encourage development of its members.

These objectives are achieved through national and regional meetings, educational conferences, and publications sponsored and organized by the section.

Pharmaceutics and Drug Delivery (PDD)

This section serves as a forum for scientists whose interests center broadly on basic pharmaceutics. Aspects such as the physical chemical characterization, evaluation of *in vitro/in vivo* performance, and problems related to the design of drug delivery systems are all encompassed by the discipline of Pharmaceutics. As such, pharmaceutics is a multidisciplinary field drawing upon the physical, biological, and engineering sciences with the unifying theme being the drug delivery system. The mission of the PDD Section is to provide a forum for interaction among scientists from these diverse backgrounds, yet with common, but also broad based, interests. This section serves to coordinate the scientific activities of its membership through national and regional meetings at which contributed papers and symposia are presented.

Pharmacokinetics, Pharmacodynamics and Drug Metabolism (PPDM)

PPDM brings together those qualified individuals investigating or interested in drug and chemical actions, disposition, and biotransformation. This section provides a forum directly dealing with all issues relative to biopharmaceutics and pharmacokinetics of new and existing drugs. It provides an opportunity for presentation of new data, and an exchange of ideas by individuals actively engaged in various facets of pharmacokinetics, pharmacodynamics, drug metabolism, biopharmaceutics and related sciences enabling them to jointly advance their field of activity. An objective of this section is to provide interaction between academia, industry and regulatory bodies via sponsorship of workshops, symposia, and seminars on current regulatory issues.

Clinical Sciences (CS)

The Clinical Sciences Section provides a clinical research dimension within the comprehensive range of pharmaceutical sciences represented in AAPS. The section will focus on therapeutics and clinical assessment of drugs including the design, conduct and analysis of clinical trials, risk assessment, pharmacoepidemiology, and therapeutic efficacy/safety research in appropriate populations. Having achieved provisional section status, CS is planning its first programming for the 1989 AAPS Annual Meeting.

CALENDAR OF EVENTS

May 22–24, 1989. Joint workshop "Bioadhesion—Possibilities and Future Trends," sponsored by the APV—Controlled Release Society. It will be held at Gorlaeus Laboratoria, Leiden University, Leiden, The Netherlands. For more information, contact: Controlled Release Society, Administrative Office, 16 Nottingham Drive, Lincolnshire, Illinois 60069, telephone (312) 940-4277; or APV, Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik e.V., Hafenstrasse 23, 6500 Mainz, Federal Republic of Germany, telephone (49) 61 31 67 78 12.

May 23–24, 1989. Fifth Annual Pittsburgh Pharmacodynamics conference, "Peptides, Peptoids, and Proteins," to be held at the Westin William Penn Hotel, Pittsburgh, Pennsylvania. Topics: preparation of synthetic peptides; computer assisted drug design of peptides; current delivery issues; methods for quantifying proteins in biological fluids and tissues; a pharmacokinetic overview of peptides, peptoids, and proteins; pharmacodynamic measures; current state of genetically engineered compounds; and regulatory issues. For additional information, contact: Pamela D. Garzone, Associate Director, Center for Pharmacodynamic Research, 527 Salk Hall, University of Pittsburgh, Pittsburgh, Pennsylvania 15261.

August 6–11, 1989. Sixteenth International Symposium on Controlled Release of Bioactive Materials and Workshop, sponsored by the Controlled Release Society and to be held at the McCormick Center Hotel, Chicago, Illinois. For more information, contact: Controlled Release Society, Administrative Office, 16 Nottingham Drive, Lincolnshire, Illinois 60015; telephone (312) 940-4277.

August 14–18, 1989. Gordon Research Conference, "Barrier Function of Mammalian Skin," to be held at Brewster Academy, Wolfeboro, New Hampshire. Chairman: R. H. Guy, Vice Chairman: R. O. Potts. Topics: stratum corneum lipids and epidermal biochemistry; air-liquid keratinocyte cultures; biophysical characterization of barrier function—structure and quantitation of permeability; perturbation of barrier function—chemical enhancers and iontophoresis; physical chemistry of barrier function—transport relationships; models for characterizing barrier function; and skin metabolism and transport. For more information, contact the Gordon Research Conferences at (401) 783-4011.