

CALL FOR ABSTRACTS REGISTRATION & PROGRAM

FOR THE

THIRTIETH ANNUAL MEETING OF THE AMERICAN COLLEGE OF TOXICOLOGY

NOVEMBER 1 – 4, 2009



**Palm Springs Convention Center
277 N Avenida Caballeros
Palm Springs, CA 92262-6440
Wyndham Palm Springs
888 Tahquitz Canyon Way
Palm Springs, CA 92262**

**Reservations – Tel: 760-322-6000 – www.wyndham-palmsprings.com
Deadline for Hotel Reservations – September 29, 2009
Deadline for Advanced Registration – October 1, 2009**

CORPORATE MEMBERSHIP

Abbott Laboratories, Abbott Park, IL
Alcon Research, Inc., Fort Worth, TX
Allergan, Irvine, CA
Altria Client Services, Inc., Richmond, Va
American Chemistry Council, Arlington, VA
American Petroleum Institute, Washington, DC
Amgen Inc., Thousand Oaks, CA
BASi, West Lafayette, IN
Battelle, Columbus, OH
Baxter Healthcare Corporation, Round Lake, IL
Bayer Healthcare Pharmaceuticals, Montville, NJ
Biogen Idec MA, Inc., Cambridge, MA
BioReliance, Rockville, MD
Boehringer Ingelheim, Ridgefield, CT
Bristol-Myers Squibb, PRI, Princeton, NJ
Cantox Health Sciences International, Mississauga, Ontario, Canada
Charles River, Wilmington, MA
Covance Laboratories Inc., Madison, WI
Data Sciences International, Saint Paul, MN
Eli Lilly and Company, Indianapolis, IN
EPL, Inc., Sterling, VA
Experimur, Chicago, IL
ExxonMobil Biomedical Sciences, Inc., Annandale, NJ
Genentech, Inc., South San Francisco, CA
GlaxoSmithKline, Research Triangle Park, NC
Halozyme Therapeutics, Inc., San Diego, Ca
Hoffmann-La Roche, Inc., Nutley, NJ
Huntingdon Life Sciences, PRC, East Millstone, NJ
J&J Pharma Co(Centocor/J&J PRD/Tibotec), Radnor, PA
MannKind Corporation, Valencia, Ca
MPI Research, Mattawan, MI
P&G Pharmaceuticals Inc., Mason, OH
Pfizer Inc., Groton, CT
Purdue Pharma, LP, Cranbury, NJ
R.J. Reynolds Tobacco Co., Winston-Salem, NC
sanofi-aventis US, Bridgewater, NJ
Schering-Plough Research Institute, Lafayette, NJ
Sequani Limited, Ledbury, United Kingdom
Takeda Global R&D, Lake Forest, IL
WIL Research Laboratories, LLC, Ashland, OH
Wyeth Research, Chazy, NY

GENERAL INFORMATION

LOCATION AND DATES

The Thirtieth Annual Meeting of the American College of Toxicology will be held at the Palm Springs Convention Center & the Wyndham Palm Springs, Palm Springs, CA, November 1 – 4, 2009.

REGISTRATION

Registration will open from:

Saturday	3:00 pm – 6:00 pm
Sunday	7:30 am - 5:30 pm
Monday	7:30 am – 5:30 pm
Tuesday	7:30 am – 5:30 pm
Wednesday	7:30 am – 3:00 pm

Sessions scheduled on Monday from 8:00 am – 12:00 noon and 2:00 pm – 5:00 pm, Tuesday from 8:00 am – 12:00 noon and 1:30 pm – 5:00 pm, and Wednesday from 8:00 am – 12:00 noon and 1:30 pm – 5:00 pm.

REGISTRATION FEES

The registration fee includes the American College of Toxicology Keynote Luncheon, Monday noon, continental breakfast Monday thru Wednesday, all coffee breaks, and the Wednesday Farewell Reception.

Member	\$400
Nonmember	\$650
Student	\$ 50
One Day Member	\$250
One Day Nonmember	\$350
One Day Student	\$ 30

To register, mail (or fax) the enclosed registration form with the appropriate

remittance to arrive by October 1, 2009 to:

Secretariat
American College of Toxicology
9650 Rockville Pike
Bethesda, MD 20814
T: 301-634-7840 F: 301-634-7852
Email: ekagan@actox.org

OR REGISTER ONLINE AT:

www.actox.org

After October 1, 2009 there will be a late fee of \$100.00 added to all registrations.

REFUND POLICY

Refunds for Course Registration and Meeting Registration will be as follows:

\$75.00 Processing Fee if canceled before September 25, 2009.

50% refund if canceled before October 1, 2009.

After October 1, 2009 no fees will be refunded.

SOCIAL ACTIVITIES

Sunday – Anniversary Celebration

Monday - ACT LUNCHEON

Monday - BRIDGE LABS RECEPTION

Tuesday– SAGE POSTER RECEPTION

Wednesday - FAREWELL RECEPTION

HOTEL RESERVATIONS

REGISTER EARLY. September 29, 2009 is the cutoff date for the “agreed upon” rates. When our room block is filled, higher rates will apply if any rooms are available.

To assure lodgings in the headquarters hotel, call 760-322-6000, or go online (see below) **NO LATER THAN SEPTEMBER 29th, 2009.**

Be sure to state that you are coming for the American College of Toxicology Conference. This way you will be given the meeting rate and the College will be credited with your reservation.

You can register online at:

http://www.wyndham.com/groupeventsnew/pspps_act/main.wnt

After SEPTEMBER 29th, 2009, the agreed-upon rates may not be available, and prevailing higher rates will be charged. Also, our room block is released to general sales on that date and the hotel could be sold out.

TRANSPORTATION

Palm Springs International Airport services most major carriers and is approximately 1.5 miles from the hotel. For free Hotel Airport Transportation, contact the hotel.

DISTINGUISHED SERVICE AWARD

At the Annual Luncheon of the American College of Toxicology a plenary lecture is presented by a distinguished member of the toxicology community. Council voted that the lecturer would be designated as the recipient of the Distinguished Service Award of the College. The criteria for selection

include, but are not limited to, an individual who has made outstanding contributions to toxicology and its relationship to the regulation of chemicals, and the improvement of public health.

PLENARY LECTURE SERIES

This year the College is fortunate to have three Plenary Lecturers:

1) Monday Morning – DOUGLAS C. THROCKMORTON, M.D., Deputy Director, US FDA, CDER, Silver Spring, MD:

2) Tuesday Morning – J. WILLIAM LANGSTON, M.D., Scientific Director, CEO & Founder, Parkinson’s Institute & Clinical Center, Sunnyvale CA

3) Wednesday Morning – BRUCE N. AMES, Ph.D., Professor, Children’s Hospital Oakland Research Institute, Oakland, CA who will talk on “*Delaying Age-related Disease with Micronutrients: Triage Theory*”.

FURST AWARD

Through a generous contribution from Dr. Arthur Furst, the American College of Toxicology was able to institute the Furst Award, an award of \$2000 for the best student paper presented at each Annual Meeting of the College. We will be presenting our Twenty First Annual Furst Award at the Annual Luncheon during the Thirtieth Annual Meeting in Palm Springs, CA.

ACT STUDENT TRAVEL AWARD

This year the College will provide travel awards in the amount of \$1000.00 to some students attending and presenting a poster at the Annual Meeting. Any student receiving a travel award is also eligible for the Furst Award.

PROGRAM

30TH ANNUAL ACT MEETING

PALM SPRINGS CONVENTION CENTER/WYNDHAM PALM
SPRINGS, PALM SPRINGS, CA

SUNDAY, November 1, 2009

CONTINUING EDUCATION COURSES
(See Separate Schedule in this Packet)

6:00 pm - 7:30 pm

ACT ANNIVERSARY PARTY

MONDAY MORNING, 11/02/09

8:00 am – 8:45 am

PLENARY LECTURE

Douglas C. Throckmorton M.D.
Deputy Director
US FDA, CDER
Silver Spring, MD

9:00 – 12:00 - **SYMPOSIUM I**

FDA 101: INTRODUCTION TO FDA'S OFFICE OF NEW DRUGS

*Co-Chairs: Norman Kim, M.S, DABT,
Senior Director, Toxicology and Preclinical
Development, Inotek Pharmaceuticals,
Lexington, MA and Timothy McGovern,
Ph.D., Consultant, SciLucent, Herndon, VA*

This symposium is intended to provide
an introduction to the U.S. FDA's Office

of New Drugs (OND) and nonclinical insights of selected divisions within the OND. The OND, contained in the Center for Drug Evaluation and Research (CDER), is composed of six distinct offices: Office of Drug Evaluation (ODE) I, ODE II, ODE III, Office of Antimicrobial Products, Office of Oncologic Drug Products, and Office of Nonprescription Products. Five of the six offices will be discussed in this session. Speakers will illustrate the organizational structure of the Divisions within each Office, and will further describe the functions and operations of the following selected Divisions: Neurology and Psychiatry (in ODE I), Pulmonary and Allergy (in ODE II), Reproductive and Urology (in ODE III), Anti-Infective and Ophthalmology (Office of Antimicrobial Products), and the Office of Oncology Drug Products (Divisions of Drug and Biologic Oncology Products). Presentations will also include information about the reviewing division, the responsibility of the pharmacology/toxicology reviewers and their supervisor, interaction with other pharmacology/toxicology reviewers within and outside their respective divisions, how consultations with other divisions are dealt with, and how divisions communicate with sponsoring companies. Nonclinical requirements and recommendations unique to these divisions in consideration of the target indications and the clinical phases of drug development will be discussed. A panel discussion will follow presentations.

9:00 am **INTRODUCTION TO DIVISION OF ANTI-INFECTIVES AND OPHTHALMOLOGY PRODUCTS** – Amy Ellis, Ph.D., US FDA. CDER. Silver Spring, MD

Co-Chairs: Matthew Reed, Ph.D., DABT, Director, Preclinical Drug Development, Lovelace Respiratory Research Institute, Albuquerque, NM and Jerry F. Hardisty, DVM, DACVP, Fellow IATP, President, Veterinary Pathologist, EPL, Inc., Research Triangle Park, NC

9:20 am **INTRODUCTION TO DIVISION OF NEUROLOGY PRODUCTS AND DIVISION OF PSYCHIATRY PRODUCTS** – Paul Roney, Ph.D., DABT, Toxicologist, Kendle International, Rockville, MD

Asthma is a condition characterized by inflammation of the lining of the airways and intermittent spasm of the underlying smooth muscle. More than 22 million Americans have asthma, and it is one of the most common chronic diseases of childhood, affecting an estimated 6 million children. Occupational asthma is the most prevalent occupational lung disease in the United States. Approximately 15 to 23 percent of asthma cases in the United States are due to occupational exposures. Comparatively more is known about the cause of asthma caused by work (occupational asthma) than about other forms of asthma. It is often but not always the result of allergy to an inhaled dust or vapor in the workplace. In the home, exposure to allergens from house dust mites can be a contributing factor in the development of asthma as well as a cause of its symptoms. Other allergens from pollen, moulds, animal dander etc can cause asthmatic symptoms. Outside the home in the general environment increase in asthmatic symptoms has been attributed to exposure to soya bean dust and to oil seed rape. The contribution to the causation of asthma by irritant gases such as sulphur dioxide, nitrogen dioxide and ozone is still unclear, although it is known that these substances can certainly aggravate symptoms in those who are already asthmatic. Since its pathogenic mechanism(s) are unknown, animal models have been developed to investigate the various disease processes, as well as to enable study of environmental and genetic factors which may contribute to disease development. Numerous parameters can be measured

9:40 am **INTRODUCTION TO DIVISION OF PULMONARY AND ALLERGY PRODUCTS** - Timothy McGovern, Ph.D., Consultant, SciLucent, Herndon, VA

10:00 am Refreshment Break

10:20 am **INTRODUCTION TO DIVISION OF REPRODUCTIVE AND UROLOGIC PRODUCTS** – Lynnda Reid, Ph.D., Pharmacology/Toxicology Team Leader, US FDA, CDER, Silver Spring, MD

10:40 am **INTRODUCTION TO DIVISION OF DRUG ONCOLOGY PRODUCTS AND DIVISION OF BIOLOGIC ONCOLOGY PRODUCTS** – David Morse, Ph.D., Principal Consultant, Parexcel Consulting, Bethesda, MD

11:00 am **PANEL DISCUSSION**

9:00 – 12:00 - SYMPOSIUM II

THE ASTHMA EPIDEMIC: RESEARCH AND DEVELOPMENT EFFORTS FOR MANAGEMENT

in animal systems, including specific and total immunoglobulin E (IgE), pulmonary eosinophilia, diaphragm contractions and airflow muscle hypertrophy. It is recognized that no single factor is sufficient to lead to a conclusion of occupational asthma, but rather that a selected combination of parameters is most fitting.

- 9:00 am **ASTHMA EPIDEMIC: AN OVERVIEW OF DISEASE PROCESS, ENVIRONMENTAL AND GENETIC FACTORS -**
David Diaz-Sanchez, Ph.D., Chief, Clinical Research Branch, US EPA, Chapel Hill, NC
- 9:30 am **ANIMAL MODELS FOR ASTHMA: CONTROVERSIAL ASPECTS AND UNSOLVED PROBLEMS –**
Edward (Ted) G. Barrett, Ph.D., Staff Scientist, Respiratory Immunology and Asthma Program, Lovelace Respiratory Research Institute, Albuquerque, NM
- 10:00 am Refreshment Break
- 10:20 am **NEW TARGETS FOR DRUG DEVELOPMENT IN ASTHMA -** *Matthew Reed, Ph.D., DABT, Director, Preclinical Drug Development, Lovelace Respiratory Research Institute, Albuquerque, NM*
- 10:50 am **DEVELOPING PHARMACEUTICALS FOR USE IN ASTHMA: TEST CASE MDIs -** *Chet L. Leach, Ph.D., DABT, Consultant in Pulmonary Drug Development, Tijeras, NM*
- 11:20 am **PANEL DISCUSSION**

9:00 – 12:00- SYMPOSIUM III

ENDOCRINE DISRUPTOR SCREENING PROGRAM (EDSP)

Co-Chairs: Irma M. Grossi, Ph.D., MBA, Sr. Director, Preclinical Pharmaceutical Services, RTI Health Solutions, Research Triangle Park, NC and Nelson Wilson, B.S., DABT, Director, Laboratory Operations & Toxicology Services, EPL, Inc., Sterling, VA

Since the publication of [Rachel Carson's *Silent Spring*](#), there has been concern that chemicals in the environment might exert profound and deleterious effects on wildlife populations, and that human health is inextricably linked to the health of the environment. Endocrine disrupting compounds encompass a variety of chemical classes, including hormones, plant constituents, pesticides, compounds used in the plastics industry and in consumer products, and other industrial by-products and pollutants. Based on this and other evidence, Congress passed the Food Quality Protection Act in 1996, requiring that USEPA initiate the Endocrine Disruptor Screening Program (EDSP) to assay pesticide chemicals and environmental contaminants for their potential to affect the estrogenic, androgenic, or thyroid hormone systems of humans and wildlife. This symposium will provide an overview of potential problems, the EPA EDSP program, and mammalian and aquatic tests that have been designed to provide the answers to these difficult issues. The faculty will include all stakeholders including scientists from the academic research community, regulatory authorities, contract research organizations, and industry.

- 9:00 am **WHAT ARE ENDOCRINE DISRUPTORS AND WHY ARE WE CONCERNED? -**
Edward F. Orlando, Ph.D., Assistant Professor, University of Maryland,

College of Agriculture and
Natural Resources, College
Park, MD

“MECHANISM-BASED TOXICOLOGY:
NICOTINE VERSUS NEONICOTINOID
INSECTICIDES”

9:30 am **UPDATE ON EPA'S
APPROACH FOR
SCREENING AND
TESTING CHEMICALS
FOR POTENTIAL
ENDOCRINE EFFECTS
(EDSP) - Les Touart, Ph.D.,
Senior Ecotoxicologist, US
EPA, Washington, DC**

MONDAY AFTERNOON, 11/02/09

2:00 – 5:00 - SYMPOSIUM IV

**REDUCING VARIABLES AFFECTING
INTERPRETATION OF TOXICOLOGY
STUDIES**

*Co-Chairs: David L. Hopper, DVM, Ph.D.,
DABT, Director of Toxicology, BASi, Mount
Vernon, IN and Jerry F. Hardisty, DVM,
DACVP, Fellow IATP, President/ Veterinary
Pathologist, EPL, Inc., Research Triangle
Park, NC*

10:00 am Refreshment Break

10:20 am **ENDOCRINE DISRUPTION
IN WILDLIFE AND
AQUATIC ANIMALS -
Jeffrey Wolf, DVM, DACVP,
Veterinary Pathologist, EPL,
Inc., Sterling, VA**

There are many variables that can affect the interpretation of toxicity studies. These variables include environmental physical, chemical and biological factors that may influence the response of the test species to test article exposure. Other critical factors include the selection of the test animal that is most appropriate for the study being conducted. A thorough knowledge of the spectrum of spontaneous disease in rodents, dogs and non-human primates is critical when interpreting findings in studies designed to minimize the number of animals on test. The selection of the appropriate diet and understanding the potential the effects of non-nutrients that may be present as dietary contaminants is critical. This symposium will discuss these factors and provide guidance to optimize the study design to manage or eliminate study variables.

10:50 am **DEVELOPMENT OF a-
MAMMALIAN ENDOCRINE
DISRUPTION TESTING -
Rochelle W. Tyl, Ph.D.,
DABT, Senior Toxicologist,
Research Triangle Institute,
Research Triangle Park, NC**

11:20 am **PANEL DISCUSSION**

12:00 pm – 2:00 pm

ACT LUNCHEON

**KEYNOTE SPEAKER &
DISTINGUISHED SERVICE
AWARDEE**

JOHN E. CASIDA, Ph.D.

Director, Professor of Entomology &
Toxicology
Environmental Chemistry & Toxicology
Laboratory
Department Environmental Science, Policy
& Management
University of California
114 Wellman Hall
Berkeley, CA

2:00 pm **HOW “NORMAL” ARE
CONTROL ANIMALS? -
Peter C. Mann, DVM,
DACVP, Manager, EPL
West, EPL, Inc., Seattle,
WA**

- 2:30 pm **RODENT DIETS AND NUTRITION AS A STUDY VARIABLE** - *Graham Tobin, Ph.D., Director, Technical Services, Teklad Diets Europe, Harlan Laboratories UK Limited, Bicester, United Kingdom*
- 3:00 pm **USE OF PLACEBO, VEHICLE, AND POSITIVE CONTROLS AND RECOVERY GROUPS TO AID IN STUDY INTERPRETATION** – *Klaus Weber, PhD, Dr. rer.nat., Dipl.Biol.,Vet.-Ing., Head of Pathology/Diagnostics, Chief Scientific Officer, RCC Ltd., Harlan Inc., Itingen, Switzerland*
- 3:30 pm Refreshment Break
- 3:50 pm **OPTIMIZING THE DESIGN OF PRELIMINARY TOXICITY STUDIES FOR PHARMACEUTICAL SAFETY TESTING** – *David L. Hopper, DVM, Ph.D., DABT, Director of Toxicology, BASi, Mount Vernon, IN*
- 4:20 pm **PANEL DISCUSSION**

2:00 – 5:00 - SYMPOSIUM V

PHOSPHOLIPIDOSIS: NONCLINICAL ASSESSMENT AND RISK EVALUATION

Chair: Elizabeth Huggins Romach, Ph.D., DABT, Director, Safety Assessment Projects, GlaxoSmithKline, Research Triangle Park, NC; Co-Chair: James Willard, Ph.D., Pharmacologist, US FDA, CDER, Silver Spring, MD

The proposed symposium on “Phospholipidosis: Nonclinical Assessment and Risk Evaluation” will include four platform presentations that will present and summarize the history

of drug-induced phospholipidosis to include, but not limited to, important chemical structural features and classes of pharmaceuticals that have been associated with phospholipidosis; light microscopic changes that may suggest the possibility of phospholipidosis; ultrastructural diagnostic criteria and appearances of affected cells/organelles, potential target organs, and potential biomarkers--research and evaluation for application in clinical studies; impact of phospholipidosis on a drug development program—risk assessment and regulatory implications of the findings, update on progress of the CDER Phospholipidosis Working Group initiative to develop regulatory guidance on drug-induced phospholipidosis; and will include a panel session. The presentations should be of interest to drug development project team leaders, toxicologists, pathologists, and clinical research managers involved in pharmaceutical drug discovery and development preclinical and clinical research activities, or discussions with regulatory agencies. Phospholipidosis continues to be an active area of regulatory interest relevant to the progression of clinical studies, approval and the marketing of pharmaceutical products; as well as an active area of research to improve knowledge of the mechanism(s) and the clinical implications of phospholipidosis.

2:00 pm **HISTORY OF DRUG INDUCED PHOSPHOLIPIDOSIS** – *Mark J. Reasor, Ph.D., DABT, Professor of Physiology and Pharmacology West Virginia University Health Sciences Center, Morgantown, WV*

2:35 pm **MORPHOLOGIC EVIDENCE OF PHOSPHOLIPIDOSIS,**

AND POTENTIAL BIOMARKERS FOR CLINICAL APPLICATION –

Richard A. Peterson, DVM, Ph.D., DACVP, Director, Molecular & Ultrastructural Pathology, GlaxoSmithKline, Research Triangle Park, NC

3:15 pm *Refreshment Break*

THE IMPACT OF NONCLINICAL PHOSPHOLIPIDOSIS ON DRUG DEVELOPMENT, RISK ASSESSMENT AND REGULATORY

IMPLICATIONS – *James S. MacDonald, Ph.D., DABT, President, Chrysalis Pharma Consulting, LLC, Chester, NJ*

4:10 pm **THE SLIPPERY SLOPE: EXPERIENCES OF THE CDER**

PHOSPHOLIPIDOSIS WORKING GROUP - *James Willard, Ph.D., Pharmacologist, US FDA, CDER, Silver Spring, MD*

4:45 pm **PANEL SESSION**

2:00 – 5:00 - SYMPOSIUM VI

COMBINATION PRODUCTS: SAFETY CONSIDERATIONS FOR PHARMACEUTICALS WHEN ADMINISTERED IN COMBINATION WITH OTHER PHARMACEUTICALS, DEVICES, OR BIOLOGICS

Co-Chairs: Nancy Holmes, Ph.D., DABT, Assistant Director, Toxicologist, Alcon Laboratories, Inc., Fort Worth, TX and Tracey Zoetis, M.S., Managing Consultant, SciLucent, LLC, Herndon, VA

Medicine is being advanced by the combination products. Drugs combined with drugs treat multiple etiologies of a single disease. Drugs or biologics

combined with the right device can enhance delivery to targeted tissues. Combination products are currently being used to treat diseases affecting broad patient populations such as those found in ocular, pulmonary, cardiovascular, metabolic, and reproductive systems. Challenges encountered during product development of various combinations will be discussed. Presentations will focus on practical aspects of nonclinical testing and regulatory approaches. This symposium will provide information necessary to design, conduct, and prepare regulatory submissions to support clinical trials with combination products.

2:00 pm **MICROSCOPIC EVALUATION OF COMBINATION PRODUCTS IN NONCLINICAL STUDIES – CHALLENGES, METHODS, AND EXAMPLES –** *Daniel J. Patrick, DVM, DACVP, Principal Pathologist, MPI Research, Mattawan, MI*

2:35 pm **NONCLINICAL TESTING STRATEGIES FOR COMBINATION PRODUCTS -** *Tracey Zoetis, M.S., Managing Consultant, SciLucent, LLC, Herndon, VA*

3:10 pm *Refreshment Break*

3:35 pm **A CASE STUDY: SAFETY EVALUATION OF DRUG-DEVICE COMBINATION PRODUCTS -** *Alan P. Brown, Ph.D., DABT, Senior Toxicologist, NAMSA, Northwood, OH*

4:05 pm **REVIEW AND APPROVAL PROCESS FOR COMBINATION PRODUCTS –** *Brian*

Harvey, M.D., Ph.D., Vice
President Regulatory Policy,
Sanofi-Aventis, Bethesda
MD

4:40 pm **PANEL DISCUSSION**

5:30 pm MEMBERS' MEETING

TUESDAY MORNING, 11/03/09

8:00 am – 8:45 am

PLENARY LECTURE

J. WILLIAM LANGSTON, M.D.

The Parkinson's Institute & Clinical Center
Sunnyvale, CA

9:00 – 12:00 - SYMPOSIUM VII

**ADVANCES IN REGULATING
CHEMICALS IN EUROPE, U.S. AND
CANADA: THE INTERSECTION OF
SCIENCE AND POLICY**

*Co-Chairs: Richard A. Becker, Ph.D., DABT,
Senior Toxicologist, American Chemistry
Council, Arlington, VA and Richard D.
Phillips, Ph.D., DABT, Senior Science
Advisor, ExxonMobil Petroleum &
Chemical, Machelen, Belgium*

There have been significant changes in the assessment and regulatory management approaches for commodity chemicals globally. In Europe, the law enacting Registration, Evaluation, Authorization and Restriction of Chemical substances (REACH), which entered into force in June 2007, requires manufacturers to obtain health, safety and environmental information on their chemical substances and to register this information in a European Chemicals Agency database. Progress with implementing REACH will be discussed. In 2006, Canada completed the systematic prioritization and

categorization of the approximately 23,000 existing substances on the Canadian Domestic Substances List (DSL) based on considerations of Persistence, Bioaccumulation and Inherently Toxic to the Environment and Greatest Potential for Human Exposure and Inherently Toxic to Humans, yielding three possible outcomes: no further action required, the chemical substance is determined to be toxic and measures may be needed for control, or it is placed on the Priority Substances List (PSL) and subjected to an in-depth assessment. Progress with the Canadian DSL process will be discussed. In the U.S., the Toxic Substances Control Act (TSCA), enacted in 1976, governs the regulation and management of commodity chemicals. Recognizing advances that have been made, ideas on approaches to improve the use of risk-based methods to enhance the U.S. system will be discussed. The efforts of the international chemicals industry to implement a global system to enhance health, safety and environmental protection for chemical production and use will also be presented. Advances in technologies will soon permit rapid screening of thousands of substances using genomics, high throughput screening and computational profiling; the promise and challenges of applying these approaches to improving chemical assessments and management actions will be discussed.

9:00 am **EARLY LESSONS FROM
REACH
IMPLEMENTATION** -
*Richard D. Phillips, Ph.D.,
DABT, Senior Science
Advisor, ExxonMobil
Petroleum & Chemical,
Machelen, Belgium*

9:25 am **LESSONS FROM
IMPLEMENTING THE
CANADIAN DANGEROUS**

SUBSTANCES

LEGISLATION – *Bette Meek, M.Sc., Associate Director of Chemical Risk Assessment, R. Samuel McLaughlin Centre for Population Health Risk Assessment, University of Ottawa, Ottawa, Canada*

9:50 am

IMPROVING THE CHEMICAL REGULATORY SYSTEM IN THE US – *Charles M. Auer, B.S., Charles Auer & Associates, LLC, Poolesville, MD*

10:15 am

Refreshment Break

10:35 am

INITIATIVES OF THE INTERNATIONAL COUNCIL OF CHEMICAL ASSOCIATIONS TO ENHANCE CHEMICAL MANAGEMENT GLOBALLY – *Gregory G. Bond, Ph.D., MPH, FACE, Corporate Director of Product Responsibility, The Dow Chemical Company, Midland, MI*

11:00 am

CHALLENGES AND OPPORTUNITIES FOR ASSESSING AND REGULATING CHEMICALS WITH GENOMICS AND HIGH THROUGHPUT MOLECULAR SCREENING TECHNIQUES – *Richard A. Becker, Ph.D., DABT, Senior Toxicologist, American Chemistry Council, Arlington, VA*

9:00 – 12:00 - SYMPOSIUM VIII

HIV – FROM PROTEST TO PROTEASE AND BEYOND

Co-Chairs: L. Peyton Myers, Ph.D., Pharmacology/Toxicology Reviewer, US FDA, Silver Spring, MD and Grushenka H. I.

Wolfgang, Ph.D., DABT, Vice President, Drug Safety Evaluation, Gilead Sciences, Inc., Foster City, CA

March 20, 1987 saw the initial approval of the first anti-HIV pharmaceutical (AZT, azidothymidine, a nucleoside reverse transcriptase inhibitor) which was a major landmark in the history of the AIDS epidemic in the US. With the need for rapid approval of drugs to treat HIV, the US Food and Drug Administration restructured and established the Division of Antiviral Products (1988) and created the accelerated approval process for serious or life-threatening illnesses (Federal Register, 1992). Since the rapid approval of the first nucleoside analogs, there are now 6 classes of anti-HIV drug products. These classes of anti-HIV drugs consist of ~30 different approved drug products. Different toxicities have been identified for each class. This symposium will cover the historical perspectives and current paradigms of HIV treatment, the classes of anti-HIV medications, US regulatory perspectives and industry challenges in nonclinical toxicity assessment, as well as current clinical practices to manage the clinical toxicology associated with anti-HIV medications.

9:00 am

INTRODUCTION OF MECHANISMS OF ACTION, HISTORICAL PERSPECTIVE, AND CHANGES IN DRUG DEVELOPMENT PARADIGMS – *Jeffrey S. Murray, M.D., Deputy Director, Division of Antiviral Products, US FDA, CDER/OAP/DAVP, Silver Spring, MD*

9:35 am

NONCLINICAL TOXICOLOGY SAFETY ASSESSMENT OF ANTI-HIV THERAPEUTICS – A REGULATORY

PERSPECTIVE - *Laine Peyton Myers, Ph.D., Pharmacology/Toxicology Reviewer, US FDA, Silver Spring, MD*

10:10 am Refreshment Break

10:20 am **NONCLINICAL TOXICOLOGY SAFETY ASSESSMENT OF ANTI-HIV THERAPEUTICS – AN INDUSTRY PERSPECTIVE**
– *Grushenka H. I. Wolfgang, Ph.D., DABT, Vice President, Drug Safety Evaluation, Gilead Sciences, Inc., Foster City, CA*

10:55 am **CLINICAL SAFETY AND TOLERABILITY OF ANTI-RETROVIRAL THERAPY –**
Richard Haubrich, M.D., Professor of Medicine, University of California San Diego, Division of Infectious Diseases, San Diego, CA

9:00 – 12:00 - SYMPOSIUM IX

IMPACT OF PRODUCT COMPARABILITY ISSUES IN BIOTHERAPEUTIC SAFETY ASSESSMENT PROGRAMS – ROLE OF NONCLINICAL ASSESSMENTS

Co-Chairs: Laura Andrews, Ph.D., DABT, Vice President – Pharmacology and Toxicology, Genzyme Corporate, Framington, MA and James D. Green, Ph.D., DABT, Senior Vice President - Preclinical and Clinical Development Sciences, Biogen Idec Inc., Cambridge, MA

The concept of product comparability is one which has been developed within the biotechnology industry over the last decade; however, the advent of biosimilar manufacturers and the establishment of new regulatory guidances in this area that address preclinical, clinical and quality requirements have impacted innovator

company's and their ability to make process changes. In 2005, ICH issued the document "Q5E Comparability of Biotechnological/Biological Products Subject to Changes in their Manufacturing Process." This guidance describes how to assess if a manufacturing change necessitates an additional clinical study to demonstrate the safety and efficacy of a biological product or whether nonclinical biochemical, bioactivity, pharmacokinetic and toxicology assessments would be sufficient. Recent additional guidance documents from Europe and Canada are also setting the stage for considerations of product comparability. This symposium will address product comparability studies for biotherapeutic products and how changes during the development process may affect the type and extent of necessary nonclinical comparability assessments. In addition to specific discussions around biologic and gene therapy comparability, this session will also provide a regulatory perspective on comparability assessments and will include case studies which highlight the challenges in biotherapeutic product comparability assessments.

9:00 am **CURRENT PERSPECTIVE ON COMPARABILITY ISSUES SUMMARY OF DIA MEETING –** *Mary Ellen Cosenza, Ph.D., DABT Executive Director, Regulatory Affairs, Amgen Inc., Thousand Oaks, CA*

9:20 am **PRECLINICAL COMPARABILITY ASSESSMENTS OF A BIOLOGIC PRODUCT –** *Laura Andrews, Ph.D., DABT, Vice President – Pharmacology and Toxicology, Genzyme Corporate, Framington, MA*

- 9:50 am **CDER PERSPECTIVE ON COMPARABILITY OF A BIOLOGIC PRODUCT** – *M. Stacey Ricci, Sc.D., Toxicologist, US FDA, CDER, Office Oncology Drug Products, Office of New Drugs, Silver Spring, MD*
- 10:20 am Refreshment Break
- 10:40 am **GENE THERAPY COMPARABILITY** – *Timothy MacLachlan, Ph.D., Genzyme Corporation, Framingham, MA*
- 11:20 am **CBER PERSPECTIVE ON COMPARABILITY** – *Ramjay Vatsan, Ph.D., GTB/Division of Cellular & Gene Therapies, US FDA, Rockville, MD*
- 11.40 **WRAP UP AND DISCUSSION SESSION** – *James D. Green, Ph.D., DABT, Senior Vice President - Preclinical and Clinical Development Sciences, Biogen Idec Inc., Cambridge, MA*

absorption and new and novel excipients may be included amongst them. New physical approaches such as nanoparticles of drug and excipients or lysosomes may offer better drug delivery especially of hard to absorb or difficult to formulate oral drugs. New excipients may improve or mask the flavor of foods, drugs and dietary supplements. Recently, impurities in drug products have become subject to greater scrutiny and various national and international guidelines, guidances and regulations have been proposed and some have been accepted for use; excipient evaluation can be included in these efforts. This symposium will discuss new developmental concepts, guidelines/guidances and regulations involving impurities in excipients, new drug delivery systems involving excipients and thoughts for possible improvement to these guidelines. This symposium will offer information to members of the food additive, drug, dietary supplement, cosmetic manufacturers and regulators regarding the safety of these new and/or promising areas of product development.

TUESDAY AFTERNOON, 11/03/09

1:30 – 5:00 - SYMPOSIUM X

TRENDS IN EXCIPIENT SAFETY EVALUATION

Co-Chairs: Robert E. Osterberg, Ph.D., ATS, Senior Consultant, Aclairo PDG., Inc., Vienna, VA and Chris DeMerlis, M.S., Manager, Regulatory Affairs, Colorcon, West Point PA

Excipients are used in all drug products and in most food products. New technologies are being tested to increase the amount or rate of

1:30 pm **INTRODUCTION** – *Chris DeMerlis, M.S., Manager, Regulatory Affairs, Colorcon, West Point PA*

2:05 pm **EXCIPIENT SAFETY FOR NEW AND SPECIALIZED AREAS OF DRUG DELIVERY** – *David W. Hobson, Ph.D., DABT, Principal, LoneStar PharmTox LLC, Boerne, TX*

2:40 pm **CURRENT AND FUTURE METHODS FOR THE SAFETY ASSESSMENT OF EXCIPIENTS** – *Robert E. Osterberg, Ph.D., ATS, Senior Consultant, Aclairo PDG., Inc., Vienna, VA*

- 3:15 pm Refreshment Break
- 3:35 pm **EXISTING PROCEDURES FOR INGREDIENT SAFETY EVALUATIONS WITH APPLICATIONS TO EXCIPIENTS: PCPC, GRAS, FDA & FEMA** – Jeffrey J. Yourick, Ph.D., DABT, Chemical S&T Manager, Chemical Medical Countermeasures, Chemical and Biological Technologies Directorate Defense Threat Reduction Agency, Fort Belvoir, VA
- 4:10 pm **TOXICOLOGICAL CONCERN FOR IMPURITY SAFETY** – Timothy J. McGovern, Ph.D., Senior Consultant, SciLucent LLC, Herndon, VA
- 4:45 pm **Q&A**

1:30 – 5:00 - SYMPOSIUM XI

DEVELOPMENTAL IMMUNOTOXICITY TESTING OF (BIO)PHARMACEUTICALS

Co-Chairs: Mark Collinge, Ph.D., Principal Scientist, Immunotoxicology CoE, Pfizer, Inc., Groton, CT and Jacintha M. Shenton, Ph.D., Senior Research Investigator, Bristol-Myers Squibb Company, East Syracuse, NY

Regulatory guidances on the subject of developmental immunotoxicity (DIT) safety testing highlight this area as an important concern that warrants sponsor attention, especially in the case of suspected immunosuppressive drugs. However, there are no accompanying recommendations concerning what studies would be appropriate for evaluating the potential immunotoxic effects on the developing fetus or neonate. This lack of specific guidance for DIT studies reflects the general paucity of information relating to the sensitivity and relevance of the non-

adult versus the adult immune systems. Moreover, there is little comparative data regarding toxic effects of chemicals or drugs on discrete windows of early immune system development. Other complicating factors include differences in placental transport and fetal drug exposures between rodents and non-human primates (NHPs), especially with regard to DIT testing of biopharmaceuticals. These factors have led in many cases to the default position that biopharmaceuticals are best tested in NHP because of the known similarities in immune system development compared with humans. In contrast, the chemical industry routinely uses a rat DIT and DART testing model. Given the desire to limit the use of NHPs for research, this symposium will address under what circumstances it may, or may not, be appropriate to use the rat model for DART and DIT testing of biopharmaceuticals. Speakers will address best practices for the chemical industry regarding DIT testing, review our current basic understanding of the developing immune systems in rodents, NHPs and humans, and also compare and contrast scientific reasons behind the different industry approaches to DIT testing. A panel discussion will follow the presentations to solicit audience input on recommendations posed by the presenters with the intent that the sum information will guide a subsequent workshop on this subject in the near future.

- 1:30 pm **CURRENT APPROACHES TO ASSESS RISK TO THE DEVELOPING IMMUNE SYSTEM: SOME PRACTICAL CONSIDERATIONS** - Michael P. Holsapple, Ph.D., A.T.S., Executive Director, ILSI Health and Environmental Sciences

	<i>Institute (HESI), Washington, DC</i>	<i>Genter, Ph.D., DABT, Associate Professor, University of Cincinnati, Cincinnati, OH</i>
2:00 pm	CRITICAL WINDOWS IN DEVELOPMENT OF THE RODENT AND PRIMATE IMMUNE SYSTEM – <i>Kenneth Landreth, Ph.D., Professor of Microbiology, Immunology & Cell Biology, West Virginia University, Morgantown, WV</i>	Chemically-induced hearing loss, or ototoxicity, is an often-overlooked endpoint in toxicology studies, despite the fact that certain pharmaceuticals, solvents, and noise are known risk factors for hearing loss in humans. This symposium brings together speakers who can address methodological issues, as well as occupational risk factors, quality of life issues, and contemporary thoughts on interventions. The symposium should be of interest to a broad audience of those attending the ACT annual meeting, and, given that this topic is not widely addressed in scientific meetings, should provide new fundamental and practical information to those attendees in the chemical and pharmaceutical industries, as well as those in academia and occupational medicine.
2:30 pm	COMPARATIVE DEVELOPMENT OF THE IMMUNE SYSTEM IN PRIMATES – <i>Prof. Dr. Eberhard Buse, Director Pathology, Covance Laboratories GmbH, Muenster, Germany</i>	
3:00 pm	Refreshment Break	
3:20 pm	REVIEW OF DRAFT OECD RECOMMENDATIONS ON DIT TESTING – <i>Michael Woolhiser, Ph.D., Science & Technology Leader, Toxicology & Environmental Research and Consulting, The Dow Chemical Company, Midland, MI</i>	
		1:30 pm INTRODUCTION AND OVERVIEW – <i>Mary Beth Genter, Ph.D., DABT, Associate Professor, University of Cincinnati, Cincinnati, OH</i>
3:50 pm	A ROSE IS A ROSE IS [NOT] A ROSE: WHY THE APPROACH TO DIT EVALUATION OF (BIO)PHARMACEUTICALS IS UNIQUE - <i>Leigh Ann Burns Naas, Ph.D., DABT, Senior Director, Pfizer Global R&D, San Diego, CA</i>	1:45 pm PRACTICAL APPROACHES FOR OTOTOXICITY TESTING INTENDED FOR REGULATORY SUBMISSION – <i>Leslie Lemke, Ph.D., DABT, Manager Pharmaceutical Toxicology, Alcon Laboratories, Fort Worth, TX</i>
4:20 pm	PANEL DISCUSSION	
1:30 – 5:00	- SYMPOSIUM XII	2:30 pm HISTOPATHOLOGIC EVALUATION OF THE MIDDLE AND INNER EAR – <i>Kenneth Schafer, DVM, Ph.D., DACVP, Senior Pathologist, Vet Path Services, Mason, OH</i>
	CONTEMPORARY ISSUES IN HEARING LOSS – FROM THE BENCH TO THE BEDSIDE <i>Co-Chairs: Leslie Lemke, Ph.D., DABT, Manager Pharmaceutical Toxicology, Alcon Laboratories, Fort Worth, TX and Mary Beth</i>	3:15 pm Refreshment Break

3:30 pm **CHEMICAL INTERACTIONS IN THE AUDITORY SYSTEM** – *Thais C. Morata, Ph.D., Research Audiologist, NIOSH, Hearing Loss Prevention Section, Cincinnati, OH*

4:45 pm **DEVELOPMENT OF A DRUG TO TREAT HEARING LOSS: STUDIES OF EFFICACY AND TOXICITY** - *Josef Miller, P.D., Ruth and Lynn Townsend Professor of Communication Disorders, Kresge Hearing Research Institute, University of Michigan, Ann Arbor, MI*

5:30 pm - 7:00 pm

POSTER SESSION & SAGE WINE & CHEESE RECEPTION

WEDNESDAY MORNING, 11/04/09

8:00 am – 8:45 am

PLENARY LECTURE

BRUCE N. AMES, Ph.D.

Professor & Senior Scientist
Children's Hospital Oakland Research
Institute
Oakland, CA

“DELAYING AGE-RELATED DISEASE WITH MICRONUTRIENTS: TRIAGE THEORY”

9:00 – 12:00 - **SYMPOSIUM XIII**

CONSUMER PRODUCTS – HOT TOPICS

Co-Chairs: Tracey L. Spriggs, Ph.D., DABT, Director Toxicology, GlaxoSmithKline Consumer Healthcare, Parsippany, NJ and Jon F. Lalko, B.S., Senior Test Program Specialist, R.I.F.M., Woodcliff Lake, NJ

This Hot Topics session will include presentations on current issues of interest related to consumer products. Presentations will span different types of consumer product, including drugs, food and cosmetics and will raise awareness on such topics as tainted products, fragrance allergen risk assessment, food allergens, animal testing ban in Europe and OTC cough cold medications.

9:00 am **INTRODUCTION** - *Tracey L. Spriggs, Ph.D., DABT, Director, Toxicology, GlaxoSmithKline Consumer Healthcare., Parsippany, NJ*

9:05 am **TAINTED PRODUCTS: BISPENOL A, VILLIAN OR GHOST?** – *Calvin C. Willhite, Ph.D., Staff Toxicologist, State of California, Department of Toxic Substances Control, Berkeley, CA*

9:35 am **RISK ASSESSMENT FOR FRAGRANCE ALLERGENS** – *Jon F. Lalko, B.S., Senior Test Program Specialist, R.I.F.M., Woodcliff Lake, NJ*

10:05 am Refreshment Break

10:25 am **FOOD ALLERGY UPDATE** – *Felicia B. Billingslea, Director, Office of Nutrition, Labeling and Dietary Supplements, US FDA, CFSAN, College Park, MD*

10:55 am **ANIMAL TESTING BAN IN EUROPE** – *Pauline McNamee, Ph.D., Principal Scientist, Procter & Gamble*

Technical Centres Ltd.,
Egham, United Kingdom

11:25 am

PERSPECTIVE ON THE EFFICACY AND SAFETY OF COUGH AND COLD MEDICINES IN CHILDREN
– Edwin Kuffner, M.D.,
Senior Director, Medical Affairs, McNeil Consumer Healthcare, Ft. Washington, PA

9:00 – 12:00 - SYMPOSIUM XIV

NETWORK BIOLOGY IN DRUG DEVELOPMENT (USE OF COMPUTER MODELING TO PREDICT PHYSIOLOGICAL RESPONSES)

Chair: Kenneth J Olivier Jr, Ph.D.,
Associate Director of Toxicology, Merrimack Pharmaceuticals, Cambridge, MA

Network Biology has many connotations, but is defined here as the practice of using computer models of known biological systems and quantitative experiments to better predict physiological responses related to disease. Recent efforts have led to a better understanding of how biological systems interact, resulting in more accurate predictions of efficacy and toxicity, to the benefit of our patients. Integrating computational modeling techniques with known biological processes, quantitative measurements, and animal studies will refine our predictive models and improve their ability to identify key molecule(s) in disease modulating system(s), thereby accelerating the development of therapeutics. For example, using *in vitro* and *in vivo* studies to define the EGFR system supports efficacy and safety evaluations and their relevance to human oncology patients. In today's drug discovery and development environment, with low productivity and success, it is imperative to move forward with several methods supporting advanced therapeutic discovery and

development paradigms and platforms with a higher probability of success in a target patient population. This symposium will review the current academic, industrial and regulatory application of Network Biology in drug discovery and predicting toxicity.

9:00 am

INTRODUCTION - Kenneth J Olivier Jr, Ph.D.,
Associate Director of Toxicology, Merrimack Pharmaceuticals, Cambridge, MA

9:10 am

NETBIO – Matt Onsum, Ph.D.,
Senior Scientist, Computational Biology, Merrimack Pharmaceuticals, Cambridge, MA

9:40 am

SIMULATIONS AND MODELING FOR PREDICTIVE TOXICOLOGY – Alan H. Roter, Ph.D.,
Vice President Informatics, Entelos, Inc., Foster City, CA

10:10 am

Refreshment Break

10:30 am

INTEGRATING EXPERIMENTAL, TEXT MINING, AND ANALYTICAL PREDICTION METHODS IN DRUG DISCOVERY - Carolyn Cho, Ph.D.,
Director, Target Generation Unit, Pfizer RTC, Cambridge, MA

11:00 am

USING SYSTEMS BIOLOGY AND PERSONAL GENOMES TO DELIVER PERSONALIZED DRUG COMBINATIONS – Hamid Bolouri, Ph.D.,
Visiting Associate Faculty, Division of Biology,, California Institute of Technology, Pasadena, CA

11:30 am **SIMULATION TECHNOLOGY FOR DRUG TESTING** - Robert Powell, Ph.D., Associate Director, Office of Translational Sciences, US FDA, CDER, Silver Spring, MD

FRCPath, Executive Vice President, Senior Scientific Consultant, Cantox Health Sciences Intl, Mississauga, Canada

9:00 – 12:00 - SYMPOSIUM XV

THRESHOLD OF TOXICOLOGIC CONCERN

Chair: Joel Bercu, M.P.H., Risk Assessment, Eli Lilly and Company, Indianapolis, IN; Co-Chair: William J. Brock, Ph.D., DABT, ATS, Brock Scientific Consulting, LLC, Montgomery Village, MD

The threshold of toxicological concern (TTC) is a method by which risk assessment decisions can be made based on limited toxicity datasets or purely on structure. Its applications have grown to several different industries such as food, pharmaceuticals, and personal care products to name a few. This course will discuss the background of the TTC and some of its assumptions. It then will discuss some of the practical applications where the TTC is applied. The TTC is used in pharmaceuticals for the control of genotoxic impurities. It also used to limit leachables / extractables for polymers that come in contact with a pharmaceutical such as stoppers and vials. Finally, the TTC is used for personal care products to demonstrate safety while limiting animal testing. In conclusion, this course will demonstrate appropriate applications of the TTC allowing the toxicologist to make decisions based on limited data.

9:00 am **THE THRESHOLD OF TOXICOLOGICAL CONCERN – BACKGROUND AND ASSUMPTIONS** - Ian C. Munro, Ph.D., FATS,

9:40 am **MANAGEMENT OF GENOTOXIC IMPURITIES IN PHARMACEUTICALS USING THE THRESHOLD OF TOXICOLOGICAL CONCERN** - Timothy Joseph McGovern, Ph.D., Consultant, SciLucent LLC, Herndon, VA

10:10 am Refreshment Break

10:25 am **USE OF THRESHOLD OF TOXICOLOGICAL CONCERN IN THE RISK ASSESSMENT OF PERSONAL CARE PRODUCTS** - Susan Felter, Ph.D., Principal Scientist, Proctor & Gamble, Cincinnati, OH

11:05 am **USE OF THE THRESHOLD OF TOXICOLOGICAL CONCERN TO EVALUATE LEACHABLES / EXTRACTABLES IN CONTAINER / CLOSURE SYSTEMS FOR PHARMACEUTICALS** - Courtney Callis, M.P.H., DABT, Associate Senior Toxicologist, Eli Lilly & Company, Bozeman, MT

WEDNESDAY AFTERNOON, 11/04/09

1:30 – 5:00 - SYMPOSIUM XVI

HOT TOPICS

Co-Chairs: Drew A. Badger, Ph.D. DABT, Senior Director, Tox & Reg Affairs, Amira Pharmaceuticals, San Diego CA and Mary Ellen Cosenza, Ph.D., DABT, Executive Director, Regulatory Affairs, Amgen Inc., Thousand Oaks, CA

The Hot Topics session will provide a timely and critical overview of key updates to the International Conference on Harmonization (ICH) Guidelines that have a significant impact on Pharmaceutical Safety Evaluation. Presentations will be provided by members of the ICH working committee which offers a unique insider look into the process and rationale behind some of the changes. Presentations will focus on two key revisions including the comprehensive multi-disciplinary guideline, M3 (Non-Clinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals) and the safety guideline S2 (Guidance on Genotoxicity Testing and Data Interpretation for Pharmaceuticals intended for Human use). The newly created safety guideline S9 (Nonclinical evaluation for anticancer pharmaceuticals) will also be discussed. In addition to ICH updates, a collection of 10-minute emerging topics including FDA's "Animal Rule" will be presented as a bonus for those who stay through the end of the session. This session is critical for regulatory toxicologists in the pharmaceutical industry as well as those that are impacted by evolving regulatory requirements which includes a majority of ACT attendees including industry, CRO, and academic scientists.

Regulatory Affairs, Amgen Inc., Thousand Oaks, CA

2: 30 pm **CHANGES TO ICHS2 (GUIDANCE ON GENOTOXICITY TESTING AND DATA INTERPRETATION FOR PHARMACEUTICALS INTENDED FOR HUMAN USE): IMPACT ON EARLY DRUG DEVELOPMENT** – *David Jacobson-Kram, Ph.D., DABT, Associate Director, Pharma/ Toxicology, US FDA - CDER, OND, Silver Spring, MD*

3:20 pm Refreshment Break

3:40 pm **UPDATE ON ICH GUIDELINE S 9 NON-CLINICAL EVALUATION FOR ANTICANCER PHARMACEUTICALS** – *John K. Leighton, Ph.D., Associate Director, Pharmacology, US FDA, CDER/OND/OODP, Silver Spring, MD*

4:30 pm **DISCUSSION**

1:30 – 5:00 - SYMPOSIUM XVII

1:30 pm **INTRODUCTION** - *Drew A. Badger, Ph.D. DABT, Senior Director, Toxicology & Regulatory Affairs, Amira Pharmaceuticals, San Diego CA*

1:40 pm **UPDATE ON ICH GUIDELINE M 3 (R2) NONCLINICAL SAFETY STUDIES FOR THE CONDUCT OF HUMAN CLINICAL TRIALS FOR PHARMACEUTICALS** - *Mary Ellen Cosenza, Ph.D., DABT, Executive Director,*

SPACE TOXICOLOGY: HUMAN HEALTH DURING SPACE OPERATIONS

Co-Chairs: Noreen Nicole Khan-Mayberry, Ph.D., NASA Space Toxicologist, Space Toxicology Office – Space Life Sciences, Houston, TX and John T. James, M.D., Ph.D., NASA Chief Toxicologist, Space Toxicology Office – Space Life Sciences, Houston, TX

Space Toxicology is a unique and targeted discipline for spaceflight, space habitation and occupation of celestial bodies including planets, moons and asteroids. Astronaut explorers face

distinctive health challenges and limited resources for rescue and medical care during space operation. A central goal of space toxicology is to protect the health of the astronaut by assessing potential chemical exposures during spaceflight and setting safe limits that will protect the astronaut against chemical exposures, in a physiologically altered state. In order to maintain sustained occupation in space on the International Space Station (ISS), toxicological risks must be assessed and managed within the context of isolation, continuous exposures, reuse of air and water, limited rescue options, and the need to use highly toxic compounds for propulsion. As we begin to explore other celestial bodies *in situ* toxicological risks, such as inhalation of reactive mineral dusts, must also be managed.

- 1: 30 pm **HISTORY OF SPACEFLIGHT TOXICOLOGY** - *John T. James, M.D., Ph.D., NASA Chief Toxicologist, Space Toxicology Office – Space Life Sciences, Houston, TX*
- 2:00 pm **SPACECRAFT MAXIMUM ALLOWABLE CONCENTRATIONS (SMACs)** – *Rochelle W. Tyl, Ph.D., Senior Fellow, RTI International, Research Triangle Park, NC*
- 2:30 pm **SPACECRAFT WATER EXPOSURE GUIDELINES (SWEGs)** – *Kenneth E. Thummel, Ph.D., Professor, Dept. of Pharmaceuticals, University of Washington, Department of Physics, Seattle, WA*
- 3:00 pm Refreshment Break
- 3:20 pm **RISK-BASED MONITORING OF**

SPACECRAFT POLLUTANT – *Noreen Nicole Khan-Mayberry, Ph.D., Space Toxicologist, NAMSA, Houston, TX*

- 3:50 pm **LUNAR DUST PULMONARY TOXICITY** – *Chiu-wing Lam, Ph.D., Senior Toxicologist, Wyle Laboratories, Houston, TX*
- 4:20 pm **Q&E**

1:30 – 5:00 - SYMPOSIUM XVIII

EXPOSURE-SPECIFIC DIFFERENCES IN INFLAMMATORY PATTERNS AND RELATIONSHIP TO CHRONIC RESPIRATORY DISEASE

Chair: Hans-Juergen Haussmann, Ph.D., Consultant, Roesrath, Germany; Co-Chair: Jack R. Harkema, DVM, Ph.D., DACVP, University Distinguished Professor, Michigan State University, East Lansing, MI

COPD is one of the most common causes of morbidity and mortality. This disease encompasses emphysema, chronic bronchitis, and obstructive bronchiolitis. Exposure to noxious stimuli that can ultimately lead to COPD initially elicit pulmonary or airway inflammatory processes, which can display exposure-specific commonalities as well as differences in the local and time-dependent accumulation of inflammatory cells and mediators. In this symposium, inflammatory patterns stemming from exposure to various aerosols, including nano-materials and cigarette smoke, and a transgenic model for airway surface dehydration will be presented and compared. Even within such groups of exposures, differences in response exist. For example, particle-induced inflammatory reactions depend on particle surface characteristics. Also, given that cigarette smoking is responsible for about 90% of COPD in developed countries, there is interest in developing cigarettes that

generate a different smoke composition than conventional ones leading to differences in inflammatory responses. However, regardless of the type of exposure, there is insufficient knowledge at present to predict if changes in inflammatory patterns can be linked to changes in the risk of developing the various forms of COPD as well as of potential co-morbidities, such as lung cancer. Establishing such relationships would be of tremendous advantage for the development of practical pathways for intervention or therapy.

Medical Center, Rochester, NY

3:50 pm

ASSESSING THE ROLE OF SURFACE CHARACTERISTICS IN NANOPARTICLE-RELATED PULMONARY TOXICITY AND INFLAMMATION – *David B. Warheit, Ph.D., DABT, ATS, DuPont Haskell Laboratory for Health and Environmental Sciences, Newark, DE*

4:25 pm

DEVELOPMENT OF CHRONIC BRONCHITIS AND EMPHYSEMA IN BETA-EPITHELIAL NA⁺ CHANNEL-OVEREXPRESSING MICE: ROLE OF AIRWAY SURFACE DEHYDRATION IN THE PATHOGENESIS OF COPD - *Jack R. Harkema, DVM, Ph.D., DACVP, University Distinguished Professor, Michigan State University, East Lansing, MI*

1: 30 pm

INTRODUCTION – *Hans-Juergen Haussmann, Ph.D., Consultant, Roesrath, Germany*

1:40 pm

RESPIRATORY TRACT LINING FLUIDS: FIRST REACTANTS WITH CIGARETTE SMOKE – *Carroll E. Cross, M.D., Pulmonary-Critical Care Medicine, University of California Davis Medical School, Sacramento, CA*

2:15 pm

MODELING CIGARETTE SMOKE-INDUCED INFLAMMATORY RESPONSES RELATED TO COPD BASED ON MECHANISTIC DATA – *Michael Peck, Ph.D., Associate Principal Scientist, Philip Morris International Research & Development, Neuchatel, Switzerland*

2:50 pm

Refreshment Break

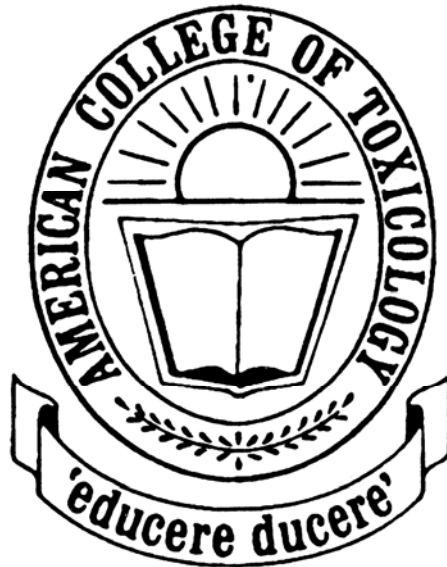
3:15 pm

ULTRAFINE PARTICLES, INFLAMMATION, AND HUMAN HEALTH – *Mark W. Frampton, M.D., Professor of Medicine & Environmental Medicine, University of Rochester*

**THIRTIETH ANNUAL MEETING
OF THE
AMERICAN COLLEGE OF TOXICOLOGY**

EDUCATION COURSES

November 1, 2009



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CONTINUING EDUCATION COURSES

NOVEMBER 1, 2009

REGISTRATION LIMITED

SUNDAY MORNING – 11/1/09

Scientific Director, Amgen Inc., Thousand Oaks, CA

8:00 – 4:30

COURSE #1

STUDY DIRECTOR TRAINING

Chair: Barbara J. Mounho, Ph.D., DABT, Scientific Director, Amgen Inc., Thousand Oaks, CA

This continuing education course is intended to provide an introduction to a study director's responsibilities and review both logistical-, regulatory- and scientific-related aspects of toxicology studies. The course will be divided into two parts (morning and afternoon sessions). The morning session will focus on the practicalities of study director responsibilities for study conduct, oversight, protocols, animal models, and final reports. This course will also review the evolution and scope of the GLP regulations and what a study director should do/not do during an FDA inspection, as well as how to manage challenges a study director can encounter in toxicology studies and how to appropriately communicate study deviations to a sponsor. The topics to be covered in the afternoon session include other scientific aspects of toxicology studies such as safety pharmacology, assessment of immune function (immunotoxicology) and review and interpretation of histopathology data.

8:10 am

STUDY CONDUCT & OVERSIGHT – STUDY DIRECTOR RESPONSIBILITIES - *Carol S. Auletta, MBA, DABT, Director, Program Management, Huntingdon Life Sciences, East Millstone, NJ*

8:45 am

STRATEGIES FOR STUDY DIRECTORS IN CHALLENGING SITUATIONS – *Suzanne Wolford, Ph.D., DABT, Study Director, Covance Inc., Madison, WI*

9:20 am

PRINCIPLES AND PRACTICES FOR GENERATING QUALITY DOCUMENTS – *Mark D. Walker, DVM, Senior Director, Scientific and Laboratory Operations, Charles River, Reno, NV*

9:55 am

Refreshment Break

10:15 am

OVERVIEW AND HISTORY OF THE GLPs – *Barbara B. Randolph, MT(ASCP), MBA, Senior Auditor, RQAP(GLP), Biotechnical Services, Inc., Mead, WA*

10:50 am

ANIMAL MODELS USED IN TOXICOLOGY STUDIES – *Laura Conour, DVM, DACLAM, Senior Director, Veterinary Services,*

8:00 am

WELCOME AND INTRODUCTION - *Barbara J. Mounho, Ph.D., DABT,*

Charles River, Shrewsbury,
MA

- 11:30 am **LUNCH BREAK**
- 1:45 pm **SAFETY PHARMACOLOGY STUDIES** – Tom Beck, Ph.D., Associate Director, Safety Pharmacology, Covance Laboratories, Inc., Madison, WI
- 2:30 pm **IMMUNOTOXICOLOGY EVALUATION FOR BIOLOGICS** – Lynne LeSauteur, Ph.D., Preclinical Services, Charles River, Senneville, Canada
- 3:10 pm Refreshment Break
- 3:50 pm **CLINICAL AND ANATOMIC PATHOLOGY FOR STANDARD PRECLINICAL TOXICOLOGY STUDIES: DATA INTEGRATION AND INTERPRETATION** – Kevin McDorman, Ph.D., DACVP, Preclinical Services, Charles River, Reno, NV

8:00 – 11:30 COURSE #2

INTERACTING WITH REGULATORY AUTHORITIES: WHAT TO DO AND WHAT NOT TO DO

Co-Chairs: Melissa Rhodes, PhD, DABT, Safety Assessment Project Manager, GlaxoSmithKline, Research Triangle Park, NC and Hanan Ghantous, PhD, DABT, Pharmacologist/Toxicologist Supervisor, US FDA, Silver Spring, MD

During the process of drug development, a Sponsor will need to interact with regulatory authorities (RA), such as the FDA and the EMEA. In order to effectively interact with these agencies, the Sponsor must remember that the RA are not the enemy. They have a genuine concern about the well being of the patients and considerable

institutional knowledge about the design and possible knowledge of other drugs in the same class. This course will discuss how to effectively interact with the RA so that Sponsors can gain the greatest benefit from their meetings.

- 8:00 am **INTERACTING WITH CDER DIVISION OF FDA** – Jeri El Hage, Ph.D., Senior Consultant, Aclairo PDG, Vienna, VA
- 8:40 am **INTERACTING WITH CBER DIVISION OF FDA** – Martin D. Green, Ph.D., Supervisory Toxicologist, US FDA, Vaccine Research and Review, Division of Vaccines and Related Product Applications, Rockville, MD
- 9:20 am **ANIMAL RULE (VACCINES IN CBER, DRUGS IN CDER)** – Christopher Ellis, Ph.D., Pharmacology/Toxicology Reviewer, US FDA, Center for Drug Evaluation and Research, Silver Spring, MD
- 10:00 am Refreshment Break
- 10:20 am **INTERACTING WITH EMEA** – Christopher Powell, FRCPATH, Director Safety Assessment, GlaxoSmithKline, Welwyn, United Kingdom
- 11:00 am **INTERACTING WITH PMDA** – Kazuichi Nakamura, D.V.M., Ph.D., Manager, Shionogi & Co., Ltd., Product Development Regulatory Affairs Department, Tokyo, Japan

8:00 – 11:30

COURSE #3

STUDY MONITORING AT CROs. KEEPING YOUR SANITY AND ACHIEVING THE BEST PRODUCT (BEST PRACTICES, PITFALLS, AND KEYS TO EFFICIENCY)

Chair: Paul L. Roney, Ph.D., DABT, Senior Consultant, Toxicology, Kendle International Inc., Rockville, MD

With the increased emphasis on outsourcing toxicology studies to specialty Contract Research Organizations (CRO), toxicologists are being asked to monitor studies being conducted outside of their organizations. In this capacity, they must ensure that the toxicology program is conducted properly and in a cost effective manner. This presents a particular challenge to the toxicologist because many toxicologists have no training in managing these types of programs. This course will provide the participants with the tools they need to succeed in this endeavor. Specifically, this course will discuss what factors the toxicologist needs to consider when selecting a CRO including bid solicitation and bid analysis (cheapest is not always best). It will also discuss the interactions between the Study Monitor and the CRO before, during and after the study. It will conclude with a CRO's Study Director's perspective of what makes an effective team between the Study Monitor and the Study Director. This course is a must for any toxicologist who is responsible for outsourcing toxicology studies, no matter what sort of company he/she works for.

8:00 am

INTRODUCTION - *Paul L. Roney, Ph.D., DABT, Senior Consultant, Toxicology, Kendle International Inc., Rockville, MD*

8:10 am

OUTSOURCING NONCLINICAL SAFETY STUDIES: BEST PRACTICES FOR SELECTING A CRO - *Jon Daniels, Ph.D., DABT, ERT, Vice President and Senior Toxicologist, Intrinsik Health Sciences Inc., Mississauga, Canada*

8:40 am

AN INDUSTRY VETERAN'S GUIDE TO EFFECTIVE STUDY MONITORING - *Steven M. Snyder, M.S., President, Outsourcing Support Services, Inc., Noblesville, IN*

9:10 am

STUDY MONITOR THE CRO's FRIEND OR FOE - *Susan McPherson, M.Sc., Scientific Program Manager, Charles River Laboratories, Senneville, Canada*

9:40 am

QA ASSESSMENT – *Kate Longman, B.S., RQAP-GLP, Manager, Quality Assurance Research, MPI Research, Inc., Mattawan, MI*

10:10 am

Refreshment Break

10:30 am

LEGAL AND FINANCIAL ARRANGEMENTS (BALANCING ACT BETWEEN YOU, THE ATTORNEYS AND SARBANES-OXLEY) - *Clynn Wilker, DVM, Ph.D., DABT, Senior Director, Preclinical Safety Assessment, Ardea Biosciences, San Diego, CA*

11:00 am

Q&A

8:00 – 11:30 COURSE #4

**ADVANCED TOPICS IN
BIOTHERAPEUTIC DRUG
DEVELOPMENT**

*Chair: Marque Todd, DVM, MS, DABT,
Regulatory Strategy Lead, Pfizer, Inc., La
Jolla, CA*

In the past several years, there has been a significant increase in the number of biotherapeutics that have entered late-stage development and it is projected that this number will expand rapidly in the next decade. It is expected that a number of these products will reach the market in the near future. As biotherapeutics are advanced through the nonclinical development process, there are scientific hurdles and potential challenges that must be overcome that are unique to later stage development and are different from those faced with pharmaceuticals. In addition, the regulatory requirements for clinical trials and product registration are rapidly evolving as worldwide regulatory agencies gain more experience with biotherapeutics. This course is designed to give participants practical, up-to-date case-driven information on the following topics in nonclinical biotherapeutic drug development: reproductive/developmental toxicity and carcinogenicity testing including the use of homologous proteins, derisking immunotoxicity and immunogenicity issues, comparability evaluation and testing, risk management and regulatory strategy considerations.

8:00 am **INTRODUCTION** - *Marque Todd, DVM, MS, DABT, Regulatory Strategy Lead, Pfizer, Inc., La Jolla, CA*

8:05 am **REPRODUCTIVE/
DEVELOPMENTAL
TOXICITY TESTING OF
BIOTHERAPEUTICS** -
William J. Breslin, Ph.D.,

*Senior Research Advisor,
NSD Safety Assessment,
Eli Lilly and Company,
Indianapolis, IN*

8:40 am **CARCINOGENICITY
TESTING OF
BIOTHERAPEUTICS** -
*Marque Todd, DVM, MS,
DABT, Regulatory Strategy
Lead, Pfizer, Inc., La Jolla,
CA*

9:15 am **DERISKING STRATEGIES
FOR IMMUNOTOXICITY
AND IMMUNOGENICITY
ISSUES** - *Daniel Wierda,
Ph.D., Research Fellow, Eli
Lilly and Company,
Indianapolis, IN*

9:50 am Refreshment Break

10:15 am **PRODUCT
COMPARABILITY
DETERMINATIONS FOR
BIOLOGICS: SCIENTIFIC
BASIS FOR
REGISTRATION
REQUIREMENTS AND
ROLE OF A PRECLINICAL
SCIENTIST** - *James
Daniel Green, Ph.D., Senior
Vice President, Preclinical
and Clinical Development,
Sciences, Biogen IDEC,
Inc., Cambridge, MA*

10:50 am **RISK MANAGEMENT AND
REGULATORY
STRATEGY** - *Jeffrey A.
Engelhardt, DVM, Ph.D.,
DACVP, President &
Pathologist, Engelhardt
Consulting, Inc., Camarillo,
CA*

8:00 – 11:30 COURSE #5

**DRUG ABUSE DEPENDENCE
ASSESSMENT: APPLICATION OF
NEUROBEHAVIORAL SCIENCES TO
ADDRESS DRUG SAFETY**

EVALUATION AND DRUG CONTROL POLICY

Chair: Theodore J. Baird, Ph.D., Director, Safety Pharmacology, MPI Research, Mattawan, MI

Due to the innovative and pioneering efforts of specialists in the field of behavioral pharmacology, predictive methodologies have been discovered and elaborated to identify and characterize potential abuse and dependence liability issues associated with either illicit or therapeutic drugs. Recent regulatory guidelines from the International Conference on Harmonisation (ICH), the European Medicines Agency (EMA), and the proposed, and as yet unpublished, federal regulatory guidelines from the United States Food and Drug Administration (FDA) may come into direct conflict with current International and National Drug Control Policy laws and regulations with respect to these study designs (Single Convention on Narcotic Drugs, 1961; Psychotropic Convention 1970; U.S. Comprehensive Drug Abuse and Control Act, 1971). The current regulatory pressure to conduct these studies under Good Laboratory Practice (GLP) guidelines sets the stage for a more detailed review by pharmaceutical company experts, IND/NDA consultants, as well as Contract Research Organizations with respect to ambiguous drug control and drug enabling policy requirements. This continuing education program will review the current models needed to comply with current EMA, FDA, and ICH guidelines with respect to preclinical abuse liability testing for health agency approval. The program will also give details of both drug safety and drug control laws and regulations that must be met for successful review at both health and law enforcement agencies, and that ultimately will ensure compliance with international and national drug control requirements.

Important distinctions between drug safety and drug control issues, as well as the appropriate application of neurobehavioral methodologies to address the questions of abuse versus dependence liability in the preclinical drug development arena, amid a changing regulatory environment, will be discussed.

- 8:00 am **AN INTRODUCTION TO DRUG ABUSE AND DEPENDENCE ASSESSMENT** - *Theodore J. Baird, Ph.D., Director, Safety Pharmacology, MPI Research, Mattawan, MI*
- 8:40 am **DRUG ABUSE AND DEPENDENCE STUDIES: BACKGROUND, EXPERIMENTAL PARADIGMS, STUDY EXECUTION, AND DATA INTERPRETATION** – *David Gauvin, Ph.D., Director, Neurobehavioral Sciences, MPI Research, Mattawan, MI*
- 9:20 am **DRUG DEVELOPMENT IN THE CONTEXT OF NATIONAL/INTERNATIONAL DRUG CONTROL POLICY** – *Frank Sapienza, Partner and Consultant, The Drug and Chemical Advisory Group, Fairfax, VA*
- 10:00 am Refreshment Break
- 10:20 am **PANEL DISCUSSION** -

SUNDAY AFTERNOON – 11/1/09

COURSE #1 - STUDY DIRECTOR TRAINING - CONTINUED

1:00 – 4:30

COURSE #6

DRUG TRANSPORTERS IN TOXICOLOGY

Chair: Lisa D. Beilke, Ph.D., Research Scientist II, Gilead, Foster City, CA

Transporters are expressed in a wide variety of tissues including liver, kidney, intestine, and brain where they play key roles in the absorption, distribution and excretion of both xenobiotics and endobiotics. In recent years, the understanding of drug transport systems has become increasingly important as we begin to comprehend how changes in their expression and function relate to pharmacological and toxicological consequences. There are several classes of transporters (ex., organic anion and cation transporters) with varying tissue distribution, expression and substrate specificity. During liver disease, a number of intrinsic adaptive responses occur to minimize the detrimental effects of accumulating endobiotics, such as bilirubin and bile acids. Characteristic adaptive modifications that occur in the liver relate to expression changes in basolateral (sinusoidal) and canalicular transport systems which are regulated by transcription factors and nuclear hormone receptors. The kidney is another site with multiple transporters involved in the active renal secretion of compounds. Included will be a discussion of renal transporters and how these transporters affect drug-drug interactions and contribute to the toxicity of antiviral nucleotides and other therapeutic agents. Finally, the design of drugs to target specific transporters could be used to more selectively deliver drugs to a target organ while avoiding distribution to other organs, thereby reducing potential side effects. Therefore, an understanding of transporters and their related issues in PKDM will be discussed to provide insight on how to evaluate lead

molecules as substrates or inhibitors in the drug discovery process.

1:00 pm

FUNDAMENTALS OF ORGANIC ANION TRANSPORT SYSTEMS – *Lauren Aleksunes, PharmD, Ph.D., Assistant Professor, Rutgers University, Ernest Mario School of Pharmacy, Piscataway, NJ*

1:40 pm

ORGANIC CATION TRANSPORTERS IN PHARMACOLOGY AND TOXICOLOGY – *Kathy Giacomini, Ph.D., Professor of Biopharmaceutical Sciences, Cellular and Molecular Pharmacology and Pharmaceutical Chemistry, University of California, San Francisco, CA*

2:20 pm

REGULATION OF TRANSPORTER EXPRESSION OF OBESITY, DIABETES, AND STEATOHEPATITIS: IMPLICATIONS FOR ALTERED DRUG ABSORPTION AND EXCRETION – *Angela Slitt, Ph.D., Assistant Professor, Department of Biomedical and Pharmaceutical Sciences, University of Rhode Island, Kingston, RI*

3:00 pm

Refreshment Break

3:10 pm

OVERVIEW OF RENAL ORGANIC ANION TRANSPORTERS AND THEIR ROLE IN TOXICITY – *Tomas Cihlar, Ph.D., Sr Principal Scientist, Biology, Gilead Science, Inc., Foster City, CA*

3:50 pm **IMPACT OF DRUG TRANSPORTERS ON PHARMACOKINETICS AND DRUG METABOLISM**
- Magang Shou, Ph.D.,
Director of PKDM, Amgen
Inc., Thousand Oaks, CA

1:00 – 4:30 COURSE #7

USE OF NON-HUMAN PRIMATES IN THE ASSESSMENT OF REPRODUCTIVE TOXICITY

Chair: Angélique Braen, Ph.D., DABT,
Toxicologist, Hoffmann-La Roche, Inc.,
Nutley, NJ

This course will focus on the use of non-human primates in the assessment of various aspects of reproductive toxicity. The course will discuss various study designs and provide examples, data interpretation, and regulatory guidance/expectations for these type of studies.

1:00 pm **INTRODUCTION** -
Angélique Braen, Ph.D.,
DABT, Toxicologist,
Hoffmann-La Roche, Inc.,
Nutley, NJ

1:40 pm **PRACTICAL ISSUES AND STUDY DESIGN OF REPRODUCTIVE TOXICOLOGY STUDIES** –
Gerhard Weinbauer, Ph.D.,
Director, Res & Safety
Assessment, Covance
Laboratories GmbH,
Muenster, Germany

2:20 pm **CASE SCENARIOS FROM PHARMACEUTICAL INDUSTRY** – Noel Dybdal,
D.V.M., Ph.D., DACVP,
Senior Pathologist,
Genentech, Inc., So San
Francisco, CA

3:00 pm Refreshment Break

3:20 pm **REGULATORY GUIDANCE AND EXPECTATIONS FOR DEVELOPMENTAL EVALUATION (US AND EX-US)** – Grace S. Lee,
Ph.D., Pharmacologist/
Toxicologist, US FDA,
CDER, Division of
Pulmonary and Allergy
Products, Silver Spring, MD

4:00 pm **Q&A**

1:00 – 4:30 COURSE #8

CONSULTING IN TOXICOLOGY

Chair: Patricia Frank, Ph.D., Patricia Frank
& Associates, Inc., Evanston, IL

For many years, toxicology consulting was a part-time filler for academicians or a fall-back position for those looking for a “real” job. Today, consulting in all areas of toxicology including regulatory toxicology (FDA, EPA, and world-wide regulatory bodies), expert testimony and areas requiring specific functional expertise such as reproductive toxicology or neurotoxicology is a full-time, recognized and needed profession. Many toxicologists reach a point in their careers where they are considering consulting as the next professional step. This course is designed to help those people explore the different areas of toxicology consulting, determine if consulting is suitable for them as well as if they are suitable for consulting, and to learn about the business of consulting. Consultants who have been in business for many years will present their insights and tips into how to be a successful consultant.

1:00 pm **INTRODUCTION TO CONSULTING** - Patricia
Frank, Ph.D., Patricia Frank
& Associates, Inc.,
Evanston, IL

1:10 pm **CONSULTING IN THE PHARMACEUTICAL INDUSTRY** – *Patricia Frank, Ph.D., Patricia Frank & Associates, Inc., Evanston, IL*

1:35 pm **EXPERT TESTIMONY** – *Richard A. Parent, Ph.D., DABT, FATS,RAC, President, Consultox, Ltd, Damariscotta, ME*

2:00 pm **CONSULTING IN THE CHEMICAL INDUSTRY** – *Thomas M Dydek, Ph.D., DABT, PE, Senior Toxicologist & Engineer, Dydek Toxicology Consulting, Austin, TX*

2:25 pm Refreshment Break

2:40 pm **THE BUSINESS OF CONSULTING** - *Shayne C. Gad, Ph.D., DABT, ATS, Gad Consulting Services, Cary, NC*

3:05 pm **TAKING THE PLUNGE-A FEW WORDS FROM A NEW CONSULTANT** - *Merrill R. Osheroff, Ph.D., DABT, President, Osheroff Consulting Services LLC, Mattawan, MI*

3:30 pm **PANEL DISCUSSION ON CONSULTING**

1:00 – 4:30 COURSE #9

PATHOLOGY FOR THE TOXICOLOGIST: BASIC CONCEPTS OF TOXICOLOGIC PATHOLOGY AND PATHOLOGY DATA INTEGRATION

Co-Chairs: Peter C. Mann, DVM, DACVP, Veterinary Pathologist/President of the Society of Toxicologic Pathology, EPL, Seattle, WA and LuAnn McKinney, DVM, DACVP, Pathologist, Silver Spring, MD

Pathology is often a determining endpoint in the safety assessment of

drugs and chemicals. It is extremely important that pathologists clearly communicate with the other scientists involved in the conduct and reporting of toxicology and hazard identification studies so that regulatory agencies can easily understand the information in the reports. This course will include a discussion of the role of the toxicologic pathologist in toxicology studies and basic principles of toxicologic pathology including terminology and lesions common to all organs. Additionally the course will focus on integration of clinical pathology (e.g. serum chemistry, hematology, urinalysis) and morphologic pathology data as well as pathology endpoints with data not traditionally generated by pathologists- i.e. drug metabolism and distribution, safety pharmacology, genetic toxicology, etc.

1:00 pm **BASIC CONCEPTS IN PATHOLOGY AND THE ROLE OF THE TOXICOLOGIC PATHOLOGIST** - *LuAnn McKinney, DVM, DACVP, Pathologist, Silver Spring, MD*

1:40 pm **HISTOPATHOLOGIC PRACTICE AND APPROACHES: RELEVANCE AND INTERPRETATION IN RISK ASSESSMENT** – *Dianne Margaret Creasy, Ph.D., FRCPath, Senior Director of Pathology, Huntingdon Life Sciences, East Millstone, NJ*

2:20 pm **THE HISTOPATHOLOGY/CLINICAL PATHOLOGY CONUNDRUM** – *Vincent Meador, DVM, Ph.D., DACVP, Senior Director, Toxicology, Amgen Inc., Seattle, WA*

3:00 pm Refreshment Break

3:30 pm

**CONTEXTUAL
INTERPRETATION OF *IN
VIVO* DATA** - *Jeffery A.
Engelhardt, DVM, Ph.D.,
DACVP, FIATP, President
and Pathologist, Engelhardt
Consulting, Inc., Camarillo,
CA*

4:10 pm

Q&A

ABSTRACT DEADLINE AUGUST 17TH, 2009

See website for details – www.actox.org

INSTRUCTIONS FOR PREPARING POSTERS FOR THE ANNUAL MEETING OF THE AMERICAN COLLEGE OF TOXICOLOGY

The Poster Session has been scheduled for Tuesday, November 3, 2009 from 5:30 pm until 7:00 pm. You will be assigned a number for the exact location of your poster.

Each presentation is assigned a 4' x 6' cork board that includes 2.2 square meters (24 square feet) on which to display data. Please identify your poster with a title and the names of the investigators in 1" (2.5 cm) lettering at the top of the display. It is very helpful to post a copy of your abstract.

Micrographs, photomicrographs, charts, and graphs should be mounted on firm mounting board. Matte finish on photographs gives the best visibility. Matte surface paper may be used, or you can simply dry glossy prints with the emulsion side of the paper facing away from the drying drum surface.

Presenters should provide their own push pins (5/8" long) for attaching posters to the display unit.

The Poster Boards will be available Sunday evening, November 1, 2009. Posters should be set up by Monday morning to be available for as long as possible to attendees.

You are expected to be present at your poster for discussion and to answer questions during the 5:30 pm to 7:00 pm Poster Session, Tuesday, November 3, 2009.

*Please remove your posters at the end of the session (7:00 pm) on Tuesday evening. **ACT is not responsible for removing or storing posters.***

APPLICATION
AMERICAN COLLEGE OF TOXICOLOGY
TRAVEL GRANT – ANNUAL MEETING, 2009

INSTRUCTIONS

1. The American College of Toxicology will be offering Travel Grants in the amount of \$1000.00 for student and junior* professional participation in the Poster Session. **The recipient must present a poster at this meeting. Abstract and forms to be in the office by August 17, 2009.**
 2. The Furst Award may also be applied for at this time. Applying for the Furst Award does not exclude you from the ACT Travel Award.
 3. If you are a student or a junior* professional and would like to apply for this grant, please complete the form included. If you wish, you may also type your answers on a separate sheet of paper and attach it to the application. Feel free to attach a resume, copy of publications, or any other documentation you feel is appropriate. All information will be kept confidential.
 4. Recipients will be determined by the ACT Awards Committee and will be informed by the beginning of October. Grants will be presented at the Annual Luncheon, Monday, November 2, 2009.
 5. Complete the meeting registration form and the travel grant application (if you have submitted an abstract) and submit to the ACT Secretariat: 9650 Rockville Pike, Bethesda, MD 20814. **The deadline for travel grant applications is the same as the Abstract deadline, August 17th, 2009.** Please remember that you also have to submit registration for the meeting.
- *A junior professional is defined as an individual holding either an A.S., B.S., B.A. or equivalent degree. Individuals holding a Ph.D., Dr.P.H., D.Sc., D.Pharm., D.V.M., M.D. or equivalent degrees are **NOT** eligible.*

REGISTRATION

THE AMERICAN COLLEGE OF TOXICOLOGY NOVEMBER 1-4, 2009

Please type or print.

Name _____
First Last

Affiliation _____

Address _____

City _____ State _____ Zip _____

Phone # _____ Fax # _____ Email _____

I require the following special accommodations for accessibility: _____

ANNUAL MEETING REGISTRATION FEES (please check) Includes ACT Keynote Luncheon, 11/02/09

___MEMBER.....\$400 ___NONMEMBER.....\$650 ___STUDENT.....\$50

LATE FEE IF REGISTRATION NOT RECEIVED BY OCTOBER 1, 2009 - \$100.00

ONE DAY FEES: PLEASE CIRCLE DAY - MONDAY - TUESDAY - WEDNESDAY

___MEMBER.....\$250 ___NONMEMBER.....\$350 ___STUDENT.....\$30

You will **NOT** be considered pre-registered unless your check (or charge) accompanies this form. Make check payable to: American College of Toxicology (U.S. funds only). Mail this form with check to: American College of Toxicology, 9650 Rockville Pike, Bethesda, MD 20814. (Tel: 301-634-7840 – FAX: 301-634-7852)

MASTERCARD/VISA/AMEX # _____ Expir.Date _____

Print Name Signature

REFUND POLICY

\$75 Processing Fee will be charged before 9/25/09 - 50% Refund if Canceled before 10/01/09

AFTER OCTOBER 1, 2009 NO FEES WILL BE REFUNDED

CONTINUING EDUCATION COURSE REGISTRATION

Courses will be held on **Sunday, November 1, 2009** at the Palm Springs Convention Center. (Pre-registration Required)
Assignment will be based on postmark of this registration form. **Registration is limited.**

FIRST NAME MI LAST NAME

AFFILIATION

STREET ADDRESS

CITY STATE ZIP COUNTRY

Phone No. Fax No. Email

8:00 – 4:30 p.m.

Course #1 Study Director Training \$300__

8:00 – 11:30 a.m.

Course #2 Interaction with Regulatory Agencies \$200__

Course #3 Study Monitoring \$200__

Course #4 Advanced Topics in Biotherapeutic Drug Development \$200__

Course #5 Drug Abuse Dependence Assessment \$200__

1:00 – 4:30 p.m.

Course #6 Drug Transporters as Toxic Agents \$200__

Course #7 Use of Non-Human Primates in the Assessment of
Reproductive Toxicity \$200__

Course #8 Consulting in Toxicology \$200__

Course #9 Pathology for the Toxicologist \$200__

STUDENTS RECEIVE A 50% DISCOUNT ON ABOVE PRICES

LATE FEE IF REGISTRATION NOT RECEIVED BY OCTOBER 1, 2009 - \$100.00

Payment must accompany this registration. Make check payable to: American College of Toxicology (U.S. Funds only)

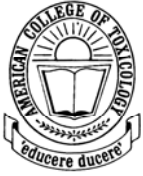
MASTERCARD/VISA/AMEX # _____ Expir.Date _____

Print Name Signature

REFUND POLICY - \$75 Processing Fee will be charged before 9/25/09 - 50% Refund if Canceled before 10/01/09

AFTER OCTOBER 1, 2009 NO FEES WILL BE REFUNDED

AMERICAN COLLEGE OF TOXICOLOGY



30th ANNIVERSARY PARTY

**“A CELEBRATION OF OUR PAST,
PRESENT & FUTURE”**

SUNDAY, NOVEMBER 1, 2009

6:00 pm – 7:30 pm

**Appetizers, Cash Bar, Presentations of our Past, Present and
Future, Live Music and more.....**



**Register for your FREE Party Favor and a Glass of
Champagne!**

Name(s):

Email: (print)

Please put all names of those attending on the form.