FIP Pharmaceutical Sciences 2010 World Congress

in association with the AAPS Annual Meeting and Exposition

Program at a Glance

November 14 – 18, 2010

Ernest N. Morial Convention Center
New Orleans, Louisiana, USA

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See page 4 for details

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See page 4 for details.

International Pharmaceutical Federation FIP

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FIP Pharmaceutical Sciences World Congress 2010 in association with AAPS Annual Meeting & Exposition

will feature Keynote speaker

Dr. Tadataka "Tachi" Yamada

Dr. Tadataka "Tachi" Yamada is President of the Bill & Melinda Gates Foundation Global Health Program. In this capacity he oversees grants totalling over $7 billion in programs directed at applying technologies to address major health challenges of the developing world including TB, HIV, malaria and other infectious diseases, malnutrition and maternal and child health. He was formerly Chairman, Research and Development and a Member of the Board of Directors of GlaxoSmithKline.

Dr. Yamada was born in Japan, and completed his education in the United States. He graduated from Stanford University with a Bachelors in history and obtained his M.D. from New York University School of Medicine. After completing his internal medicine training at the Medical College of Virginia he became an investigator in the United States Army Medical Research Institute of Infectious Diseases, trained in gastroenterology at the UCLA School of Medicine and assumed his first faculty position there. He later moved to the University of Michigan where he ultimately became Chairman, Department of Internal Medicine and Physician-in-Chief of the University of Michigan Medical Center before joining GlaxoSmithKline.

A scientist and scholar in gastroenterology, Dr. Yamada is the author of more than 150 original manuscripts on the subject and is the editor of *The Textbook of Gastroenterology*. The studies undertaken by Dr. Yamada and his collaborators led to basic discoveries in the post-translational processing and biological activation of peptide hormones, the structure and function of receptors for hormones regulating gastric acid secretion, and the regulation of genes involved in the acid secretory process.

In recognition of his contributions to medicine and science he has been elected to membership in the Institute of Medicine of the National Academy of Sciences (US), the Academy of Medical Sciences (UK) and the National Academy of Medicine (Mexico) and he has received an honorary appointment as Knight Commander of the Most Excellent Order of the British Empire (KBE). He has also been the recipient of numerous awards including the Distinguished Achievement Award in Gastrointestinal Physiology from the American Physiological Society, the Friedenwald Medal from the American Gastroenterological Association, the Distinguished Faculty Achievement Award from the University of Michigan and the Distinguished Medical Scientist Award from the Medical College of Virginia. Dr. Yamada is a Fellow of the Imperial College of Medicine, a Master of the American College of Physicians, a Fellow of the Royal College of Physicians, a Past-President of the Association of American Physicians and a Past-President of the American Gastroenterological Association. He has also been a Member of the Board of Directors of the American Board of Internal Medicine and the National Board of Medical Examiners.

Advance your knowledge and exposure at the premier pharmaceutical event. You can also register with your colleagues and SAVE hundreds of dollars by taking advantage of the group discounted rates.

With over 100 programming sessions, this can be your best opportunity to meet colleagues, learn about and promote breakthrough research and technologies, and improve your professional edge.

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Take advantage of this opportunity to register you and your colleagues for this meeting and save hundreds of dollars!

Group registration will be applied as follows:
Four fully paid registrations qualify for a $100.00 discount for everyone in the group.

This policy is NOT applicable for the following registration types:

- Students
- Exhibitors
- Reduced Combination Registration
- One-day and Two-day Registrations
- Expo Hall/Career Center Only

Registration must be in groups of four or more paid registrants from the same organization, and cannot be combined with any other offer. All members of the group must be registered at the same time. Previously registered attendees may not be added to a new group. **Group Registrations are not valid after October 8, 2010 and are available through online registration only.**

To register your group online, go to the registration site **http://www.pswc2010.org**

Save up to 10 Percent!

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Register for the following and become eligible for a reduced combination registration fee:

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Register online and use the Sustaining Sponsor registration. Contact **registration@aaps.org** for the company discount code. Receive $125 off your registration for the FIP PSWC 2010/AAPS Annual Meeting & Exposition. **The deadline for the discount is October 8, 2010.** The discount is not available for combination registrations, one-day or exposition only registration. Discount is applicable only for the FIP PSWC 2010/AAPS Annual Meeting & Exposition Group registrations, and not to workshop, short course or open forum registrations.

See you in New Orleans!

The most celebrated and historic core of this Louisiana city — including the Faubourg Marigny, French Quarter, Central Business District, Warehouse and Arts District, Magazine Street, Garden District, Audubon Park and Zoo and St. Charles Avenue — remains both physically and spiritually intact and is thriving. The cultural riches, sensual indulgences and unparalleled service that define the New Orleans experience continue to flourish, as they have for centuries. The city is open, as historically and culturally rich and charming as ever, and eager to welcome visitors again. With more than 28,000 hotel rooms, famed restaurants, and vibrant music clubs, New Orleans attracts and accommodates more than 10 million people each year.

For more information on all New Orleans has to offer you, visit **www.neworleanscvb.com/pswc2010.**

The FIP PSWC 2010/AAPS Annual Meeting & Exposition will be held at the Ernest N. Morial Convention Center New Orleans (MCCNO), conveniently located to major points throughout the city.

The MCCNO lays just steps away from the world-famous attractions of the French Quarter, while the historic St. Charles streetcar line runs past the elegant homes of the Garden District. The excitement of New Orleans transforms an obligatory business trip into an unexpected experience. The MCCNO is approximately 15 miles from Louis Armstrong New Orleans International Airport.

For more information on the Ernest N. Morial Convention Center New Orleans, visit **www.mccno.com.**

Ernest N. Morial Convention Center New Orleans
900 Convention Center Blvd.
New Orleans, LA 70130

Co-Sponsoring & Supporting Organizations

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APSTJ The Academy of Pharmaceutical Science and Technology, Japan

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apsa Australasian Pharmaceutical Science Association

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American Pharmacists Association Improving medication use. Advancing patient care. APhA

Indian Pharmaceutical Association

Sociedad Española de Farmacia Industrial y Galénica

CSPS Canadian Society of Pharmaceutical Scientists

TiFTAD Turkish Pharmaceutical Technology Scientists Association

Iranian Association of Pharmaceutical Scientists

Chinese Pharmaceutical Association

SUPPORTED BY:

TOPRA The Organisation for Professionals in Regulatory Affairs

American Society for Clinical Pharmacology and Therapeutics

ABCF Associação Brasileira de Ciências Farmacêuticas

APV International Association for Pharmaceutical Technology

Belgian Society of Pharmaceutical Sciences

CASSS An International Separation Science Society

DIA Drug Information Association

BMES The Full Service Professional Society for Biomedical Engineering & Bioengineering

CRS Delivering Bioactives Controlled Release Society

edqm European Directorate for the Quality of Medicines & HealthCare

EAPB

European Association of Pharma Biotechnology

USP U.S. PHARMACOPEIA The Standard of Quality℠

PQRI Product Quality Research Institute

South African Association of Pharmacists in Industry

ALA Association for Laboratory Automation

American Association of Colleges of Pharmacy AACP Discover • Learn • Care: Improve Health

ISSX International Society for the Study of Xenobiotics

uphat DuPHAT

SAPRAA

American College of Clinical Pharmacology

ACS Chemistry for Life™ American Chemical Society

SOT Society of Toxicology Creating a Safer and Healthier World by Advancing the Science of Toxicology

FAPA 1964 Federation of Asian Pharmaceutical Associations

FDA Food & Drug Administration

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Saturday, November 13, 2010

7:00 am – 5:00 pm
Registration

8:30 am – 5:00 pm
AAPS Executive Council Meeting

2:00 pm – 5:00 pm
Speaker Ready Room

PSWC 2010 CONGRESS FOR STUDENTS AND POSTDOCTORAL FELLOWS

An additional fee is required to attend this meeting.

8:00 am – 10:00 am
Plenary Session

Drug Discovery for Neglected Diseases: The Essential Ps
William Charman, Ph.D.
Monash University

The Pharmaceutical Sciences in 2020: Four Scenarios
Daan Crommelin, Ph.D.
Utrecht University

Critical Research Techniques for Pharmaceutical R&D
Mario Rocci, Jr., Ph.D.
Icon Development Solutions

10:30 am – 12:00 pm
Poster Session

1:00 pm – 2:00 pm
Breakout Sessions

How to Advance your Career in Academia
Speaker to be Determined

How to Advance your Career in Industry
Speaker to be Determined

How to Advance your Career in Government Agencies
Speaker to be Determined

2:00 pm – 3:00 pm
Breakout Sessions

Women in Pharmaceutical Sciences
Speaker to be Determined

Resumé Writing
Speaker to be Determined

Job Interview Techniques
Speaker to be Determined

3:30 pm – 5:00 pm
Poster Session

5:00 pm – 6:00 pm
Reception

PRE-CONGRESS WORKSHOPS

An additional fee is required to attend pre-conference workshops.

8:30 am – 5:00 pm
AAPS Workshop on Contemporary Challenges and Advances Impacting the Development of Veterinary Pharmaceuticals
(Day One of Two-Day Workshop)

8:30 am – 5:00 pm
AAPS Workshop on Harmonization of Regulatory Approaches for Evaluating Therapeutic Equivalence and Interchangeability of Multisource and Complex Drug Products
(Day One of Two-Day Workshop)

8:30 am – 5:00 pm
USP Workshop on the Pharmacopeia's Role in Improving Global Health

U.S. PHARMACOPEIA
The Standard of Quality℠

Co-sponsored by AAPS
(Day One of Two-Day Workshop)

8:30 am – 5:00 pm
ACCP Workshop on 6th International Symposium on Microdialysis in Drug Research and Development 2010

Co-sponsored by AAPS
(Day One of Two-Day Workshop)

8:30 am – 5:00 pm
CRS Workshop on Using Population Pharmacokinetics to Support the Development of Clinically Relevant Specifications for Extended Release Formulations

Co-sponsored by AAPS
(One-Day Workshop)

Sunday, November 14, 2010

7:00 am – 7:00 pm
Registration

7:00 am – 5:00 pm
Speaker Ready Room

8:00 am – 5:00 pm
Press Room

12:00 pm – 5:00 pm
Student Lounge

12:00 pm – 5:00 pm
International Lounge

PSWC 2010 CONGRESS FOR STUDENTS AND POSTDOCTORAL FELLOWS

An additional fee is required to attend this meeting.

7:45 am – 9:45 am

Graduate Student Symposium in Biotechnology (BIOTEC)
Sponsored by

Graduate Student Symposium in Drug Design & Development (DDD)

Graduate Student Symposium in Formulation Design & Development (FDD), Manufacturing Science & Engineering (MSE) and Physical Pharmacy & Biopharmaceutics (PPB)
Sponsored by

Bristol-Myers Squibb Company

10:00 am – 12:00 pm

Graduate Student Symposium in Analysis & Pharmaceutical Quality (APQ)
Sponsored by

APQ
AAPS ANALYSIS AND PHARMACEUTICAL QUALITY SECTION

Graduate Student Symposium in Pharmacokinetics, Pharmacodynamics & Drug Metabolism (PPDM) and Clinical Pharmacology & Translational Research (CPTR)
Sponsored by

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Answers That Matter.

12:00 pm – 1:00 pm
Mentoring Luncheon

1:00 pm – 2:30 pm
Poster Session

PRE-CONGRESS WORKSHOPS

An additional fee is required to attend pre-conference workshops.

8:30 am – 4:00 pm
AAPS Workshop on Contemporary Challenges and Advances Impacting the Development of Veterinary Pharmaceuticals
(Day Two of Two-Day Workshop)

8:30 am – 4:00 pm
AAPS Workshop on Harmonization of Regulatory Approaches for Evaluating Therapeutic Equivalence and Interchangeability of Multisource and Complex Drug Products
(Day Two of Two-Day Workshop)

8:30 am – 4:00 pm
USP Workshop on the Pharmacopeia's Role in Improving Global Health

USP U.S. PHARMACOPEIA
The Standard of Quality℠

Co-sponsored by AAPS
(Day Two of Two-Day Workshop)

8:30 am – 4:00 pm
ACCP Workshop on 6th International Symposium on Microdialysis in Drug Research and Development 2010

Co-sponsored by AAPS
(Day Two of Two-Day Workshop)

SHORT COURSES

An additional fee is required to attend short courses.

8:30 am – 4:00 pm

Short Course #1
Stability Testing in Pharmaceutical Development
(APQ, MSE & FDD)

Short Course #2
Mechanistic PK/PD Modeling
(PPDM, CPTR, PCOL)

Short Course #3
ICH Guidelines Q8, Q9, Q10 and Q11: How Do They all Fit Together?
(APQ & RS)

Short Course #4
Nanotechnology from A-Z: Achievement in Drug Delivery and Tissue Engineering
(FDD & PPB)

Short Course #5
Helping the Medicine Go Down - Pediatric Medicines: Formulation, Manufacturing and Compliance Challenges
(FDD, MSE & RS)

Short Course #6
Developments in Technologies for Process Related Impurities Detection and Identification for Biologics
(BIOTEC, RS & APQ)

12:00 pm – 1:00 pm
Short Course/Workshop Lunch

4:30 pm – 6:30 pm
Opening Session

Keynote Address
Tadataka "Tachi" Yamada, M.D.
President
Bill & Melinda Gates Foundation
Global Health Program

FIP Presidential Address

AAPS Presidential Address

Awards Presentations

Welcome Reception
Immediately Following the Opening Session
Hilton Riverside Hotel

Monday, November 15, 2010

7:00 am – 6:00 pm
Registration

7:00 am – 5:00 pm
Speaker Ready Room

7:00 am – 5:00 pm
Press Room

7:00 am – 5:00 pm
Student Lounge

7:00 am – 5:00 pm
International Lounge

SESSION TOPIC KEY

(APQ) Analysis and Pharmaceutical Quality
(BIOTEC) Biotechnology
(CPTR) Clinical Pharmacology and Translational Research
(DDD) Drug Design and Discovery
(FDD) Formulation Design and Development
(MSE) Manufacturing Science and Engineering
(PPB) Physical Pharmacy and Biopharmaceutics
(PPDM) Pharmacokinetics, Pharmacodynamics and Drug Metabolism
(RS) Regulatory Sciences

(E&C) Education and Curriculum
(ES) Environmental Sciences
(GH) Global Health
(MCNP) Medicinal Chemistry and Natural Products
(PCOL) Pharmacology and Biochemistry
(SS) Safety Sciences

Please visit the full Preliminary Program at www.pswc2010.org for a listing of sessions by topic track.

MONDAY MORNING ROUNDTABLES

8:00 am – 10:00 am

Development of Effective Fixed Dose Combination Therapies for Global Diseases: Recent Successes and Advances
(PPB & GH)

Session Chairs
Tycho H. Heimbach, Ph.D.
Novartis Pharmaceuticals

Handan He, Ph.D.
Novartis Pharmaceuticals

MONDAY MORNING ROUNDTABLES

8:00 am – 10:00 am *(continued from page 9)*

Saving Lives with Combined Antimalarial Therapies via Optimizing Dosing Regimen and PK/PD in Children and Pregnant Women. (Sulfadoxine-Pyrimethamine, Artemether-Lumefantrine, Coartem)
Jan-Stefan VanderWalt, Ph.D.
University of Cape Town

Finally Beating Malaria: Successful Development of a Fixed Dose Combination of Artemether and Lumefantrine
Unmesh Deodhar, Ph.D.
Novartis Pharma AG

Impacting HIV Patients' Lives Around the Globe: Successful Development Fixed Dose Combination of Three Drugs: Efavirenz, Tenefovir and Emtriva
Munir Hussain, Ph.D.
Bristol-Myers Squibb

Pharmacogenetics: A Testing Issue
(CPTR & PPDM)

Session Chairs
Lawrence L. Fleckenstein, Ph.D.
University of Iowa

David A. Flockhart, M.D., Ph.D.
Indiana University

Clinically Available Pharmacogenomic Tests
David A. Flockhart, M.D., Ph.D.
Indiana University

Challenges of the Clinical Application of Pharmacogenetic Testing
Kathryn A. Phillips, Ph.D.
University of California, San Francisco

FDA Perspective on Pharmacogenetic Testing
Lawrence J. Lesko, Ph.D. (Invited)
U.S. Food and Drug Administration

Can Nanoparticles be Simultaneously Used for Multimodality Imaging and Targeted Drug Delivery?
(PPB & FDD)

Session Chairs
Duxin Sun, Ph.D.
University of Michigan

Gert Storm, Ph.D.
Utrecht University

Delivery of siRNA and Peptide for Cancer Therapy
Leaf Huang, Ph.D.
University of North Carolina

MRI Detection of Imaging-guided Drug Delivery: The Role of Lipo-cest Agents
Silvio Aime, Ph.D.
University of Torino

Mimicking the Design of Nature's Own Nanoparticles to Create Multifunctional Agents
Willem Mulder, Ph.D.
Mount Sinai School of Medicine

Analytical Instrument Qualification: Towards Globalization
(APQ)

Session Chairs
Paul Smith, Ph.D.
Perkin-Elmer

Frank Gargiulo, M.S.
MannKind Corporation

Somak Das, M.S.
Bristol-Myers Squibb

AIQ: A USP Perspective
Horacio Pappa, Ph.D.
U.S. Pharmacopeia

AIQ in QA/QC Operations
Nicholas Buhey, Ph.D.
U.S. Food and Drug Administration

A European Perspective on AIQ
Bob McDowell, Ph.D.
Scientific Consultant

Sharing Global Best Practices in Educating Pharmaceutical Scientists
(MSE & E&C)

Session Chairs
Jian-Xin Li, Ph.D.
Evonik Degussa Corporation

Daan J. Crommelin, Ph.D.
Top Institute Pharma

Asian Perspective: Education and Training Programs
Paul Wan Sia Heng, Ph.D.
National University of Singapore

European Perspective: Public Private Partnerships and their Role in Education
Daan J. Crommelin, Ph.D.
Top Institute Pharma

U.S. Perspective: Industrial Pharmacy Education for the Future
Larry Augsburger, Ph.D.
University of Maryland

Customized Vaccines for the Future (BIOTEC)

Session Chairs
Camilla Foged, Ph.D.
The Devish University of Pharmaceutical Sciences

Enrico Mastrobattista, Ph.D.
Utrecht Institute for Pharmaceutical Sciences

Customized Vaccines for the Future
Derek O'Hagan, Ph.D.
Novartis Vaccines & Diagnostics

Customized Vaccines for the Future: Needles or Needleless?
Wim Jiskoot, Ph.D.
Leiden University

Vaccines for the 21st Century
Christian Mandl, Ph.D., M.D.
Novartis Vaccines & Diagnostics

MONDAY MORNING PROFESSIONAL DEVELOPMENT SESSION
8:00 am – 10:00 am

Alternative Careers: The Path Less Traveled
Clifford Minz, Ph.D.
BioCrowd.com

PLENARY SESSION
10:00 am – 12:00 pm

Presentation Title to be Determined
Leslie Z. Benet, Ph.D.
University of California, San Francisco

Presentation Title to be Determined
Michael Karas
Goethe Universitat

Third Speaker to be Determined

AWARDS CEREMONY
12:00 pm - 1:00pm

EXPOSITION AND CAREER CENTER
12:00 pm – 5:30 pm

Exposition

AAPS Career Center
Funded by a Grant from AstraZeneca life inspiring ideas

CONTRIBUTED PAPERS POSTER SESSION
1:00 pm – 5:00 pm

HOT TOPICS
12:15 pm – 1:30 pm

Topic #1 to be Determined

Topic #2 to be Determined

AAPS FOCUS GROUP MEMBERSHIP MEETINGS
12:15 pm – 1:15 pm

MONDAY AFTERNOON PROFESSIONAL DEVELOPMENT SESSIONS
1:00 pm – 3:00 pm
Making the Most out of the Conference
Brianna Blaser, Ph.D.
AAAS/*Science* Careers

2:00 pm – 4:00 pm
How to Survive a Merger
Megan Driscoll
PharmaLogics

MONDAY AFTERNOON SYMPOSIA
Monday afternoon symposia are supported by a grant from sanofi aventis Because health matters

1:30 pm – 4:00 pm

Pharmaceuticals Without Borders I: Developing and Delivering Medicines to Underserved Populations (GH)

Session Chairs
Lawrence L. Fleckenstein, Ph.D.
University of Iowa

William Charman, Ph.D.
Monash University

Vaccinology and Global Health: New Technologies Create Global Opportunities
Andrin Oswald, M.D.
Novartis Vaccines & Diagnostics

The Bill & Melinda Gates Foundation's Strategy on Neglected Tropical Diseases
Julie Jacobson, M.D.
Bill and Melinda Gates Foundation

MONDAY AFTERNOON SYMPOSIA

Monday afternoon symposia are supported by a grant from

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Because health matters

1:30 pm – 4:00 pm *(continued from page 11)*

Contribution of Public and Private Partnerships to Delivering Low-cost Pharmaceuticals
Simon Croft, Ph.D.
London School of Hygiene and Tropical Medicine

Nature's Chemical Diversity: Science and Practice (DDD & MCNP)

Session Chairs
Maureen A. McKenzie, Ph.D.
Denali BioTechnologies, Inc.

De-an Guo, Ph.D.
Shanghai Research Center

Targeted Phytochemicals from Selected Plants and their Biotechnology
Peter Kaufman, Ph.D.
University of Michigan

Marine Drug Discovery: Novel Leads from Cyanobacteria and their Modes of Action
Hendrik Luesch, Ph.D.
University of Florida

Drug Discovery and Early-phase Development of Anti-Alzheimers Agents from Natural Products
John R. Cashman, Ph.D.
Human BioMolecular Research Institute

Microarray Analysis as a Tool to Elucidate the Mechanism of Action of St. John's Wort
Veronika Butterweck, Ph.D.
University of Florida

Modern Research of Chinese Herbal Medicines
De-an Guo, Ph.D.
Shanghai Research Center

Nutraceuticals: Quality by Design (MSE & FDD)

Session Chair
Walter Chambliss, Ph.D.
University of Mississippi

Critical Quality Attributes for Dietary Supplements
Brad Williams (Invited)
U.S. Food and Drug Administration

Managing Quality of Botanical Dietary Supplements through Implementation of cGMP Concepts: Challenges and Opportunities
Ikhan Khan, Ph.D.
University of Mississippi

Experiences Implementing Quality Systems in a Botanical Supplement Manufacturing Operation in the U.S.
Loren Israelsen
United Natural Products Alliance

Lessons Learned from Implementing Quality Systems in China
De-An Guo, Ph.D.
Chinese Academy of Sciences

Drug-drug Interactions: Are they Predictable? (PPDM)

Session Chairs
R. Scott Obach, Ph.D.
Pfizer Inc.

Akihiro Hisaka, Ph.D.
University of Tokyo

Title to be Determined
Akihiro Hisada, Ph.D.
University of Tokyo

Title to be Determined
Karen Yeo, Ph.D.
SimCYP Ltd.

Title to be Determined
Kazuya Maeda, Ph.D.
University of Tokyo

Title to be Determined
Ping Zhao, Ph.D. (Invited)
U.S. Food and Drug Administration

Bioanalytical Procedures and Regulation: Towards Global Harmonization (APQ & RS)

Session Chairs
Mark E. Arnold, Ph.D.
Bristol-Myers Squibb

Brian P. Booth, Ph.D.
U.S. Food and Drug Administration

Howard M. Hill, Ph.D.
Huntingdon Life Sciences

Introduction
Brian P. Booth, Ph.D. *(Invited)*
U.S. Food and Drug Administration

Presentation Title to be Determined
Howard M. Hill, Ph.D.
Huntingdon Life Sciences

Regulated Bioanalysis in Support of Global Drug Registration Applications: An Industry Perspective
Eric J. Woolf, Ph.D.
Merck and Co., Inc.

An EU Regulatory Perspective on Bioanalytical Harmonization
Olivier LeBlaye, Pharm.D.
AFSSAPS (French Health Products Safety Agency)

Treating Blindness in the Developing World
(GH & FDD)

Session Chairs
Adrian Raiche, Ph.D.
SurModics Pharmaceuticals

Ruiwen Shi, Ph.D.
Allergan

Prevalence of Preventable and Treatable Blindness: A Global Health Perspective
Peter Ackland
International Agency for Prevention of Blindness

Case Study: Global Distribution of Avastin for Ocular Application
Malik Kahook, M.D.
University of Colorado Denver

Strategies for Ophthalmic Formulation Development
Michelle Marra, Ph.D.
Pfizer Global Research & Development

Developing Thermostable Vaccines: Progress, Challenges and Opportunities
Dexiang Chen, Ph.D.
PATH

Improved Pulmonary Delivery of Drugs and Biologics
(FDD & PPB)

Session Chairs
Amit Misra, Ph.D.
Central Drug Research Institute

Hirokazu Okamoto, Ph.D.
Meijo University

Peter York, Ph.D., D.Sc.
Institute of Pharmaceutical Innovation

Pulmonary Delivery of Microspheres that Activate Lung Macrophages Infected with Tuberculosis Bacteria
Amit Misra, Ph.D.
Central Drug Research Institute

Particle Engineering for Respiratory Drug Delivery
Peter York, Ph.D., D.Sc.
Institute of Pharmaceutical Innovation

Pulmonary Treatment of Tuberculosis: Isn't the Dose Too Large for Us?
Henderik W. Frijlink, Ph.D.
University of Groningen

Progress in Modeling Disease Progression
(PPDM & CPTR)

Session Chairs
Liping Zhang, Ph.D.
Bristol-Myers Squibb

Nick Holford, M.D., M.S.
University of Auckland

Peter Milligan, Ph.D.
Pfizer Inc.

Disease Systems Analysis: Utility of Collaborative Data Resources
Meindert Danhof, Ph.D.
Leiden University

Disease Modifying Treatments: Design and Analysis for Demonstrating Disease Modifying Effects
Nick Holford, M.D., M.S.
University of Auckland

Modeling of the Tumor Growth: Survival Link During Anti-cancer Treatment
Rene Bruno, Ph.D.
Certara

Linking Short-term Viral Kinetics to Long-term Progression and Outcome
Alan Perelson, Ph.D.
Los Alamos National Laboratory

MONDAY AFTERNOON ROUNDTABLES

Monday afternoon roundtables and mini-symposia are supported by a grant from

2:00 pm – 4:00 pm

Antibody Interference in Bioanalytical Methods
(BIOTEC & APQ)

Session Chairs
Joleen T. White, Ph.D.
Bristol-Myers Squibb

Michaela Golob, Ph.D.
MerckSerono

Introduction to Risk-based Approach to Evaluating Potential Interference
Michaela Golob, Ph.D.
MerckSerono

MONDAY AFTERNOON ROUNDTABLES

Monday afternoon roundtables and mini-symposia are supported by a grant from

Daiichi-Sankyo

2:00 pm – 4:00 pm *(continued from page 13)*

"Houston, We Have a Problem Here": How to Spot Interference from an Anti-drug Antibody on an Existing PK Immunoassay and What Might be Done to Mitigate the Problem
Jeffrey M. Sailstad
Sailstad and Associates Inc.

Reactive Impurities in Excipients: Characterization and Stabilization Strategies (FDD & PPB)

Session Chairs
Ajit S. Narang, Ph.D.
Bristol-Myers Squibb

Sherif Badawy, Ph.D.
Bristol-Myers Squibb

Case Studies of Drug Product Instability Attributed to Reactive Components of Pharmaceutical Excipients
Robert Reed, Ph.D.
Celsion Corporation

Controlling Reactive Components in Polymeric Pharmaceutical Excipients
Shaukat Ali, Ph.D.
BASF Corporation

Characterization and Control of Reactive Components in PVA-based Film Coatings
Thomas P. Farrell, Ph.D.
Colorcon

Non-clinical Dose Formulation: Time for Regulatory Guidance? (RS & APQ)

Session Chair
Peter D. Bryan, Ph.D.
Celgene Corporation

NCDFA: A Toxicologist Prospective
Speaker to be Determined

Investigation of Out-of-Specification Results for NCDFA
Rodrigo Laureano, M.S.
Celgene Corporation

NCDFA: A Regulatory Prospective
Peter D. Bryan, Ph.D.
Celgene Corporation

Solid State Forms of Drugs and Intellectual Property (RS, PPB & FDD)

Session Chairs
Keiji Yamamoto, Ph.D.
Chiba University

Abbie E. Gentry, Ph.D.
McNeil Consumer Healthcare

Crystal Design for the Optimal Performance of Solid Pharmaceuticals
Katsuhide Terada, Ph.D.
Toho University

Strategies for Patenting Novel Crystalline Forms of Drug Products
Jeffrey A. Lindeman, Ph.D.
O'Brien Jones PLLC

Patent Implications of Amorphorous States
Eyal H. Barash, J.D.
Aptuit Inc.

MONDAY AFTERNOON MINI-SYMPOSIA

Monday afternoon roundtables and mini-symposia are supported by a grant from

Daiichi-Sankyo

2:00 pm – 4:00 pm

AAPS/ACCP Joint Session: Genomics Issues and Solutions in Oncology, Drug Discovery and Development (CPTR & DDD)

Session Chairs
Daniel E. Salazar, Ph.D.
Daiichi Sankyo Pharma Development

Hyo-Jeong Kuh, Ph.D.
The Catholic University of Korea

Overview of Genomics and Other Biomarkers in Oncology Drug Discovery and Development
Gary Kelloff, M.D.
National Institute of Health Sciences

Oncogenomics as a Basis for Cancer Therapy Development
Axel Ulrich, Ph.D.
Max Planck Institute for Biochemistry

The Oncologists 6th Vital Sign: A Context of Vulnerability
Daniel D. Von Hoff, M.D.
Translational Genomics Research Institute

Transport Proteins I: Regulatory Mechanisms that Modulate Drug Disposition and Response (PPDM & PCOL)

Session Chairs
Guofeng You, Ph.D.
Rutgers University

Kathleen M. Giacomini, Ph.D.
University of California, San Francisco

The Diversity in Post-translational Modification of Drug Transporters: Known and Novel
Guofeng You, Ph.D.
Rutgers University

Gene Regulation of Drug Transporters: Implications to Drug Disposition
Ken-ichi Inui, Ph.D.
Kyoto University Hospital

SNPs in Noncoding Regions of Transporters: Role in Variation in Transporter Expression and Drug Response
Kathleen M. Giacomini, Ph.D.
University of California, San Francisco

AAPS RESEARCH ACHIEVEMENT AWARD LECTURES

4:00 pm – 5:00 pm

Analysis and Pharmaceutical Quality (APQ) Research Achievement Award Lecture

Biopharmaceutics (PPB) Research Achievement Award Lecture

AAPS JOINT MEMBERSHIP MEETINGS AND RECEPTIONS

5:00 pm – 7:30 pm

Analysis & Pharmaceutical Quality (APQ) Section

Biotechnology (BIOTEC) Section

Clinical Pharmacology & Translational Research (CPTR) Section

Drug Design & Discovery (DDD) Section

Formulation Design & Development (FDD) Section

Manufacturing Science & Engineering (MSE) Section

Physical Pharmacy & Biopharmaceutics (PPB) Section

Regulatory Sciences (RS) Section

Tuesday, November 16, 2010

6:00 am – 5:00 pm
Speaker Ready Room

7:00 am – 5:30 pm
Registration

7:00 am – 5:00 pm
Press Room

7:00 am – 5:00 pm
Student Lounge

7:00 am – 5:00 pm
International Lounge

TUESDAY MORNING SUNRISE SESSIONS

7:00 am - 8:15 am

High pH Mobile Phase (LC-MS/MS) to Optimize Analytical Sensitivity (APQ)

Session Chair
Fabio Garofolo, Ph.D.
Algorithme Pharma, Inc.

History and Fundamentals of the Use of High pH Mobile Phase in Bioanalysis: A Review of the Literature
Ray Briggs, Ph.D.
Icon Development Solutions

Application of High pH Mobile Phase in LC-ESI(+)-MS/MS Under Reverse Phase and Hydrophilic Interaction Chromatography Mode to Obtain Optimal Sensitivity for Bioanalysis
Fabio Garofolo, Ph.D.
Algorithme Pharma, Inc.

Nose to Brain Delivery: Reality or Just Blowing Smoke? (FDD & PPDM)

Session Chairs
Dennis O'Connor, Ph.D.
Boehringer-Ingelheim

Lisbeth Illum, M.Pharm, Ph.D., D.Sc.
Critical Pharmaceuticals Limited

Nose to Brain Drug Delivery
Lisbeth Illum, M.Pharm, Ph.D., D.Sc.
Critical Pharmaceuticals Limited

Intranasal Delivery of Drugs to the Brain
Shyeilla Dhuria, Ph.D.
Novartis Pharmaceuticals Corporation

TUESDAY MORNING SUNRISE SESSIONS
7:00 am – 8:15 am *(continued from page 15)*

Device Characteristics for Nose to Brain Drug Delivery
Per Djupesland, M.D., Ph.D.
OptiNose

Placental ABC Transporters: Impact on Drug/Xenobiotic Disposition and Toxicity (PPDM & CPTR)

Session Chairs
Qingcheng Mao, Ph.D.
University of Washington

Takuya Fujita, Ph.D.
Ritsumeikan University, Faculty of Pharmaceutical Sciences

Role of Placental P-Glycoprotein and BCRP in Fetal Drug Exposure
Qingcheng Mao, Ph.D.
University of Washington

Transport Activity and Impact of Human Placental Multidrug Resistance-associated Proteins (MRPs)
Phillip M. Gerk, Ph.D., Pharm.D.
Virginia Commonwealth University

PEGylated Proteins: Analytical and Pharmacokinetic Issues (BIOTEC & PPDM)

Session Chairs
Murli Krishna, Ph.D.
Bristol-Myers Squibb

Yoshinobu Takakura, Ph.D.
Kyoto University

The Current Status and Challenges of PEGylated Proteins
Francesco M. Veronese, Ph.D.
University of Padua

Experimental Challenges in the Bioanalysis of PEGylated Peptides
Mark J. Rose, Ph.D.
Amgen Inc.

Development of Novel Strategies for PEGylated Proteins
Yasuo Tsutsumi, Ph.D.
Osaka University

The Art and Science of Model Evaluation (PPDM & CPTR)

Session Chairs
Liping Zhang, Ph.D.
Bristol-Myers Squibb

Saeho Chong, Ph.D.
Seoul National University

Basic Concepts for Population Pharmacometric Model Building and Diagnostics
Liping Zhang, Ph.D.
Bristol-Myers Squibb

Methods and Techniques for Population Pharmacometric Model Building and Diagnostics
Andrew Hooker, Ph.D.
Uppsala University

CONTRIBUTED PAPERS POSTER SESSION
8:00 am – 12:00 pm

TUESDAY MORNING PROFESSIONAL DEVELOPMENT SESSIONS
8:00 am – 10:00 am
Work/Life Balance
Brianna Blaser, Ph.D.
AAAS/*Science* Careers

9:00 am – 11:00 am
Facilitation Skills
Megan Driscoll
PharmaLogics

10:00 am – 12:00 pm
Social Media and Career Development for Life Sciences
Clifford Mintz, Ph.D.
BioCrowd.com

TUESDAY MORNING SYMPOSIA
8:30 am - 11:00 am

ASCPT/AAPS Joint Symposium: Phase 0 Pharmacodynamics Trials in Oncology – A Paradigm Shift in Drug Development? (CPTR & PPDM)

Session Chairs
David Y. Mitchell, Ph.D.
Mitchell Pharmaceutical Consulting

Alex Sparreboom, Ph.D.
St. Jude Children's Research Hospital

Speakers and Presentation Titles to be Determined

Neutralizing Antibodies: Alternatives to Cell-based Assays (BIOTEC & APQ)

Session Chairs
George R. Gunn, Ph.D.
Centocor Research & Development

Deborah Finco, M.S.
Pfizer Inc.

Case Studies: Comparative Analysis of Cell-based and Competitive Ligand Binding Assays for the Characterization
Bonnie Wu, Ph.D.
Centocor Research & Development

Nonclinical Case Study Using Competitive Ligand Binding and Cell-based Assay Formats for Assessing Neutralizing Antibodies
Daniel J. Baltrukonis, M.A.
Pfizer Inc.

Anti-ranibizumab Neutralizing Antibody Assays: A Ligand-Binding Immunoassay with Improved Sensitivity Relative to a Cell-based Assay
Mauricio Maia, Ph.D.
Genentech/Roche

Intelligent Pharmaceutical Product Design and Processing using Data Mining Methods (MSE & FDD)

Session Chairs
Peter York, Ph.D., D.Sc.
Institute of Pharmaceutical Innovation

Elizabeth Colbourne, Ph.D.
Intelligensys Ltd.

Intelligent Design and Manufacturing of Solid Dosage Forms in the 21st Century
Murat Turkoglu, Ph.D.
Marmara University

Neural and Evolutionary Computing in Pharmaceutical Formulation
Elizabeth Colbourne, Ph.D.
Intelligensys Ltd.

A Novel Statistical Approach in Pharmaceutical Formulation Development
Kozo Takayama, Ph.D.
Hoshi University

Applications of Neural Network Data Mining to Drug Delivery Systems
Svetlana Ibric, Ph.D.
Belgrade University

The Gut Wall as a Metabolic Barrier to Drug Development (PPDM & PPB)

Session Chairs
Manthena V. Varma, Ph.D., M.S.
Pfizer Inc.

J. Brian Houston, Ph.D., D.Sc.
University of Manchester

Interplay Between Dissolution, Passive Permeability, Affinity to Efflux Transporters and Gut Wall Metabolism on the Fraction Absorbed and Metabolized During Gut First-pass: How Quantitative Can We Get Beyond BCS Classification and to what Effect?
Amin Rostami-Hodjegan, Ph.D., Pharm.D.
University of Sheffield

Consideration to Physicochemical and Biochemical Aspects in Evaluating the Role of Gut-wall Metabolism to Oral Bioavailability
Manthena V. Varma, Ph.D., M.S.
Pfizer Inc.

In Vitro-In Vivo Extrapolation of High Intestinal First-pass Extraction: How Good are our Predictions?
Aleksandra Galetin, Ph.D.
University of Manchester

Influence of Dietary Substances on the Intestinal First-pass Extraction of Drugs
Mary F. Paine, Ph.D., R.Ph.
University of North Carolina

Translation of Pharmaceutical Science to Practice (CPTR & E&C)

Session Chairs
Toshiyuki Sakaede, Ph.D.
Kyoto University

Cynthia Reilly
American Society of Health-System Pharmacists

Metabolic Analysis of Serum Specimens from Patients Suffering from Drug-induced Liver Injury: Towards Translational Research
Hiroshi Suzuki, Ph.D.
University of Tokyo

Title to Be Determined
Shiew-Mei Huang, Ph.D. (Invited)
U.S. Food and Drug Administration

Biological Effects of Blood Glucose Level Control
Tatsurou Yagami, Ph.D.
Himeji Dokkyo University

TUESDAY MORNING SYMPOSIA

8:30 am – 11:00 am *(continued from page 17)*

Blockbuster Trials Evaluating Tight Glycemic Control In Critically Ill Patients: Confirming Impact and Implementing Change
Judith Jacobi, Pharm.D., FCCM
Clarian Health

Affinity-based Media: Analytical Aspects and Applications (APQ)

Session Chairs
Jun Haginaka, Ph.D.
Mukogawa Women's University

Irving W. Wainer, Ph.D.
National Institutes of Health

Cellular Membrane Chromatography: Working at the Intersections of Pharmacology and Chromatographic Science
Irving W. Wainer, Ph.D.
National Institutes of Health

Enzyme-based Columns for Chiral Separation and Reactions
Gabriella Massolini, Ph.D.
University of Pavia

Highly Selective Enrichment of Phosphopeptides by Hydroxy Acid-modified Metal Oxide Chromatography for Phosphoproteome Analysis
Yasushi Ishihama, Ph.D.
Keio University

Monodispersed Molecularly Imprinted Polymers for Pharmaceutical and Biomedical Analysis
Jun Haginaka, Ph.D.
Mukogawa Women's University

The Revival of Synthetic Peptides and Small Proteins in Biopharmaceuticals (BIOTEC & DDD)

Session Chair
Tudor Arvinte, Ph.D.
University of Geneva

Title to Be Determined
Gregoire Schwach, Ph.D.
Ferring Pharmaceuticals A/S

Title to Be Determined
Sachin Mittal, Ph.D.
Merck Research Laboratories

Title to Be Determined
Gunther Loidl, Ph.D.
Bachem AG

Title to Be Determined
Tudor Arvinte, Ph.D.
University of Geneva

TUESDAY MORNING ROUNDTABLES

9:00 am - 11:00 am

A Close Look at Subvisible Particles in Protein Therapeutics (BIOTEC & APQ)

Session Chairs
Wim Jiskoot, Ph.D.
Leiden University

John F. Carpenter, Ph.D.
University of Colorado

Applications of Subvisible Particle Analysis in the Development of Protein Therapeutics
Mariana Dimitrova, Ph.D.
MedImmune

Understanding of Subvisible Particles in Protein Therapeutic Products
Jun Liu, Ph.D.
Genentech, Inc.

Visualizing Subvisible Particles in an Academic Setting
Wim Jiskoot, Ph.D.
Leiden University

How Predictive are Animal Models of Clinical Efficacy? (CPTR & PPDM)

Session Chairs
Arnab Mukherjee, Ph.D.
Pfizer Inc.

Jing Liu, Ph.D.
Pfizer Inc.

How to Get it Right More Often: An Industry Perspective
Don Nichols, Ph.D.
Pfizer Global Research & Development

Mechanism Based PK/PD for Translation
Meindert Danhof, Ph.D.
Leiden University

Integrative Biology Approaches for Target Selection
Debra N. Klatte, Ph.D.
Boehringer-Ingelheim

Integrating Dissolution Testing with Permeability to Predict Product Performance (PPB & FDD)

Session Chairs
Lillian Zhang, Ph.D.
U.S. Food and Drug Administration

James E. Polli, Ph.D.
University of Maryland

Per Artursson, Ph.D.
University of Uppsala

Using Dissolution and Permeability Modeling to Predict Formulation Performance
Bertil Abrahamsson, Ph.D.
AstraZeneca

Dissolution Specifications: Consideration of Dissolution and Permeation Kinetics in Overall Absorption Kinetics
James E. Polli, Ph.D.
University of Maryland

Simultaneous Assessment of Dissolution and Permeation of Oral Drug
Shinji Yamashita, Ph.D.
Setsunan University

TUESDAY MORNING MINI-SYMPOSIA
9:00 am – 11:00 am

Metabolomics in Pharmaceutical Development (PPDM & CPTR)

Session Chair
Rima Kaddurah, Ph.D.
Duke University

Speakers and Presentation Titles to be Determined

Risk Management Planning: An Essential Component of Pharmacovigilance (RS & SS)

Session Chairs
Carlos Langezaal, Ph.D.
TOPRA

Yusuke Tanigawara, Ph.D.
Keio University

Summary of the Work and Outcome of the ICH E2e Working Group and the Impact on Pharmacovigilance Activities
Yusuke Tanigawara, Ph.D.
Keio University, School of Medicine

FDA Experience with Recently Issued Industry Guidance Documentation on Risks Evaluation and Minimization Systems
Gerald Dalpan, M.D. (Invited)
U.S. Food and Drug Administration

Pharmacovigilance and Risk Management Planning with Principles and Practicalities from a Global Industry Perspective
Nayan Acharya, MBBS, MRCP
Eli Lilly and Co.

Ocular Drug Delivery (PPB & PPDM)

Session Chairs
Arto O. Urtti, Ph.D.
University of Helsinki

Hideyoshi Harashima, Ph.D.
Hokkaido University

Anterior Segment Drug Delivery Systems: Challenges and Solutions
Hitoshi Sasaki, Ph.D.
Nagasaki University

Drug Delivery to Posterior Segments: Barriers, Delivery Systems and Models
Arto O. Urtti, Ph.D.
University of Helsinki

Encapsulated Cell Technology for the Retinal Drug Delivery
Weng Tao, M.D., Ph.D.
Neurotech

EXPOSITION & CAREER CENTER
9:30 am – 6:15 pm
Exposition

AAPS Career Center
Funded by a Grant from AstraZeneca life inspiring ideas

HOT TOPICS
12:00 pm – 1:15 pm

Topic #3 to be Determined

Topic #4 to be Determined

AAPS FOCUS GROUP MEMBERSHIP MEETINGS
12:00 pm – 1:00 pm

CONTRIBUTED PAPERS POSTER SESSION
1:00 pm – 5:00 pm

TUESDAY AFTERNOON PROFESSIONAL DEVELOPMENT SESSIONS
1:00 pm – 3:00 pm
Networking Strategies
Brianna Blaser, Ph.D.
AAAS/*Science* Careers

TUESDAY AFTERNOON PROFESSIONAL DEVELOPMENT SESSIONS

(continued from page 19)

2:00 pm – 4:00 pm

Transitioning Between Academia and Industry
Megan Driscoll
PharmaLogics

TUESDAY AFTERNOON SYMPOSIA

1:30 pm - 4:00 pm

Biosimilars and Follow-on Biologics: A Global Perspective (BIOTEC & RS)

Session Chairs
Robert G. Bell, Ph.D.
Drug & Biotechnology Development, LLC

Teruhide Yamaguchi, Ph.D.
National Institute of Health Sciences

The U.S. FDA Perspective
Keith Webber, Ph.D. (Invited)
U.S. Food and Drug Administration

The EMEA Perspective
Marie-Christine Bielsky, M.D.
MHRA

The Japanese Perspective
Teruyo Arato, Ph.D.
Pharmaceutical and Medical Devices Agency

The Asian Experience
Junzhi Wang, Ph.D.
State Food and Drug Administration

Pharmaceuticals Without Borders II: The Regulatory and Supply Chain Challenges of Providing Medicines to Emerging Markets (GH)

Session Chairs
Kenneth Norris, Ph.D.
Pfizer Inc.

John F. Carpenter, Ph.D.
University of Colorado

Overcoming the Challenges of Regulatory Filing and Supplying Pharmaceuticals to Emerging Markets
Speaker to be Determined
World Health Organization

CPPs (Certificate of Pharmaceutical Products) and Associated Challenges for International Registration Submissions
Julie Dennis, Ph.D.
Pfizer Global Research & Development

How Can QbD Submissions be used in Emerging Markets
Adran Sabir, Ph.D.
Dr. Reddy's Laboratories Ltd

Penetrating the Brain (PPDM)

Session Chairs
Margareta Hammarlund-Udenaes, Ph.D.
University of Uppsala

Jean-Michel Scherrmann, Ph.D.
University of Paris Descartes

Drug Discovery Aspects of Brain Penetration: How to Optimize New Drugs
Margareta Hammarlund-Udenaes, Ph.D.
University of Uppsala

Transporter Expression and Anticancer Drug Distribution to Brain Tumors
Quentin Smith, Ph.D.
Texas Tech University Health Sciences Center

Molecular Mechanisms of Transport Systems at the Blood-brain Barrier as a Pathway and Target of Drugs
Sumio Ohtsuki, Ph.D.
Tohoku University

Balance Between Transport and Enzyme Activity in the Blood-brain Barrier Influences Drug Penetration in the Brain
Jean-Michel Scherrmann, Ph.D.
University of Paris Descartes

Single Cell Analyses for Accelerating Drug Discovery and Diagnosis (DDD & APQ)

Session Chair
Tsutomu Masujima, Ph.D.
Hiroshima University

Chemical Cytometry: The Chemical Analysis of Single Cells
Norman Dovichi, Ph.D.
University of Washington

Single Cell Analysis for High-throughput Screening
Renato Zenobi, Ph.D.
ETH Zurich

Introduction of Metal Nanoparticles and Metal Nanorods into Cells for Drug Delivery and Disease Diagnosis
Edward S. Yeung, Ph.D.
Iowa State University

Live Single-cell Mass Spectrometry for Drug Discovery and Diagnosis
Tsutomu Masujima, Ph.D.
Hiroshima University

Novel Drug Delivery Systems: Definition of New Excipients (FDD & PPB)

Session Chairs
Otilia M. Koo, Ph.D.
Bristol-Myers Squibb

Paul Wan Sia Heng, Ph.D.
National University of Singapore

Advances and Examples of New Excipients in Novel Drug Delivery Systems
Otilia M. Koo, Ph.D.
Bristol-Myers Squibb

Characterization Requirements of New Excipients
Thorsten Schmeller, Ph.D.
BASF Corporation

Updates on New Excipients Evaluation Procedure by IPEC
Richard C. Moreton, Ph.D.
Finnbrit Consulting

Regulatory Approval Process for Drug Products Containing New Excipients: Case Studies
Wendy Dulin, Ph.D.
Pfizer Inc.

Standards for Essential Drugs (APQ)

Session Chairs
Anthony J. DeStefano, Ph.D.
United States Pharmacopeia

Raimar Loebenberg, Ph.D.
University of Alberta

The Value of In Vitro Dissolution Testing
Raimar Loebenberg, Ph.D.
University of Alberta

Biowaivers Based on the Biopharmaceutics Drug Classification System
Jennifer Dressman, Ph.D.
Johann Wolfgang Goethe University

Comparison of the Pharmaceutical Quality of Essential Drugs on the South American Market
Nadia A. Chacra, Ph.D.
University of Sao Paulo

The Role of the USP in Providing Needed Standards
Roger L. Williams, M.D.
United States Pharmacopeia

Bridging the Gap between Traditional Medicine and the Western Approach to Natural Products
(DDD, GH & APQ)

Session Chairs
Mary A. Murray, Ph.D.
Nutrilite Health Institute

Xiaoliang Wang, Ph.D.
Institute of Materia Medica, CAMS

Speakers and Presentations to be Determined

TUESDAY AFTERNOON ROUNDTABLES
2:00 pm - 4:00 pm

Technology Transfer and Process Validation in the Context of QbD (RS & MSE)

Session Chairs
Prabu Nambiar, Ph.D., RAC
Vertex, Inc

Thirunellai G. Venkateshwaran, Ph.D.
Wyeth Research

FDA's New Guidance on Process Validation and FDA's Perspectives on Process Validation Under cGMP Initiative for 21st Century
Rick Friedman, Ph.D. (Invited)
U.S. Food and Drug Administration

Process Validation Under QbD Paradigm: EMEA Perspectives
Evdokia Korakianiti, Ph.D.
European Medicines Agency

Continuous Quality Verification: Alignment of ASTM E-55 Standards with the FDA Process Validation Guidance
Gretchen A. Allison
Pfizer Inc.

Is the Cocktail Approach Useful in the Assessment of Drug-drug Interactions? (PPDM)

Session Chairs
Lillian Zhang, Ph.D.
U.S. Food and Drug Administration

Hiroyuki Kusuhara, Ph.D.
University of Tokyo

Things to Consider in "Cocktail" Approaches
Uwe Fuhr, Ph.D.
University Hospital of Cologne

TUESDAY AFTERNOON ROUNDTABLES

2:00 pm - 4:00 pm *(continued from page 21)*

Application in Drug Development: An Industry Perspective
Honghui Zhou, Ph.D.
Johnson and Johnson

A Regulatory Perspective on Utilization of Cocktail Approach In Clinical Investigation
FDA Speaker to be Determined

TUESDAY AFTERNOON MINI-SYMPOSIA

2:00 pm – 4:00 pm

Current Status of Oligonucleotide Chemistry and Application (DDD & MCNP)

Session Chairs
Christian Hoe, Ph.D.
University of Sydney

Shigeki Sasaki, Ph.D.
Kyushu University

A New Tool for Site-specific Modification of RNA
Shigeki Sasaki, Ph.D.
Kyushu University

Activating Gene Expression with Small RNAs
David Corey, Ph.D.
University of Texas

Oligonucleotide-based Strategies to Inhibit the Heart-pathogenic Coxsackievirus B3
Jens Kurreck, Ph.D.
University of Stuttgart

Pharmacogenetics: Educating the Doctor, the Pharmacist and the Patient
(CPTR, E&C & PPDM)

Session Chairs
Okezie I. Aruoma, Ph.D., D.Sc.
Touro College of Pharmacy

Ross A. McKinnon, Ph.D.
University of South Australia

Hiroshi Suzuki, Ph.D.
University of Tokyo

Drug Interactions, Pharmacogenetics and Pharmacogenomics: Teaching the Pharmacist and the Patient
Okezie I. Aruoma, Ph.D., D.Sc.
Touro College of Pharmacy

Role of Pharmacist in Education of Pharmacogenetics and Pharmacogenomics in Japan
Hiroshi Suzuki, Ph.D.
University of Tokyo

Reforming Pharmaceutical Education to Accelerate the Uptake of Personalized Medicine
Ross A. McKinnon, Ph.D.
University of South Australia

Quality Assurance of Medicines: The Detection of Counterfeits and Adulterants (RS, APQ & SS)

Session Chair
Stephen T. Colgan, Ph.D.
Pfizer Global Research & Development

Counterfeiting from the European Perspective
Aline Franco, Ph.D.
Interpol

Counterfeiting from the AEI Perspective
Roger Bates, Ph.D.
American Enterprises Institution

Strengthening Developing Countries to Detect Counterfeit and Sub-standard Medicines
Patrick Lukulay, Ph.D.
United States Pharmacopeia

AAPS RESEARCH ACHIEVEMENT AWARD LECTURES

4:00 pm – 5:00 pm

Drug Design & Discovery (DDD) Research Achievement Award Lecture
Funded by a grant from

Formulation Design & Development (FDD) Research Achievement Award Lecture
Funded by a grant from

EXPOSITION COCKTAIL RECEPTION

Funded by Grants from Exhibitors and

4:45 pm – 6:15 pm

AAPS SECTION MEMBERSHIP MEETINGS AND RECEPTIONS

5:30 pm – 7:15 pm

Pharmacokinetics, Pharmacodynamics & Drug Metabolism (PPDM) Section

OPEN FORUMS

7:00 pm – 9:30 pm

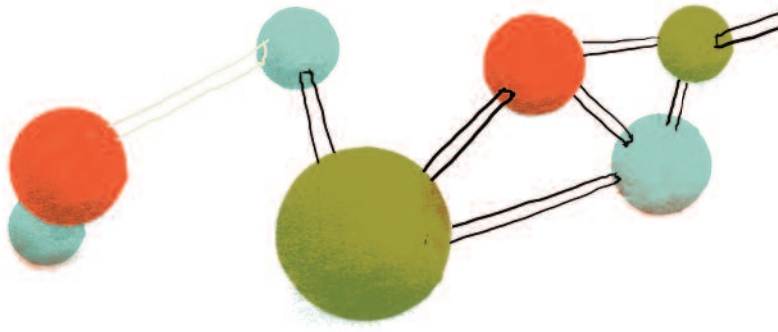
An additional fee is required to attend open forums.

Clinical Pharmacology and Translational Research (CPTR) Open Forum

Open Source Development of Mechanistic/ Systems Biology Models in Clinical Pharmacology and Translational Research: Do the Challenges Outweigh the Potential Benefits?

Regulatory Sciences (RS) Open Forum

Practical Considerations for the 505 (B) (2) Regulatory Pathway and Patent Protection for Fixed Dose Combination Products and Other Products



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Wednesday, November 17, 2010

6:00 am – 5:00 pm
Speaker Ready Room

7:00 am – 5:30 pm
Registration

7:00 am – 5:00 pm
Press Room

7:00 am – 5:00 pm
Student Lounge

7:00 am – 5:00 pm
International Lounge

WEDNESDAY MORNING SUNRISE SESSIONS

7:00 am - 8:15 am

Pediatric Drug Development: A Learning Curve for Grown-up Scientists and Regulators (PPDM & FDD)

Session Chairs
Tycho H. Heimbach, Ph.D.
Novartis Pharmaceuticals

Jeffrey Barrett, Ph.D.
Children's Hospital of Philadelphia - University of Pennsylvania

Children are Not Small Adults: Challenges in Pediatric Dose Projection: PK/PD and Clinical Trial Design
Jeffrey Barrett, Ph.D.
Children's Hospital of Philadelphia - University of Pennsylvania

Enzyme Directed Prodrug Activation (DDD & MCNP)

Session Chairs
Majid Moridani, Pharm.D., Ph.D.
Texas Tech University Health Sciences Center

Lawrence L. Fleckenstein, Ph.D.
University of Iowa

The Role of P450 Genetic Variations in Prodrug Design
Majid Moridani, Pharm.D., Ph.D.
Texas Tech University Health Sciences Center

Carboxylesterases: Targets for Drug and Prodrug Efficacy and Pharmacokinetics
Teruko Imai, Ph.D.
Kumamoto University

Improving Oral Absorption of Compounds Using High Energy Forms: Evaluation of Physical Stability (PPB & FDD)

Session Chairs
David T. Vodak, Ph.D.
Bend Research, Inc.

Katsuhide Terada, Ph.D.
Toho University

Physical Stability of Amorphous Formulations: Is it Predictable?
Kohsaku Kawakami, Ph.D.
National Institute for Materials Science, Biomaterials Center

Experimental and Theoretical Methods for Reliable Formulation of Kinetically Stable Solid Amorphous Dispersions
Dwayne T. Friesen, Ph.D.
Bend Research, Inc.

Analytical Techniques
Martyn Davies, Ph.D.
University of Nottingham

Inflammation and Stress Signaling (PCOL & PPDM)

Session Chair
Hiroyuki Arai, Ph.D.
University of Tokyo

Makoto Arita, Ph.D.
University of Tokyo

Speakers and Presentation Titles to be Determined

Nanoparticulate Drug Delivery Systems: Fundamentals (FDD & PPB)

Session Chairs
Himanshu Bhattacharjee, Ph.D.
University of Tennessee

Beom-Jin Lee, Ph.D.
Kangwon National University

Rogerio Gaspar, Ph.D.
University of Lisboa

Nanoparticles and Drug Delivery: Basics
Deepak Thassu, Ph.D., M.B.A.
Pharmanova

Presentation Title to be Determined
Beom-Jin Lee, Ph.D.
Kangwon National University

CONTRIBUTED PAPERS POSTER SESSION
8:00 am – 12:00 pm

WEDNESDAY MORNING PROFESSIONAL DEVELOPMENT SESSIONS
8:00 am – 9:30 am
Fellows Application Process
Satyam M. Upadrashta, Ph.D., RAC
Aradigm Corp.

9:00 am – 11:00 am
Transitioning Between Small and Large Pharma
Megan Driscoll
PharmaLogics

WEDNESDAY MORNING SYMPOSIA
8:30 am - 11:00 am
Wednesday Morning Symposia are supported by a grant from

AstraZeneca
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Implementation of Dried Blood Spot (DBS) Sampling in Regulated Bioanalysis (APQ & PPDM)

Session Chairs
Fabio Garofolo, Ph.D.
Algorithme Pharma, Inc.

Stephen Lowes, Ph.D.
Advion BioServices, Inc.

Introduction to DBS Technique and Comparison Between DBS and Plasma in Incurred Samples
Fabio Garofolo, Ph.D.
Algorithme Pharma, Inc.

Recent Advances and Future Directions in the Use of DBS Samples for the Quantitative Bioanalysis of Drugs
Neil Spooner, Ph.D.
GlaxoSmithKline

Clinical Pharmacokinetic Aspects of DBS: Pros & Cons
Gary T. Emmons, Ph.D.
Sanofi-Aventis

Advantages and Disadvantages of Using DBS Samples in Regulated Bioanalysis: EBF Perspective
Philip Timmerman, M.S.
Johnson and Johnson Pharmaceutical Research & Development

Rational Drug Design and Discovery via Computational Modeling (DDD)

Session Chairs
Chang-Guo Zhan, Ph.D.
University of Kentucky

Akiko Itai, Ph.D.
Institute of Medicinal of Molecular Design, Inc.

Speakers and Presentation Titles to be Determined

Immune Response to Biotechnology Products (BIOTEC & PCOL)

Session Chairs
Eva H. Moller, Ph.D.
University of Copenhagen

Tatsuro Irimura, Ph.D.
University of Tokyo

Dendritic Cells in the Immune Response
Tatsuro Irimura, Ph.D.
University of Tokyo

Immunogenicity of Genetically Modified Foods
Reiko Teshima, Ph.D.
National Institute of Health and Sciences

Predicting Immunogenicity: Assessing the Unwanted Response to Biomolecules
Erwin L. Roggen, Ph.D.
Novozymes

Formulation-related Causes of Immunogenicity
Wim Jiskoot, Ph.D.
Leiden University

Transporter Proteins II: How to Scale In Vitro Data on Human Transporters to Predict In Vivo Outcome (PPDM)

Session Chairs
Sibylle Neuhoff, Ph.D.
Simcyp

Hiroyuki Kusuhara, Ph.D.
University of Tokyo

Involvement and Interaction of Transporters in Intestinal and Pulmonary Absorption of Drugs
Ikumi Tamai, Ph.D.
Kanazawa University

Hepatic Organic Anion Transporters: Role in Drug Disposition and Pharmacogenetics of Acquired Liver Injury
Bruno Stieger, Ph.D.
University of Zurich

Blood-brain Barrier Pharmacoproteomics: Quantitative Transporter Protein Analysis for In Vitro-In Vivo, Interspecies and Diseased State Differences
Tetsuya Terasaki, Ph.D.
Tohoku University

The Role of Transporters During Drug Development: The Perspective from the FDA
Shiew-Mei Huang, Ph.D. (Invited)
U.S. Food and Drug Administration

Imaging Technology for Understanding Process in Pharmaceutical Manufacturing (PPB & MSE)

Session Chair
Etsuo Yonemochi, Ph.D.
Toho University

Insight into Dissolution Processes using Real Time UV Imaging Together with Solid State Analysis with Raman Spectroscopy
Jukka Rantanen, Ph.D.
University of Copenhagen

A Novel Rapid Quantitative Analysis of Drug Migration on Tablets Using Laser Induced Breakdown Spectroscopy
Andre Blain, Ph.D.
Pharma Laser

Terahertz Imaging of Film Coatings: From Research and Development to Real Time Process Control
J Axel Zeitler, Ph.D.
University of Cambridge

Annular Bed Flow Patterns in a Bottom Spray Coating Process and their Influence on Pellet Coat Uniformity
Paul Wan Sia Heng, Ph.D.
National University of Singapore

New Molecular Targets-based Anti-cancer Drugs: From Small Molecules to Antibodies (DDD & BIOTEC)

Session Chairs
Takao Yamori, Ph.D.
Japanese Foundation for Cancer Research

Robert H. Shoemaker, Ph.D.
DPT

Identification of a Novel Pi3k Inhibitor for Cancer Treatment
Takao Yamori, Ph.D.
Japanese Foundation for Cancer Research

Monoclonal Antibody Against Cell Membrane Carbohydrate Antigen as a Possible Cancer Treatment
Tong H. Chang, Ph.D.
GlycoNex Inc.

A New Metastasis Associated Gene, MACC1: From Bench to Bedside
Ulrike Stein, Ph.D.
Max Delbrück Center for Molecular Medicine

Therapeutic Targeting of Alveolar Soft Part Sarcoma
Robert H. Shoemaker, Ph.D.
DPT

Delivery of Poorly Soluble Drugs: Evolving Science and Technology (PPB & FDD)

Session Chairs
Ping Gao, Ph.D.
Abbott Laboratories

Juan M. Irache, Ph.D.
University of Navarra

Lipid Nanocapsules: A Tool for Improving Oral Drug Absorption?
Jean Pierre Benoit, Ph.D.
University of Angers

Overview of Fundamental Aspects of Supersaturation-based Drug Delivery and Drug Product Development
Ping Gao, Ph.D.
Abbott Laboratories

Factors Contributing to the Development of Successful Amorphous Dispersions: Supersaturation and Formulation Stability
Markus Brewster, Ph.D.
Johnson & Johnson

Delivery of Poorly Soluble Drugs: Evaluation of In Vitro and In Vivo Performance
Lawrence Yu, Ph.D. (Invited)
U.S. Food and Drug Administration

Pharmacogenetics: Found in Translation? (CPTR & PPDM)

Session Chairs
Anke-Hilse Maitland-van der Zee, Pharm.D.
Utrecht University

Donna Arnett, Ph.D.
University of Alabama at Birmingham

Stephen Kimmel, M.D., Ph.D.
University of Pennsylvania

Introduction in Pharmacogenetics
Anke-Hilse Maitland-van der Zee, Pharm.D.
Utrecht University

WEDNESDAY MORNING SYMPOSIA

Wednesday Morning Symposia are supported by a grant from

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8:30 am – 11:00 am *(continued from page 27)*

Pharmacogenetics of Adverse Drug Reactions
Ann Daly, Ph.D.
Newcastle University

Pharmacogenetics of Antidepressants
Julia Kirchheiner, Ph.D.
Ulm University

How do we Bring Pharmacogenetics into Practice?
Stephen Kimmel, M.D., Ph.D.
University of Pennsylvania

WEDNESDAY MORNING ROUNDTABLES

9:00 am - 11:00 am

Development and Evaluation of Academic Curriculum and Clinical Clerkship for Modern Pharmaceutical Education (E&C)

Session Chairs
Tetsumi Irie, Ph.D.
Kumamoto University

Henri Manasse, Ph.D.
American Society of Health-system Pharmacists

Issues and Challenges in Contemporary Pharmacy Education in Practice & Science
Jerry L. Baumann, Pharm.D.
University of Illinois at Chicago

Curriculum Development: Content and Policies
Koichiro Ozawa, Ph.D.
Hiroshima University

Experiential Education in Clinical Practice
Steven L. Sheaffer, Pharm.D.
University of the Sciences in Philadelphia

Dissolution Testing: Relevance in a Quality by Design Approach to Drug Release (APQ & FDD)

Session Chairs
Saji K. Thomas, Ph.D.
Par Pharmaceutical

Horst-Dieter Friedel, Ph.D.
Bayer Schering Pharma

Vivian A. Gray
V. A. Gray Consulting, Inc.

Dissolution and QbD: An EMEA Perspective
Speaker to be Determined

Dissolution and Its Relevance in Life Cycle of a Product: An FDA Perspective
Patrick Marroum, Ph.D. (Invited)
U.S. Food and Drug Administration

Dissolution and QbD an Industry Perspective
Andreas Abend, Ph.D.
Merck & Co., Inc.

WEDNESDAY MORNING MINI-SYMPOSIA

9:00 am – 11:00 am

Nanotechnology: Clinical Aspects (CPTR & FDD)

Session Chair
Yasuhiro Matsumura, M.D., Ph.D.
National Cancer Center Hospital East

Speakers and Presentation Titles to be Determined

Nuclear Receptors: Important New Players in Pharmacology (PCOL & DDD)

Session Chairs
Heyo K. Kroemer, Ph.D.
Ernst Moritz Arndt University

Erin Schuetz, Ph.D.
St. Jude Children's Research Hospital

Nuclear Receptors and Transport Proteins: From Physiology to Therapeutic Relevance
Henriette M. Schwabedissen, M.D.
Ernst Moritz Arndt University

Car at the Crossroads of Xenobiotic Metabolism, Diabetes and Fatty Liver Disease
David D. Moore, Ph.D.
Baylor College of Medicine

HNF4: Its Ligand and Drug Prospects
Frances M. Sladek, Ph.D.
University of California, Riverside

The Globalization of Pharmaceutical Regulation (RS)

Session Chair
Carlos Langezaal, Ph.D.
TOPRA

Setting Up the Office of International Programs Within the Japanese PMDA and the PMDA Mechanisms for Sharing Information Between Health Authorities
Toshiyoshi Tominaga, Ph.D.
Pharmaceuticals and Medical Devices Agency

FDA Mechanisms for Sharing Information Between Regulators
Janice Soreth, Ph.D. (Invited)
U.S. Food and Drug Administration

EMEA Mechanisms for Sharing Information Between Health Authorities
Hilde Boone
European Medicines Agency

Cutting Edge in Vaccine Delivery (BIOTEC)

Session Chairs
Shinsaku Nakagawa, Ph.D.
Osaka University

Kazuo Maruyama, Ph.D.
Teikyo University

DDS Technology for Dc-based Cancer Immunotherapy
Shinsaku Nakagawa, Ph.D.
Osaka University

Cancer Immunotherapy Utilized Ultrasound Sensitive Liposomes (Bubble Liposomes)
Ryo Suzuki, Ph.D.
Teikyo University

Transcutaneous and Intradermal Vaccination by Means of Microneedles and Nanoparticles
Joke Bouwstra, Ph.D.
Leiden University

Transcutaneous Vaccination System Using a Hydrogel Patch Formulation
Naoki Okada, Ph.D.
Osaka University

EXPOSITION & CAREER CENTER
9:30 am – 4:30 pm
Exposition

AAPS Career Center
Funded by a grant from AstraZeneca
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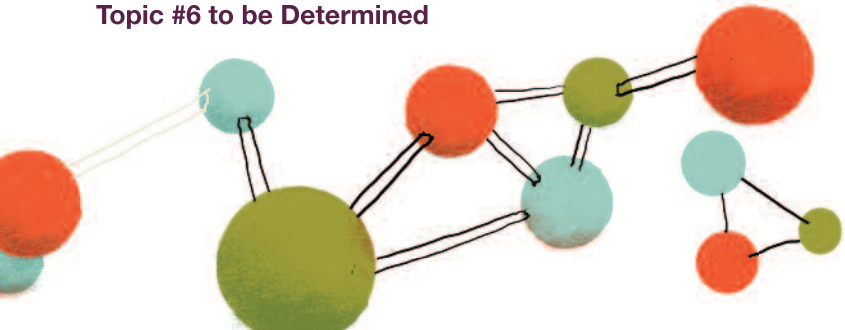
HOT TOPICS
12:00 pm – 1:15 pm

Topic #5 to be Determined

Topic #6 to be Determined



AAPS FOCUS GROUP MEMBERSHIP MEETINGS
12:00 pm – 1:00 pm

CONTRIBUTED PAPERS POSTER SESSION
1:00 pm – 5:00 pm

WEDNESDAY AFTERNOON PROFESSIONAL DEVELOPMENT SESSIONS
1:00 pm – 3:00 pm
How to Publish in an AAPS Peer-reviewed Academic Journal
Carolyn Honour
Springer

2:00 pm – 4:00 pm
Strategic Job Search
Megan Driscoll
PharmaLogics

WEDNESDAY AFTERNOON SYMPOSIA
1:30 pm - 4:00 pm

Pharmaceuticals Without Borders III: Ensuring the Integrity and Quality of Medicines Reaching the Patient (GH)

Session Chairs
Sabine Kopp, Ph.D.
World Health Organization

Cynthia K. Brown, Ph.D.
Eli Lilly & Co.

The Challenges of Delivering Quality Medicines to a Global Patient Population
Andreas Seiter, Ph.D.
The World Bank

Ensuring the Quality of Pharmaceutical Ingredients and Finished Products: Scope, Impact and Prevention
Adriaan J. van Zyl, M.Pharm, Ph.D.
World Health Organization

The Impact of Diversion within the Global Supply Chain
Martin G. Fitzgerald, M.S., J.D.
GIRP - European Association of Pharmaceutical Full-line Wholesalers

WEDNESDAY AFTERNOON SYMPOSIA

1:30 pm – 4:00 pm *(continued from page 29)*

A Case Study: How to Address Drug Quality with Local Resources
Shaohong Jin, Ph.D.
National Institute for the Control of Pharmaceutical and Biological Products

Pharmacogenetics: Translational Aspects (CPTR & PPDM)

Session Chairs
Urs A. Meyer, M.D.
University of Basel

Mary V. Relling, Pharm.D.
St. Jude Children's Research Hospital

The Contribution of Pharmacogenetics to Personalized Medicine
Urs A. Meyer, M.D.
University of Basel

Pharmacogenetic Variation in Smoking and Treatment Response
Rachel F. Tyndale, Ph.D.
University of Toronto

Clinical Pharmacogenomics in Cancer
Mary V. Relling, Pharm.D.
St. Jude Children's Research Hospital

Pharmacogenomics of Drug Hypersensitivity Reactions
Munir Pirmohamed, M.D., Ph.D.
The University of Liverpool

In Vitro Release of Drugs from Non-oral Dosage Forms (PPB, APQ & FDD)

Session Chairs
Todd L. Cecil, Ph.D.
U.S. Pharmacopeia

Chikako Yomota, Ph.D.
National Institute of Health Sciences

Horst-Dieter Friedel, Ph.D.
Bayer Schering Pharma

Review of FIP: Special Dosage Forms Guidance
J. Michael Morris, Ph.D.
Irish Medicines Board

Unique Issues for Inhalation Products
Neal Davies, Ph.D., R.Ph.
Washington State University

New Approaches for Complex Parenteral Products
Diane J. Burgess, Ph.D.
University of Connecticut

Targeted Intracellular Drug Delivery with Liposomes
Kazuo Maruyama, Ph.D.
Teikyo University

Natural Products: Interface Between Science and Practice (DDD & MCNP)

Session Chairs
Carmen Tamayo, M.D.
Foresight Links Corporation

Michiho Ito, Ph.D.
Kyoto University

Health Claims and Botanical Drug Development: From Seed to Patients
Carmen Tamayo, M.D.
Foresight Links Corporation

Field Research on Herbal Medicines and Related Research Works Aiming at their Development and Use in Practice
Michiho Ito, Ph.D.
Kyoto University

Quality, Efficacy and Safety of Herbal Medicines
Silvia Etcheverry, Pharm.D.
Bioxel Laboratory

Quality Control of NPS: An Evidence Based Approach
Paula Brown, M.S.
British Columbia Institute of Technology

Preservatives in Parenteral Products (FDD & BIOTEC)

Session Chair
Qiang Ye, Ph.D.
Otonomy, Inc.

Current Preservative Use in Parenteral Drug Products
Sandeep Nema, Ph.D.
Pfizer Global Biologics Pharmaceutical

Preservative-drug, Preservative-excipient and Preservative-package Interactions
Tony Pidgeon, Ph.D.
Patheon, Inc.

Preservative-free Sterile Products
David S. Baker, Ph.D.
QLT Plug Delivery, Inc.

Regulatory Landscape of Preservatives in Parenteral Drug Products
Elaine Morefield, Ph.D. (Invited)
U.S. Food and Drug Administration

Nanocrystals: Production, Stability and Applications (MSE & PPB)

Session Chairs
Jamshed Anwar, Ph.D.
University of Bradford

Rainer H. Müller, Ph.D.
Free University Berlin

Nanocrystals: Properties, Production Methods and Stability Issues
Rainer H. Müller, Ph.D.
Free University Berlin

Targeting Applications of Nanocrystals in Drug Delivery
Barrett E. Rabinow, Ph.D.
Baxter Healthcare Corporation

Towards Stabilizing Nanocrystals: Calculation of Surface & Interfacial Free Energy
Jamshed Anwar, Ph.D.
University of Bradford

Phase Stability of Inorganic Nanocrystals: Lessons for Organic Nanocrystals
Amanda S. Barnard, Ph.D.
CSIRO Materials Science & Engineering

Prediction of Human Oral Pharmacokinetic Profiles from Preclinical and In Vitro Data (PPDM)

Session Chairs
Zheng Yang, Ph.D.
Bristol-Myers Squibb

Jin-Ding Huang, Ph.D.
National Cheng Kung University

Application of PBPK to the Prediction of Human Concentration - Time Profiles from Preclinical Data: Pfizer Experience
Hannah Jones, Ph.D.
Pfizer Global Research & Development

Prediction of Human Pharmacokinetic Profiles Based on *In Silico* Approaches and Normalization of Animal PK Profiles
Toshihiro Wajima, Ph.D.
Shionogi & Co.

Evaluation of Various Methodologies in Predicting Human Oral Pharmacokinetic Profiles from Preclinical Data: Experience with BMS Compounds
Zheng Yang, Ph.D.
Bristol-Myers Squibb

Pharma Initiative in Human PK Prediction to Shorten the Cycle Time with Improved Efficiency for New Drug Development
Sherry Ku, Ph.D.
Wyeth Pharmaceuticals

siRNA Delivery: Challenges and Opportunities (DDD & BIOTEC)

Session Chairs
Majid Moridani, Pharm.D., Ph.D.
Texas Tech University Health Sciences Center

Hiroaki Okada, Ph.D.
Tokyo University of Pharmacy and Life Sciences

Non-viral and Disease-specific Delivery Systems for siRNA Therapy
Ick Chan Kwon, Ph.D.
Korea Institute of Science and Technology

Transdermal Preparation for Treating Atopic Dermatitis in Mice by siRNA
Hiroaki Okada, Ph.D.
Tokyo University of Pharmacy and Life Sciences

Development of Targeted Nanogels for siRNA Delivery to Tumor Vasculature
Rakesh K. Singh, Ph.D.
University of Nebraska Medical Center

Non-viral Approaches for Gene Drug Discovery and Gene Therapy
Dexi Liu, Ph.D.
University of Pittsburgh

WEDNESDAY AFTERNOON ROUNDTABLES

2:00 pm - 4:00 pm

What Do Industry and Regulators Need from Imaging? (CPTR & RS)

Session Chairs
Narayan P. Cheruvu, Ph.D.
Covidian Ltd

Mary E. Spilker, Ph.D.
Pfizer Global Research & Development

Speakers and Presentation Titles to be Determined

PK: Bottom-up, Top-down or Both? (PPDM)

Session Chairs
Geoff Tucker, Ph.D.
Academic Unit of Clinical Pharmacology

Yuichi Sugiyama, Ph.D.
The University of Tokyo

Presentation Title to be Determined
Nick Holford, M.D., M.S.
University of Auckland

Presentation Title to be Determined
Amin Rostami-Hodjegan, Ph.D., Pharm.D.
University of Sheffield

WEDNESDAY AFTERNOON MINI-SYMPOSIA

2:00 pm - 4:00 pm

Computer-aided Drug Development: A Rational Approach to Improve Speed and Reduce the Cost
(PPB & FDD)

Session Chairs
Jean M. Surian, Ph.D.
AstraZeneca

Fumiyoshi Yamashita, Ph.D.
Kyoto University

Persuing the Drug-likeness Concept in Drug Discovery
Tudor Oprea, Ph.D.
University of New Mexico

Monte Carlo Simulations to Predict Drug Physical Properties in Aqueous Solutions
Lennart Lindfors, Ph.D.
AstraZeneca

Data Mining and Visualization Techniques for ADME Screening
Fumiyoshi Yamashita, Ph.D.
Kyoto University

New Synthetic Technology in Drug Development
(DDD & MCNP)

Session Chairs
Kiyoshi Tomioka, Ph.D.
Kyoto University

Kai-Xian Chen, Ph.D.
Chinese Academy of Science

Drug Discovery
Paul J. Reider, Ph.D.
Princeton University

Asymmetric Synthesis of Pharmaceuticals
Kiyoshi Tomioka, Ph.D.
Kyoto University

Safety Sciences: Education and Training
(SS & E&C)

Session Chairs
Ole J. Bjerrum, Ph.D.
University of Copenhagen

A. Wallace Hayes, Ph.D., D.A.B.T.
Harvard University

New Public Private (EU/EFPIA) Supported Pan European Modular Program for Training of Pharmaceutical Safety Scientists
Ole J. Bjerrum, Ph.D.
University of Copenhagen

Where is the U.S. in its Training Program
A. Wallace Hayes, Ph.D., D.A.B.T.
Harvard University

Industrial and Regulatory Needs for Drug Safety Education and Training in a Global Perspective
Eva M. Muchitsch, D.V.M
Baxter Innovations GmbH

Pharmaceutical Waste and Environmental Pollution
(ES & SS)

Session Chairs
Tetsuji Nishimura, Ph.D.
National Institutes of Health

Bent Halling-Sørensen, Ph.D.
University of Copenhagen

Speakers and Presentation Titles to be Determined

AAPS RESEARCH ACHIEVEMENT AWARD LECTURES

4:00 pm - 5:00 pm
Pharmacokinetics, Pharmacodynamics & Drug Metabolism (PPDM) Research Achievement Award Lectures
Funded by Grants from

ARRAY BIOPHARMA NOVARTIS

AAPS FOCUS GROUP MEMBERSHIP MEETINGS

5:00 pm – 6:00 pm

PSWC CLOSING DINNER

7:00pm-10:00pm

An additional fee is required for this event.
Court of Two Sisters Pavilion

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School of Pharmacy

Thursday, November 18, 2010

6:00 am – 12:00 pm
Speaker Ready Room

7:00 am – 2:30 pm
Registration

7:00 am – 12:00 pm
Student Lounge

7:00 am – 12:00 pm
International Lounge

8:00 am – 12:00 pm
Press Room

THURSDAY MORNING SUNRISE SESSIONS
7:00 am - 8:15 am

Fractal Pharmacokinetics and Non-linear Dynamics (PPDM)

Session Chairs
Luis M. Pereira, Ph.D.
Harvard Medical School

Panos E. Macheras, Ph.D.
University of Athens

Nonlinear Dynamics in PK/PD Analysis
Robert R. Bies, Pharm.D., Ph.D.
Indiana University

Nonexponential Transit Time Distributions in Pharmacokinetic Systems
Michael Weiss, Ph.D.
Martin Luther University

Pharmaceutical Stability: Science and Regulation (RS, FDD & PPB)

Session Chairs
Prabu Nambiar, Ph.D., RAC
Vertex, Inc.

Latiff Hussain, Ph.D.
U. S. Food and Drug Administration

Pharmaceutical Stability: Science and Regulation
Prabu Nambiar, Ph.D., RAC
Vertex, Inc.

Stability Requirements for Generic Drug Approvals
Latiff Hussain, Ph.D. (Invited)
U.S. Food and Drug Administration

Traditional Medicines in a New Paradigm of Global Health (DDD, MCNP & CPTR)

Session Chairs
Tsutomu Hatano, Ph.D.
Okayama University

Zuguang Ye, Ph.D.
Chinese Academy of Medical Sciences

Effects of Tannins and Related Polyphenols on Antibiotic-resistant Bacteria
Tsutomu Hatano, Ph.D.
Okayama University

Characterization of Natural Ligands for Aryl Hydrocarbon Receptor Using a Reporter Gene Assay
Yoshiaki Amakura, Ph.D.
Matsuyama University

Standardized Evaluation of TCM Drug Safety and its Safe use in China
Zuguang Ye, Ph.D.
Chinese Academy of Medical Sciences

Personalized Medicine: Integrated Technologies (DDD, CPTR, PPDM & PCOL)

Session Chairs
Wolfgang Sadee, Ph.D.
Ohio State University

Hitoshi Sasaki, Ph.D.
Nagasaki University

Large-scale Genotyping and Full Sequencing in Personalized Medicine: How to Search for the Missing Heritability of Complex Diseases and Response to Therapies
Wolfgang Sadee, Ph.D.
Ohio State University

The Changing Nature of Biomarkers: How to Optimize an Individual's Drug Therapy
Hitoshi Sasaki, Ph.D.
Nagasaki University

CONTRIBUTED PAPERS POSTER SESSION
8:00 am – 12:00 pm

THURSDAY MORNING SYMPOSIA
8:30 am - 11:00 am

Predicting Clinical Outcome Events Using Biomarkers for Drug Development (CPTR)

THURSDAY MORNING SYMPOSIA

8:30 am – 11:00 am *(continued from page 35)*

Session Chairs
Pollen K. Yeung, Ph.D.
Dalhousie University

Lawrence J. Lesko, Ph.D.
U.S. Food and Drug Administration

Bruno Flamion, M.D., Ph.D.
EMEA/CHMP Scientific Advice Working Party

Modeling Clinical Outcome and Biomarker Response in Clinical Trials: Applications and Impact on Decision-making in Drug Development
Richard L. Lalonde, Pharm.D.
Pfizer Inc.

Use of Biomarkers in the Early Clinical Development of a Hypnotic with a New Mechanism of Action
Jasper Dingemanse, Pharm.D., Ph.D.
Actelion Pharmaceuticals Ltd.

Role of Biomarker-clinical Outcome Relationship in Clinical Drug Development: FDA Experience
Kevin M. Krudys, Ph.D. (Invited)
U.S. Food and Drug Administration

Open Source Biomarkers: Practice and Pitfalls
John A. Wagner, M.D., Ph.D.
Merck & Co., Inc.

Molecular Imaging Technologies for ADME-Tox Studies
(PPDM, FDD & PPB)

Session Chair
Shinji Yamashita, Ph.D.
Setsunan University

New Strategy of Microdosing Study with Molecular Imaging Technology
Yuichi Sugiyama, Ph.D.
The University of Tokyo

Pharmacokinetic Studies with PET
Bengt Langstrom, Ph.D.
Uppsala University

Molecular Imaging of Oral Drug Absorption with PET
Shinji Yamashita, Ph.D.
Setsunan University

PET and Fluorescent Imaging to Study ADME of Tumor Targeting Antibody
Duxin Sun, Ph.D.
University of Michigan

New Molecular Targets for Drug Discovery
(PCOL & DDD)

Session Chairs
Gavin Brooks, Ph.D., M.Pharm
University of Reading

James E. Bradner, M.D.
Dana-Farber Cancer Institute/Harvard Medical School

G-Protein Coupled Receptors as Targets for the Treatment of Human Disease
Martin J. Lohse, Ph.D.
University of Wuerzburg

The Notch Signaling Pathway as a Target for Human Disease
James E. Bradner, M.D.
Dana-Farber Cancer Institute/Harvard Medical School

Targeting the Cell Cycle Machinery for the Treatment of Cardiovascular Disease
Gavin Brooks, Ph.D., M.Pharm
University of Reading

Protein Kinases and Phosphatases as Drug Targets
Alexander Levitzki, Ph.D.
The Hebrew University of Jerusalem

Continuous Manufacturing: Benefits and Challenges
(MSE)

Session Chairs
Sharmista Chatterjee, Ph.D.
U.S. Food and Drug Administration

Jiahui Hu, Ph.D.
Novartis

Continuous Micro Reactor Technology for Drug Substance Synthesis
Brian Marquardt, Ph.D.
Univerity of Washington

Continuous Manufacturing for Drug Products
James Kraunsoe, Ph.D.
AstraZeneca, UK

Regulatory Perspective on Continuous Manufacturing
Christine Moore, Ph.D. (Invited)
U.S. Food and Drug Administration

Systems Approaches to Adverse Drug Reactions (SS & PPDM)

Session Chair
Nico Vermeulen, Ph.D.
VU University / LACDR

Reactive Intermediates: The Molecular Basis for Human ADRs
Nico Vermeulen, Ph.D.
VU University / LACDR

Cellular Toxicogenomics as a Predictive Tool for Human ADRs
Bob van de Water, Ph.D.
Leiden University

Pharmacogenomics and Human ADRs
Magnus Ingelman-Sundberg, Ph.D.
Karolinska Institute

Systems Pharmacology Approaches to Study Human ADRs
Kevin Park, Ph.D.
The University of Liverpool

New Frontiers in Biologics Development: Understanding and Mitigating Uncommon Protein Degradation Pathways (BIOTEC & PPB)

Session Chairs
Pankaj V. Paranjpe, Ph.D.
Bristol-Myers Squibb

Vikram Sadineni, Ph.D.
Bristol-Myers Squibb

Zhi-Nan Chen, Ph.D.
Chinese Academy of Engineering

Disulfides and their Stability in Peptides and Proteins
Christian Schöneich, Ph.D.
University of Kansas

The Science of Freezing: Control, Excipients, Storage and Freeze-drying (PPB, MSE & FDD)

Session Chairs
Tapan K. Das, Ph.D.
Pfizer Inc.

Hirofumi Takeuchi, Ph.D.
GIFU Pharmaceutical University

Gerhard Winter, Ph.D.
University of Munich

Process of Freezing and Thawing, and Impact of Slow/Fast Freeze-thaw on Phase Properties
Raj Suryanarayanan, Ph.D.
University of Minnesota

Biologics Freezing, Cryoconcentration and Impact on Stability
Angela T. Kantor, Ph.D.
Wyeth

Freeze Thaw and Freeze Drying of Nanoparticles and Vaccine
Erhard W. Hinrichs, Ph.D.
University of Groningen

Molecular Mobility of Freeze-dried Formulation
Sumie Yoshioka, Ph.D.
National Institute of Health and Sciences

Transporter Proteins III: Clinical Relevance and Applications (PPDM & CPTR)

Session Chairs
Ikumi Tamai, Ph.D.
Kanazawa University

Bruno Stieger, Ph.D.
University of Zurich

Involvement and Interaction of Transporters in Intestinal and Pulmonary Absorption of Drugs
Ikumi Tamai, Ph.D.
Kanazawa University

Hepatic Organic Anion Transporters: Role in Drug Disposition and Pharmacogenetics of Acquired Liver Injury
Bruno Stieger, Ph.D.
University of Zurich

Blood-brain Barrier Pharmacoproteomics: Quantitative Transporter Protein Analysis for In Vitro-In Vivo, Interspecies and Diseased State Differences
Tetsuya Terasaki, Ph.D.
Tohoku University

The Role of Transporters During Drug Development: The Perspective from the FDA
Shiew-Mei Huang, Ph.D. (Invited)
U.S. Food and Drug Administration

THURSDAY MORNING MINI-SYMPOSIA

9:00 am - 11:00 am

Similarities and Differences in Global Safety Regulation (SS & RS)

Session Chairs
Prabu Nambiar, Ph.D., RAC
Vertex, Inc.

Eva-Maria Muchitsch, Ph.D.
Baxter Innovations GmbH

Drug Development and Evolution of Current Global Safety/Pharmacovigilance Regulations
Jack Weet, Ph.D.
Vertex, Inc.

THURSDAY MORNING MINI-SYMPOSIA

9:00 am – 11:00 am *(continued from page 37)*

Challenges and Practical considerations of Implementing a Global Safety/Pharmacovigilance Program: US Perspectives
Speaker to be Determined

Challenges and Practical Considerations of Implementing a Global Safety/Pharmacovigilance Program: EU Perspectives
Eva-Maria Muchitsch, Ph.D.
Baxter Innovations GmbH

Genotoxic and Carcinogenic Impurities: Control and Regulation (APQ & RS)

Session Chairs
Arya P. Jayatilaka, Ph.D.
Pfizer Inc.

Jan Zorgdrager, Ph.D.
Solvay Pharmaceuticals B.V.

A Rationale for Determining, Testing and Controlling Specific Impurities in Pharmaceuticals that Possess Potential for Genotoxicity
Gopi Vudathala, Ph.D.
Sanofi-Aventis

Advances in Analysis of Genotoxic Impurities in API
Arya P. Jayatilaka, Ph.D.
Pfizer Inc.

Quality of Manufactured Medicines – Genotoxic Impurities: Current Perspectives
Peter Kasper, Ph.D.
Federal Institute for Drugs and Medical Devices

Individualizing (Small Molecule) Drugs: From Subtype Specificity to Multi-target Design and Metabolic Network Strategies
(DDD & PCOL)

Session Chair
Christian R. Noe, D.Sc., M. Pharm.
University of Vienna

From Genome to Drugs: Assessing Kinase Inhibitor Selectivity and Implications for Drug Discovery
Patrick P. Zarrinkar, Ph.D.
Ambit Biosciences

Design of Multi-target Drugs
Klaus P. Bøgesø, D.Sc.
Lundbeck

Differential Network-based Strategies: Counting on Data
Hans V. Westerhoff, Ph.D.
University Manchester

Lipid-based Drug Delivery Systems
(FDD, PPB & MSE)

Session Chairs
Dawn D. Downey, Ph.D.
Patheon, Inc.

Yunxia (Vivian) Bi, Ph.D.
AstraZeneca

Formulation Development Using Lipid Excipients
Chris Porter, Ph.D.
Monash University

Physical Characterization of Semi-solid Lipidic Formulations
Duncan Q.M. Craig
University of East Anglia

The Science and Art of Manufacturing Soft and Hard Shell Liquid-filled Capsules
David Fulper, Ph.D.
Catalent Pharma Solutions, Inc.

Excipients for Protein Drugs Revisited
(BIOTEC & APQ)

Session Chairs
Hanns-Christian Mahler, Ph.D.
F. Hoffmann-La Roche Ltd.

Mary Cromwell, Ph.D.
Genentech, Inc.

Excipients for Protein Formulation Revisited
Hanns-Christian Mahler, Ph.D.
F. Hoffmann-La Roche Ltd.

Crystallization of Excipients
Tim Kamerzell, Ph.D.
Genentech, Inc.

The Use and Fate of Polysorbates in Protein Formulations
Kishore Ravuri, Ph.D.
F. Hoffmann-La Roche Ltd.

BCS and BDDCS Based Strategies for Oral Drug Development
(FDD & PPDM)

Session Chairs
Leslie Z. Benet, Ph.D.
University of California

Hiroaki Yuasa, Ph.D.
Nagoya City University

Presentation Title to be Determined
Leslie Z. Benet, Ph.D.
University of California

Risk Factors in Human Bioinequivalence of Oral Dosage
Shinji Sakuma, Ph.D.
Setsunan University

Pharmaceutical Challenges to Alzheimer's Disease
(DDD & MCNP)

Session Chairs
Takeshi Iwatsubo, Ph.D.
University of Tokyo

Peter Seubert, Ph.D.
Elan Corporation

Alzheimer Drug Mechanisms
Taisuke Tomita, Ph.D.
University of Tokyo

Presentation Title to be Determined
Peter Seubert, Ph.D.
Elan Corporation

Presentation Title to be Determined
Douglas Galasko, Ph.D.
University of California

Presentation Title to be Determined
Bart De Strooper, Ph.D.
Katholik University of Leuven

FIP PSWC 2010/AAPS ANNUAL MEETING & EXPOSITION ADJOURNMENT

12:00 pm

Thursday, November 18, 2010

POST-CONGRESS EVENTS

OPEN FORUMS

1:00 pm - 5:00 pm

An additional fee is required to attend open forums.

Formulation Design & Development (FDD) Open Forum

Formulation Strategies for Poorly Soluble Drugs

Including Selected Highlights from the AAPS 2010 Arden Conference

1:30 pm - 5:00 pm

Analysis and Pharmaceutical Quality (APQ) Open Forum

Global Harmonization of Modern Bioanalytical Regulatory Practices

APQ Open Forum is supported by grants from

Roche Advion ICON A Symbol of Excellence

Manufacturing Science & Engineering (MSE) Open Forum

Particles in Biopharmaceutical Parenteral Products

MSE Open Forum is supported by a grant from

Pfizer

Pharmacokinetics, Pharmacodynamics & Drug Metabolism (PPDM) Open Forum

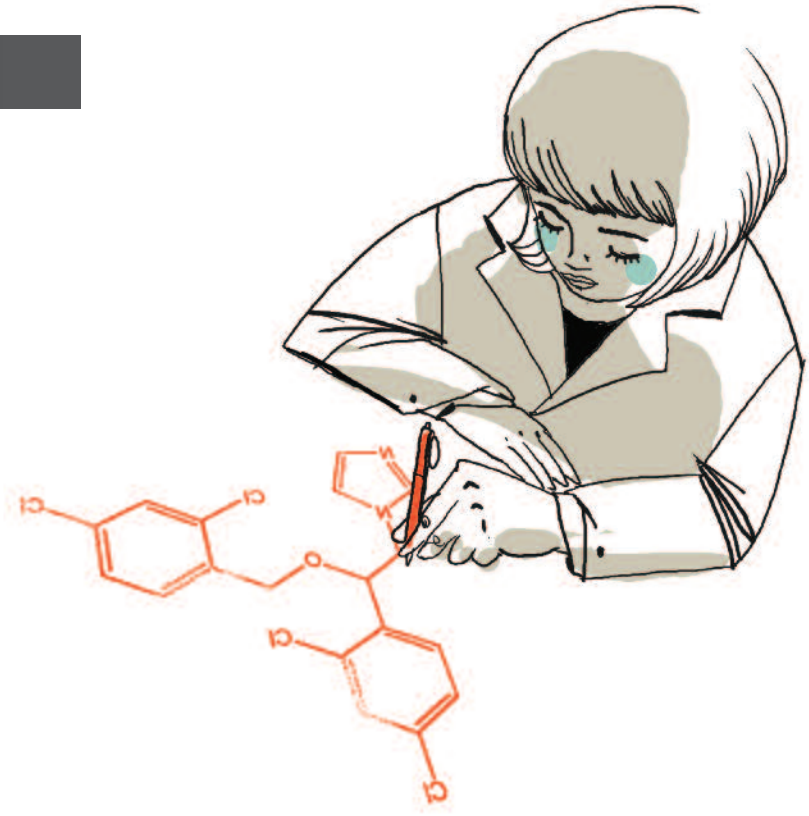
Ethnic Sensitivity in PK/PD: Leveraging Clinical Development in Emerging Countries — Using Knowledge of Ethnic Differences to Facilitate Drug Development

Physical Pharmacy & Biopharmaceutics (PPB) Open Forum

The BCS, BDDCS and Regulatory Guidances

Regulatory Sciences (RS) Open Forum

Establishing Clinically Relevant Dissolution Specifications in the Quality-by-Design World: Practical Implications and Regulatory Challenges



Travelship Information

AAPS and FIP are pleased to provide student travelship to the FIP PSWC 2010/AAPS Annual Meeting & Exposition in New Orleans, Louisiana, November 14-18, 2010. Below are the criteria for travelship acceptance. Applications are due on May 12, 2010.

Awardees will be notified of acceptance by July 15, 2010.

Travelship Criteria:

1. Must have a paper submitted and accepted to the PSWC/Annual Meeting & Exposition or the Student and Postdoctoral Fellow Meeting.
2. International awardees will receive the funding in person at the meeting
3. Must be traveling more than 300 miles from New Orleans
4. Applicants must be the presenting author or first author on the paper.
5. Applicants must be a full time student or employed as a post-doctoral fellow. Verification will be required by an Advisor, Department Chair or Dean of the College or School.
6. Applicants can only receive one travelship. If applicant is an award winner, he/she is not eligible for a travelship.

FIP PSWC 2010/AAPS Annual Meeting & Exposition Travelship Application
www.pswc2010.org/travelships

FIP Pharmaceutical Sciences 2010 World Congress

in association with the AAPS Annual Meeting and Exposition

Short Course Application Form

For Graduate Students and Postdoctoral Fellows Only

The first five applicants per short course will be selected to purchase short course registration for the reduced rate of $50. Reduced fees are available on a space-available basis. Please print or type. Incomplete forms will not be considered. Reduced fees are not applicable after October 8, 2010.

Please print or type. Incomplete forms will not be considered.

First Name

Last (Family) Name

AAPS Member ID (required)

Institution

Address

City

State/Province

Postal Code

Country

Day Phone

Evening Phone

Fax

Email

Are you a member of an AAPS Student Chapter?

❍ Yes ❍ No

If so, which one?

Payment Method

AAPS does not accept government training forms nor purchase orders. Federal Tax ID #521444968

❍ **Check #** Payable to: AAPS-2010PSWC/AM

(U.S. dollars drawn on a U.S. bank)

❍ **Charge**

❍ Visa ❍ MasterCard ❍ American Express ❍ Discover

Card Number

Exp. Date

Card Holder's Name

Authorized Signature

Amount to Charge

Short Course Selections

My top three choices are (rank in order with #1 as your first choice):

Sunday, November 14, 2010 • 8:30 am – 4:00 pm

_____ **SC #1: Stability Testing in Pharmaceutical Development**

_____ **SC #2: Mechanistic PK/PD Modeling**

_____ **SC #3: ICH Guidelines Q8, Q9, Q10 and Q11: How Do They All Fit Together?**

_____ **SC #4: Nanotechnology from A-Z: Achievement in Drug Delivery and Tissue Engineering**

_____ **SC #5: Helping the Medicine Go Down - Pediatric Medicines: Formulation, Manufacturing and Compliance Challenges**

_____ **SC #6: Developments in Technologies for Process Related Impurities Detection and Identification for Biologics**

Up to five applicants will be selected for each Short Course on a first-come, first-served basis.

❍ I am also registered for the FIP PSWC 2010/AAPS Annual Meeting and Exposition.

❍ I want to purchase Continuing Education Credits for the Short Course.

A reduced registration fee of $50 will be requested upon notification of acceptance. If you also request Continuing Education Credits, an additional $50 fee will apply. Applications are not transferable.

The signature of your Dean or Department Chair is required to certify your full-time status to be eligible for this fee.

Signature

Date

❍ If I am not accepted for a reduced, charge me for the full rate for the Short Course selected.

Mail or fax this form to:
2010 Short Course Application Form
AAPS
Attn: Kate McHugh
2107 Wilson Blvd., Suite 700
Arlington, VA 22201-3042

Fax: (703) 243-5582

Questions? **Phone: (703) 248-4793**
Email: registration@aaps.org

Deadline: October 8, 2010

Register!

University of Wisconsin-Madison School of Pharmacy
Delivering pharmaceutical professional development for over 50 years

Short Courses for the Pharmaceutical Industry
May 2010 • Madison, WI

Monday	Tuesday	Wednesday	Thursday	Friday
3	4	5	6	7
Practical Toxicology in Drug Development				
Preformulation and Stabilization of Pharmaceuticals				
Principles of Solid Dosage Forms				
10	11	12	13	14
Nucleic Acid Therapeutics				
Introduction to the Regulatory Process for Drug Development				
An Introduction to Drug Metabolism and Transporters				
17	18	19	20	21
Applied Pharmacology to Drug Action				
Pharmacokinetics, Bioavailability and Bioequivalence				

Practical Toxicology in Drug Development

The course will cover the regulatory, scientific, and strategy of employing non-clinical toxicology methods and provide a basic understanding of the value and limitations of non-clinical safety evaluations.

Preformulation and Stabilization of Pharmaceuticals

The purpose of this course is to provide the learner with an understanding of the underlying scientific principles governing the development of solid dosage forms.

Principles of Solid Dosage Forms

The objective of this short course is to provide the formulation and analytical scientist with an understanding of preformulation science, physical and chemical characterization, and stability of solid- and liquid-dosage forms.

Nucleic Acid Therapeutics

The intent of this short course is to provide an introduction to various classes of nucleic acid therapeutics, including gene therapy, antisense oligonucleotides, microRNA, and siRNA.

Intro to the Regulatory Process for Drug Development

Participants will find this program to be an excellent up-to-date resource for understanding the regulations related to the development and manufacture of pharmaceutical products.

An Introduction to Drug Metabolism and Transporters

The purpose of this course is to provide the learner with a basic understanding of drug metabolism and its role in drug discovery and development.

Applied Pharmacology to Drug Action

The purpose of this course is to provide the learner with a basic understanding of pharmacology: the effects of drugs on living systems.

Pharmacokinetics, Bioavailability and Bioequivalence

The purpose of this course is to provide the learner with a basic understanding of pharmacokinetics, bioavailability and bioequivalence.

For complete program information or to register online visit our website:
www.pharmacy.wisc.edu/esp/ShortCourses

Join our Linkedin group: University of Wisconsin Extension Services in Pharmacy Industrial Professional Development

Extension Services in Pharmacy
School of Pharmacy
University of Wisconsin-Madison

To see other programs offered by Extension Services in Pharmacy, visit our website
http://ce.pharmacy.wisc.edu

Contact Extension Services in Pharmacy:
Phone: 608-262-3130
Email: cemail@pharmacy.wisc.edu

Two great reasons to use The University of Iowa Pharmaceuticals for your next Sterile Product

Since the merger of Pharmaceutical Service and the Center for Advanced Drug Development to form The University of Iowa Pharmaceuticals (UIP), we have made a host of improvements in our Sterile Products operation.

- All of our Clean Rooms are now equipped with automatic vial fillers.
- A new automatic vial washer has been installed in our component preparation area.
- Our lyophilization cycle development capabilities have been significantly enhanced with the purchase of a new integrated differential thermal analyzer, integrated freeze-drying microscope, and development scale lyophilizer.

The University of Iowa Pharmaceuticals has successfully passed a pre-approval inspection (PAI) for an aseptically filled sterile drug product.

- This accomplishment validates the significant upgrades UIP has made in its sterile products manufacturing area.
- This successful PAI represents the second approval this year for UIP to provide manufacturing and/or testing services to clients in support of commercial products.
- UIP is uniquely positioned to provide contract manufacturing services for low volume parenteral products from inception through commercial launch and beyond.

In addition to sterile product clinical and small scale contract manufacturing services, we continue to offer a full line of contract manufacturing and analytical testing services to support both clinical and small scale commercial products.

UIP is offering FREE lyophilization cycle development.*

*Through credit on subsequent batches produced at UIP. Offer subject to a limited time.

For more information visit our website
www.pharmacy.uiowa.edu/uip
Call: Mickey L. Wells, Ph.D., at 319-335-8674, email: mickey-wells@uiowa.edu

THE UNIVERSITY OF IOWA PHARMACEUTICALS

FIP Pharmaceutical Sciences 2010 World Congress

in association with the AAPS Annual Meeting and Exposition

Registration Form • page 1

APS101

November 14 – 18, 2010 • New Orleans, LA

First Name _____ Middle Initial _____

Last (Family) Name _____ Nickname for Badge _____

Job Title _____

Organization _____

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City _____ State/Province _____ Postal Code _____

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Fax _____ Mobile _____

Email _____

Emergency Contact Name _____ Phone _____

❍ The information above has changed.

❍ I require special services in accordance with the Americans with Disabilities Act.

❍ Check this box if you do not wish to be included in promotional mailings or faxes from AAPS exhibitors sent prior to the FIP PSWC 2010/AAPS Annual Meeting & Exposition.

Instructions

- Type or print all information.
- **Credit card payments** are available **online only** at **www.pswc2010.org**
- Payment must accompany your form for registration to be processed.
- Keep a copy of your completed registration form for your records.
- Group and combo registration are available **online only** at **www.pswc2010.org**
- All information must be completed in full to receive a badge.
- Please fax completed forms to 301-694-5124
- Please mail forms with payment to:
  FIP PSWC 2010/Annual Meeting
  PO Box 590
  Frederick, MD 21705

Combination Registration available online only.
10% discount for short course and Full Congress.

Register for the FIP PSWC 2010/ AAPS Annual Meeting and Exposition and a Short Course and receive a 10% discount. Combo registration available ONLINE ONLY at **www.pswc2010.org.**

AAPS Cancellation Policy

FIP Pharmaceutical Sciences World Congress 2010 in association with the AAPS Annual Meeting & Exposition

All requests for refunds must be submitted in writing and emailed to registration@aaps.org or faxed to (703) 243-5582. Registration refunds will be issued for all requests received by October 15, 2010, less an administrative fee ($100 for members and non-members/$30 for student registrants). Refunds will not be issued for requests made after October 15, 2010. Registration substitutions from the same company may be submitted in writing at any time without penalty. If the membership status of the substitute differs from that of the original registrant, a refund or additional charge may apply.

Business Information

Primary Job Function (Check One)

❍ A Academic
❍ B Consultant
❍ C Corporate Management
❍ D Engineer
❍ E Marketing/Sales
❍ F Media
❍ G Production/Planning
❍ H Purchasing
❍ I QA/QC
❍ J R&D
❍ K Regulatory Sciences
❍ L Other

Primary Business/Industry (Check One)

❍ A Academia
❍ B Analytical Testing Lab
❍ C Association
❍ D Biotechnology
❍ E ContractVClinical Research
❍ F Cosmetics
❍ G Foods
❍ H Government
❍ I Manufacturing
❍ J Materials Manufacturing
❍ K Medical Devices/Diagnostics
❍ L Publications
❍ M Other

Purchasing Authority

❍ A Authorize
❍ B Purchase
❍ C Recommend
❍ D Specify
❍ E No Purchasing Authority

Area of Interest (Check All That Apply)

❍ A Analytical Services
❍ B Chemicals
❍ C Chromatography
❍ D Contract/Clinical Services
❍ E Dissolution Test Equipment
❍ F Drug Delivery Systems
❍ G Excipients
❍ H Ingredients
❍ I Packaging
❍ J Pumps
❍ K Raw Materials
❍ L Software
❍ M Spectroscopy
❍ N Tablet Presses
❍ O Test Equipment
❍ P Other

Registration

Please check Registration Type and circle the dollar amount.

	Early Registration Received on or before September 10, 2010	On-Site Registration Received on September 11, 2010 — on-site
Full Congress*	$850	$1,150
Government*	$620	$620
Student (PSWC Only)*	$175	$210
Student (PSWC + Student Congress)*	$300	$350
Will you be attending Magazine Street function? ❍ YES ❍ NO Shuttle to Magazine Street — www.magazinestreet.com Are you a member of an AAPS Student Chapter? ❍ YES ❍ NO	$5	$5
One Day Full Congress — *Circle One:* M T W R	$250	$350
One Day Student — *Circle One:* M T W R	$65	$90
Spouse/Guest	$50	$60

*Every current active AAPS Member will have their membership term extended for an additional twelve months; membership dues are included in the registration rate, so no need pay your membership renewal dues separately.

Please fax completed forms to 301-694-5124

First Name Last Name

Please check Registration Type and circle the dollar amount.

	Early Registration Received on or before September 10, 2010	On-Site Registration Received on September 11, 2010 — on-site
Special Events *(an additional Fee is required to attend these sessions)*		
Short Course	$790	$885
Open Forum — *Circle One:* APQ FDD MSE PPB PPDM RS(2)	$75	$100
Open Forum with Dinner — *Circle One:* CPTR RS(1)	$175	$200

Short Course Registration *(Additional fee required)* — Sunday, November 14, 2010

If registering for a Short Course, check the course in which you wish to enroll and circle the appropiate fee below. Course registration is limited and accepted on a first-come, first-served basis.

- ❍ SC #1 – Stability Testing in Pharmaceutical Development
- ❍ SC #2 – Mechanistic PK/PD Modeling
- ❍ SC #3 – ICH Guidelines Q8, Q9, Q10, Q11: How Do They All Fit Together?
- ❍ SC #4 – Nanotechnology from A to Z – Achievement in Drug Discovery and Tissue Engineering
- ❍ SC #5 – Helping the Medicine Go Down – Pediatric Medicines: Formulation, Manufacturing and Compliance Challenges
- ❍ SC #6 – Developments in Technologies for Process Related Impurities Detection and Identification for Biologics

Open Forum Information

CPTR Open Forum (with Dinner) ~ Tuesday, November 16, 2010 7:00pm – 9:30pm
Open Source Development of Mechanistic/Systems Biology Models in Clinical Pharmacology and Translational Research: Do the Challenges Outweigh the Potential Benefits

FDD Open Forum ~ Thursday, November 18, 2010 1:00pm – 5:00pm
Formulation Strategies for Poorly Soluble Drugs

MSE Open Forum ~ Thursday, November 18, 2010 1:30pm – 5:00pm
Particles in Biopharmaceutical Parenteral Products

PPDM Open Forum ~ Thursday, November 18, 2010 1:30pm – 5:00pm
Ethnic Sensitivity in PK/PD: Leveraging Clinical Development in Emerging Countries — Using Knowledge of Ethnic Differences to Facilitate Drug Development

PPB Open Forum ~ Thursday, November 18, 2010 1:30pm – 5:00pm
The BCS, BDDCS and Regulatory Guidances

RS Open Forum (1) ~ Tuesday, November 16, 2010 7:00pm - 9:30pm
Practical Considerations for the 505 (B) (2) Regulatory Pathway and Patent Protection for Fixed Dose Combination Products and Other Products

RS Open Forum (2) ~ Thursday, November 18, 2010 1:30pm – 5:00pm
Establishing Clinically Relevant Dissolution Specifications in the Quality-by-Design World: Practical Implications and Regulatory Challenges

Workshop 1: AAPS Workshop on Contemporary Challenges and Advances Impacting the Development of Veterinary Pharmaceuticals		
Two Day Workshop: Saturday, November 13, 2010 8:30am – 5:00pm and Sunday, November 14, 2010 8:30am – 4:00pm		
Workshop	$1,325	$1,490
Government	$450	$525
Student	$70	$80
Workshop 2: AAPS Workshop on Harmonization of Regulatory Approaches for Evaluating Therapeutic Equivalence and Interchangeability of Multisource and Complex Drug Products		
Two Day Workshop: Saturday, November 13, 2010 8:30am – 5:00pm and Sunday, November 14, 2010 8:30am – 4:00pm		
Workshop	$1,325	$1,490
Government	$450	$525
Student	$70	$80
Workshop 3: USP Workshop on the Pharmacopeia's Role in Improving Global Health		
Two Day Workshop: Saturday, November 13, 2010 8:30am – 5:00pm and Sunday, November 14, 2010 8:30am – 4:00pm		
AAPS Member	$850	$850
Non Member	$975	$975
Workshop 4: ACCP Workshop on 6th International Symposium on Microdialysis ion Drug Research and Development 2010		
Two Day Workshop: Saturday, November 13, 2010 8:30am – 5:00pm and Sunday, November 14, 2010 8:30am – 4:00pm		
ACCP and AAPS Member Rate	$825	$825
Nonmember rate	$975	$975
Student/Trainee Member Rate	$275	$275
Student/Trainee Nonmember Rate	$315	$315
Workshop 5: CRS Workshop on Using Population Pharmacokinetics to Support the Development of Clinically Relevant Specifications for Extended Release Formulations		
One Day Workshop: Saturday, November 13, 2010 8:30am – 5:00pm	$995	$1,095

Additional Fees

CE Short Course	$50	$50
CE Annual Meeting	$50	$50
Closing Dinner	$125	$125
Located at the *Pavilion of the Two Sisters*: http://neworleanscitypark.com/pavilion.html		
Tipitina's Music Club Entry Fee:	Please register On-Site at our Tours Desk	
Saturday, November 13, 2010 *(Music Acts TBA in September)*		
Shuttle Bus to Magazine Street and Tipitina's Music Club	$5	$5

Payment Method — Check or Wire Transfer ONLY

Credit Card Payment Available Online Only at **www.pswc2010.org.**

AAPS does not accept purchase orders or government training forms. Federal Tax ID #521444968

❍ Check #_____, Payable to AAPS-2010PSWC/AM
(U.S. dollars drawn on a U.S. bank)

Signature Date

Total Fees

FIP PSWC 2010/AAPS Annual Meeting & Exposition	$

Special Events

Vet Pharm Workshop	$
Harmonization Workshop	$
USP Workshop	$
ACCP Workshop	$
CRS Workshop	$
Short Course	$
Open Forum(s)	$
Additional Fees	$
TOTAL	$

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November 14 – 18, 2010

Ernest N. Morial Convention Center
New Orleans, Louisiana, USA

Program at a Glance