

**ANNOUNCING AN APPLIED
TOXICOLOGY WORKSHOP
DEDICATED TO REDUCING
SAFETY-RELATED ATTRITION.**

DATES

Monday, May 11 – Wednesday, May 13, 2009

VENUE

Harvard Medical Conference Center
77 Avenue Louis Pasteur
Boston, Massachusetts

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**APPLIED PHARMACEUTICAL
TOXICOLOGY 2009**

OVERALL THEME

*Innovation, Insight, and Impact of Safety
Assessment in Drug Discovery and Development:
From Small Molecules to Biologics*

ORGANIZING COMMITTEE

Presiding Chair: Jim Xu – Merck
Chair-Elect: Kevin Leach – Merck

DISCOVERY TOXICOLOGY

Chair: Kevin Leach, Merck
Chair-Elect: Bruce Car, BMS
Committee: Drew Badger,
Amira Pharmaceuticals
Oliver Flint, BMS
Laszlo Urban, Novartis

DEVELOPMENT TOXICOLOGY

Chair: Rick Robertson, BMS
Chair-Elect: Jim Green, Biogen Idec
Committee: Page Bouchard, Archemix
Laura Andrews, Genzyme

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APPLIED PHARMACEUTICAL TOXICOLOGY 2009 AGENDA

DISCOVERY TOXICOLOGY

Monday, May 11, 2009 and Tuesday, May 12, 2009

Plenary Speakers

Bruce Car, BMS:

The mindset of discovery toxicology

Session I:

Leveraging Animal Models in Discovery

Lois Lehman, BMS:

Applying efficacy models to hazard identification: Valuable tools or red herrings?

John Donello, Allergan:

Don't kill my compound too quickly: Memoirs of a pharmacologist

Don Robertson, BMS:

Metabonomics approaches to discovery toxicology studies

Drew Badger, Amira:

Bridging the gap between discovery and regulatory toxicology

Session II:

Integrative Systems Approaches to Discovery Toxicology

Vishal Vaidya, Harvard:

KIM1 biomarker discovery of kidney tox

Bill Foster, BMS:

Applying toxicogenomics to risk assessment in discovery

Doug Lauffenburger, MIT:

Systems biology approaches to understanding idiosyncratic liver toxicity

Dmitri Mikhailov, Novartis:

Applying informatics to enhance quality of integrated safety assessment

Session III:

Application of in vitro Screening Technologies to Discovery Toxicology

Oliver Flint, BMS:

Adrenocortical toxicity following CYP11A1 metabolism of a kinase inhibitor

Steven Whitebread, Novartis:

Developing drugs with a good safety profile: The impact of in vitro safety pharmacology profiling

Scott Obach, Pfizer:

Covalent protein binding

Bob Chapin, Pfizer:

Utility of stem cells in tox studies

Allison Easter, AZ: TBA

DEVELOPMENT TOXICOLOGY

Tuesday, May 12, 2009 and Wednesday, May 13, 2009

Session I:

Predictivity of Non-clinical Safety Studies for Small Molecules

(Chair: Rick Robertson, BMS)

Derek Leishman, Lilly:

How well do non clinical studies predict clinical cardiac safety?

Paul Levesque, BMS:

Customizing CV safety strategy for early risk perspective

Dale L. Morris, Pfizer:

On- and off-target toxicities of p-38 MAP kinase inhibitors in the rat, dog, and monkey

Ronald Snyder, Schering:

The use of in silico and direct genotoxicity testing to evaluate potential genotoxicity impurities in drug products

Session II:

Non-clinical Development of Biologics

(Chair: Laura Andrews, Genzyme)

Jim Green, Biogen Idec:

Unique aspects of safety assessment programs for biologics

Laura Andrews, Genzyme:

Program designs and the selection of species utilized for safety assessment studies

Pauline Martin, Centocor:

Reproductive and development toxicology assessments for biologics

Shawn Heidel, Lilly:

Carcinogenicity assessments for biologics

Rafael Ponce, Amgen:

Immunogenicity issues related to the safety assessments of biologics

Session III:

Non-clinical Development of Oligonucleotide Therapeutics

(Chair: Page Bouchard, Archemix)

Art Levin, Consultant:

Introductory talk on the history of oligonucleotide therapeutics and broad based "class" effects and considerations

Scott Henry, ISIS:

Antisense oligonucleotide toxicology, specific considerations in program and study design, and general overview of key findings and risk assessment perspectives

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Tuesday, May 12, 2009 and Wednesday, May 13, 2009

Session III: (continued)

Christina Gamba-Vitalo, Alnylam:

siRNA toxicology, specific considerations in program and study design, and general overview of key findings and risk assessment perspectives

Page Bouchard, Archemix:

Aptamer toxicology, specific considerations in program and study design, and general overview of key findings and risk assessment perspectives

Husam Younis, Pfizer:

Immunostimulatory oligo toxicology, specific considerations in program and study design, and general overview of key findings and risk assessment perspectives

OTHER CONFERENCES BY THE BOSTON SOCIETY

Applied Pharmaceutical Chemistry
May 21 - 22, 2009

Applied Nanotechnology
July 28, 2009

Applied Pharmaceutical Software
July 29, 2009

Applied Proteomics Biotechnology
July 30, 2009

Applied Pharmaceutical Analysis
September 13 - 17, 2009

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