

ISRTP Workshop Program
Progress and Barriers
To Incorporating Alternative Toxicological Methods in the US

November 17, 8:30 – 4:30

November 18, 8:00 – 3:00

Marriott Waterfront Hotel
Baltimore, MD

Workshop Objective:

The objective of this workshop is to explore progress to date in implementing new, revised and alternative toxicological test methods across regulatory evaluation frameworks and decision-making programs in the US, identify barriers to progress and explore potential bridges to facilitate overcoming such barriers. These barriers may be technical, regulatory, economic or societal.

Workshop Work Products:

The workshop work products will include PowerPoint presentations to be posted on the ISRTP website as well as a written summary (to be published in *Regulatory Toxicology and Pharmacology*) that will include the recommendations of the panel discussions.

Workshop Outcomes:

- Better understanding of current alternatives research and validation efforts in the US (who, what, objectives of research; availability of resources);
- Enhanced understanding of environment stimulating alternatives research and how this is or is not linked with the regulatory communities who rely on test methods;
- Identification and understanding of barriers that impede progress;
- Recommendations to overcome these barriers.

Workshop Sponsors:

Procter & Gamble
National Institute of Environmental Health Sciences, National Toxicology
Program
American Chemistry Council
Cosmetic, Toiletry, and Fragrance Association
Dow Chemicals
U.S. Army Edgewood Chemical Biological Center
Yves Rocher
Humane Society of the United States
Doris Day Animal League

Endorsed by the Society of Toxicology

Please visit www.isrtp.org for program updates and registration information.

Program

November 17, 2005

7:30 – 8:30 Continental Breakfast

8:30 Welcome & Workshop Objectives: Goals & objectives of the workshop
Christopher J. Borgert (Treasurer, ISRTP)

8:45 Opening Address: The Future is Now - - Developing Partnerships to Advance the Development, Validation and Acceptance of New, Revised and Alternative Methods
Christopher Portier (NTP / NIEHS)

9:30 Session 1: Research, Development & Validation of Alternative Methods within the US Federal Government
This session will cover current efforts in US to develop, validate and incorporate new, revised and alternative toxicological methods into regulatory evaluation frameworks and decision-making programs.

Session Chairs: Sara Amundson (Doris Day Animal League)
Rick Becker (American Chemistry Council)

9:30 Session Introduction, Session Chairs

9:35 EPA's Computational Toxicology Program
David Dix (US EPA)

10:00 NTP's Vision of High Throughput Screening and Other Alternative Methods
Christopher Portier (NIEHS / NTP)

10:25 – 10:35 Break

10:35 Perspective on Standardization, Validation, and Use of Alternative Methods Within FDA CDER
Abigail Jacobs (FDA, CDER)

11:00 The Roles of NICEATM and ICCVAM
William Stokes (NIEHS / NICEATM)

11:25 Panel Discussion and Audience Dialogue

12:00-1:30 Lunch

1:30 Session 2: Emerging Alternative Methodologies with Potential Applicable to a Broad Spectrum of Toxicity Evaluation Strategies

Speakers will be asked to cover some of the scientific, technical, and sociological challenges that need to be met before the new methods can be effectively applied.

Session Chair: William Stott (Dow Chemicals)

1:30 Session Introduction, William Stott

1:35 The Future of SAR and Predictive Toxicology in a Flattening World
Ann Richard (US EPA / NCCT)

2:00 Computational Approach to Systems Toxicology – a Common Path to Mechanism and Biomarkers
Pieter Muntendam (BG Medicine)

2:25 – 2:55 Break

2:55 An Overview of High-Throughput Screening
William Janzen (Amphora)

3:20 Organ on a Chip
Albert Li (The ADMET Group)

3:45 Panel Discussion and Audience Dialogue

4:30 Adjourn

November 18, 2005

7:00 – 8:00 Continental Breakfast

8:00 Session 3: Tiered Evaluation Strategies

Speakers will be asked to address the current status of tiered strategies and where their use is envisioned in the future; what are some of the key barriers to wider use?

Session Chairs: Jay Ansell (Yves Rocher North America, Inc.)
Simon Webb (Procter & Gamble)

8:00 Session Introduction, Jay Ansell / Simon Webb

8:10 Tiered Evaluation Strategies: Experiences from HPV Programs
Larry Rampy (American Chemistry Council)

8:40 ILSI Agricultural Chemical Safety Assessment (ACSA) Project: A Tiered Testing Approach
Ann Blacker (Bayer Crop Science)

9:10 Intelligent Testing Under REACH
David Owen (Shell Chemicals)

9:40 – 9:50 Break

9:50 Canadian Experiences Under CEPA/DSL
Bette Meek (Health Canada)

10:20 Tiered Evaluation Strategies: An Animal Protection Perspective
Martin Stephens (Humane Society of the United States)

10:50 Panel Discussion and Audience Dialogue

11:30 – 12:30 Lunch

12:30 Session 4: Roundtable Discussion

Discussion will identify: 1) What are the critical (4-5) barriers and 2) What are the key recommendations for overcoming these barriers?

A rapporteur will capture dialog & recommendations.

Facilitated Discussion Leader:		Leon Bruner (Gillette)
Stakeholders:	Academic	Alan Goldberg (JHU)
	Government	William Stokes (NIEHS/NICEATM)
	Animal Welfare	Andrew Rowan (HSUS)
	Industry	William Stott (Dow Chemicals)
	Private Sector / Contract Research	Rodger Curren (IIVS)

1:45 – 2:15 Break

3:00 - Adjourn