

***Genetic Toxicology in the 21<sup>st</sup> Century:  
The Scientific Basis for New Technologies and Regulatory Guidance***

September 15-16, 2010  
John M. Clayton Hall Conference Center  
University of Delaware, Newark, DE

Scientific Meeting Program

**Wednesday, September 15, 2010**

***Breakfast and Registration***

7:30 – 8:20 a.m.

---

***Welcome and Introduction***

8:20 – 8:30 a.m. Sandy Weiner, Johnson & Johnson, GTA Chair

---

***Symposium I***

8:30 a.m. – 10:15 a.m. ***Screening Strategies and Methods to Predict Genotoxicity***

Chairs: Patricia Escobar and Kamala Pant

---

8:30 – 8:45 a.m. Bacterial mutagenicity screening and an overview of pharmaceutical strategies  
Brinda Mahadevan, Merck Research Laboratories

8:45 – 9:15 a.m. Integration of genotoxicity and general toxicity screening approaches in Drug  
Discovery  
Marlies De Boeck, Johnson & Johnson

9:15 - 9:45 a.m. Genotoxicity testing without *in vivo* data: Challenges for the cosmetic industry and  
possible solutions  
Stefan Pfuhler, Procter & Gamble

9:45 – 10:15 a.m. The role of quantitative high throughput testing in genetic toxicology  
Raymond Tice, Biomolecular Screening Branch, National Toxicology Program  
National Institute of Environmental Health Sciences

---

10:15 – 10:30 a.m. *Coffee break*

---

***Symposium II***

10:30 a.m.-12:10 p.m. ***Cellular Response to DNA damage***

Chairs: Ofelia Olivero and Margaret Pratt

---

10:30 – 10:55 a.m. Biomonitoring of human DNA damage: The promise for prediction of human  
cancer risk  
Miriam Poirier, National Cancer Institute, NIH

10:55 – 11:20 a.m. Environmental epigenomics and disease risk  
Randy Jirtle, Duke University

11:20 a.m. – 11:45 a.m. Causes and consequences of chromosomal aberrations in cancer cells  
Thomas Ried, National Cancer Institute, NIH

11:45 a.m. – 12:10 p.m. Genetic susceptibility to breast cancer in Puerto Rico  
Jaime Matta, University of Puerto Rico

---

---

**Lunch and Awards Presentation**

12:10 – 1:15 p.m.

---

---

**Symposium III**

1:15 – 4:15 p.m.      **Integration of single or multiple genotoxicity endpoints into in vivo studies**  
Chairs: Krista Dobo and Andrew Olaharski

---

1:15 – 1:45 p.m.      Session Introduction: Advantages and disadvantages of integrating genetic toxicology assessment into in vivo studies.  
Sheila Galloway, Merck

1:45 – 2:15 p.m.      Integrating in vivo comet and in vivo micronucleus assessment into a single acute study  
Ulla Plappert, Novartis

2:15- 2:45 p.m.      *Coffee break*

2:45 – 3:15 p.m.      Integration of the Pig-a mutation assay into a 28-day study design.  
Steve Dertinger, Litron

3:15 – 3:45 p.m.      A multi-endpoint comparison of in vivo genotoxicity using a 28-day study design:  
In vivo micronucleus, in vivo comet and Pig A  
Zoryana Cammerer, Pfizer

3:45 – 4:15 p.m.      Open discussion

---

---

**Poster Session**

5:30 – 7:00 p.m. (Presenters will be at posters)

---

---

**Dinner (included in the 2-day registration fee)**

7:00 – 8:30 p.m.

---

---

## Thursday, September 16, 2010

### **Breakfast and Registration**

7:00 – 8:00 a.m.

---

---

### **Symposium IV**

8:00 – 10:15 a.m.      ***In Silico Analysis: Theory and Applications***

Chairs: Brinda Mahadevan & Sandy Weiner

---

8:00 – 8:20 a.m.      Introduction and overview of in silico analysis  
Russell Naven, Pfizer Global R & D

8:20 – 8:45 a.m.      Use of QSAR in genetic toxicology: Real-life examples using in silico modeling  
Charlotta Fred, AstraZeneca

8:45 – 9:10 a.m.      Applications of QSAR for regulatory use at the FDA  
Dan Benz, US-FDA

9:10 – 9:35 a.m.      In silico prediction of the mutagenicity of aromatic amines based on nitrenium ion  
stabilities  
Ray Kemper, Boehringer-Ingelheim

9:35 – 9:50 a.m.      *Coffee break*

9:50 – 10:15 a.m.      New developments in in silico analysis for genotoxicity prediction  
Ron Snyder, Merck Research Laboratories

---

---

### **Symposium V**

10:15 a.m. – 12:00 p.m.      ***New Technologies***

Chairs: Chris Farabaugh and Zhanna Sobol

---

10:15 – 10:45 a.m.      New and emerging technologies for genetic toxicology testing: Results of a HESI-  
IVGT workshop and critical analysis  
Jennifer Sasaki, Johnson and Johnson

10:45 – 11:10 a.m.      Photogenotoxicity and photocarcinogenesis  
Paul Howard, National Center for Toxicological Research (NCTR), US-FDA

11:10 – 11:35 a.m.      Genotoxicity of nanoparticles  
Maria Donner, DuPont

11:35 a.m.–12:00 p.m.      Genetic toxicology of oligonucleotide therapeutics  
Husam Younis, Isis Pharmaceuticals, Inc.

---

---

### **Lunch and Business Meeting**

12:00 – 1:00 p.m.

---

---

**Symposium VI**

1:00 – 3:50 p.m.      **Update on Actual and Proposed Regulatory Changes**  
Chairs: Jane Clarke and Graeme Smith

---

1:00 – 1:25 p.m      How to follow up on positive *in vitro* results  
Kerry Dearfield, USDA

1:25 – 1:50 p.m      ICH S2 revision update  
Anita Bigger, FDA

1:50 – 2:15 p.m      Status of OECD guideline for the *in vitro* micronucleus assay: How did it get  
where it is and where is it going?  
Marilyn Aardema, Marilyn Aardema Consulting LLC

2: 15– 2:30 p.m      *Coffee break*

2:30 – 2:55 p.m      OECD draft testing guideline 487 and beyond: Further validation of *in vitro* MN  
testing by flow cytometry  
Jing Shi, BioReliance

2:55 – 3:20 p.m      A perspective about on-going debates within GeneTox testing  
David Eastmond, University of California, Riverside

3:20 – 3:50 p.m.      Open discussion

---

---

**Closing Comments**

3:50 p.m.      Sandy Weiner, Johnson & Johnson, GTA Chair

---

---