

**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.

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*Welcome and Introduction*

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

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*Symposium I*

8:30 a.m. – 10:15 a.m. **Screening Strategies and Methods to Predict Genotoxicity**  
Chairs: Patricia Escobar and Kamala Pant

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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  
Marillies 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 and Kristine Witt  
Biomolecular Screening Branch, National Toxicology Program  
National Institute of Environmental Health Sciences

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10:15 – 10:30 a.m. *Coffee Break*

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*Symposium II*

10:30 a.m.-12:15 p.m. **Cellular Response to DNA damage**  
Chairs: Ofelia Olivero and Margaret Pratt

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10:30 – 11:00 a.m. Cellular senescence as a p53- and microRNA- dependent tumor suppressor  
mechanism  
Curtis Harris, National Cancer Institute, NIH

11:00 – 11:30 a.m. Environmental Epigenomics and Disease Risk  
Randy Jirtle, Duke University

11:30 a.m. – 12:00 p.m. Causes and consequences of chromosomal aberrations in cancer cells  
Thomas Ried, National Cancer Institute, NIH

12:00 – 12:15 p.m. Genetic susceptibility to breast cancer in Puerto Rico  
Jaime Matta, University of Puerto Rico

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***Lunch and Awards Presentation***

12:15 – 1:15 p.m.

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***Interactive Workshop I***

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

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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. 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

3:15 – 3:45 p.m. Validation of the in vivo Pig A assay using a 28-day study design  
Steve Dertinger, Litron

3:45 – 4:15 p.m. Open discussion

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***Poster Session***

5:30 – 7:00 p.m.

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

7:00 – 8:30 p.m.

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Thursday, September 16, 2010

***Breakfast and Registration***

7:00 – 8:00 a.m.

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***Symposium III***

8:00 – 10:15 a.m.      ***In Silico Analysis: Theory and Applications***  
Chairs: Brinda Mahadevan & Sandy Weiner

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

8:20 – 8:45 a.m.      New developments in in silico analysis for genotoxicity prediction  
Ron Snyder, Merck Research Laboratories

8:45 – 9:10 a.m.      Use of QSAR in genetic toxicology: Real-life examples using silico modeling  
Charlotta Fred, AstraZeneca

9:10 – 9:35 a.m.      Applications of QSAR for regulatory use  
Dan Benz, US-FDA

9:35 – 9:50 a.m.      Coffee break

9:50 – 10:15 a.m.      In silico prediction of the mutagenicity of aromatic amines based on nitrenium ion  
stabilities  
Ray Kemper, Boehringer-Ingelheim

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***Symposium IV***

10:15 a.m. – 12:00 p.m.      ***New Technologies***  
Chairs: Chris Farabaugh and Zhanna Sobol

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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 – 11:15 a.m.      Photogenotoxicity and Photocarcinogenesis  
Paul Howard, National Center for Toxicological Research (NCTR), US-FDA

11:15 – 11:45 a.m.      Genotoxicity of Nanoparticles  
Maria Donner, DuPont

11:45 a.m.–12:00 p.m.      Genetic Toxicology of Oligonucleotide Therapeutics  
Husam Younis, Isis Pharmaceuticals, Inc.

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***Lunch and Business Meeting***

12:00 – 1:00 p.m.

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***Interactive Workshop II***

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

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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– 2:05 p.m      *Coffee Break*

2:05 – 2:30 p.m      The status of *in vitro* micronucleus in the OECD guidelines  
Marilyn Aardema

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

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***Closing Comments***

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

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