

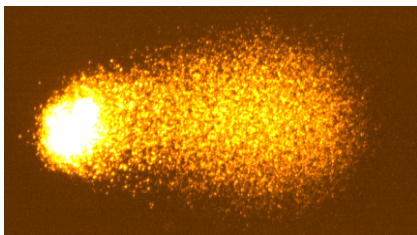


**The Genetic Toxicology Association
Announces a Two-Day Meeting**

**Current Regulatory and Scientific
Issues in Genetic Toxicology**

September 10 – 11, 2008

**John M. Clayton Hall Conference Center
University of Delaware
Newark, Delaware**



Visit the GTA web-site for updates to meeting information at
www.gta-us.org

Genetic Toxicology Association Meeting
Current Regulatory and Scientific Issues in Genetic Toxicology

September 10 -11, 2008
John M. Clayton Hall Conference Center
University of Delaware, Newark, DE

Scientific Program

Wednesday, September 10th, 2008

Breakfast and Registration

8:00 – 9:20 a.m.

Welcome and Introduction

9:20 – 9:30 a.m. Matt Cowlen, GTA Chair

Keynote Presentation

9:30 – 10:30 a.m. Review of 30 Years of Research on the Occurrence, Genotoxicity, and
Carcinogenicity of Disinfection By-products in Drinking Water: Roadmap for
Research
David DeMarini, US-EPA

Symposium

10:30 a.m.–1:00 p.m. ***New Developments in Genetic Toxicity Testing: Employing the Best
Science***
Chairs: Warren Ku, Jay Goodman

10:30– 11:00 a.m. Genotoxicity and Carcinogenicity Testing: What are We Doing and What Should We
Be Doing?
Jay Goodman, Michigan State University

11:00 – 11:30 a.m. *Coffee Break*

11:30 – 12:00 a.m. Why Not a Single Test?
Jiri Aubrecht, Pfizer Global R & D

12:00 – 12:30 p.m. New Applications of the Comet Assay in GeneTox Testing
Patricia Escobar, Boehringer-Ingelheim

12:30 – 1:00 p.m. Genetic Toxicology Assessment: Balancing Regulation and Science
Jim MacGregor, Toxicology Consulting Services

Lunch

1:00 – 2:00 p.m.

Interactive Workshop

2:00 – 4:30 p.m. ***Case Studies in Genetic Toxicology***
30 minute presentations, followed by 20 minutes of panel discussion
Chairs: Maria Donner, Krista Dobo
Moderator: Rosalie Elespuru
Expert Panel: Maik Schuler, Dan Levy, David Brusick

Interactive Workshop (continued)

- 2:00 – 2:50 p.m. Risk Assessment of Genotoxic Impurities: The Case of EMS
Elmar Gocke, Roche
- 2:50 – 3:40 p.m. What Makes an *In Vitro* Positive Irrelevant? A Case Study with Eugenol
Dan Levy, CFSAN, FDA
- 3:40 – 4:30 p.m. Risk Management Strategies for Bacterial Mutagens
Michelle Kenyon, Pfizer Global R & D
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Award Presentations and Business Meeting

4:30 – 5:30 p.m.

Poster Session/Mixer

5:30 – 7:30 p.m.

Thursday, September 11th, 2008**Registration and Student Networking Breakfast – Meet the Experts**

7:30 – 8:30 a.m.

Mini-Symposium

- 8:30 – 9:30 a.m. **Chemical Carcinogenicity and Cancer Risk Assessment**
Chairs: Chris Farabaugh, Magnus Evertson
-
- 8:30 – 9:00 a.m. Prediction of Non-genotoxic Carcinogenesis in Rats Using Changes in Gene Expression Following Acute Dosing
Paul Nioi, Schering-Plough Research Institute
- 9:00 – 9:30 a.m. Use of Genotoxicity Data in Mode of Action Analysis for Human Health Risk Assessment
Channa Keshava, US-EPA
-
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Symposium

- 9:30 a.m. – 12:00 **Assay Improvements and New Technologies**
Chairs: Jane Clarke, Brinda Mahadevan
-
- 9:30 – 10:00 a.m. Overview of the Latest Recommendations for Interpreting Data from the Mouse Lymphoma Assay
Martha Moore, US-FDA, NCTR
- 10:00 – 10:30 a.m. *Coffee Break*
- 10:30 – 11:00 a.m. The Comet Assay: Breaking With Tradition
Marie Vasquez, Helix Inc.
- 11:00 – 11:30 a.m. High Density Electro-optical Toxicity Screening Arrays and Complementary Biocolloid LC-MS Methods
Jim Rusling, University of Connecticut
- 11:30 – 12:00 p.m. Pig-A Gene – A New Endogenous Target for Detection of In Vivo Mutation Using Flow Cytometry
Vasily Dobrovolsky, US-FDA, NCTR
-

Lunch and Award Presentations

12:00 – 1:00 p.m.

Interactive Workshop

1:00 – 4:00 p.m. **ICH/HESI/IVGT Update and Panel Discussion**

Chairs: Jiaqin Yao, Leon Stankowski

Moderator: Dan Benz

Expert Panel: Sheila Galloway, Rosalie Elespuru, Bhaskar Gollapudi, David Jacobson-Kram

1:00 – 1:30 p.m.

Changes to ICH S2: Why They Are Needed, How They Will Help.

David Jacobson-Kram, US-FDA

1:30 – 2:00 p.m.

Update on ICH Guidelines

Sheila Galloway, Merck Research Laboratories

2:00 – 2:15 p.m.

Coffee Break

2:15 – 2:45 p.m.

ILSI and ICH Battery Maintenance: Increased Voltage or Hazard Identification Short Circuit?

Rosalie Elespuru, US-FDA CDRH

2:45 – 3:15 p.m.

The ILSI-HESI Initiative on Relevance and Follow-Up of Positive Results in *In Vitro* Genetic Toxicity Testing (IVGT)

Bhaskar Gollapudi, Dow Chemical Company

3:15 – 4:00 p.m.

Expert Panel Discussion

Closing Comments

4:00 p.m.

Matt Cowlen – GTA Chair

Program Committee

Matt Cowlen

Inspire (GTA Chairman)

Chris Farabaugh

Covance Laboratories (GTA Assistant Treasurer)

Jiaqin Yao

CDER/FDA (GTA board)

Warren Ku

Pfizer Global R&D (GTA board)

Organizing Committee

Matt Cowlen

Inspire (GTA Chairman)

Jane Clarke

BioReliance (GTA board)

Krista Dobo

Pfizer Global R&D (GTA newsletter editor)

Maria Donner

DuPont Haskell (GTA Membership Chair)

Patricia Escobar

Boehringer Ingelheim (GTA board)

Magnus Evertson

Boehringer Ingelheim Pharmaceuticals, Inc (GTA Secretary)

Chris Farabaugh

Covance Laboratories (GTA Assistant Treasurer)

Warren Ku

Pfizer Global R&D (GTA board)

Brinda Mahadevan

Schering-Plough (GTA board)

Ofelia Olivero

NCI (GTA Student Outreach)

Leon Stankowski

Covance Laboratories (GTA Treasurer)

Jiaqin Yao

CDER/FDA (GTA board)

2008 BOARD OF DIRECTORS ELECTION CALL FOR GTA BOARD OF DIRECTOR NOMINEES

This year at the fall meeting, two members of the board of directors (Warren Ku and Matt Cowlen) will complete their terms in office. Therefore the board of directors is calling on the GTA membership for nominees, with elections to be held at the upcoming meeting. Members of the board of directors serve a 3 year term and are responsible for a variety of activities. A couple of the primary responsibilities include planning and chairing meetings and attending up to 4 board meetings a year. Serving as a member of the board of directors provides an opportunity to get to know others in the field, and directly influence the current activities and future direction of the association. Please contact Matt Cowlen if you would like to nominate someone for the fall election. (Contact information located on the back of the Newsletter).

MEETING REGISTRATION FORM

REGISTER AND PAY ON-LINE at <http://www.gta-us.org>.
Alternatively you can register by completing this form and sending it along with payment to the GTA Treasurer, Leon Stankowski. Registration includes full hot breakfast and lunch both days as well as food and beverages for coffee breaks and at the poster session/mixer.

Name, Affiliation & Address:

Register By August 24:

- Student Registration - FREE
- \$225 Member Registration
- \$275 Non-member Registration

After August 24/ Including On-Site

- \$50 Student Registration
- \$275 Member Registration
- \$325 Non-member Registration

Annual Membership Dues

- \$40 Full Members
- \$20 Student Members

Phone: _____ Fax: _____

TOTAL Enclosed: _____

Email: _____



Check here if information has changed.

Registration does not include dues. Make checks payable to: Genetic Toxicology Association
Send this form to:

Leon Stankowski
Treasurer, Genetic Toxicology Association
Covance Laboratories, Inc.
9200 Leesburg Pike
Vienna, VA 22182
Fax (703) 759-5782
E-mail: leon.stankowski@covance.com

Poster Session Call For Abstracts – Deadline Extended to August 18, 2008

You are invited to present a poster at the meeting on Wednesday, September 10, 2008. Abstracts should be submitted via the GTA web-site by August 18, 2008 (www.gta-us.org). For updates and more information on the poster session and abstract submission, please visit the GTA web-site at www.gta-us.org.

Meeting Venue

The meeting will be held at the John M. Clayton Hall Conference Center on the campus of the University of Delaware in Newark, DE (not to be confused with Newark, NJ). Newark, DE is just north of the Delaware-Maryland border. Philadelphia, PA is the closest city for airport connections. The closest train station is Newark, DE (about a 15 minute cab ride from Newark to Wilmington).

DIRECTIONS TO THE UNIVERSITY OF DELAWARE / LAIRD CAMPUS

*From the North (Including the Philadelphia Airport**):* Take Interstate 95 South to Delaware exit 1B which is Route 896 North towards Newark, Delaware. Stay on Route 896 through the campus of the University of Delaware in Newark. Route 896 winds through the campus following S. College Ave. to Main St., where it turns left on Main St. until it reaches New London Rd., where it turns right to follow New London Rd. Clayton Hall is on the right on New London Rd./Route 896, at the University of Delaware Laird Campus, which is just north of the main campus. Remember, STAY ON RT. 896!

From the South: Take Interstate 95 North to Maryland exit 109B which is Route 279 East. Continue on Route 279 which becomes Delaware Route 2 upon crossing the state line. Follow Route 2 into the town of Newark, turning right onto West Delaware Ave. to stay on Route 2. At the intersection with S. College Ave. (Route 896), turn left. Stay on Route 896 through the campus of the University of Delaware in Newark. Follow S. College Ave. briefly to Main St., where Route 896 turns left on Main St. until it reaches New London Rd, where it turns right to follow New London Rd. Clayton Hall is on the right on New London Rd./Route 896, at the University of Delaware Laird Campus which is just north of the main campus. Remember, STAY ON RT. 896!

**In addition to rental car availability at Philadelphia airport, Delaware Express Shuttle provides around-the-clock service to the Newark area. Reservations must be made 24 hrs in advance (800-648-5466 or www.delexpress.com). Return pickup is approximately 2 hours prior to flight time.

ACCOMMODATIONS

The following four hotels are in Newark, Delaware. The Courtyard by Marriott is on the University of Delaware campus adjacent to Clayton Hall. The GTA has secured a block for rooms for a discounted rate. This rate is available until the block of rooms has been reserved or 30 days prior to the meeting (whichever comes first).

Courtyard by Marriott

400 Pencader Way
Tel: 302-737-0900
Restaurant on premises
Free continental breakfast
Walk to the Meeting, Adjacent to Clayton Hall

Homewood Suites

640 South College Avenue
Tel: 302-453-9700
Free continental breakfast

Sleep Inn

630 South College Avenue
Tel: (302)453-1700 or 800-753-3746
Local restaurants will deliver to your room

Embassy Suites

654 South College Avenue
Tel: (302)368-8000
TGIF on premises
Free continental breakfast

Other hotels/motels clustered off of Delaware I-95:

Fairfield Inn by Marriott

Exit 4B from Delaware I-95
65 Geoffrey Drive
Tel: (302) 292-1500 or
800-228-2800

McIntosh Motor Inn

Exit 3 from Delaware I-95
100 McIntosh Plaza
Tel: (302) 453-9100 or
800-444-2775
Free continental breakfast

Holiday Inn

Exit 3 from Delaware I-95
1203 Christiana Road (Route 273)
Tel: (302) 737-2700 or 800-465-4329
Restaurant on site

Hampton Inn

Exit 3 from Delaware I-95
5 Concord Lane
Tel: 800-426-7866

Best Western Newark

Exit 3 from Delaware I-95
260 Chapman Road
Tel: 800-633-3203

Courtyard by Marriott

Exit 4B from Delaware I-95
48 Geoffrey Drive
Tel: 800-321-2211

Commercial Exhibitors

Space will be available for commercial exhibitors. Companies active in the area of genetic toxicology or related businesses, are encouraged to present their products or services at this meeting.

Corporate Sponsorship

The GTA, a tax-exempt educational and scientific organization, is inviting organizations to support our efforts to foster sustained excellence in genetic toxicology. Any contributions will be used to help support activities promoting scientific excellence and education in this field. Two contribution mechanisms are available: 1) Annual Sustaining

Membership (Gold: \$500 or Silver: \$250) for non-designated use by the GTA, and 2) Targeted Contribution towards a specific event or function (e.g. a meeting session, break or lunch; offsetting general meeting expenses; student travel award).

For further information regarding exhibiting or sponsorship contact:

Leon Stankowski, Treasurer
Genetic Toxicology Association
Covance Laboratories, Inc.
9200 Leesburg Pike
Vienna, VA 22182
Phone: (703) 245-2200 X5329
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Our Sponsors

