GTA 2018 Annual Meeting Schedule: May 2-4

Day 1: Wednesday May 2nd

Workshop I: ***Deriving compound specific exposure limits for chemicals used in pharmaceutical synthesis***

1:30 – 5:30 p.m. Chairs: Krista Dobo, Pfizer Worldwide Research and Development and Will Drewe, Lhasa Limited

Presenters: Joel Bercu, Gilead
Trish Parris, Astra Zeneca
John Nicolette, Abbvie
Zhanna Sobol, Pfizer Worldwide Research and Development

Abstract:
The calculation of compound specific Acceptable Intakes (AIs)/Permissible Daily Exposures (PDEs) to establish allowable limits for impurities in pharmaceuticals is an accepted practice. However, the process is often time consuming and costly, with the potential for duplicative and/or non-equivalent assessments being generated at multiple companies and submitted to regulatory agencies. Led by Lhasa Limited, the AI/PDE project has brought together an expert, cross-industry consortium to share and harmonise AI and PDE monographs for reagents and solvents commonly used in pharmaceutical synthesis. This workshop will seek to introduce the AI/PDE data sharing project and explore, through a series of case studies and discussion topics, some of the common challenges encountered when developing a monograph, including data selection, assignment of safety factors, approaches to use in absence of data, and approaches for establishing limits for different routes of administration.

Workshop II:	***Latest Developments in Regulation and Assessment of Combustible and Alternative Tobacco Products***
Sponsored by:	***Altria Client Services, British American Tobacco, Charles River Laboratories, Japan Tobacco, Reynolds American Incorporated Services Company, Philip Morris International***
1:00 – 6:00 p.m.	Chairs: Leon Stankowski, Charles River Laboratories, Martha Moore, Ramboll Environ International
Presenters:	Phil Yeager, US FDA Center for Tobacco Products Hans Rosenfeldt, US FDA Center for Tobacco Products Julie Clements, Covance Kei Yoshino, Japan Tobacco Jingjie Zhang, Altria Client Services Marianna Gaca, British American Tobacco Betsy Bombick, Reynolds American Incorporated Services Company Daniel Smart, Philip Morris International

Abstract:
Genetic toxicity testing has been used for many years to assess tobacco products, particularly as a part of product stewardship. They have been applied to a variety of products, including individual ingredients, combustible cigarettes, heat-not-burn cigarettes, cigars, water pipes, smokeless tobacco, etc. These tests have provided data to: 1) evaluate the potential toxicity of individual additives; 2) provide direct comparison of combustible tobacco products; and 3) compare traditional combustible tobacco products with various newer tobacco products with potentially reduced health risks. In recent years, new regulations and guidances have been adopted in a number of countries that recommend or require specific genetic toxicology tests as a part of a battery of tests that are to be conducted and submitted. More recently, electronic nicotine delivery systems (ENDS) have become subject to these regulations and guidelines, and genetic toxicology tests are now being applied to these products. This workshop will provide a general overview of the international regulation of tobacco products, and the associated – and challenging – technical issues, as related to genetic toxicology testing of these products. Specific research approaches and studies, using several different genetic toxicology assays for assessing combustible or heated tobacco products, as well as ENDS, will be presented.

GTA 2018 Annual Meeting Schedule: May 2-4

Day 2: Thursday May 3rd
Breakfast and Registration
7:30 – 8:30 a.m.

Welcome and Introduction

8:30 – 8:40 a.m. Michelle Kenyon**,** *Pfizer Worldwide Research and Development*
GTA Chair

Keynote Speaker
Sponsored by: Pfizer

8:40 – 9:40 a.m. **CRISPR overview and practical applications**
Yan Zhang, University of Michigan

Symposium I: ***CRISPR, a powerful new technology: Applications and regulatory issues***
Sponsored by: ***Charles River Laboratories***

9:40 – 11:40 a.m. Chairs: Sarah Hurtado, Charles River Laboratories, Jeff Bemis, Litron Laboratories

9:40 – 10:10 a.m. **CRISPR-Directed Gene Editing in vitro; a Novel System for the Identification of Regulatory and Genotoxic Factors in a Cell-Free Environment**
Eric Kmiec, Helen F. Graham Cancer Center

10:10 – 10:40 a.m. **Combined CRISPRi/a-Based Chemical Genetic Screens Reveal that Rigosertib is a Microtubule-Destabilizing Agent**
Marco Jost, UCSF

10:40 – 11:10 a.m. ***Coffee Break***
Sponsored by: ***Environmental Mutagenesis and Genomics Society***

11:10 – 11:40 a.m. **Regulatory Considerations for CRISPR/Cas-based Gene Edited Products: An FDA Perspective**
Sandhya Sanduja, US FDA

11:40 – 12:00 p.m. ***GTA 2017 Business Meeting***

12:00 – 1:10 p.m. ***Networking Lunch***

Symposium II: ***Case Studies/Key Problems in Genetic Toxicology***
Sponsored by: ***Society of Toxicology***

1:10 – 2:20 p.m. Chairs: Stephanie Kellum, DuPont, Jennifer Sasaki, Genentech

1:10 – 1:25 p.m. **Case Study: I Can See Clearly Now (Genetox is Done!)**
John Nicolette, Abbvie

1:25 – 1:40 p.m. **Sex, Drugs and GeneTox**
Zhanna Sobol, Pfizer Worldwide Research and Development

1:40 – 2:00 p.m. **Risk Assessment of Two Mutagenic Diboron Reagents**
Krista Dobo, Pfizer Worldwide Research and Development

2:00 – 2:20 p.m. **Are All Ames Strains in the OECD Mutagenicity Test Guideline 471 Useful and Necessary? An Analysis of Large Mutagenicity Data Sets for the IWGT**
Richard Williams, Lhasa

2:20 – 2:50 p.m. ***Coffee Break***

Symposium III ***Case Studies Focus Topic: Aryl Boronic acids in Pharmaceutical Development***
Sponsored by: ***Society of Toxicology***

2:50 –3:50 p.m. Chairs: Stephanie Kellum, DuPont, Jennifer Sasaki, Genentech

2:50 – 3:10 p.m. **Introduction and Review of Bacterial Mutagenicity of Aryl Boronic Acids**
Joel Bercu, Gilead

3:10 – 3:30 p.m. **Genotoxicity of Aryl Boronic Acids In Vitro in Mammalian Cells**
Michelle Kenyon, Pfizer Worldwide research and Development and Vijay Reddy, Merck

3:30 – 3:50 p.m. **In Vivo Genotoxicity of Aryl Boronic Acids**
Melisa Masuda-Herrera, Gilead

Speed Session of Poster Presentations

3:50 – 4:30 p.m. Chairs: Maria Engel and Randy Spellman, Pfizer Worldwide Research and Development

Poster Session and Cocktails

Sponsored by: ***MilliporeSigma***

5:00 – 7:00 p.m. *Presenters will be at their posters as follows:*
Odd numbers from 5:00 to 6:00 p.m.
Even numbers from 6:00 to 7:00 p.m.

7:00 – 8:30 p.m. ***Dinner (included in the 2-day registration fee)***

Special Event: ***Natural Foods and Dietary Supplements Safety: Consumer perceptions and scientific reality***
Jim MacGregor discusses content from his upcoming book on the impact of natural products on human health.

Sponsored by: ***Litron Laboratories***

GTA 2018 Annual Meeting Schedule: May 2-4

Day 3: Friday May 4th
Breakfast and Registration
7:00 – 8:15 a.m.

Welcome to Day 2
8:15 – 8:30 a.m. Sara Hurtado, Charles River Laboratories, Chair-Elect

Symposium IV: ***IWGT 2017 Update***
Sponsored by: ***MilliporeSigma***

8:30 – 9:45 a.m. Chairs: Kevin Cross, Leadscope, Rosalie Elespuru, US FDA

8:30 – 8:45 a.m. 3D Models – Rodger Curren, Institute for In Vitro Sciences (IIVS)

8:45 – 9:00 a.m. Ames – Errol Zeiger, Errol Zeiger Consulting

9:00 – 9:15 a.m. Aneugens – Maik Schuler, Pfizer Worldwide Research and Development

9:15 – 9:30 a.m. In Vitro Mutation – Bhaskar Gollapudi, Exponent

9:30 – 9:45 a.m. In Vivo Strategy – Dan Levy, US FDA

9:45 – 10:15 a.m. ***Coffee Break***

10:15 – 11:00 a.m. ***Award Presentations***

Symposium V: ***Tools and Approaches for Clinical Biomonitoring of Genomic Damage***
Sponsored by: ***Pfizer***

11:00 –12:00 p.m. Chairs: Jeff Bemis, Litron Laboratories, Michelle Kenyon, Pfizer Worldwide Research and Development

11:00 – 11:20 a.m. **Comprehensive Analysis of DNA Repair Capacity in Human Leukocyte Subtypes**
Zach Nagel, Harvard University

11:20 – 11:40 a.m. **Genetic Variant in DNA Repair Gene GTF2H4 is Associated with Lung Cancer Risk**

Qingyi Wei, Duke University

11:40 – 12:00 p.m. **Advanced Tools for DNA Repair and DNA Damage Analysis**
Robert Sobol, University of South Alabama Mitchell Cancer Institute

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12:00 – 1:15 p.m. Lunch

Symposium VI: ***Mechanisms of Action***
Sponsored by: ***Bristol-Myers Squibb***

1:15 - 2:45 p.m. Chairs: Steven Bryce, Litron Laboratories, Maik Schuler, Pfizer Worldwide Research and Development

1:15 - 1:45 p.m. **New Application of Predictive Toxicogenomic Signatures to Identify Genotoxic Agents**
Chris Corton, US EPA

1:45 - 2:15 p.m. **The Role of Cellular imaging in the Mode of Action Assessment of Clastogens and Aneugens**
Liz Rubitski, Pfizer Worldwide Research and Development

2:15 - 2:45 p.m. **Genotoxic Mode of Action of Acrylamide**
Nikolai Chepelev, Health Canada

2:45 – 3:00 p.m. ***Concluding Remarks***
Sara Hurtado, Charles River Laboratories, Chair-Elect