Course Description

This annual ACT course, formerly titled Toxicology for Industrial and Regulatory Scientists, provides basic training in general toxicology. Using pharmaceutical development as examples, participants will obtain an overall understanding of the principles of toxicology and nonclinical safety evaluation. The course will include discussion of regulatory case studies and hands-on analyses of nonclinical data. The course is intended to benefit individuals working with small and large molecules from biotechnology and pharmaceutical companies, CROs, and regulatory agencies, or individuals interested in or currently practicing toxicology.

Monday, April 25

**Principles of Toxicology**
A. Wallace Hayes, Harvard School of Public Health

**Introduction to Pharmacology for the Toxicologist**
Amy Avila, US Food and Drug Administration

**Principles of Drug Metabolism and Toxicokinetics and Applications to Industrial Toxicology**
Matthew Bogdanffy, Boehringer-Ingelheim Pharmaceuticals, Inc.

**Safety Pharmacology for Human Pharmaceuticals**
Simon Authier, CiToxLab North America

Tuesday, April 26

**General Toxicology**
Lorraine Buckley, Eli Lilly & Company

**Toxicology of Organ Systems**
Mary Beth Genter, University of Cincinnati

**Clinical Pathology: Principles for Industrial and Regulatory Scientists**
Denise Bounous, Bristol Myers Squibb Company

**Pathology in Toxicology Studies**
Thomas Steinbach, Experimental Pathology Laboratories, Inc.

Wednesday, April 27

**Genetic Toxicology**
Mark Powley, US Food and Drug Administration

**Evaluation of Potential Carcinogenicity**
James Popp, Stratoxon LLC

**Reproductive/Developmental Toxicology**
Kok Wah Hew, Takeda Pharmaceutical International Co.

**Immunotoxicology**
Gary Burleson, Burleson Research Technologies, Inc. (BRT)

Thursday, April 28

**Nonclinical Safety Evaluation of Biotechnology-Derived Therapeutics**
Melanie Hartsough, Biologics Consulting Group, Inc.

**Regulatory Toxicology—A Nonclinical Pharmacology and Toxicology Perspective**
Hanan Ghantous, US Food and Drug Administration

**Risk Assessment**
Melissa Rhodes, Roivant Sciences

**Practical Application: Nonclinical Case Studies**
Hanan Ghantous, US Food and Drug Administration

Friday, April 29*

**Regulatory Submissions: Preparation of Nonclinical Documents**
Paul Nugent, Pfizer, Inc.

**Review of Drug G: History and Outcome**
Kenneth Hastings, Hastings Toxicology Consulting, LLC

*Course ends at noon.

Course Organizers:
Course Director: Kok Wah Hew, PhD, DABT, Takeda Pharmaceutical International Co.
Hanan Ghantous, PhD, DABT, US Food and Drug Administration
Timothy McGovern, PhD, US Food and Drug Administration

www.actox.org