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 23

**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 Pharmaceutical Toxicology**
Debie Hoivik, Boehringer-Ingelheim Pharmaceuticals, Inc.

**Safety Pharmacology for Human Pharmaceuticals**
Mary Jeanne Kallman, Kallman Preclinical Consulting

Tuesday, April 24

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

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

**Clinical Pathology: Principles for Pharmaceutical and Regulatory Scientists**
Lila Ramaiah, Bristol-Myers Squibb

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

Wednesday, April 25

**Genetic Toxicology**
Mark Powley, Merck and Co.

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

**Reproductive/Developmental Toxicology**
Alan Hoberman, Charles River

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

Thursday, April 26

**Nonclinical Safety Evaluation of Biotechnology-Derived Therapeutics**
Melanie Hartsough, Hartsough Nonclinical Consulting, LLC

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

**Risk Assessment**
Melissa Rhodes, Roivant Sciences

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

Friday, April 27*

**Preparation of Nonclinical Documents for Regulatory Submission**
Paul Nugent, Pfizer, Inc.

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

*Course ends at noon.

Course Organizers:
Joseph Francisco, PhD, Charles River
Hanan Ghanitoue, PhD, DABT, US Food and Drug Administration
Timothy McGovern, PhD, US Food and Drug Administration

REGISTER NOW

**Early-Bird Registration Deadline: February 19**

**Regular Registration: February 20–April 20**

For more course information and to register, visit www.actox.org

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