This annual ACT course provides basic training in general toxicology. Using pharmaceutical development as an 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, March 30

**Principles of Toxicology**  
A. Wallace Hayes, University of South Florida, College 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, Akebia Therapeutics

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

Tuesday, March 31

**General Toxicology**  
Lorrene Buckley, Eli Lilly and Company

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

**Clinical Pathology: Principles for Pharmaceutical and Regulatory Scientists**  
Lila Ramaiah, Pfizer, Inc.

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

Wednesday, April 1

**Genetic Toxicology**  
Mark Powley, Merck & Co., Inc.

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

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

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

Thursday, April 2

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

**Risk Assessment**  
Melissa Rhodes, Aerami

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

**Cell and Gene Therapy**  
Sandhya Sanduja, US Food and Drug Administration

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

Friday, April 3*

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

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

*Course ends at noon.

Course Organizers:  
Joseph Francisco, PhD, Charles River  
Hanan Ghanotous, PhD, DABT, US FDA  
Timothy McGovern, PhD, US FDA

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**Course Description**

Early-Bird Registration Deadline: February 3

Regular Registration: February 4–March 27

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

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