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 24**

**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**  
Matthew Bogdanffy, Boehringer-Ingelheim Pharmaceuticals, Inc.

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

**Tuesday, April 25**

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

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

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

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

**Wednesday, April 26**

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

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

**Reproductive/Developmental Toxicology**  
Kok Wah Hew, Takeda Pharmaceuticals USA, Inc.

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

**Thursday, April 27**

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

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

**Risk Assessment**  
Melissa Rhodes, Roivant Sciences

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

**Friday, April 28**

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

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

*Course ends at noon.

**Course Organizers:**

**Course Director:** Kok Wah Hew, PhD, DABT, Takeda Pharmaceuticals USA, Inc.

Hanan Ghahtous, PhD, DABT, US Food and Drug Administration

Timothy McGovern, PhD, US Food and Drug Administration

Joseph A. Francisco, PhD, Charles River

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**Early Registration Deadline: February 20**

**Late Registration:**  
February 21–April 21

For course information and registration, visit [www.actox.org](http://www.actox.org)