Toxicology for Pharmaceutical and Regulatory Scientists

March 30–April 3, 2020

Gaithersburg Marriott Washingtonian Center
Gaithersburg, Maryland, United States

Course Description

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 Ghantous, *US Food and Drug Administration*

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

Practical Application: Nonclinical Case Studies
Hanan Ghantous, *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 Ghantous, *PhD, DABT, US FDA*
Timothy McGovern, *PhD, US FDA*

REGISTER ONLINE

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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