Toxicology for Pharmaceutical and Regulatory Scientists

April 23–27, 2018
Gaithersburg Marriott Washingtonian Center
Gaithersburg, Maryland
United States

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
Lorrene Buckley, Eli Lilly & Company

Toxicology of Organ Systems
Mary Beth Genter, 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 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 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 Ghantous, 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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