Toxicology for Industrial and Regulatory Scientists

April 27–May 1, 2015
MedImmune
Gaithersburg, Maryland
United States

Course Description

This annual ACT course 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 27

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 Industrial Toxicology
Matthew Bogdanffy, Boehringer-Ingelheim Pharmaceuticals, Inc.

Safety Pharmacology for Human Pharmaceuticals
Russell Bialecki, AstraZeneca Pharmaceuticals

Tuesday, April 28

General Toxicology
Lorrene Buckley, Eli Lilly & Company

Toxicology of Organ Systems
Mary Beth Genter, University of Cincinnati

Clinical Pathology: Principles for Industrial and Regulatory Scientists
Robert Hall, Covance Laboratories Inc.

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

Wednesday, April 29

Genetic Toxicology
Mark Powley, US Food and Drug Administration

Evaluation of Potential Carcinogenicity
James Popp, Stratoxon LLC

Reproductive/Developmental Toxicology
Kok Wah Hew, Takeda Pharmaceutical Company

Immunotoxicology
Gary Burleson, Burleson Research Technologies, Inc. (BRT)

Thursday, April 30

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

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

Risk Assessment
Ernie Harpur, Newcastle University

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

Friday, May 1*

Regulatory Toxicology of Chemical, Agrochemicals, and Other Nonpharmaceuticals
William Brock, Brock Scientific Consulting, LLC

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

**Course ends at noon.*

Course Organizers:

Course Director: Kok Wah Hew, PhD, DABT, Takeda Pharmaceutical Company

Hanan Ghantous, PhD, DABT, US Food and Drug Administration
Timothy McGovern, PhD, US Food and Drug Administration

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