

Pharmaceutical Toxicology: Toxicology in the Nonclinical Development of Drugs & Biologics

Course # T33

September 22 - September 23, 2010

Start - 8:00 Finish - 5:00

Hotel Information:

Hyatt Arlington
1325 Wilson Boulevard
Arlington, VA 22209
(703) 525-1234

Rate: \$ 239

Deadline for Group Rate: 2010-08-08

Registration Rate:

\$1,495.00 Register by 08/8/10

\$1,695.00 Register after 08/8/10

Cancellation Date: 9/13/10 (Cancellation fee is determined by date cancelled.)

Continuing Education Credit:

ACPE: 0708-0000-10-030-L01-P (1.4 CEU)

Initial Release Date: 9/22/10

CBRN: N/A

CME: 14 Hours of Category 1 Credit

VNA: 07-04-01 14 Contact Hours

Course Description:

This course will be held at:

The PERI Training Facility

1616 N Fort Myer Drive Suite 1430

Arlington, VA 22209

Day 1: 8:00 AM - 5:00 PM

Day 2: 8:00 AM - 5:00 PM

This course provides the essential foundation for toxicology in the nonclinical development and regulatory approval of drugs and biologics. FDA-required nonclinical safety studies and ICH guidelines for the IND and NDA/BLA will be covered. Nonclinical toxicology is presented in the context of successful development plans that cover how safety studies integrate with nonclinical pharmacology, pharmacokinetic/toxicokinetic studies and the chemistry and clinical parts of the project. This is one of the critical courses for learning how $\hat{\text{risk/benefit}}$ assessments are made.

Who Should Attend:

This course should be required training for all drug developers, not just toxicologists. It is invaluable to chemistry, nonclinical, clinical, and regulatory staff because of the mutual dependency among these disciplines for successful safety assessments and clinical trials of new drugs. A solid foundation for professional development of doctoral, administrative, project management, and laboratory support staff is provided.

Educational Objectives:

Upon completion of this course, participants should be able to:

- Describe the FDA and ICH requirements for safety studies
- Design an integrated nonclinical development plan
- Present nonclinical data to FDA
- Determine how toxicology studies are mutually dependent upon pharmacology, pharmacokinetic, clinical trial design, and physical/chemical/biological characterization of the test material

- Define what "case-by-case" means in nonclinical development and how it influences safety assessments

Key Topics:

- Designing Nonclinical Toxicity Studies in Relationship to the Rest of the Project Plan
- How Nonclinical Toxicology Studies Support Clinical Development and Clinical Risk/Benefit Decisions
- Pharmacokinetics
- Toxicokinetics
- Pre-IND Consultation Program
- Safety Pharmacology Studies
- Ophthalmic Drug Development Toxicology Requirements
- Intravenous Toxicology Studies
- Genetic Toxicology
- Carcinogenicity Studies
- Reproductive Toxicology
- Immunotoxicological Evaluation INDs
- Dose Range-Finding and Repeated Dose Toxicity Studies

Course Director(s):

Peter C Hoyle, PhD
President
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