

Pediatric Drug Development Course # T13

July 21 - July 22, 2010

Start - 8:00 Finish - 4:30

Hotel Information:

[Hyatt Arlington](#)

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

Rate: \$ 239

Deadline for Group Rate: 2010-01-16

[Hotel Policy](#)

Registration Rate:

\$1,495.00 Register by 06/6/10

\$1,695.00 Register after 06/6/10

Cancellation Date: 7/12/10 (Cancellation fee is determined by date cancelled.)

[Register Now](#)

[Registration Policy](#)

Continuing Education Credit:

ACPE: 0708-0000-10-020-L03-P (1.4 CEU)

Initial Release Date: 7/21/10

CBRN: N/A

CME: 14 Hours of Category 1 Credit

VNA: 07-04-01 14 Contact Hours

[Continuing Education Policy](#)

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 - 4:30 PM

This course will provide an overview of key issues in the development of pediatric drug development. Experts from the industry, FDA and academia will address issues including but not limited to pediatric vs. adult clinical trials; regulatory considerations; ethics; design of pediatric clinical trials, statistical consideration in trial design, and patient recruitment and retention.

Who Should Attend:

This course is directed towards professionals involved in pediatric clinical trials and affiliated with pharmaceutical and biotech companies; academic and government institutions and contract research organizations. This includes clinicians, project planners, monitors, nurses, physician assistants and regulatory professionals who could benefit from a review of recent advances and progress in the field.

Educational Objectives:

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

- Identify key anatomical/physiological differences between adults and children
- Describe clinical lab values in children.
- Discuss the uniqueness of pediatric clinical pharmacology (i.e. drug metabolism)
- Identify unique aspects of pediatric clinical trials and incorporate these aspects into trial design
- Create successful pediatric IRB submissions
- Identify key attributes of a good pediatric CRO
- Develop recruitment and retention plans for pediatric trials
- Recognize differences between EU and US pediatric drug development

- Identify FDA's requirements of a written request
- Name pediatric sites and networks that can assist with studies in pediatric subjects

Key Topics:

- Anatomy and Physiology
- Biochemistry
- Trial Design ¿ PI v. PII/III
- Successful Pediatric IRB Submissions
- Pediatric Clinical Trials vs. Adult Clinical Trials
- Ethical Issues in Pediatric Clinical Trials
- Transparency & Dissemination of Data
- Recruitment and retention
- Monitoring of Pediatric Clinical Trials
- Drug Approval: FDA vs. EMEA
- Pediatric Clinical Pharmacology
- Safety Monitoring eg., vitals, clinical labs, clinical signs of unwellness

Course Director(s):

Ernest A Kopecky, PhD, MBA
Head, Pain and Neuroscience, Clinical Research and Development
Endo Pharmaceuticals, Inc.