

## Advanced Good Clinical Practices Course # T25

September 27 - September 28, 2010

Start - 8:00 Finish - 5:00

### Hotel Information:

[Hyatt Arlington](#)

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

Rate: \$ 239

Deadline for Group Rate: 2010-08-14

[Hotel Policy](#)

### Registration Rate:

\$1,495.00 Register by 08/14/10

\$1,695.00 Register after 08/14/10

Cancellation Date: 9/18/10 (Cancellation fee is determined by date cancelled.)

[Register Now](#)

[Registration Policy](#)

### Continuing Education Credit:

ACPE: 0708-0000-10-022-L03-P (1.4 CEU)

Initial Release Date: 9/27/10

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 - 5:00 PM

This course is recommended for Good Clinical Practices (GCPs) professionals with at least five years experience. This course builds on the basic GCP training with a focus on GCP auditing techniques and strategies. The course provides an advanced in-depth, application-oriented training delivered by faculty members who have extensive experience in the GCP arena.

### Who Should Attend:

This course will be extremely valuable for regulatory managers, compliance auditors, QA managers, clinical investigators, academic research directors and clinical coordinators/monitors.

### Educational Objectives:

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

- Upon completion of this course, participants should be able to:
- Establish effective relationships with stake holders to insure productive clinical trial management
- Analyze complex auditing situations, including systems auditing, and report findings/action plans to senior management.
- Evaluate initial and ongoing relationships with CROs
- Describe opportunities and challenges of conducting international trials

### Key Topics:

- Overview of the FDA

- Assessment of Clinical Data
- Conducting Clinical Trials in Developing Countries
- Contract Research Organization and Partnership Evaluations
- Beyond the Regulations: GCP Challenges
- FDA's Division of Scientific Investigations (DSI) Update
- The Value in the Vision: Future Role of Regulatory Compliance Professionals
- Fraud/Scientific Misconduct and Case Histories
- Electronic Records at Clinical Sites
- Overview of Computer Technology in Auditing
- Ethics, Conflicts of Interest, and Informed Consent

**Course Director(s):**

Kathleen A. Moran, MS

Head of Quality, Research and Development

GE Healthcare