



ACADEMY FOR CLINICAL EXCELLENCE

2½-DAY WORKSHOP ON

“FUNDAMENTALS OF CLINICAL RESEARCH & GCP”

OCTOBER 7-9, 2004 AT HYDERABAD

Academy for Clinical Excellence (ACE www.aceindia.org) is a premier institute that provides training in clinical research. It was set up in October 2002 at the Bombay College of Pharmacy through the initiative and financial contribution of Pfizer India Limited, Mumbai and Suven Life Sciences Limited, Hyderabad.

The Academy is conceived, as a one-stop-shop for all training needs of all clinical research professionals in the country. The workshop will provide an overview of the drug development process and a background of clinical research with emphasis on the Good Clinical Practice guidelines. The course will be highly interactive with Q & A sessions, quizzes and group discussions.

We at Asian Clinical Trials Pvt. Ltd (ACT) are conducting for the second time this 2½-day workshop on 'Foundation of Clinical Research and GCP' in collaboration with ACE at Hyderabad between October 7 and 9, 2004. The workshop will provide an overview of the drug development process and a background of clinical research with emphasis on the Good Clinical Practice guidelines

These are the topics:

- Overview of drug development & Clinical trial process
- ICH-GCP – History and evolution, and Indian GCP (CDSCO)
- Regulations affairs for the clinical research professional
- Ethics (Role of IRB)
- Informed consent
- Sponsor responsibilities
- Investigator responsibilities
- Monitoring a clinical study
- Handling investigational product
- Safety reporting
- Data Safety Monitoring Board
- Clinical Data management
- Biostatistics
- Audit and inspections

Participant fees: Rs. 2,500 (Industry)
Rs. 1,500 (Academics and Govt. Institutions)
Rs. 1,000 (PG students)
Rs. 750 (UG students)



Academy for Clinical Excellence

Kalina, Santacruz (E), Mumbai 400 098

Tel: 022~ 2667 1032, Email: acebcp@eth.net, www.aceindia.org

REGISTRATION FORM

Dr./Mr./Ms. (Name as you would like it on the certificate)

Designation.....

Organization.....

Address

.....

City..... State..... Pin.....

Email:

Tel No..... Fax No.....

Please photocopy one form per person attending the course and send (DD in favor of "Bombay College of Pharmacy – Academy for Clinical Excellence" payable at Mumbai) to:



Asian Clinical Trials Pvt Ltd

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