Good Clinical Practice for Research Professionals

Good Clinical Practice (GCP) is the international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials involving human subjects. In many parts of the world, GCP is now a legal requirement and may be a pre-requisite for the acceptance of clinical research results

Do you work in Clinical Research?

Are you looking for a course to increase your knowledge and understand of what GCP means for your clinical practice? The key to working appropriately in clinical trials is an understanding of the overall picture and why GCP is important to all parties: sponsors, sites, trial volunteers, ethics and regulators. In addition the course covers the international perspective including the FDA code of federal regulations and the EU Directive, and how these impact on your studies.

Who should attend?

Clinical researchers working in any area who wish to review and apply their knowledge gained in formal GCP training

Program details

DAY 1

1. Welcome
2. Introduction to Clinical Research
3. Ethics
4. Informed Consent
5. Sponsor Responsibilities
6. Investigator Responsibilities
7. Recruitment

DAY 2

8. Research Records & Documents
9. Adverse Experience Reporting
10. Audits & Inspections
11. Fraud & Misconduct

Course details

The program includes:

- Details and updates of ICH GCP
- Trial design, documents and processes
- Sponsor/regulatory audits and inspections
- Quality materials and resources
- Accredited and certified trainers
- Course materials, certificate, meals & refreshments

- Duration**:** 2 days
- Time: 09:00 -18:00
- Dates: Refer to website: www.apcra.com
- Venue: Central, Hong Kong
- Cost: $3500 HKD