

GOOD CLINICAL PRACTICE (GCP)

Refresher

VENUE

Ground Floor Training Room 31 Princess of Wales Terrace Parktown, Johannesburg, 2193

Courses are also offered in Durban on a regular basis.

On-site training for groups of 20 or more will be considered, subject to viability.

COURSE FEE

R 1,400 incl VAT(Non-WHC) R 900 excl VAT(WHC Divisions)

COURSE DURATION

4 hours (Start and end times may vary slightly, confirmation will be provided on registration)

BOOKING

Please contact us at: +27 11 274 9256/9327/9200 training@academicadvance.co.za http://www.academicadvance.co.za

INTRODUCTION

In accordance with the requirement by SAHPRA (MCC) that all study personnel must refresh their knowledge and renew their GCP certificates every 3 years.

COURSE OVERVIEW

This course is a revision of Good Clinical Practice principles and processes for all clinical trial personnel who have previously attended GCP training, incorporating current ICH and SA GCP Guidelines. The course is interactive and discussion around current issues is encouraged.

COURSE CONTENT

- Good Clinical Practice
- Historical Perspective and Update
- GCP Audits and Inspections
- Research Involving Genetic Studies
- Litigation in Clinical Trials
- Informed Consent Deficiencies
- Conflict of Interest
- Breach of Contract
- Compensation
- Class Action
- Topical Issues in Clinical Research:
- **DOH Guidelines**
- SAHPRA policies

ACCREDITATION AND REGISTRATION

- The course is HPCSA accredited— 4 CPD and 2 Ethics points
- This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors. http://www.transceleratebiopharmainc.com/gcp-

training-attestation/list-of-training-providers

TARGET AUDIENCE

All clinical research personnel, who have previously completed a recognised GCP course: Investigators, Study coordinators, Managers etc.

