

# GOOD CLINICAL PRACTICE (GCP) BASIC COURSE



## Introduction

Medical research involving human subjects is strictly controlled by the Medicines Control Council of South Africa and it is mandated that the study team be well versed with the International (ICH) and SA Good Clinical Practice guidelines. Each member of the team must be in possession of a valid, recognised GCP certificate.

## Course Overview

The GCP Basic course is an introductory 1½ day course that will give a detailed overview of clinical research, the ICH and SA GCP guidelines and the process of conducting successful clinical trials from start to finish. Certificates of completion are issued on the successful completion of an open book post-course assessment.

## Course Content

Day 1	Day 2
<ul style="list-style-type: none"><li>• Drug Development Process</li><li>• Historical Review of GCP</li><li>• South African GCP</li><li>• Regulatory Process in South Africa</li><li>• Study Documents</li><li>• Patient Recruitment and Retention</li><li>• Informed Consent</li></ul>	<ul style="list-style-type: none"><li>• Investigational Product</li><li>• Safety Reporting</li><li>• Responsibility of the Study Team</li><li>• Standard Operating Procedures</li><li>• Laboratory Issues</li><li>• Monitoring</li><li>• Audits</li></ul>

## Accreditation and Registration

- The course is HPCSA accredited—11 CPD points plus 4 Ethics points .
- The certificate is recognised by the Ethics Committees and Medicines Control Council of South Africa.
- 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

Investigators, study coordinators, scientists and project or site managers new to clinical trials.

## Course Duration

1 ½ days

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

## Course Fee

R 3,000.00 incl VAT (Non-WHC)

R 2,150.00 ex VAT (WHC Divisions/Syndicates)

## Venue

BEESA Conference Centre,  
Unit 3, Sherborne Square,  
5 Sherborne Rd, Parktown, 2193

Courses are also offered in Durban on a regular basis and in Cape Town subject to a minimum number of attendees.

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

## Booking

Please contact Melody Maddocks or Janine Roper.

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<http://www.academicadvance.co.za>