

# Good Clinical Practice – Beginner Course

- ▶ 1 Day course ( Maximum of 8 hours teaching time)
- ▶ General approved at level 1 for 7 points (MDB001/023/01/2018)
- ▶ Ethics: 2 points (MDB001/024/01/2018)
- ▶ Cost : R3000

The course is an overview of various concepts of clinical research and an introduction of Good Clinical Practice, in accordance to SA GCP and ICH GCP.

## Outline

- Introduction to GCP
- Historical Events
- What is Clinical Research?
- Study Design
- Role Players: Sponsor/CRO, Ethics/RA, Investigator/Quality Management/Monitor/Audits/Inspections/Research Team /Investigators meeting
- Essential Documents
- Source Documents
- Informed Consent
- Study Conduct: SOPs/ Protocol compliance/Eligibility/Monitoring/Lab/Retention/ Screening/Enrolment/Training
- Drug Development
- Safety of participant and Safety reporting
- Study Completion and Archiving
- Questions, evaluation and Post assessment.

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# Good Clinical Practice – Refresher Course

- ▶ 1 Day course ( Maximum of 8 hours teaching time)
- ▶ CPD 4 general points (MDB001/025/01/2018)
- ▶ Ethics: 1 point ( MDB001/026/051/2018)
- ▶ Cost : R1000

Suitable for Individuals needing to renew their GCP certification and for a more interactive update/recap on the concepts around clinical research in accordance to SA GCP and ICH GCP.

## Outline

- Refreshing of Definitions : Sponsor/Monitor/Auditor/Investigator/Clinical Research
- Historical Events
- Ethics Committee
- Definition: GCP/ICH
- Role players and Responsibilities
- Study conduct: SOPs/Source Documents/Essential Documents/Quality Management/Monitor/Compliance
- Participant Safety and Safety Reporting
- Interactive quiz and discussions about various concepts around clinical research
- Questions, Evaluation and Post Assessment

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