ABC of Quality Control

Running a clinical trial is a complex and detailed process. Maintaining accurate records and quality data throughout a clinical trial is a continual, dynamic process.

Trial requirements are carefully prescribed in detailed documents such as the protocol, the ICH and SA GCP guidelines, data management plan and the project plan.

Description

This practical course will equip clinical research site personnel with the relevant knowledge and tools to ensure successful study conduct from start to finish, in preparation for monitoring audits and site inspections.

Available as classroom training

Content

Introduction.
Module 1: Site Organisation.
Module 2: Site Preparation.
Module 3: Site Conduct.
Module 4: Site Management.
Module 5: Study Close Out and Archiving.
Module 6: Audits and Inspections.
Final Assessment.

Cost

Classroom - R4,100 (VAT incl.)

WHC divisions | projects:
Classroom - R2,800

For group discounts, please contact us at:
training@academicadvance.co.za

Duration

The classroom training is two full days (from 08h30 to 16h00).

Target Audience

Clinical research personnel such as investigators, study coordinators, and project managers with a valid GCP certificate and preferably some work experience in the clinical research field.

Certification

Delegates are required to complete a final assessment with at least 70% accuracy.
Upon successful completion of the course, the delegate will be given access to the Certificate of Completion.

CPD Points

CPD points will be issued with the certificate of completion.

(12 CPD points | 2 Ethics points).

In-house Training

In-house training will be considered, subject to viability.

academic advance

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Learning outcomes

Module 1: Site Organisation

- Describe the research team.
- Understand Standard Operating Procedures.
- Understand equipment calibration.

Module 2: Site Preparation

- Understand study preparation and start-up.
- Explain essential site documents.
- Explain site documents.

Module 3: Site Conduct

- Define "informed consent".
- Understand protocol adherence.
- Describe safety reporting.
- Understand drug management.
- Understand study monitoring visits.

Module 4: Site Management

- Understand human resource management.
- Understand financial management.
- Understand feasibility management.
- Understand patient recruitment and retention management.
- Understand study conduct management.
- Understand essential document and filing management.
- Understand quality management.
- Understand communication management.

Module 5: Study Close-Out and Archiving

- Understand study close-out.
- Explain archiving and the archiving process.

Module 6: Audits and Inspections

- Define "audit".
- Define "inspection".
- Describe the focus of audits/inspections.
- Describe common audit findings.
- Describe the consequences of audits/inspections.

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