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: Study Preparation.
Module 3: Study Conduct.
Module 4: Site Management.
Module 5: Study Close Out and Archiving.
Module 6: Audit Preparation and Management.
Final Assessment.

Cost

Classroom - R4,350 (VAT incl.)

WHC Divisions | Projects:
Classroom - R2,970

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, including Investigators, Study Coordinators, and Project Managers, who hold a valid GCP certificate and ideally possess relevant 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.

In-House Training

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

academic advance

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Learning Outcomes

Module 1: Site Organisation

- Recognise the role of site organisation in clinical research success.
- Define the roles and responsibilities of clinical trial site Investigators.
- Develop clear processes and infrastructure for efficient operations.
- Ensure accountability and minimise errors in site management.

Module 2: Study Preparation

- Prepare essential site and source documents.
- Conduct feasibility assessments and select appropriate sites.
- Submit regulatory and ethics applications effectively.
- Plan and organise site initiation meetings for study start-up readiness.

Module 3: Study Conduct

- Obtain and document informed consent accurately.
- Follow study protocols and address deviations appropriately.
- Report safety issues and adverse events in compliance with regulations.
- Manage investigational products effectively and maintain compliance.

Module 4: Site Management

- Implement effective human resource and financial management practices.
- Develop and execute strategies for participant recruitment and retention.
- Maintain essential documents with proper organisation and filing systems.
- Conduct internal quality control and foster effective communication.

Module 5: Study Close-Out and Archiving

- Perform study close-out visits and account for all required documentation.
- Notify regulatory authorities and ethics committees of study termination.
- Manage the return or destruction of study drugs and equipment.
- Archive study documents systematically for future reference and compliance.

Module 6: Audit Preparation and Management

- Prepare comprehensively for audits and inspections.
- Identify key focus areas of GCP audits and inspections.
- Address audit findings and implement corrective actions promptly.
- Apply insights from audits to enhance site practices and processes.