FOOD AND DRUGS AUTHORITY TRAINING ON GOOD CLINICAL PRACTICE AND RELATED REGULATORY REQUIREMENTS

DATE: 14th—16th AUGUST, 2019
VENUE: REV. VERONICA DARKO CONFERENCE ROOM, NURSING & MIDWIFERY COUNCIL, SHIASHIE, ACCRA

Background

This GCP course is designed to provide practical training that would result in an enhanced understanding of regulatory requirements for the conduct of Clinical Trials in Ghana.

The training course which is run regularly by the Authority has been updated with the objective of providing an insight into the current requirement that the FDA would expect clinical trialists to abide by in their researches as well as to provide a platform for experience sharing and a common professional approach in order to pave the way for mutual recognition and acceptance and stimulating efficiency that would allow faster medicinal product development to the benefit of the patients and health care. A highlight feature is on the revised ICH Guidelines (E6R2)

General Outline of Workshop

i. Good Clinical Practice Principles
ii. Regulatory Framework - FDA and ICH
iii. The Clinical Trial Application Requirements
iv. Research Ethics
v. Essentials before, during and after the conduct of a clinical trial
vi. Trial Monitoring Including A Session On FDA GCP Inspections

Targeted Persons

This course is designed to provide practical training for all who are or intend to be involved in interventional clinical research involving humans and pharmaceuticals. It will also be of interest to those with managerial responsibilities for research institutions. It is recommended for all Principal Investigators with trials on-going in Ghana and sponsors who intend to fund a trial in Ghana within the next one year to send at least one representative to this workshop.

Objectives

At the end of this course, participants should at least be able to:

i. Appreciate the legal role of the regulator in clinical trials.
ii. Understand the basis for GCP principles.
iii. Get a clear understanding of the requirements for clinical trial applications to the FDA.
iv. Discuss requirements for GCP inspections.
v. Provide an overview of the essential requirements for the conduct of a clinical trial.

DAY 1

08:30 am

- Arrival and Registration of Participants
- Welcome Message
- Overview of Workshop
- Self-Introductions
- Pre-Course Test
- Introduction to Product Development and Clinical Trials

HEALTH BREAK

- FDA's Mandate – Law, Guidelines and Tools for Regulating Clinical Trials in Ghana
- History and Principles of GCP

LUNCH

- Roles and Responsibilities of Stakeholders
  - ⇒ Regulator
  - ⇒ Ethics Bodies
  - ⇒ Sponsor
  - ⇒ Investigator (Monitor, Study Coordinator , Lab and Data Manager)
- Case Study I (Basic GCP Principles + Roles and Responsibilities)
- Discussion of Case Study I
- General Questions and Discussions

END OF DAY 1

DAY 2

08.30 am

- Arrival of Participants
- Recap/discussions on previous day's presentation
- Overview of Day 2 activities
- Ethical issues (Ethics Review, Informed Consent, General Care and Welfare of Participants)
- Quality Assurance and Quality Control in Clinical Trials

HEALTH BREAK

- Computer Validation System
- Case Study II (Quality Assurance and Quality Control)
- Discussion on Case Study II

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- Laboratory Equipment Calibration
- Investigational Product Management on site (Product Availability)
- GC Net System (Product Importation)
- General Questions and Discussions

END OF DAY 2

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DAY 3

8.30a.m

- Arrival of Participants
- Recap/ discussions on previous day's presentation
- Overview of Day 3 activities
- Case Study III (Import Permit Application)

HEALTH BREAK

- Discussion on Case Study III
- Reporting from Trial Sites
- GCP Inspections
- Case Study IV (GCP Inspection Findings/ Observations and Grading)

- Discussion on Case Study IV
- Questions and General Discussions
- Post-Course Test
- Course Evaluation
- Wrap-up and Presentation of Certificates

LUNCH

END OF WORKSHOP

RESGISTRATION FORM

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTER

☐ Prof. ☐ Dr. ☐ Mr. ☐ Mrs. ☐ Ms.

Last Name

First Name

Institution

Position/Role

Postal Address

Telephone (mobile)

Email*

* (Required for confirmation)

FEES: GHS800 per participant

Fees paid would cover course materials, lunch and one coffee break each day.

Participants would have to bear the cost of their accommodation and transportation to and from the venue of the workshop.

It is recommended that payment of the fees be made before the date of the workshop. Proof of payment would be required before a participant would be allowed entry into the workshop.

Payments can be made at any of the FDA offices countrywide.

PAYMENT METHODS

Cash/Banker's draft to any of FDA's offices nationwide.

Nominees are expected to pay by Friday, 2nd August , 2019 to enable the FDA make suitable arrangements for their participation.

By signing below, I confirm that I agree with FDA's Terms and Conditions of attendance

Date	Signature

All cancellations must be made in writing and must be received at the FDA Head Office for at least ten (10) working days prior to the event start date.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event . Please notify the FDA Office of any such substitutions as soon as possible.

Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo , and/or digital camera, to be used by FDA in promotional materials, publications, and website.