TRAINING ON QUALITY ASPECTS OF DOSSIER AND BIOEQUIVALENCE REQUIREMENTS FOR PHARMACEUTICAL REGULATORY FILINGS

Course Description

These two days training course will introduce and detailed the requirements on the pharmaceutical quality and bioequivalence requirements for regulatory filings.

The training program will be carried out in two (2) sessions with each session lasting for two (2) days. It will be delivered through an interactive power point presentations and breakout sessions for case studies and group works. The case studies are meant to provide first-hand experience to the participants where they can apply the theory learnt.

The following include but are not limited to topic areas to be discussed:

- Risk-based registration and reliance routes to registration of Medicines
- Trend analysis of filed applications- Quality and BE/Clinical
- Technical presentation based on the observed deficiencies
    - Control of Impurities in API and FPP.
    - Polymorphism and Particle Size Characterization
    - Acceptance criteria for Dissolution and reporting of dissolution results
- Bioequivalence Requirements
- SmPC and PIL

Who Should Attend

This training is designed to further improve the quality of regulatory filings for the grant of marketing authorization for pharmaceutical products. It is also aimed at reducing timelines for processing of applications thereby impacting on the availability quality and affordable medicines to the Ghanaian. The focus of the topics will benefit individuals in the pharmaceutical industry such as the Quality Assurance Managers, Regulatory Affairs Managers, Production Managers and Regulatory contact persons for applicants and importers who want to improve their knowledge on the Quality aspects of the dossier and Bioequivalence requirements for the grant of marketing authorization.

Below are the details of the training program:

First Session:

Date: 12th-13th September 2022

Time: 9.00am each day.

Venue: Noble International Business School (NiBS), (Behind FDA Head Office) Shiashie, Accra

Second Session:

Date: 14th-15th September 2022

Time: 9.00am each day.

Venue: Noble International Business School (NiBS), (Behind FDA Head Office) Shiashie, Accra

Payment of Course Fee

The fee for the two-day training is GH¢1000.00 per participants.

Payment should be made to the Cashier at the FDA Head Office, Shiashie-Accra.

Payment for the training program should be made not later than **26th August 2022**

Registration

Interested Individuals and pharmaceutical companies can register for this training by completing the training registration form and submit to the FDA not later than **26h August 2022**.

Please note that a participant can only attend one session of the training program.