Bioavailability/ Bioequivalence Training Course

The course is designed as a six-week competency based training program. The training has three parts (a) readings, and assignments for 3 weeks, (b) intensive one-week training on the key principles of interchangeability, application of concepts of ethics, clinical conduct, study designs, pharmacokinetics, statistics, bioanalysis and method validation, in bioequivalence (BE), and (c) demonstration of competence through review of actual bioequivalence data submitted for applications for registration of medicines. The second part is only applicable to participants working for medicines regulatory authorities or equivalent, or those in academia.

Pre-requisites

The participants should have a bachelor's degree in pharmacy, pharmaceutical sciences, chemistry, medicine, veterinary or the life sciences with at least two years working experience in a relevant field such as in medicines regulation, pharmaceutical manufacturing industry, research and/or academia.

Participants should have requisite knowledge of basic principles of biopharmaceutics, pharmacokinetics, therapeutics, statistics, bio analysis and method validation.

MCAZ

Medicines Control Authority of Zimbabwe

106 Baines Avenue, Harare, Zimbabwe

www.mcaz.co.zw

Protecting your right to quality medicines and medical devices

Course Format

The course format and delivery has been carefully selected to ensure that completion for the course simulates the real life of a regulatory officer responsible for performing the product assessments or regulatory officer at pharmaceutical or clinical research organization responsible for quality assurance and compliance, regulatory filing of study results. The goal is to ensure successful conduct of bioequivalence studies meeting regulatory requirements and / or appropriate review of the bioequivalence submissions for registrations of medicines. As such, two key principles are applied; competence based approach (rather than knowledge and memory based approach) and participant centered learning.

Course Objectives:

The objective of this course is to train and equip participants with the requisite knowledge and skills relating to demonstration of interchangeability to enable them to evaluate data to demonstrate interchangeability through bioequivalence for registration of medicines.

Learning Outcomes

By the end of this course, participants should be able to:

1. *Recognise* and *articulate* the scientific & regulatory basis and assumptions for demonstration of interchangeability,
2. Demonstrate *knowledge*, *understanding* and *application* of key principles of ethics, good clinical practice (GCP), biopharmaceutics, pharmacokinetics, statistics and bioanalysis in bioequivalence,
3. *Analyse* and *draw conclusions* on available data to demonstrate bioequivalence based on application of relevant requirements in applicable regulatory guidelines
4. *Review* and *write* a scientific assessment report on data submitted in the application for registration of a medicine in accordance with applicable regulatory guidelines

Course Content

The course content is divided into three components as follows:

Foundation:

- Regulatory requirements for registration of medicines
- Demonstration of interchangeability

Scientific Principles

- Good Clinical Practice (GCP)
- Biopharmaceutics
- Pharmacokinetics
- Statistical methods in bioequivalence
- Bioanalytical methods
- Bio analytical methods validation
- Comparative dissolution

Application

- Study designs
- Study conduct
- Data analysis

Target Group

While the primary focus is on regulators, the course is relevant to professionals in the pharmaceutical industry and contract research organisation (CRO) responsible for design, analysis, filing and compliance with regulatory requirements.

The RCORE will provide partial funding to cover the course fee for eligible participants from regulatory agencies. The bioequivalence course is offered once a year in October / November of each year.

Participants on the Regulatory Science Fellowship can take this course as part of their core modules.

The programme design ensures the following volume of learning and experiential experience to complete the course requirements:

PART I:

Pre-course reading assignments	15 hours
Total contact time (in classroom)	30 hours
Non-contact time (Self-study)	15 hours
Total volume of learning	**60 hours**

PART II: Experiential learning

Supervised Practice	60 hours
Practice-unsupervised	30 hours
Total volume of learning	**90 hours**

Successful completion of Part II of the course will require participants to complete written scientific assessment reports for the 3 assigned bioequivalence reviews.

Participants will have to complete the course work and pass a final exam at the end of Part I to receive a certificate of completion.

Participants will receive a certificate of competence on successful completion of Part II of the course.

Application Process

Interested candidates are required to submit a completed application form (available on the website www.mcaz.co.zw), and support letter from the employer (including confirmation of the funding) to the Director - General, MCAZ by email training@mcaz.co.zw ; mcaz@mcaz.co.zw.

About MCAZ

MCAZ is a statutory body established by an act of Parliament, The Medicines and Allied Substances Control Act (MASCA) [Chapter 15.03]. MCAZ is a designated Regional Centre of Regulatory Excellence (RCORE) by NEPAD Planning and Coordinating Agency.

About ICHE

The Institute of Continuing Health Education is a department in the University of Zimbabwe, College of Health Sciences (UZCHS).
It provides a facility for all forms of continuing health education for health professionals: certificated education, personal professional development, as well as skills renewal.