Bioequivalence Workshop

Presenter:
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Introduction:
Bioequivalence is a term in pharmacokinetics used to assess the expected *in vivo* biological equivalence of two preparations of a medicine. If two products are said to be bioequivalent it means that they would be expected to be, for all intents and purposes, the same.

To this regard, bioequivalence studies are used in the Pharmaceutical Industry, not only to show biological equivalence amongst variances of an innovator product manufactured by the same company and arising from life-cycle of the product, but also to show biological equivalence between an innovator product and a generic medicine.

This workshop will attempt to equip you with the knowledge to understand the link between pharmacokinetics and biological activity, the scientific basis of bioavailability and bioequivalence, the regulatory requirements for bioequivalence (study design, protocol, reports, etc.) and the interpretation of the data obtained from a bioequivalence study.

Who should take this course?
1. Regulatory Affairs pharmacists / scientists responsible for:
    - performing the due diligence on a generic pharmaceutical product dossier received from a principal.
    - compilation and submission of a generic pharmaceutical product dossier to SAHPRA / SAA.
    - the life-cycle management of an innovator and generic pharmaceutical product dossier for submission to SAHPRA / SSA.

2. Marketing / Commercial Managers in the Generic Industry wanting to understand the basis of bioequivalence, substitution, and interchangeability.

3. Medical Advisors wanting to understand the basis of bioequivalence, substitution, and interchangeability.

Course Format:
Online on Microsoft Teams

Course Content:

<u>Day 1: Tuesday 17 November 2020 (8:30 – 14:00):</u>

1. Introduction and scientific / regulatory definitions
2. Pharmacokinetics: Understanding the pharmacological basis of bioequivalence studies
3. Regulatory requirements and acceptance criteria of bioequivalence studies

Day 2: Wednesday 18 November 2020 (8:30 – 14:00):

1. Interpretation bioequivalence study results
2. Due diligence of a bioequivalence study report

Course Outcomes:

At the end of this workshop the attendee will:

1. Know the definitions and terminology associated with pharmaceutical equivalent formulations, pharmaceutical alternative formulations, bioavailability, bioequivalence, substitution and interchangeability.
2. Know the application of bioequivalence studies in drug development, formulation development, clinical trials and life-cycle management of pharmaceuticals.
3. Understand the pharmacological basis of bioavailability and bioequivalence studies.
4. Understand different bioequivalence study designs.
5. Be able to interpret the statistical analysis of data obtained from a bioequivalence study, including Confidence Intervals (CI) and the acceptance limits.
6. Be able to perform a due diligence on a bioequivalence study report.