Life & Health

FDA BIMO Course Series

BIMO is a comprehensive, agency-wide program of on-site inspections and data audits designed to monitor all aspects of the conduct and reporting of FDA-regulated research. BIMO inspection triggers include:

- *Marketing applications subject to IDE*
- *Early intervention (surveillance or routine), sponsor IRBs, Clinical Investigators and CROs*
- *New or novel technology*
- *Vulnerable population (e.g. pregnant women, children, prisoners, elderly)*
- *Complaints ("for cause")*

About the BIMO Training Program

The FDA's BIMO (Bioresearch Montoring) online training program is designed for FDA Investigators, Supervisors, Compliance Officers and Chief Science Officers (CSOs) from other Centers who have limited experience in the BIMO program and who will conduct inspections or review Establishment Inspection Reports (EIRs) of Clinical Investigators (CIs), Institutional Review Boards (IRBs), Sponsors, Monitors, Contract Research Organizations (CROs) and in vivo Bioequivalence inspections.

Using this BIMO training program, clinical professionals can become more familiar with the FDA's expectations and prepare accordingly.

BIMO: Introduction (BIMO01)

FDA CRADA

This course provides an overview of the FDA's BIMO program and the methods and techniques used in conducting and reporting Nonclinical Laboratory, Clinical Investigator, IRB, Sponsor/Monitor and in vivo Bioequivalence inspections. This course provides an overview and historical perspective of the FDA's BIMO program.

BIMO: General Inspection Assignment Process (BIMO02)

FDA CRADA

This course provides an overview of the methods and techniques used in conducting and reporting Clinical Investigator, IRB, Sponsor/Monitor and in vivo Bioequivalence inspections. This course provides an overview of the general inspection assignment process, site selection, background materials used in a BIMO inspection and regulatory consequences of the BIMO program.

BIMO: Part 50 & 56 – Institutional Review Boards (IRBs) (BIMO03)

FDA CRADA

This course provides an overview of the methods and techniques used in conducting and reporting CI, IRB, Sponsor/Monitor and in vivo Bioequivalence inspections. This course provides an overview of the regulations applicable to the protection of human subjects who participate in clinical research typically involving test articles which are unapproved for marketing, but approved for research by the FDA.

BIMO: Clinical Investigator Responsibilities (BIMO04)

FDA CRADA

This course focuses on the responsibilities of a clinical investigator who participates in clinical research involving unapproved test articles that are under FDA's jurisdiction.

After completing this course, you will be able to recognize the important regulations applicable to clinical investigators and identify how they can be applied to accomplish objectives of FDA's compliance program in this area. You will be able to identify the responsibilities of clinical investigators, which will allow you to successfully conduct inspections in the BIMO program.

BIMO: Sponsor/Monitor Responsibilities (BIMO05)

FDA CRADA

This course focuses on the responsibilities of sponsors and monitors of clinical research involving unapproved test articles that are under the jurisdiction of the FDA.

After completing this course, you will be able to recognize the roles and responsibilities of both sponsors and monitors in conducting clinical trials and utilize that knowledge to successfully conduct inspections in the BIMO program.

BIMO: In Vivo Bioequivalence Program Part I (BIMO06)

FDA CRADA

The FDA inspects the facilities of sponsors or their contractors who conduct bioequivalence studies, under the In Vivo Bioequivalence Compliance Program. It is one of the seven compliance programs of the Bioresearch Monitoring (BIMO) Program. Included in the FDA inspections are the clinical facilities where bioequivalence studies are conducted (i.e., subjects are enrolled, dosed and biological samples are collected) and analytical facilities where biological samples are analyzed to determine the concentrations of the drug.

This course will introduce you to some brand name and generic drugs, explain the importance of bioavailability and describe the underlying concept of bioequivalence for comparison of drug performance. This course will also discuss the implementation of the In Vivo Bioequivalence Compliance Program.

BIMO: In Vivo Bioequivalence Program Part II (BIMO07)

FDA CRADA

The FDA inspects the facilities of sponsors or their contractors who conduct bioequivalence studies, under the In Vivo Bioequivalence Compliance Program. It is one of the seven compliance programs of the Bioresearch Monitoring (BIMO) Program. Included in the FDA inspections are the clinical facilities where bioequivalence studies are conducted (i.e., subjects are enrolled, dosed and biological samples are collected) and analytical facilities where biological samples are analyzed to determine the concentrations of the drug.

This course will introduce you to the challenges of inspecting clinical and analytical facilities and the various technical terms commonly used in bioavailability and bioequivalence studies.