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The Global Bioequivalence Harmonisation Initiative

PQRI/EUFEPS GLOBAL Bio Equivalence HARMONISATION INITIATIVE: 6th International Workshop – GBHI 2024

In Collaboration with



Hosted by



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TUES. – WED.
APRIL 16–17, 2024

IN PERSON
WORKSHOP



USP Meeting Center
12601 Twinbrook Pkwy
Rockville, MD

We are pleased to announce Product Quality Research Institute (PQRI) is joining the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) and the European Federation for Pharmaceutical Sciences (EUFEPS) in co-sponsoring the “6th International Workshop on Global Bioequivalence Harmonization Initiative.”

The Global Bioequivalence Harmonisation Initiative (GBHI) is intended to support the process of global harmonization via scientific discussion among international stakeholders. The first GBHI Conference, held in March 2015, and all subsequent conferences have been successful due to the active participation and presentation by speakers and participants from global academia, industry, and regulatory agencies. The GBHI workshop should be an ideal platform for scientists from the pharmaceutical industry and academia to exchange their experiences and views with the regulators and engage in active scientific discussions. The GBHI Workshop location alternates between Amsterdam, the Netherlands, and the US. The 6th GBHI Workshop will be held in the US in 2024. Global regulatory, academia and industrial speakers will be invited to the discussions.

We welcome you to attend the 6th GBHI Workshop!

The topics at GBHI 2024 may include but are not limited to the following:

- Moving the needle towards convergence on ICH M13 topics
- BE Study considerations for modified-release (MR) products (Solid oral MR, long-acting injectables (LAIs), transdermal products)
- pAUC considerations in bioequivalence assessment of different drug products (solid oral immediate-release (IR) and MR products, LAI, liposomes)
- Bioequivalence assessment for orally inhaled drug products

FDA and PQRI will be holding a Workshop: [Challenges and Opportunities for Modified Release Oral Drug Product Development – A Forum for Stakeholder Engagement](#) following GBHI on April 18. This Workshop will further explore discussions on MR products that will not be covered in GBHI. [NOTE: Separate registration required.]



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Stay up to date by visiting the
Workshop Website at: <https://pqri.org/gbhi-2024/>