



In Person Event



Registration Open Click here to Register



THURSDAY, APRIL 18, 2024

Following PQRI/EUFEPS 6th International Workshop –GBHI 2024



USP Meeting Center 12601 Twinbrook Pkwy Rockville, MD



8 AM - 5 PM



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Stay up to date by visiting the Workshop Website:

https://pqri.org/fda-pqrimr-workshop/

FDA/PQRI Workshop:

Challenges and Opportunities for Modified Release Oral Drug Product Development

A Forum for Stakeholder Engagement

WORKSHOP OBJECTIVES

This FDA/PQRI Workshop will bring together leaders and subject matter experts from regulatory agencies, industry, and academia to discuss critical topics related to modified release (MR) drug products for oral administration.

This workshop aims to facilitate interaction among stakeholders to:

- Review recent advances in pharmaceutical science and technology for MR drug products.
- Discuss special topics related to demonstrating BE for generic MR products.
- Discuss current state modeling approaches for BE assessment for MR drug products to support regulatory approval.
- Identify factors constituting alternative in vitro approaches to support BE for additional strengths of MR products.

PQRI encourages anyone who is interested in MR product development to register for this workshop and join the in-depth discussion surrounding MR product development.

For those who plan to attend the <u>6th GBHI Workshop</u> (April 16-17), this Workshop will further explore discussions on MR products that will not be covered in GBHI.