U.S. FOOD & DRUG ADMINISTRATION

PQRI Product Quality Research Institute

In-Person Event Only

SAVE THE DATES!

REGISTRATION TO OPEN IN MID DECEMBER 2024

THURS.- FRI., MARCH 20-21, 2025

Bethesda Marriott Pooks Hill
Bethesda, MD

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Stay up to date by visiting the PQRI Website: https://pqri.org/fda-pqri-anda-quality-workshop/

FDA/PQRI Workshop:

Exclusive Face-to-Face Workshop with Senior-Level FDA Experts: *ANDA Quality with CDER's Office of Pharmaceutical Quality*

WORKSHOP OBJECTIVES

This FDA/PQRI Workshop will bring together experts from industry and senior leaders from CDER's Office of Pharmaceutical Quality (OPQ) for interactive discussions on critical topics related to generic drug manufacturing and quality.

Attendees of this *in-person only* workshop can expect live educational presentations from senior, highly experienced regulatory experts on quality topics across the generic drug lifecycle. These focused presentations will cover topics including expectations for applicants of generic drug products, common pitfalls and CMC issues for generic drug manufacturers, and the policy landscape for generic drugs.

This workshop will also provide attendees with interactive discussions with OPQ senior-level experts and leaders on real-world issues related to generic drugs. These live, in-person, interactive sessions between FDA experts and workshop participants will offer a unique opportunity for focused interactions on generic drugs.

PQRI and FDA invite regulatory affairs, CMC, and quality assurance specialists from generic drug manufacturers to join experts and leaders from CDER's OPQ in Rockville, Maryland for this rare opportunity. Only select recordings of the live presentations may be made available for the public after the workshop. In-person attendance will contribute to strengthening the global commitment to pharmaceutical quality.