Virtual Event

REGISTRATION IS OPEN.
CLICK HERE TO REGISTER

TUES. - WED.
SEPT. 26-27, 2023

VIRTUAL WORKSHOP

10 AM - 3 PM each day

+1 (202) 230-5607

PQRISecretariat@pqri.org

Stay up to date by visiting the Workshop Website at:
https://pqri.org/fda-pqri-aiworkshop/

www.pqri.org

PQRI Product Quality Research Institute

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA/PQRI Workshop on the Regulatory Framework for the Utilization of Artificial Intelligence in Pharmaceutical Manufacturing

An Opportunity for Stakeholder Engagement

WORKSHOP OBJECTIVES

This FDA/PQRI Workshop will bring together leaders from regulatory agencies, industry, and academia to discuss critical topics related to the use of artificial intelligence (AI) in pharmaceutical manufacturing.

The National Academies of Sciences, Engineering, and Medicine (NASEM) noted that FDA is likely to see substantial innovations in pharmaceutical manufacturing which may impact process measurement, modeling, and control. AI technologies represent an area of rapid technology growth for designing, monitoring, and controlling manufacturing processes. Such AI technologies may challenge traditional approaches to regulating pharmaceutical manufacturing.

This workshop aims to facilitate interaction among AI stakeholders on critical areas for development, implementation, and regulatory consideration including uses in process development and control, operation of Pharmaceutical Quality Systems, lifecycle approaches, and Current Good Manufacturing Practice.

The FDA recently published a discussion paper on this topic in the Federal Register and the comment period ended on May 1, 2023.

PQRI encourages anyone interested in utilizing AI technologies in pharmaceutical manufacturing to register for this workshop and join the discussion.