Conference Description:
The 4th FDA/PQRI Quality Conference will bring together leaders from regulatory agencies, industry, and academia to discuss key, critical topics in drug product quality. Following morning plenary sessions on Days 1 & 2, attendees will breakout into themed concurrent tracks:

**Track #1: Novel Approaches to Improve Treatment Outcome and Patient Safety**
- Providing the intended therapeutic effect, in a safe manner, is the centerpiece of a quality drug product. The complexity of novel formulations and modalities increases the needs for robust characterization of such products and integration of knowledge/data to first understand and subsequently project their clinical behavior. Novel characterization methodologies and tools and modeling and simulation approaches will be discussed towards these goals.

**Track #2: Emerging Technologies and Patient Centricity in Early Drug Development**
- Current and future thinking on the role of new/emerging technologies in driving contemporary early development across the broad small-to-large molecule spectrum. Advancing understanding, dialogue and awareness of opportunities to “design in” patient centricity as a core attribute and consideration in early drug development to enhance the overall patient experience.

**Track #3: Novel Manufacturing Technologies and Challenges for the Production of Patient-Centric Drug Products**
- The rapidly evolving manufacturing methods for gene and cell based therapies and continuous processes require new approaches related to analytics, validation and registration. This Track will explore each of these areas and the evolving expectations.

Day 3 will include a Special Plenary Session with FDA and the introduction of a new FDA Initiative (details to come).

Now Accepting Poster Abstracts, see website for details.


Conference Information can be found at:: [http://pqri.org/4th-fda-pqri-conference/](http://pqri.org/4th-fda-pqri-conference/)

Questions? Contact the PQRI Secretariat at: PQRISecretariat@pqri.org.

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