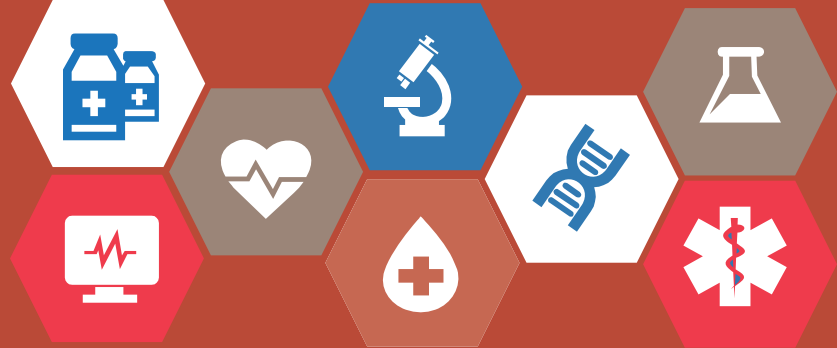


Industry, Government and Academia Collaborating for Excellence in Pharmaceutical Research



PQRI Development Technical Committee (DTC)

Current Projects:

4th PQRI/FDA Conference on Advancing Product Quality (April 9-11, 2019) - Developing and supporting Development Track for Conference

Parenteral and Ophthalmic Drug Products (PODP) - Best practices and toxicological evaluation approaches for extractables and leachables in parenteral and ophthalmic drug products (PODP).

- April 18-19, 2018 PQRI PODP Workshop

Stability Shelf Life - Investigating and developing improved statistical approaches for setting shelf life based on stability data. Paper published September 2017.

Emerging Projects:

Development of White Paper on Vial Transfer Spikes

MISSION

The mission of the Development Technical Committee is to promote scientific studies to engender science-based regulatory policy relating to the development of drugs and drug products, working with industry, academia, pharmacopeias, and regulatory agencies.

Past Project Examples: (Reports, White Papers available at: <http://pqri.org/publications/>)

Container-Closure - Demonstrated that MVTR/Unit is a Critical Parameter in defining equivalence; definition of optimal parameters for bottles, low and high barrier films. Standard WVTR Test Method ratified as D7709-11 by ASTM D10.32; publication of draft Barrier Performance Determination Method in USP; USP/PQRI Workshop; publication of PF Stimuli Article Development and Application of MVTR/Unit Data in Regulatory Submissions.

Excipients - Published survey results and FDA concepts on Excipient Control Strategies; held a workshop on current industry and regulatory practices.

Leachables & Extractables in Orally Inhaled & Nasal Drug Products - Developed recommendations for E&L in orally inhaled & nasal drug products, related training courses and scientific publications, including the book *Leachables and Extractables Handbook: Safety Evaluation, Quantification, and Best Practices Applied to Inhalation Drug Products*.

Stability Shelf Life - Published alternate statistical techniques for estimating shelf-life.

Sulfonate Esters - Developed highly sensitive analytical test methods to detect sulfonic acid esters and used them to study targets in varying conditions.

Call for Volunteers

If you are a member of a PQRI member organization (CHPA, FDA, Health Canada, IPEC-Americas, PDA or USP) and want to participate in the DTC or a Working Group, please contact the PQRI Secretariat (PQRIsecretariat@pqri.org) for further information.



Benefits of Participating in PQRI

- Collaborate and share knowledge with peers in the industry and with regulators
- Work directly with regulatory agency scientists and industry experts
- Opportunities to participate in leadership roles, to make presentations in public forums, and to publish
- Help direct the consortium's activities related to current and emerging drug product quality topics
- Develop creative and collaborative approaches to addressing challenges related to regulation/science of drug products
- Develop and expand your network of industry peers



Product Quality Research Institute

www.pqri.org