# 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 D7709-11by 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.

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www.pqri.org

# 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

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