Product Quality Research Institute

Introduction to PQRI
Industry, government, and academia collaborating for excellence in pharmaceutical research, product quality, and regulation
The Product Quality Research Institute (PQRI) is a non-profit consortium of organizations working together to generate and share timely, relevant, and impactful information that advances drug product quality, manufacturing, and regulation.
PQRI will be the leading organization in creating best practice and conducting joint research in support of biopharmaceutical regulation, through a unique global collaboration among academia, industry, and regulatory agencies, leveraging their intellectual, scientific and technical resources to advance drug development and regulation to benefit patients.
Who We Are - Members

- FDA: U.S. Food & Drug Administration
- Health Canada
- CHPA: Consumer Healthcare Products Association
- PQRI: Product Quality Research Institute
- PDA: Parenteral Drug Association
- USP: U.S. Pharmacopeial Convention
Why PQRI?

- PQRI’s inclusion of regulatory agencies and standard-setting bodies as members, facilitates collaboration pathways across regulators, academia and industry.
- PQRI provides resources to support research projects that serve as stimuli for global regulatory policy developments.
- PQRI helps its member organizations meet their missions by identifying work of broad interest to those organizations' members.
- PQRI provides a non-competitive platform that encourages and facilitates inter-organizational collaboration.
Benefits of PQRI Membership and Participation

• Engage in a unique, diverse, neutral forum of thought leaders from regulatory agencies, standard setting bodies, industry and academia at strategic and technical levels, to conduct research and share knowledge on emerging scientific and regulatory quality challenges

• Impact global regulatory guidance and standards

• Mutually accomplish goals that cannot be achieved by individual organizations alone, by leveraging the energy, resources, and intelligence of leading global organizations

• Develop broad consensus, to bring maximum value to members and patients
## Current PQRI Work Groups

<table>
<thead>
<tr>
<th>Biopharmaceutics Technical Committee (BTC)</th>
<th>Development Technical Committee (DTC)</th>
<th>Manufacturing Technical Committee (MTC)</th>
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<tbody>
<tr>
<td>Working Group on Multiple level C IVIVC, level A IVIVC, and BE in defining clinically relevant specifications for IR and MR products</td>
<td>PODP: Best practices and toxicological evaluation approaches for extractables and leachables in parenteral and opthalmic drug products (PODP)</td>
<td>Elemental Impurities</td>
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<td>• Phase 2 Study-conducting EI research to investigate variability of ICP-MS analysis of elemental impurities</td>
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<td>• 3rd Workshop (Nov 2-3, 2017)</td>
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<td>Topical Drugs Classification System [sponsored with MTC]</td>
<td>Stability Shelf Life: Investigating and developing improved statistical approaches for setting shelf life based on stability data</td>
<td>Topical Drugs Classification System [with BTC]</td>
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<td>Development of a Biopharmaceutics Classification System (BCS) for Pulmonary Drugs and Drug Products</td>
<td>Development of White Paper on Vial Transfer Spikes (developing)</td>
<td>Disinfectant Coupon Testing</td>
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<td>2018 Webinar Series:</td>
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<td>Cleaning validation/qualification (developing)</td>
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<td>• April 9, 2018</td>
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<td>• June 19, 2018</td>
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<td>• October 23, 2018</td>
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<td>• November/December 2018</td>
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<td>See <a href="#">website</a> for details</td>
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<td>BTC Benchmarking Survey (developing)</td>
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<td>Definition of lot and discard approaches in continuous manufacturing (developing)</td>
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<tr>
<td>QbD Working Group: White paper on &quot;Challenges to and Opportunities in Comprehensive QbD Implementation“ (developing)</td>
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Selected PQRI Outputs

Evolution of Choice of Solubility and Dissolution Media After Two Decades of Biopharmaceutical Classification System

Authors: Nadia Bou-Chacra, Katherine Jasmine Curo Melo, Ivan Andrés Cordova Morales, Erika S. Stippler, Filippos Kesisoglou, Mehran Yazdani, Raimar Löbenberg

More available at: www.pqri.org/publications
Selected PQRI Outputs

The Effect of Excipients on the Permeability of BCS Class III Compounds and Implications for Biowaivers
Authors: Alan Parr, Ismael J. Hidalgo, Chris Bode, William Brown, Mehran Yazdani, Mario A. Gonzalez, Kazuko Sagawa, Kevin Miller, Wenlei Jiang, Erika S. Stippler

On the Shelf Life of Pharmaceutical Products
Authors: Robert Capen, David Christopher, Patrick Forenzo, Charles Ireland, Oscar Liu, Svetlana Lyapustina, John O’Neill, Nate Patterson, Michelle Quinlan, Dennis Sandell, James Schwenke, Walter Stroup and Terrence Tougas

More available at: www.pqri.org/publications
Selected PQRI Outputs

FDA-PQRI: Process Drift

Pharmaceutical Technology®

Detection, Measurement, and Control in Pharma Manufacturing
PQRI-FDA Workshop Summary on Process Drift

Margaret M. Szymczak, Richard L. Friedman, Rajandra Upoor, and Avraham Yacobi

A PQRI White Paper

Process Robustness – A PQRI White Paper

by PQRI Workgroup Members

More available at: www.pqri.org/publications

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Examples of PQRI Outputs

Reviewed in International Journal of Toxicology (2012;31[5]:496-7)

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# Example PQRI Impact/Support on Regulatory Guidance, Standards

<table>
<thead>
<tr>
<th>PQRI Project</th>
<th>Supported Guidance/Guidelines, Standards</th>
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<tr>
<td><strong>BCS Class III Biowaivers</strong></td>
<td>FDA Draft Guidance, Waiver of in vivo BA and BE studies for IR solid orals based on BCS</td>
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<tr>
<td><strong>Process Robustness</strong></td>
<td>ICH Q8, Q9</td>
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<tr>
<td><strong>Extractables &amp; Leachables</strong></td>
<td>FDA Draft Guidance, MDIs/DPIs USP 1663 USP 1664</td>
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<tr>
<td><strong>Container Closure</strong></td>
<td>FDA Guidance, Changes to an approved NDA or ANDA</td>
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UPCOMING: 4th PQRI/FDA conference to be held April 9-11, 2019. Registration to open in September 2018

Past Conferences:
1st FDA/PQRI Conference on Evolving Product Quality
• September 16-17, 2014
• A Summary of the Inaugural FDA/PQRI Conference

2nd FDA/PQRI Conference on Advancing Product Quality
• October 5-7, 2015
• A Summary of the Second FDA/PQRI Conference

3rd FDA/PQRI Conference on Advancing Product Quality
• March 22-24, 2017
• Presentations
### Additional Select PQRI Conferences/Workshops

#### 2018
- **PQRI Workshop on Safety Thresholds and Best Demonstrated Practices for Parenteral and Ophthalmic Drug Products (PODP)** (April 18-19, 2018)

#### 2017
- **PQRI/USP Workshop on ICH Q3D Elemental Impurities Requirements – Recent Experience and Plans for Full Implementation in 2018** (Nov 2-3, 2017)
- **ISPE/FDA/PQRI 2017 Quality Manufacturing Conference** (June 5-7, 2017)

#### 2016
- **PQRI/USP Workshop on Implementation Status of ICH Q3D Elemental Impurity Requirements- Analytical and Risk Assessment Challenges** (Nov. 9-10, 2016)
- **ISPE 2016 Process Validation/Process Validation Statistics Conferences** (October 24-27, 2016) Co-Sponsored by PQRI
- **PDA Biosimilars Conference** (June 20-21, 2016) Co-Sponsored by PQRI
- **ISPE/FDA/PQRI Quality Manufacturing Conference** (June 6-8, 2016)

#### 2015
- **PQRI/USP Workshop on Elemental Impurity Requirements in a Global Environment – Next Steps?** (March 31-April 1, 2015)
Looking Forward: Strategic Goals

1. Be recognized internationally as a leading forum for advancing science in support of regulation.

2. Engender pro-active participation from all member organizations at all levels of consortium activity.

3. Build and maintain a portfolio of projects of high value to industry and regulators.

4. Expand membership and outreach internationally to industry, academics and regulatory agencies to enhance and further diversify expertise and information sharing.

5. Enhance member organization benefits through PQRI activities work product.

PQRI 2018-2022 Strategic Plan

August 2018
BTC Past Projects Examples


- **BCS Review Paper – Two Decades of the Biopharmaceutics Drug Classification System: An Update on Solubility and Dissolution** (published July 2017)

- **BCS Class III Biowaivers** - Evaluation of commonly used excipients in IR solid dosage forms on the intestinal permeability of several BCS III drugs provides a basis to extend BCS biowaivers to Class III drugs and supports a revision of the FDA guidance.

- **Sequential Design** - Scientific and regulatory research in bioavailability and bioequivalence study designs provided support for FDA policies and guidances for in vitro and in vivo methodologies.
DTC Past Projects 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.


- **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.
MTC Past Projects Examples

(Reports, White Papers available at: http://pqri.org/publications/)

- **Process Robustness** -- developed a White Paper on process robustness concept and how it applies to development, scale up, and manufacture of pharmaceutical products.

- **Post Approval Changes for Sterile Products** -- published report providing regulatory CMC information relevant to development of a Post Approval Guidance for Sterile Drug Products for Human, Veterinary, and Well Characterized Biological Products.

- **Case Studies for Risk Management** -- developed case studies providing specific pharmaceutical examples using different QRM tools, and recommendations for which tools to use in different areas, and training guides.

- **Biologicals Inspection Survey** -- surveyed the biological products manufacturing industry, with emphasis on inspection and compliance of program operations; published report.

- **Specification Design and Lifecycle Management** – created a concept paper to stimulate discussion on processes and activities that occur from creation through development and commercialization of molecule to drug product.

- **Transdermals** – published an update to the 1997 SUPAC Transdermal White Paper to include QbD, PAT, and FDA and industry initiatives on development, scale-up, manufacture and control of transdermals.
Questions?

Contact the PQRI Secretariat at:

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PQRI_secretariat@pqri.org