Product Quality Research Institute

Introduction to PQRI
Global Reach

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.
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 regulators, 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 external stakeholders
# 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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</table>
| Solubility, Permeability Review Paper    | PODP: Best practices and toxicological evaluation approaches for extractables and leachables in parenteral and ophthalmic drug products | Elemental Impurities  
- Phase 2 Study  
- Workshop (Nov 2-3, 2017) |
| Multiple level C IVIVC, level A IVIVC, and BE in defining clinically relevant specifications for IR and MR products | Stability Shelf Life: Investigating and developing improved statistical approaches for setting shelf life based on stability data | Excipient Variability |
| Mechanistic oral absorption modeling and simulation studies | Feasibility of establishing a formulation decision tree for optimizing the oral bioavailability of poorly soluble drugs (BCS II and IV drugs) [developing] | Topical Drugs Classification System [with BTC] |
| Topical Drugs Classification System [sponsored with MTC] | | Coupon testing [developing] |
| In Silico Formulation Design Space [developing] | | Cleaning validation/qualification [developing] |
Selected PQRI Outputs

**Pharmaceutical Research**

The Effect of Excipients on the Permeability of BCS Class III Compounds and Implications for Biowaivers

Authors: Alan Parr, Ismael J. Hidalgo, Chris Rode, William Brown, Mehran Yazdantian, Mario A. Gonzalez, Kazuko Sagawa, Kevin Miller, Wenlei Jiang, Erika S. Stippler

Access the most recent version at doi: 10.5731/pdajpst.2013.00936

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**PDA Journal of Pharmaceutical Science and Technology**

The Product Quality Research Institute (PQRI) Leachables and Extractables Working Group Initiatives for Parenteral and Ophthalmic Drug Product (PODP)

Diane Paskiet, Dennis Jenke, Douglas Ball, et al.

*PDA J Pharm Sci and Tech* 2013, 67, 430-447
Access the most recent version at doi: 10.5731/pdajspst.2013.00936

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On the Shelf Life of Pharmaceutical Products

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

*AAPS PharmSciTech*
September 2012, Volume 13, Issue 3, pp 911-918

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More available at: [www.pqri.org/publications](http://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, Rajendra Upoor, and Avraham Yacobi

Process Robustness – A PQRI White Paper
by PQRI Workgroup Members
Michael Giodek, Merck & Co.; Stephen Liebowitz, Bristol-Myers Squibb; Randal McCarthy, Schering Plough; Grace McNally, FDA; Cynthia Oksanen, Pfizer; Thomas Schultz, Johnson & Johnson; Mani Sundararajani, AstraZeneca; Rod Vorkapich, Bayer Healthcare; Kimberly Vukovinsky; Pfizer, Chris Watts, FDA; and George Mililli, Johnson & Johnson - Mentor

More available at: www.pqri.org/publications

June 2017
Examples of PQRI Outputs

Leachables and Extractables Handbook

Safety Evaluation, Qualification, and Best Practices Applied to Inhalation Drug Products

Reviewed in International Journal of Toxicology (2012;31[5]:496-7)
## 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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<tbody>
<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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FDA/PQRI Conferences

UPCOMING:
Next conference to be scheduled in 2019.

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

UPCOMING:
• PQRI/USP Workshop on ICH Q3D Elemental Impurities Requirements – Recent Experience and Plans for Full Implementation in 2018 (Nov 2-3, 2017)

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

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

02. Be recognized internationally as a forum for advancing science in support of regulatory advancement

03. Expand membership of PQRI internationally to enhance and further diversify expertise, and assist in funding research

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

05. Expand outreach to global industry, regulatory and academic stakeholders

June 2017
BTC Past Projects Examples

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

- **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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