MISSION

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 global drug product quality, manufacturing, and regulation.
VISION

PQRI will be the leading organization in creating best practices and conducting joint research in support of pharmaceutical and 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 – Our Members

PQRI
Product Quality Research Institute

CHPA
CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

FDA
U.S. FOOD & DRUG ADMINISTRATION

PDA
Parenteral Drug Association

Health Canada

IPEC
INTERNATIONAL PHARMACEUTICAL EXCIPIENTS COUNCIL

U.S. Pharmacopoeial Convention

August 2018
What Does PQRI Do?

• Unites thought leaders from regulatory agencies, standard setting bodies, industry and academia to conduct research and share knowledge on emerging scientific and regulatory quality challenges

• Provides a unique, neutral forum to develop broad consensus among a diverse collection of industry organizations and regulatory bodies

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

• Impacts global regulatory guidance and standards, bringing maximum value to members and patients
What Makes PQRI Unique?

• PQRI’s inclusion of regulatory agencies and standard-setting bodies as members as well as its distinct organizational structure, allows for direct connection between regulators, academia and industry and fosters cross-collaborative pathways between these various stakeholders
• PQRI provides resources to support research projects that serve as stimuli for and help shape global regulatory policies
• PQRI helps its member organizations meet their missions by identifying work of broad interest to those organizations' members
• PQRI provides a platform that encourages and facilitates inter-organizational collaboration
Benefits of PQRI Membership

Benefits to member organizations include:
• Play a direct role in shaping the consortium’s activities and setting its scientific and regulatory priorities.
• Unlimited participation on PQRI technical committees and working groups
• Engage with other key stakeholders and impact global regulatory standards and guidance

Benefits to individual members of PQRI organizations include:
• Collaborate, share knowledge and work directly with peers in the industry and with regulators. Expand your network.
• Opportunities to participate in leadership roles, present in public forums, and to publish in peer-reviewed scientific journals
• Develop creative and collaborative approaches to addressing current and emerging challenges related to regulation, development and quality of drug products
• Help direct and drive the consortium’s technical and scientific activities
PQRI Organizational Chart 2018

Board of Directors
Margaret M. Szymczak, Chair; Mehran Yazdanian, Ph.D., Treasurer
Stephen Tyler; Tina Morris, Ph.D., Jennifer Ahearn

Steering Committee
Stephen Tyler, Chair; Jennifer Ahearn, Vice-Chair
John Punzi, Ph.D. (CHPA); Dave Schoneker (IPEC-Americas); Tina Morris, Ph.D. (PDA); Lawrence Yu, Ph.D., (FDA); Anita DiFranco (Health Canada); Horacio Pappa, Ph.D., (USP)

FDA/PQRI Conferences on Advancing Product Quality

PQRI Secretariat

Development Technical Committee
Chris Moreton, Ph.D., Chair
Diane Paskiet, Vice Chair

Biopharmaceutics Technical Committee
Filippos Kesisoglou, Ph.D., Chair
Wenlei Jiang, Ph.D., Vice Chair

Manufacturing Technical Committee
Glenn Wright, Chair
The Board of Directors and Steering Committee are the dual governing bodies of PQRI.

• The **Board of Directors** is vested with the administrative management, growth, and operation of the Institute, except for those activities involving scientific decision making, which are delegated to the PQRI Steering Committee.
  – Each non-governmental member organization is entitled to nominate members to be elected to the Board, which consists of five seats, including the Chair and Treasurer.

• The **Steering Committee** has sole authority over all scientific activities conducted under the auspices of the Institute and is responsible for recommending the disbursement of funds towards those activities, to the Board of Directors.
  – Each member organization is entitled to representation on the Steering Committee and one vote on requiring matters.
Technical Committees

PQRI consists of three Technical Committees, each with a broad disciplinary focus that collectively spans the drug product regulatory lifecycle. Technical Committees provide scientific guidance, direction and oversight to the PQRI Working Groups and recommendations to the Steering Committee.

- The mission of the Development Technical Committee (DTC) 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.
- The mission of the Manufacturing Technical Committee (MTC) is to leverage our manufacturing expertise to define science-based approaches that appropriately integrate risk assessment and will encourage innovation and continuous quality improvement in pharmaceutical manufacturing and flexibility in the associated regulatory processes.
- The mission of the Biopharmaceutics Technical Committee (BTC) is to identify, disseminate, and facilitate scientific and technical projects to address gaps in biopharmaceutical aspects of drug development and global regulatory guidance. The BTC will translate current and emerging ideas in the pharmaceutical field into proposals for implementing unbiased research projects and delivering results that impact regulatory policies.
### 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>
| Multiple level C IVIVC, level A IVIVC, and BE in defining clinically relevant specifications for IR and MR products | Best practices and toxicological evaluation approaches for extractables and leachables in parenteral and ophthalmic drug products (PODP)  
- White paper  
- Workshops | Research study to investigate variability of ICP-MS analysis of elemental impurities  
- White paper  
- Workshops |
| **Topical Drugs Classification System** [sponsored with MTC]  
  - White papers  
  - Workshops | Investigating and developing improved statistical approaches for setting shelf life based on stability data  
- White paper  
- Workshop | **Topical Drugs Classification System** [with BTC]  
  - White papers  
  - Workshops |
| Development of a Biopharmaceutics Classification System (BCS) for Pulmonary Drugs and Drug Products | Development of Guidance and Standards for Vial Transfer Devices (developing) | Pharmaceutical Excipient Variability and Its Impact on Pharmaceutical Products  
- Publication |
| **2018 Webinar Series:** See [website](#) for details | | Cleaning validation/qualification (developing) |
| BTC Benchmarking Survey (developing) | | Cleaning validation/qualification (developing) |
| Challenges to and Opportunities in Comprehensive QbD Implementation (developing) | | Definition of lot and discard approaches in continuous manufacturing (developing) |
Selected PQRI Publications

The AAPS Journal

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

Authors and affiliations

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

AAPS PharmSciTech

Evaluating Current Practices in Shelf Life Estimation

Authors and affiliations

Robert Capen, David Christopher, Patrick Forenzo, Kim Huynh-Ba, David LeBlond, Oscar Liu, John O’Neill, Nate Patterson, Michelle Quinlan, Radhika Rajagopalan, James Schwenke, Walter Stroup

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

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

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)

On the Shelf Life of Pharmaceutical Products

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

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 Yacobion

Process Robustness – A PQRI White Paper

by PQRI Workgroup Members

Michael Giodek, Merck & Co., Stephen Lipkowitz, Bristol-Myers Squibb; Randall McCarthy, Bristol-Myers Squibb; Grace McNulty, FDA; Cynthia Okashea, Pfizer; Thomas Schultz, Johnson & Johnson; Mari Sundaramjian, AstraZeneca; Rod Worktoph, Bayer Healthcare; Kimberly Volovitsky, Pfizer; Chris Watts, FDA; and George Moe, Johnson & Johnson - Merck

More available at: www.pqri.org/publications
Examples of PQRI Publications

Reviewed in International Journal of Toxicology (2012;31[5]:496-7)
# PQRI Impact - Regulatory Guideline and Standards

<table>
<thead>
<tr>
<th>PQRI Project</th>
<th>Supported Guidance and Standards</th>
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<tbody>
<tr>
<td>BCS Class III Biowaivers</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>Process Robustness</td>
<td>ICH Q8, Q9</td>
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<tr>
<td>Extractables &amp; Leachables</td>
<td>FDA Draft Guidance, MDIs/DPIs USP 1663 USP 1664</td>
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<tr>
<td>Container Closure</td>
<td>FDA Guidance, Changes to an approved NDA or ANDA</td>
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UPCOMING: 4th PQRI/FDA Conference on Advancing Product Quality: 
*Patient Centric Product Design, Drug Development, and Manufacturing*

Past Conferences:

**3rd FDA/PQRI Conference on Advancing Product Quality**
- March 22-24, 2017
- [Presentations](#)

**2nd FDA/PQRI Conference on Advancing Product Quality**
- October 5-7, 2015
- *[A Summary of the Second FDA/PQRI Conference](#)*

**1st FDA/PQRI Conference on Evolving Product Quality**
- September 16-17, 2014
- *[A Summary of the Inaugural FDA/PQRI Conference](#)*
Additional Select PQRI Conferences/Workshops

2018
• **USP Workshop: Enhanced Approaches for Analytical Procedure Lifecycle: An Alternative to Traditional Validation** (Sept. 24-25, 2018) PQRI Member Event

• **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)
Looking Forward: Strategic Goals

1. Promote science-based regulation by developing and delivering a portfolio of projects and public platforms of high value to industry and regulators.

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

3. Enhance member organization benefits through PQRI work product.

4. Build and maintain international recognition as a leading forum for advancing science in support of regulation.

PQRI 2018-2022 Strategic Plan
**BTC Past Projects**


- **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

(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

(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.

- **Biologics 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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PQRISecretariat@pqri.org