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.

July 2020
VISION

Through a unique global collaboration among academia, industry, and regulatory agencies, PQRI will be the leading organization in creating best practices and conducting joint research in support of pharmaceutical and biopharmaceutical regulation, leveraging its 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

IPEC
INTERNATIONAL PHARMACEUTICAL EXCipients COUNCIL

PDA
Parenteral Drug Association

Health Canada

U.S. Pharmacopoeial Convention

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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

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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. The Board has authority over the collection and disbursement of funds and the administrative procedures required to ensure the effective operation of the Institute.
  - 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 provide scientific guidance, direction, and oversight to the PQRI Working Groups and recommendations to the Steering Committee. PQRI consists of three Technical Committees, each with a broad disciplinary focus that collectively spans the drug product regulatory lifecycle.

- 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 **Product Quality Technical Committee (PQTC)** is to leverage our regulatory, quality, and manufacturing expertise to define science-based approaches (appropriately integrating an assessment of risk) that 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>Product Quality Technical Committee (PQTC)</th>
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<tbody>
<tr>
<td><strong>IVIVC</strong> – Best practices for the application of multiple level C IVIVC, level A IVIVC, and BE in defining clinically relevant specifications for IR and MR products</td>
<td><strong>Extractables &amp; Leachables in Parenteral Drug Products</strong> - Establishing best practices and thresholds for toxicological evaluation approaches for extractables and leachables in parenteral drug products.</td>
<td><strong>Elemental Impurities</strong> - Conducting research to investigate variability of ICP-MS analysis of elemental impurities and address key technical challenges in complying with ICH Q3D. Three workshops have been held to share industry experiences related to implementation of ICH Q3D. Another will be held in November 2020.</td>
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<td>Development of a <strong>Topical Drugs Classification System</strong> (TCS) [joint effort with PQRI PQTC]</td>
<td><strong>Polymeric Excipient Risk Assessment</strong> - Development of a risk assessment strategy to provide scientific justification for reduced safety testing of new higher molecular weight polymeric excipients for non-parenteral administration.</td>
<td>Development of a <strong>Topical Drugs Classification System</strong> (TCS) [joint effort with PQRI BTC]</td>
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<tr>
<td>Development of a <strong>Biopharmaceutics Classification System for Inhaled Medicines</strong> (iBCS)</td>
<td>Development of Guidance and Standards for <strong>Closed System Transfer Devices</strong> (developing)</td>
<td><strong>Artificial Intelligence (AI) Application in Continuous Process Verification (CPV)</strong> (developing)</td>
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<td><strong>Webinar Series:</strong> See <a href="#">website</a> for details</td>
<td></td>
<td><strong>Restricted Delivery Systems in Children’s OTC Liquid Medications</strong> (developing)</td>
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Selected PQRI Publications

The AAPS Journal
July 2017, Volume 19, Issue 4, pp 969-1001 | Cite as

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, Filippou Kesisoglou, Mehran Yazdani, Raimar Løbenberg

AAPS PharmSciTech
pp 1-13 | Cite as

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'Neil, 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

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

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.

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

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 Yacobi

Process Robustness – A PQRI White Paper

More available at: www.pqri.org/publications

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Examples of PQRI Publications

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

<table>
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<tr>
<th>PQRI Project</th>
<th>Supported Guidance and 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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<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: 5th PQRI/FDA Conference on Advancing Product Quality: *Patient Centric Product Design, Drug Development, and Manufacturing*
To be held in Spring 2021

Past Conferences:

4th PQRI/FDA Conference on Advancing Product Quality: *Patient Centric Product Design, Drug Development, and Manufacturing*
- April 9-11, 2019
- Presentations

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 Events

2020
• PQRI Biopharmaceutics Technical Committee (BTC) Webinars

• PQRI Workshop on ICH Q3D Elemental Impurities Requirements – November 2020

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)
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

July 2020
BTC Past Projects

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

- **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.
PQTC 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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PQRI_secretariat@pqri.org