MISSION

The Product Quality Research Institute (PQRI) is a non-profit consortium of organizations, including standard setting and regulatory agencies, working together to generate and share timely, relevant, and impactful information that advances global drug product quality, manufacturing, and regulation.
Through a unique global collaboration among academia, industry, and regulatory agencies, PQRI will continue to be a leading organization in creating best practices and conducting joint research in support of global 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
Taking healthcare personally.

IPAC-RS
International Pharmaceutical Aerosol Consortium on Regulation & Science

IPEC Americas
Excipients Council

FDA
U.S. Food & Drug Administration

PDA
Parenteral Drug Association

Health Canada

USP
United States Pharmacopeia
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 PQRI’s activities and setting its scientific and regulatory priorities
- Cross-collaborate efficiently among PQRI members to broaden understanding of industry and regulatory concerns, needs and trends.
- Engage with other key stakeholders and impact global regulatory standards and guidance
- Access to all PQRI technical committees and working groups

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 PQRI’s technical and scientific activities
PQRI Organizational Chart 2022

Board of Directors

Glenn Wright, Chair (PDA) Mehran Yazdanian, Ph.D., Treasurer (Teva; USP)
Diane Paskiet (West Pharmaceutical Services, Inc.; PDA), John Punzi, Ph.D. (CHPA),
Wenlei Jiang, Ph.D., (FDA; non-voting Board member)

Steering Committee

Wenlei Jiang, Ph.D., Chair (FDA) Diane Paskiet, Vice Chair (West Pharmaceutical Services, Inc.; PDA)
John Punzi, Ph.D. (CHPA); Jennifer Wylie, Ph.D. (Merck; IPAC-RS); Dave Schoneker (IPEC-Americas); Glenn Wright (PDA); Lawrence Yu, Ph.D., (FDA); Anita DiFranco (Health Canada); Horacio Pappa, Ph.D., (USP);
Jennifer Ahearn, Immediate Past Chair (ESi, CHPA)

Development Technical Committee
Doug Kiehl, Chair (Eli Lilly & Company; USP)
Susan Rosencrance, Ph.D., Vice Chair (FDA)

Biopharmaceutics Technical Committee
Ajit Narang, Ph.D., Chair (ORIC Pharmaceuticals; IPEC-Americas)
Andreas Abend, Ph.D., Vice Chair (Merck & Co., Inc.; IPEC-Americas)

Product Quality Technical Committee
Cat Vicente, Chair (Johnson & Johnson, CHPA)
Jean Poulos, Vice Chair (Rochem International; PDA)

FDA/PQRI Conferences on Advancing Product Quality

PQRI Secretariat
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

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.
<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>Biopharmaceutics Classification System for Inhaled Medicines (iBCS)</strong> (in progress)</td>
<td><strong>Extractables &amp; Leachables in Parenteral Drug Products</strong> - To justify the use of safety thresholds for identification and risk assessment of PODP leachables, the WG conducted and evaluated the results of extraction studies on polymeric materials and evaluated a database of over 600 potential leachables. Based on their findings, the WG developed a set of best practices for parenteral drug products. See <a href="#">publication</a>.</td>
<td><strong>Elemental Impurities</strong> - Conducted research to investigate variability of ICP-MS analysis of elemental impurities and address key technical challenges in complying with ICH Q3D. (Phase 2 Study completed, papers in progress.) Held four workshops to share industry experiences related to implementation of ICH Q3D. (See <a href="#">website</a>.)**</td>
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<td><strong>Standardization of an in vivo predictive dissolution methodologies and in silico bioequivalence study</strong> (in progress)</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><strong>Topical Drugs Classification System (TCS)</strong> [joint effort with PQTC] (papers in progress)</td>
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<tr>
<td><strong>Topical Drugs Classification System (TCS)</strong> [joint effort with PQTC] (papers in progress)</td>
<td><strong>Guidance for Interconnectivity between Vial Container Closure Systems and Vial Transfer Devices</strong> (survey conducted and paper in progress)</td>
<td><strong>Artificial Intelligence (AI) Application in Continuous Process Verification (CPV)</strong> (in progress; experiments conducted at UMBC and University of Barcelona) (papers in progress)</td>
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<td><strong>Evaluate Use of In-silico Crystal Structure Prediction (CSP) in Drug Development and Harmonize on Data Interpretation</strong> (Proposal under consideration)</td>
<td><strong>Materials Qualification and Control for Drug (or Biologic)/Device Combination Products</strong> (WG being formed)</td>
<td><strong>Restricted Delivery Systems in Children’s OTC Liquid Medications</strong> (in progress)</td>
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| **Quarterly Webinar Series** See [website](#) for details | **Webinar on Extractables & Leachables testing for Transdermal Delivery Systems**. (to be held 2Q 2022) | **Cross TC Collaboration Focus Groups**: Patient Centric Specifications and Drug/Device Combination Products
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
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
Authors and affiliations
Nadia Bou-Chacra, Katherine Jasmine Curo Melo, Ivan Andrés Cordova Morales, Erika S. Stipler, Filippos Kesisoglou, Mehran Yazdanian, Raimar Löbenberg

Safety Thresholds and Best Demonstrated Practices for Extractables and Leachables in Parenteral Drug Products (Intravenous, Subcutaneous, and Intramuscular)

Product Details
Date of Publication: Feb 2022
ISBN Number: 9781945584305
Number of Pages: 94
PDA Item No: 48007

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 Rode, William Brown, Mehr Kevin Miller, Weiwei Jiang, Erika S. Stiplier

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/pdajpst.2013.00936

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

Evaluating Current Practices in Shelf Life Estimation

Authors: 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

PQRI Confidential
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

by PQRI Workgroup Members

Michael Giodek, Manck & Co., Stephen Liebowitz, Bristol-Myers Squibb; Randal McCarthy, Schering Plough; Lance McPhail, FDA; Cynthia Okerson, Pfizer; Thomas Schultz, Johnson & Johnson; Mani Sundaramoorthy, AstraZeneca; Rod Verkleij, Bayer HealthCare; Kimberly Vokounosky; Bihar Chris Watts, FDA; and George Kass, Johnson & Johnson - Mentor

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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Past Conferences:

5th PQRI/FDA Conference on Advancing Product Quality: Advancing Quality & Technology of Future Pharmaceuticals
- December 1-3, 2021 (Virtual Event)

- 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 Conferences/Workshops

2022

• PQRI Workshop: *Managing Excipient and API Impact on Continuous Manufacturing* (May 17 – 18, 2022) VIRTUAL EVENT

2020

• [PQRI Biopharmaceutics Technical Committee (BTC) Webinars](#) (2018-2021)

• [4th PQRI Workshop on ICH Q3D Elemental Impurities Requirements](#) (November 9-10, 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)

• [ISPE/FDA/PQRI 2017 Quality Manufacturing Conference](#) (June 5-7, 2017)
Questions

Contact the PQRI Secretariat at:

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PQRISecretariat@pqri.org