MISSION

Established in 1999, 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

- CHPA (Consumer Healthcare Products Association)
- FDA (U.S. Food & Drug Administration)
- Health Canada
- PDA (Parenteral Drug Association)
- IPAC-RS (International Pharmaceutical Aerosol Consortium on Regulation & Science)
- ELSIE (European Strategies and Leadhables Safety Information)
- IPEC Americas (International Pharmaceutical Excipients Council, Americas)
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)  
**Mohran Yazdani**, Ph.D., Treasurer (Teva, USP)  
**Diane Paskiet**, (West Pharmaceutical Services, Inc.; PDA)  
**John Punzi**, Ph.D. (Consultant, PDA)  
**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)  
**Stacey Platzer**, (Bausch, CHPA)  
**Bobbijo Redler**, Ph.D. (Merck, ELSE)  
**Jennifer Wylie**, Ph.D. (Merck, IPAC-RS)  
**Dave Schoneker** (IPEC-Americas)  
**Glenn Wright** (PDA)  
**Adam Fisher**, Ph.D., (FDA)  
**Anita DiFranco** (Health Canada)  
**Horacio Pappa**, Ph.D., (USP)  
**Jennifer Ahearn**, Immediate Past Chair (ESi, CHPA)

FDA/PQRI Conferences on Advancing Product Quality

PQRI Secretariat

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)  
**Joan Poulos**, Vice Chair (Rochem International, PDA)
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.
<table>
<thead>
<tr>
<th>Biopharmaceutics Technical Committee (BTC)</th>
<th>Development Technical Committee (DTC)</th>
<th>Product Quality Technical Committee (PQTC)</th>
</tr>
</thead>
</table>
| **Biopharmaceutics Classification System for Inhaled Medicines** (iBCS) (in progress)  
  - Publications #1 and #2 just published | **Extractables & Leachables in Parenteral Drug Products** - To justify the use of safety thresholds for identification and risk assessment of POPD 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 publication.  
  - Developing a PDP Training Course | **Elemental Impurities** - 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 website.) |
| **Standardization of an in vivo predictive dissolution methodologies and in silico bioequivalence study** (in progress) | **Polymeric Excipient Risk Assessment** - 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. | **Topical Drugs Classification System (TCS) [joint effort with BTC] (papers in progress)** |
| **Topical Drugs Classification System (TCS) [joint effort with PQTC] (papers in progress)** | **Guidance for Interconnectivity between Vial Container Closure Systems and Vial Transfer Devices** (survey conducted and paper published)  
  [https://journal.pda.org/content/76/2/163](https://journal.pda.org/content/76/2/163) | **Workshop on Excipient and API Impact on Continuous Manufacturing** (May 17 – 18) (See website) |
| **Quarterly Webinar Series** (see slide in background section)  
  See website for details  
  - May 24th: Approaches to Establishing Bioequivalence Safe Space for Orally Administered Drug Products: Applications and Case Studies | **Materials Qualification and Control for Drug (or Biologic)/Device Combination Products** (WG being formed) | **Artificial Intelligence (AI) Application in Continuous Process Verification (CPV)** (in progress; experiments conducted at UMBC and University of Barcelona) (papers in progress) |
| **Hot Topic Discussions:** Invite SMEs to BTC calls for Roundtable with interested PQRI members (open to other TCs)  
  - June 24: Challenges in the development of formulations for pediatric patients. | **Webinar on Extractables & Leachables testing for Transdermal Delivery Systems.** (to be held in 2022) | **Restricted Delivery Systems in Children’s OTC Liquid Medications** (in progress) |
| **Cross TC Collaboration Focus Groups:** Patient Centric Specifications and Drug/Device Combination Products | **Use of Recycled Plastics in Pharmaceutical Manufacturing** (Proposal under consideration) | |
Promote science-based regulation by developing and delivering a portfolio of projects and public platforms of high value to industry and regulators

Enhance member organization benefits through PQRI work product

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

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

PQRI 2018-2022 Strategic Plan
Selected PQRI Publications

Safety Thresholds and Best Practices for E&L in Parenteral DP
— LinkedIn post:

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

PDF Single user

Member Price: $0   Nonmember Price: $0   Gov. Price: $0

The Product Quality Research Institute (PQRI) Leachables and Extractables (L&E) Working Group provided recommendations to the US Food and Drug Administration in 2006 on safety thresholds and best demonstrated practices for orally inhaled and nasal drug products (ONDP). The published PQRI E&L recommendations for ONDP have been globally referenced by regulatory authorities. Risk for package-product interaction is highest in ONDP; however, there is a high risk of package-product interaction in parenteral drug products (PDP) and subsequently safety thresholds and best practices specific for PDP were developed. Threshold concepts introduced by ONDP were extrapolated for PDP, are based on daily dose, and include the safety concern threshold (SCT), the analytical evaluation threshold (AET) for compound identification, and the qualification threshold (QT) for identified non-mutagenic compounds. This document describes the E&L strategy for PDP and provides examples for small and large volume parenterals with additional considerations for biological products. Studies to support characterization of materials and simulation for intended use are described with justification for solvent selection, exposure conditions, extract concentrations and analyses. Contributions were made by over ninety individuals who are highly experienced scientists including toxicologists, analytical chemists, and others from industry and government. It is the hope and intent of the Working Group that the recommendations contained within this document will serve to guide the pharmaceutical development process for PDP and facilitate the approval and manufacture of safe, effective, and quality medicines. The members of the PDP E&L Working Group acknowledge PQRI and its member organizations for providing this forum to make this collaboration possible and the dedicated scientists and regulators that provided the essential information to make these recommendations possible.
Selected PQRI Publications

**Molecular Pharmaceutics**

https://pubs.acs.org/doi/full/10.1021/acs.molpharmaceut.2c00113
https://pubs.acs.org/doi/10.1021/acs.molpharmaceut.2c00112

**iBCS: 1. Principles and Framework of an Inhalation-Based Biopharmaceutics Classification System**

Jayne E. Hastedt*, Per Bäckman, Antonio Cabal, Andy Clark, Carsten Ehrhardt, Ben Forbes, Anthony J. Hickey, Guenther Hochhaus, Wenlei Jiang, Stavros Kassinos, Philip J. Kuehl, David Prime, Yoen-Ju Son, Simon Teague, Ulrika Teherl, and Jennifer Wylie

Cite this: Mol. Pharmaceutics 2022, XXXX, XXX, XXX-XXX
Publication Date: May 16, 2022
https://doi.org/10.1021/acs.molpharmaceut.2c00113
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**iBCS: 2. Mechanistic Modeling of Pulmonary Availability of Inhaled Drugs versus Critical Product Attributes**


Cite this: Mol. Pharmaceutics 2022, XXXX, XXX, XXX-XXX
Publication Date: May 24, 2022
https://doi.org/10.1021/acs.molpharmaceut.2c00112
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Selected PQRI Publications

Principles for Management of Extractables and Leachables in Ophthalmic Drug Products

Christopher Houdian, Andréa Desardis Rodrigues, Brenda Bleeker Smith, Tao Vang and Mall Richardson

PDA Journal of Pharmaceutical Science and Technology February 2022 10(2):74-4. DOI: https://doi.org/10.17221

Abstract

Ophthalmic solutions and suspensions have long been classified into a high risk category with respect to concerns over extractables and leachables (E&L), though specific guidance on the management of leachables in these products is generally absent from regulatory authorities’ scientific literature. As a result, ophthalmic drug products (ODPs) were originally included in the scope of the Product Quality Research Institute Leachables and Extractables Working Group Parenteral and Ophthalmic Drug Products (PQRI-PopoP). Relative to other high concern dos forms such as metered dose inhalers or injectables, ODPs possess unique challenges with respect to the nature of impactful E&L as well as the safety assessment of leachables. For example, use of semipermeable low density polyethylene primary packaging for ODP necessitates a shift in focus on E&L from secondary packaging sources. For safety assessment, a key challenge is lack of a sufficient database developed on all relevant ophthalmic toxicity endpoints. As result working group is unable to recommend a Safety Concern Threshold (SCT) for E&L or ODP. Nevertheless, the ophthalmic industry has developed a number of time-tested practices to minimize E&L for ODP. This article describes those science-based practices and key considerations in analysis, management, and safety assessment of E&L in ODP.

Survey Report on Complaints Related to the Interconnectivity between Vial Containers and Transfer Devices

Cathy Zhao, Edwin Barnard, Joanne Beyer, Robin Samuel and Naneel Bhatvararam

PDA Journal of Pharmaceutical Science and Technology June 2021, 10(3):324-33. DOI: https://doi.org/10.17221

Abstract

To address the challenges related to the interconnectivity between vial container closure systems and vial transfer devices, pharmaceutical, elastomer and transfer device manufacturers have formed a working group under the Product Quality Research Institute (PQRI) to establish best practices for the evaluation of the assembly of vial transfer devices and vial systems. As part of the project, the first activity was to quantify the nature and frequency of issues (complaints). To this end, the working group conducted a survey with questionnaires related to categories and numbers of complaints, regions/countries where complaints were received and nature of the manufacturers who received the complaints. The survey was distributed to the sixteen companies participating in the working group and eleven companies submitted a response. Besides quantifying and ranking the frequency of issues, the survey determined what issues are common across all companies and what issues may be product-specific or specific by manufacturer. In this report, the analysis and outcomes of the survey will be presented, and the next steps will be discussed.
Selected PQRI Publications

On the Shelf Life of Pharmaceutical Products
Robert Capen1, 13, David Christopher2, Patrick Forenzo2, Charles Ireland3, Oscar Liu4, S Dennis Sandell3, James Schwenke10, Walter Stroup11 and Terrence Tougas
AAPS PharmSciTech
September 2012, Volume 13, Issue 3, pp 911-918

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

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 Giodak, Manek & Co., Stephen Liebschutz, Bristol-Myers Squibb; Randal McCarthy, Schering-Plough; Bruce McNab, FDA; Cynthia Olsson, Pfizer; Thomas Schott, Johnson & Johnson; Mani Sunkara, AstraZeneca; Rod Verkadehch, Bayer Healthcare; Kimberly Vokounsky; Robert Chris Watts, FDA; and George Kiriakel, 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>
</tr>
</thead>
<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>
</tr>
<tr>
<td><strong>Process Robustness</strong></td>
<td>ICH Q8, Q9</td>
</tr>
<tr>
<td><strong>Extractables &amp; Leachables</strong></td>
<td>FDA Draft Guidance, MDIs/DPIs USP 1663 USP 1664</td>
</tr>
<tr>
<td><strong>Container Closure</strong></td>
<td>FDA Guidance, Changes to an approved NDA or ANDA</td>
</tr>
</tbody>
</table>
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

  VIRTUAL EVENT

- 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)
Questions

Contact the PQRI Secretariat at:

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PQRISECRETARIAT@PQRI.ORG