# Cross-industry organizations

## The Product Quality Research Institute: Its continued journey of excellence

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*PQRI Chairman of the Board*

It's hard to believe but the Product Quality Research Institute (PQRI) has entered its 22nd year as a non-profit consortium of organizations that work together to generate and share timely, relevant and impactful information focused on advancing pharmaceutical product quality, manufacturing and regulation. In addition to industry-related non-profit organizations, PQRI members also include regulatory agencies and standard-setting bodies.

### PQRI's structure

Established in 1999, PQRI is structured with a Board of Directors, Steering Committee and three technical committees (Biopharmaceutics Technical Committee, Development Technical Committee and Product Quality Technical Committee) that oversee PQRI projects. Each committee has a mission:

- **Biopharmaceutics Technical Committee (BTC).** Identify, disseminate and facilitate scientific and technical projects to address gaps in the biopharmaceutical aspects of drug development and global regulatory guidance. To translate current and emerging ideas in the pharmaceutical field into proposals for implementing unbiased research projects and delivering results that impact regulatory policies.
- **Development Technical Committee (DTC).** 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.
- **Product Quality Technical Committee (PQTC).** Leverage 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.

The types of project work being conducted is based on the needs of both industry and regulators. Project topic areas covered in the past include: Post Approval Changes (PAC) for Sterile Products, Blend Uniformity, Aseptic Processing, RFID, Extractables and Leachables for OINDPs, Specification Design and Life Cycle, Risk Management, Elemental Impurities and Container/Closure Systems, to name a few. The outputs from these projects have varied and include journal papers, articles, workshops, webinars, conferences and formal recommendations.

### Current PQRI member organizations include:

- Consumer Healthcare Products Association (CHPA)
- International Pharmaceutical Excipients Council of the Americas (IPEC-Americas)
- Parenteral Drug Association (PDA)
- United States Pharmacopeia (USP)
- Health Canada
- US Food and Drug Administration (FDA)
- International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS), which rejoined PQRI in July 2021.

### Project areas currently underway or in planning include:

- PQRI Webinar Series
- Leachables and Extractables Thresholds and Best Practices for Parenteral Drug Products
- Leachables and Extractables for Transdermal Dosage Forms
- Guidance for Interconnectability of Vial Transfer Systems
- Device Materials Qualification and Control for Drug/Device Combination Products
- Safety Assessments for Systemic Toxicity and PDE Calculation Standardization
- Polymeric Excipient Risk Assessment Strategy
- Artificial Intelligence Application in Continuous Validation of the Manufacturing Process
- A Topical Drug Classification System
- Restricted Delivery Systems in Children's OTC Liquid Medications
- Elemental Impurities Phase 2 Study

- Standardization of *In Vivo* Predictive Dissolution Methodologies and *In Silico* Bioequivalence Study
- Clinically Relevant Drug Product Specifications—Development Through Application
- Managing Excipient and API Impact on Continuous Manufacturing Workshop (May 2022)
- An Inhalation Biopharmaceutics Classification System

## An update on developing an inhaled drug product classification system

Over the last several years, a team of PQRI scientists from industry, academia and the FDA have been collaborating to develop an inhalation-based biopharmaceutics classification system (iBCS) for inhaled drugs. Like the oral gastrointestinal biopharmaceutics classification system (giBCS) developed almost 30 years ago, a classification system for inhaled drugs based on drug substance physicochemical properties and drug product performance attributes would provide a qualitative assessment of the technical and clinical risks associated with the development of an orally inhaled drug. To develop an iBCS, the elucidation of the potential iBCS grid boundaries would be based on the functional outputs from a physiologically based pharmacokinetics (PBPK) model using varying solubility, permeability and regional dose values as inputs. As with the giBCS, the iBCS is intended to be a classification system and not a substitute for bioequivalence (BE). However, once analytical methodologies are available and deemed acceptable to classify inhaled drugs, it is envisioned that an iBCS class would provide insight into the potential for drugs to achieve *in vitro/in vivo* correlations. Before it is finalized, the proposed iBCS will be pressure-tested by assessing its ability to provide meaningful classification of existing orally inhaled drug products with respect to technical and clinical risks.

The PQRI working group has presented iBCS principles and strategies at multiple meetings, including the 4th PQRI FDA joint conference in April 2019, the COST Action SimInhale Conference in Athens in September 2019, the DDL conference in Edinburgh in December 2019 and the ISAM Meeting in Boise in May 2021. In addition, the iBCS working group held a webinar in October 2021 and the recording is available on the PQRI website. The team is in the process of drafting three manuscripts that will describe 1) the foundational principles and framework of an iBCS, 2) a sensitivity assessment of product and molecular attributes using PBPK modeling and 3) a proposed iBCS. A fourth paper will explore the gaps and pathway leading to the application of an iBCS.

## Benefits for member organization and their members include:

**Member organizations:**

- 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.
- Have access to all PQRI technical committees and working groups.

**Individual members of PQRI organizations:**

- Can collaborate, share knowledge and work directly with peers in the industry and with regulators, expanding your network.
- Have opportunities to participate in leadership roles, present in public forums and 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.

## Getting involved in PQRI

Interested in learning more about PQRI or having your organization join PQRI? Contact the PQRI Secretariat at PQRISecretariat@pqri.org or visit the PQRI website at www.pqri.org. We will be happy to send you more information or to speak with you about the benefits of membership.

Membership in PQRI is open to government organizations and non-government organizations. Membership is at the organizational level (not an individual level).

The 5th PQRI/FDA Conference on Advancing Product Quality*: Advancing Quality & Technology of Future Pharmaceuticals* was scheduled to be held virtually, December 1-3, 2021. For more information visit https://pqri.org/5th-pqri-fda-conference/.