PQRI
Product Quality Research Institute

A neutral forum for regulators and industry to advance pharmaceutical regulations, standards and science.

About Us

Established in 1999, the Product Quality Research Institute (PQRI) originated from a collective effort between the FDA and several of the pharmaceutical industry's major trade associations. Their goal was to create a safe haven in which scientists from industry, academia, and regulatory agencies could collaborate to advance pharmaceutical and biopharmaceutical regulatory science and guidance.

The Mission

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 drug product quality, manufacturing, and regulation.

The Vision

Through a unique 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.

Our Members

FDA U.S. FOOD & DRUG ADMINISTRATION
ELSIE Extractables and Leachables Safety Information Exchange
Health Canada
International Pharmaceutical Excipients Council IPEC AMERICAS
IPAC-RS International Pharmaceutical Aerosol Consortium on Regulation & Science
PDA Parenteral Drug Association Connecting People, Science and Regulation®
USP®

For more than 20 years PQRI has been delivering on the promise of bringing thought leaders together to advance regulatory and scientific projects of shared importance. PQRI's unique construct allows scientists from different industry associations, academic research institutions, and regulatory agencies, such as FDA, to collaborate in an effective and efficient model. PQRI is a win for everyone, including patients who are at the center of everything we do in this industry.

Glenn E. Wright
Chairman of the Board, PQRI
Vice President of Scientific and Regulatory Affairs, PDA

Projects & Accomplishments

To learn more about PQRI's current projects and view a glimpse of some of the important work completed through PQRI Working Groups, visit the PQRI website by scanning the QR code.

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Benefits of PQRI Membership

Organizations

- Play a direct role in shaping activities and setting its scientific and regulatory priorities.
- Cross-collaborate efficiently among 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 technical committees and working groups.

Individuals

- Collaborate, share knowledge, and work directly with peers in the industry and with regulators.
- Opportunities to participate in leadership roles, present in public forums, and to publish in scientific journals.
- Develop approaches to addressing current and emerging challenges related to regulation, development, and quality of drug products.
- Help direct and drive technical and scientific activities.

PQRI FDA Conference

A key asset of PQRI is the regular Conferences with the FDA. These conferences bring regulators, industry professionals, and academic researchers together to create a synergized path toward enhanced science and risk-based harmonized global pharmaceutical quality.

Organizational Structure

Board of Directors — **Steering Committee**

Technical Committees

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.

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.

Biopharmaceutics Technical Committee (BTC)

Identify, disseminate, and facilitate scientific and technical projects to address gaps in biopharmaceutical aspects of drug emerging ideas in the pharmaceutical field into proposals for implementing unbiased research projects and delivering results that impact regulatory policies.

PQRI Secretariat Support

Faegre Drinker serves as Legal Counsel and Secretariat to PQRI. Composed of attorneys, scientists, policy analysts and project managers, the Consortia Management Team forms and supports life sciences industry collaborations that help global companies address complex regulatory, compliance and other topics of mutual interest. For more than 25 years, the team's work has focused on issues impacting the pharmaceutical and medical device industries.

Interested in becoming a PQRI Member? Contact the **PQRI Secretariat**. 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 individual).

pqri.org