What is PQRI

The Product Quality Research Institute (PQRI) was established in 1999, and brings together members of the pharmaceutical industry, academia and regulatory agencies to develop science-based approaches to regulation. Since its inception, PQRI has coordinated the volunteer work of industry and agency scientists and academics to conduct in-depth studies of a broad range of technical issues important to the pharmaceutical and biopharmaceutical industry. PQRI is a unique organization in which scientists and experts from industry, regulatory agencies, and academia collaborate closely to develop work products in direct support of regulatory guidance. PQRI and its mission is singularly relevant given the current rapid growth in new and varied drug product modalities, advancements in manufacturing paradigms, and the ever increasing need for efficient but high quality research, development and manufacturing frameworks.

Mission

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.

Vision

PQRI will be the leading organization in creating best practice and conducting joint research in support of pharmaceutical and biopharmaceutical regulation, through a unique global collaboration among academia, industry, and regulatory agencies, leveraging their intellectual, scientific and technical resources to advance drug development and regulation to benefit patients.
Current Members and Benefits

- Consumer Healthcare Products Association (CHPA)
- U.S. Food and Drug Administration (FDA)
- Health Canada (HC)
- International Pharmaceutical Excipients Council of the Americas (IPEC-Americas)
- Parenteral Drug Association (PDA)
- United States Pharmacopeia (USP)

PQRI members have the opportunity to:

- Engage in a unique, diverse, neutral forum of thought leaders from regulatory agencies, standard setting bodies, industry and academia at strategic and technical levels, to conduct research and share knowledge on emerging scientific and regulatory quality challenges.
- Impact global regulatory guidance and standards.
- Mutually accomplish goals that cannot be achieved by individual organizations alone, by leveraging the energy, resources, and intelligence of leading global organizations.
- Develop broad consensus, to bring maximum value to members and patients.

Strategy

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 activities and work product.
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**

- Publish PQRI work in leading peer-reviewed journals.
- Present PQRI work at key conferences and through partnership with member organizations.
- Hold conferences, workshops, symposia and webinars to bring together regulators, industry and academia on priority topics relevant to current and emerging regulatory/scientific issues.
- Provide research funds to high priority topics as determined by the membership.
- Establish new projects based on member input, on high priority scientific/regulatory topics within each technical committee – development, biopharmaceutics, manufacturing, in area, such as:
  - Development and qualification of drug development tools, including analytics
  - Emerging manufacturing technologies – tools, controls, metrics; large and small molecules
  - Patient-centered drug development
  - Drug/device and biologics/device combination products
- Create new projects from PQRI conferences, workshops, symposia, and webinar output.
Strategic Goals

2. **EXPAND MEMBERSHIP AND OUTREACH INTERNATIONALLY TO INDUSTRY AND REGULATORY AGENCIES, TO ENHANCE AND FURTHER DIVERSIFY EXPERTISE AND INFORMATION SHARING**

- Add at least one new member organization each year; capture interest of potential members through specific on-going projects.
- Hold periodic information-sharing summits with potential members to identify areas of mutual interest.
- Provide benefits/value presentations, webinars, and brochures to potential members.
- Proactively highlight PQRI’s mission, benefits and goals.

3. **ENHANCE MEMBER ORGANIZATION BENEFITS THROUGH PQRI ACTIVITIES AND WORK PRODUCT**

- Provide members with clear benefits to participation and engagement.
- Provide tools to raise awareness of PQRI within member organizations, and to help members better leverage and benefit from PQRI work and output.
- Partner with member organizations to highlight PQRI output in member journals, public meeting platforms, and other pathways that will bring benefit to members.
- Build Technical Committee membership – ensure that all Technical Committees have at least one representative from each member organization.
- Empower Working Groups with clear understanding of role/responsibilities, expectations, ability to present work directly to Technical and Steering Committees.
- Establish an award/recognition program for exemplary contributions.