CROSS-INDUSTRY Organizations

2023 Activities and accomplishments of the Product Quality Research Institute (PQRI)

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On behalf of the Product Quality Research Institute (PQRI)

Introduction to PQRI

The Product Quality Research Institute (PQRI; www.pqri.org) was established in 1999 as 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. PQRI remains a forum for scientists from industry, academia and regulatory agencies to tackle a broad range of technical issues important to the pharmaceutical and biopharmaceutical industry. Through the joint activities conducted by the technical committees and working groups, PQRI produces high-impact work products to advance drug development, manufacturing and regulation to benefit patients.

PQRI member organizations include:

- US Food and Drug Administration (FDA)
- Health Canada (HC)
- International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS)
- International Pharmaceutical Excipients Council of the Americas (IPEC-Americas)
- Extractables and Leachables Safety Information Exchange (ELSIE)
- Parenteral Drug Association (PDA)
- United States Pharmacopeia (USP)

PQRI technical and scientific initiatives

In 2023, PQRI member organizations worked together to deliver a portfolio of projects with high value to industry and regulators. The Biopharmaceutics, Development and Product Quality Technical Committees drove important and timely technical and scientific initiatives with the vision of advancing drug product quality, manufacturing and regulation.

One significant effort conducted by PQRI was a response to the proposed ban of per- and polyfluoroalkyl substances (PFAS) by the European Chemicals Agency (ECHA). PQRI developed a questionnaire, which was completed by PQRI members as well as other stakeholders in the industry, to capture the scale of the impact that the proposed PFAS restrictions would have across the pharmaceutical supply chain. Following the survey, PQRI conducted a public webinar to raise awareness of this issue, and developed a position paper that was submitted to ECHA, which outlined the particular scientific challenges faced in replacing PFAS and PFAS-containing products. A copy of the position paper is available on the PQRI website.

The Product Quality Technical Committee (PQTC) managed a number of important initiatives within its portfolio. The Elemental Impurities Working Group and the AI Application in Continuous Process Verification (CPV) Working Group prepared manuscripts that will be submitted for publication soon. Also, under the PQTC's oversight, a study on Flow Restrictor Delivery Systems in OTC Children's Medication was completed.

The Biopharmaceutics Technical Committee (BTC) continues to drive several initiatives in topic areas including pediatric formulation assessment, crystal structure prediction, inhalation biopharmaceutics, long acting injectables, model informed drug development, *in vivo* predictive dissolution methodologies, bioequivalence of additional strengths of modified release products and patient centric specifications. The PQRI Standardization of *in vitro* Predictive Dissolution Methodologies and *in silico* Bioequivalence Study Working Group published the article, "Harmonizing Biopredictive Methodologies Through the Product Quality Research Institute (PQRI) Part I: Biopredictive Dissolution of Ibuprofen and Dipyridamole Tablets" in the AAPS Journal. The Inhalation Biopharmaceutics Classification System (iBCS) Working Group presented at conferences, including DDL and ISAM, and prepared several manuscripts. The third article, "iBCS:3. A Biopharmaceutics Classification System for Orally Inhaled Drug Products," was recently published in the ACS Journal, *Molecular Pharmaceutics.*

The Development Technical Committee (DTC) is actively engaged in several ongoing projects and collaborations. A new working group will launch in 2024 on Creation of Recommended Best Practices for Extractable Analysis to Reduce Uncertainty Due to Variation in Practice. The DTC is exploring collaborative opportunities with the Center for Research on Complex Generics (CRCG) as well as the SEMI Nano-Bio Materials (NBMC) consortium. Other areas of future exploration include materials disruption and impact of sustainability initiatives, disruptive and transformative technologies, and materials qualification and control for drug/device combination products focusing on design controls, regulatory aspects and safety.

PQRI workshops

PQRI conducted several high-impact workshops and events in 2023. PQRI collaborated with the FDA to jointly organize an FDA/PQRI virtual workshop on the "Regulatory Framework for the Utilization of Artificial Intelligence in Pharmaceutical Manufacturing: An Opportunity for Stakeholder Engagement." The workshop attracted a large audience and the free-flowing dialogue was most beneficial as industry communicated to the FDA the increasing implementation of AI technology in their companies (see FDA FRAME website for more details).

A hybrid PQRI workshop covering the Global Regulatory and Technical Challenges of Titanium Dioxide (TiO2) Use in Pharmaceuticals was held in 2023. The discussions were highly informative, and learnings were incorporated into a position paper that was shared with regulatory agencies earlier in 2024. The position paper is posted on the PQRI website.

Other workshops in 2024 will cover the following topics: MIDD Approaches in Ediatric Formulation Development, Global Bioequivalence Harmonisation (GBHI 2024), and Challenges and Opportunities for Modified Release Oral Drug Product Development.

For more information

Please follow us on LinkedIn and visit the PQRI website to stay informed about PQRI's ongoing activities and upcoming events. Past PQRI webinar recordings are available here: https://pqri.org/events/. For questions about PQRI and membership, contact the PQRI Secretariat at PQRISecretariat@pqri.org.