CROSS-INDUSTRY Organizations

An update from the Product Quality Research Institute (PQRI)

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On behalf of the Product Quality Research Institute (PQRI)

An overview of PQRI

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 information that advances global drug product quality, manufacturing and regulation. PQRI was established in 1999 to create a safe haven in which scientists from industry, academia and regulatory agencies could collaborate. In 2022, PQRI continued to produce impactful work product as a leading organization leveraging its intellectual, scientific and technical resources to advance drug development and regulation to benefit patients.

PQRI member organizations

Current PQRI member organizations include:

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

PQRI member organizations collaborate to tackle industry and regulatory concerns, needs and trends. Members also engage with other key stakeholders and impact global regulatory standards and guidance. In November 2022, PQRI partnered with the FDA to host a workshop on the Regulatory Framework for Distributed and Point-of-Care Pharmaceutical Manufacturing. This event brought together leaders from regulatory agencies, industry and academia to facilitate interaction among DM/POC stakeholders on critical areas for development and implementation of these technologies.

PQRI technical and scientific activities

The Biopharmaceutics Technical Committee, Development Technical Committee and Product Quality Technical Committee drive PQRI's scientific activities by addressing ongoing regulatory and scientific issues, and delivering a high-value portfolio of projects to industry and regulators.

Biopharmaceutics Technical Committee (BTC)

The BTC had a highly productive year. The BTC's Inhalation BCS Working Group came together as a partnership between industry, academia and the FDA to develop an inhalation-based biopharmaceutics classification system (iBCS). The Working Group presented at multiple conferences and had two manuscripts published in *Molecular Pharmaceutics*:

- iBCS 1: Principles and Framework of an Inhalation-Based Biopharmaceutics Classification System (https://pubs.acs.org/doi/full/10.1021/acs.molpharmaceut.2c00113)
- iBCS. 2: Mechanistic Modeling of Pulmonary Availability of Inhaled Drugs versus Critical Product Attributes (https://pubs.acs.org/doi/10.1021/acs.molpharmaceut.2c00112)

The BTC organized hot topic discussions covering the development of long-acting injectables and challenges in the development of formulations for pediatric patients. PQRI plans to organize a workshop in 2023 related to the latter topic. In 2022, the BTC also held a webinar on Approaches to Establishing Bioequivalence Safe Space for Orally Administered Drug Products: Applications and Case Studies.

Development Technical Committee (DTC)

The DTC produced many impactful deliverables in 2022 including a webinar on the Extractables and Leachables Testing for Transdermal Delivery Systems, which focused on regulatory and scientific challenges associated with the execution of extractable and leachable studies for transdermal delivery systems, and explored how principles of safety thresholds may be applied. The DTC's Interconnectability between Vial Container Closure Systems/Vial Transfer Devices Working Group presented their work at the 2022 PDA Parenteral Packaging Conference. The DTC's Parenteral and Ophthal-

mic Drug Product E&L Working Group presented at several international conferences and had their work highlighted in *The Medicine Maker* and *European Pharmaceutical Review*. The Working Group published two manuscripts:

- Safety Thresholds and Best Demonstrated Practices for Extractables and Leachables in Parenteral Drug Products - PDA Bookstore, 2022 (https://pqri.org/wp-content/uploads/2022/03/PQRI-PDP-Recommendation-2022.pdf)
- Principles for Management of Extractables and Leachables in Ophthalmic Drug Products - PDA J Pharm Sci Technol 2022 (https://journal.pda.org/content/early/2022/02/15/pdajpst.2022.012744)

In 2023, a new DTC Working Group will delve into the topic of developing a structured approach to material qualification and control for drug-device or biologic-device combination products.

Product Quality Technical Committee (PQTC)

The PQTC held a successful workshop on Excipient and API Impact on Continuous Manufacturing (CM) in May 2022. The workshop addressed several areas, including identifying and evaluating excipient and API properties that could impact the CM process; mitigation of failure modes; how to design for excipient and API variability in CM; how to develop new excipients and grades designed for CM; and implications for CM of API composites.

In 2023, the PQTC will hold the Titanium Dioxide (TiO_2) Workshop—Global Regulatory and Technical Challenges, which will bring together materials suppliers, the pharmaceutical industry and regulatory experts to discuss the impact of removing titanium dioxide from solid oral dosage forms. PQRI will also hold a workshop on Co-processed Excipients to Enhance Medicinal Product Development and Continuous Manufacturing.

Other PQTC activities include exploring artificial intelligence (AI) applications in continuous process verification (CPV) and restricted delivery systems in children's OTC liquid medications. PQTC's Elemental Impurities (EI) Working Group shared industry experiences related to implementation of ICH Q3D, is submitting a paper to the *Journal of Trace Elements and Minerals*, and participated in a workshop at Excipient World 2022 to share its work.

Learn more and stay connected

Remember to follow us on LinkedIn and visit the PQRI website to stay informed about ongoing activities and upcoming events. Past PQRI webinar recordings are also available.

PQRI membership is open to any association interested in the regulatory and quality issues of pharmaceutical, biological or combination products and devices. For questions, contact the PQRI Secretariat at PQRISecretariat@pqri.org.