Industry, Government and Academia Collaborating for Excellence in Pharmaceutical Research

PQRI Manufacturing Technical Committee (MTC)

Current Projects:

4th PQRI/FDA Conference on Advancing Product Quality (April 9-11, 2019) - Developing and supporting Manufacturing Track for Conference.

Elemental Impurities Study - Conducting EI research to investigate variability of ICP-MS analysis of elemental impurities.

Elemental Impurities Workshop - Third Workshop held in November 2017 to share industry experiences with implementation of the ICH Q3D guideline. Presentations posted on PQRI website.

Topical Drug Classification System (with the PQRI Biopharmaceutics Technical Committee) - Webinar held on April 9, 2018, see website for recording.

Disinfectant Coupon Testing - Develop guidance in regards to the need and value of performing site specific coupon testing for disinfectant qualification.

Emerging Projects:

- Cleaning Validation/Testing
- Definition of Lot and Discard Approaches in Continuous Manufacturing

MISSION

The mission of the Manufacturing Technical Committee is to leverage our manufacturing expertise to dene science-based approaches that appropriately integrate risk assessment and will encourage innovation and continuous quality improvement in pharmaceutical manufacturing and flexibility in the associated regulatory processes.

Past Project Examples: (Reports, White Papers available at: http://pqri.org/publications/)

Process Robustness – developed a White Paper on process robustness concept and how it applies to development, scale up, and manufacture of pharmaceutical products.

Post Approval Changes for Sterile Products – published report providing regulatory CMC information relevant to development of a Post Approval Guidance for Sterile Drug Products for Human, Veterinary, and Well Characterized Biological Products.

Case Studies for Risk Management – developed case studies providing specific pharmaceutical examples using different QRM tools, and recommendations for which tools to use in different areas, and training guides.

Biologicals Inspection Survey – surveyed the biological products manufacturing industry, with emphasis on inspection and compliance of program operations; published a report.

Specification Design and Lifecycle Management – created concept paper to stimulate discussion on processes and activities that occur from creation through development and commercialization of molecule to drug product.

Transdermals – published an update to the 1997 SUPAC Transdermal White Paper to include QbD, PAT, and FDA and industry initiatives on development, scale-up, manufacture and control of transdermals.

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www.pqri.org

Call for Volunteers

If you are a member of a PQRI member organization
(CHPA, FDA, Health Canada, IPEC-Americas, PDA or USP) and want
to participate in the MTC or a Working Group, please contact the PQRI Secretariat
(PQRISecretariat@pqri.org) for further information.

Benefits of Participating in PQRI

- Collaborate and share knowledge with peers in the industry and with regulators
- Work directly with regulatory agency scientists and industry experts
- Opportunities to participate in leadership roles, to make presentations in public forums, and to publish
- Help direct the consortium's activities related to current and emerging drug product quality topics
- Develop creative and collaborative approaches to addressing challenges related to regulation/science of drug products
- Develop and expand your network of industry peers

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