PQRI DTC 2022 Webinar Series

Extractables and Leachables Testing for Transdermal Delivery Systems

Moderators: Desmond Hunt, Ph.D., Senior Principle Scientist, USP

Meenal Chavan, Ph.D., Senior Pharmaceutical Quality Assessor, Office of Lifecycle Drug Products (OLDP), Office of Pharmaceutical Quality (OPQ), CDER, FDA

Speakers: Cedar Boakye, Ph.D., Drug Product Quality Assessor, OLDP, OPQ, CDER, FDA

Gyorgy Vas, Ph.D., Business Technical Scientific Liaison, Intertek Pharmaceutical Services

PQRI

Product Quality Research Institute

November 2022

Agenda

I. *Welcome and Overview of Webinar*

Moderators: Desmond Hunt, Ph.D. and Meenal Chavan, Ph.D.

II. *Extractables and Leachables Studies for Transdermal and Topical Delivery Systems: Current Regulatory Perspectives*

Cedar Boakye, Ph.D., US FDA

III. *Common practices and gaps associated with performing extractable and leachable testing for transdermal delivery systems*

Gyorgy Vas, Ph.D., Intertek

IV. *Moderated Q&A Session with the speakers*

Webex Housekeeping

- Panelists will be listed here.
- The Attendee list is only available to Panelists and Host. (You will only see your name listed.)
- The Chat function has been disabled for Attendees. You may receive chats from the Host, but you cannot reply.
- Type your question in the Q&A box or raise your hand to be unmuted. Be sure your Q&A is set to ASK All Panelists.

All Attendees are muted.

The recording will be posted on the PQRI website at www.pqri.org after the webinar.

Product Quality Research Institute (PQRI)

What is PQRI? *A neutral form for regulators and industry to advance pharmaceutical regulations, standards and science.*

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.

CHPA® CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
Taking healthcare personally.

FDA U.S. FOOD & DRUG ADMINISTRATION

Health Canada

PDA Parenteral Drug Association

INTERNATIONAL PHARMACEUTICAL IPEC AMERICAS EXCIPIENTS COUNCIL

IPAC-RS International Pharmaceutical Aerosol Consortium on Regulation & Science

ELSIE Extractables and Leachables Safety Information Exchange

usp

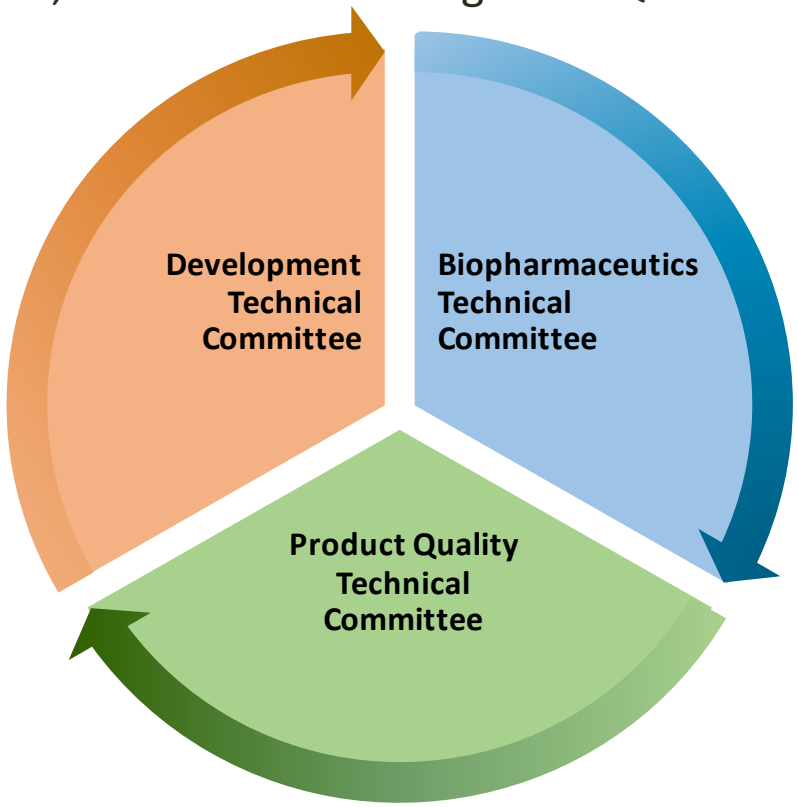
PQRI Product Quality Research Institute

What Does PQRI Do ?

- Unites thought leaders from regulatory agencies, standard setting bodies, industry and academia to conduct research and share knowledge on emerging scientific and regulatory quality challenges
- Provides a unique, neutral forum to develop common understandings of current scientific, technical and regulatory challenges among a diverse collection of industry organizations and FDA and other regulatory bodies
- Creates opportunities to accomplish mutual goals that cannot be achieved by individual organizations
- Impacts global regulatory guidance and standards, bringing maximum value to members and patients

PQRI Structure

- PQRI consists of two governing bodies – a Board of Directors and Steering Committee and three **Technical Committees**,
- Technical Committees each have a broad disciplinary focus that collectively spans the drug product regulatory lifecycle. They establish and provide scientific guidance, direction and oversight to PQRI working groups and research projects.
    - Current PQRI Technical Committees:
        - Biopharmaceutics Technical Committee (BTC)
        - Development Technical Committee (DTC)
        - Product Quality Technical Committee (PQTC)
    - This webinar is sponsored by the **DTC**.
    - You can find out more information about the TCs on the PQRI website: https://pqri.org/about-pqri/



PQRI Webinars (since 2018)

Posted at https://www.gotostage.com/channel/pqriwebinars

2022 Webinars

- ***DTC Webinar: Extractables and Leachables Testing for Transdermal Delivery Systems (November 2022)*** Presenters: Cedar Boakye, Ph.D., Drug Product Quality Assessor, OLDP, OPQ, CDER, FDA and Gyorgy Vas, Ph.D., Business Technical Scientific Liaison, Intertek Pharmaceutical Services
- ***Approaches to Establishing Bioequivalence Safe Space for Orally Administered Drug Products: Applications and Case Studies (May 24, 2022)*** Presenters: Filippos Kesisoglou, Ph.D., Merck and Xavier Pepin, Pharm.D., Ph.D., SimulationsPlus

2021 Webinars

- ***Exploring the Development and Utility of an Inhalation-based Biopharmaceutics Classification System (iBCS) (Oct. 27, 2021)*** Presenters: Jayne E. Hastedt, Ph.D. and Per Bäckman, Ph.D.; Panelists: Barbara Schug, Ph.D., SocraTec R&D GmbH, Ajit Narang, Ph.D., ORIC Pharmaceuticals Inc. and FDA Panelists: Bing Cai, Ph.D., Ross Walenga, Ph.D., Bryan Newman, Ph.D. , Bhagwant Rege, Ph.D., Renishkumar Delvadia, Ph.D.
- ***BTC/DTC Development and Biopharmaceutics of Long-Acting Injectables (April 8, 2021)*** Presenters: Liang Zhao, Ph.D., US FDA and Viera Lukacova, Ph.D., Simulations Plus, Inc.

2020 Webinars

- ***Biopharmaceutics of mAbs: Fundamentals and Pharmaceutical Development Aspects (December 9, 2020)*** Presenters: Mikolaj Milewski, Ph.D. and Jingtao Zhang, Ph.D., Merck & Co., Inc.
- ***Regulatory Requirements and Scientific Considerations for Biosimilar Products (September 16, 2020)*** Presenters: Stacey Ricci, M.Eng., Sc.D, FDA; Leah Christl, Amgen; Sundar Ramanan, Ph.D., MBA, BioCon
- ***BTC/PQTC Webinar Series: Excipient Considerations for Parenteral Drug Development (July 29, 2020)*** Presenters: Janeen Skutnik-Wilkinson (Biogen) and Thomas Tice, Ph.D., Evonik
- ***The Challenge and the Promise: Developing Complex Drug Products (April 28, 2020)*** Presenters: Wenlei Jiang, Ph.D., FDA and Adrian Goodey, Ph.D., Merck

This FDA/PQRI Workshop will bring together leaders from regulatory agencies, industry, and academia to discuss critical topics in distributed manufacturing and point of care manufacturing.

Future pharmaceutical manufacturing may occur not only in large manufacturing facilities; it may occur in smaller, more geographically distributed facilities or even at the point of care. The National Academies of Sciences, Engineering, and Medicine noted in a 2021 report that FDA is likely to see substantial innovations in integrated, flexible, and distributed manufacturing (DM). These innovations include modular approaches to streamline drug and biologic production and the deployment and use of highly portable manufacturing units that could enable point of care (POC) manufacturing. These types of technologies may challenge the traditional approaches to regulating pharmaceutical manufacturing.

FDA has also encountered the rapid emergence of advanced manufacturing technologies in various investigational biological products, such as tissue-based, cell and gene advanced therapy products, intersecting with critical areas associated with DM and POC manufacturing. Such biologics are generally more complex with undefined critical quality attributes and often have different manufacturing paradigms. This is particularly true for cellular and gene therapy products and tissue-engineered products.

The Workshop aims to facilitate interaction among DM/POC stakeholders on critical areas for development and implementation of these technologies including terminology, technical challenges to adoption, operation of Pharmaceutical Quality Systems, good manufacturing practice expectations, and the unique challenges and considerations that apply to complex biologics.

PQRI encourages anyone interested in DM/POC to register for this workshop to learn from experts and contribute ideas.

FDA/PQRI Workshop on the Regulatory Framework for Distributed and Point of Care Pharmaceutical Manufacturing: An Opportunity for DM/POC Stakeholder Engagement

November 14 – 16, 2022

Information the PQRI website:
https://pqri.org/fda_pqri_poc_dm_workshop/

100% Virtual Event

Today's Moderators

Desmond Hunt, Ph.D., Senior Principle Scientist
U.S. Pharmacopeial Convention
dgh@usp.org

Dr. Desmond G. Hunt has been with USP since 2005 and holds the position of Sr. Principle Scientist in the Compendial Science Group-General Chapters. He is the scientific liaison to the Packaging and Distribution and Dosage Forms Expert Committees, where he works to develop and revise USP Standards. He has authored many publications and peer-reviewed articles and is a frequent speaker and instructor on topics related to pharmaceutical packaging, particulate matter in parenteral and ophthalmic dosage forms and good storage and transportation practices. He participates on several industry Working Groups and Technical Committees related to his areas of expertise. Dr. Hunt obtained his M.S. and Ph.D. from the University of Texas at Austin and prior to joining USP, was a Research Fellow at the National Institutes of Health, Bethesda, MD, USA

Meenal Chavan, Ph.D., Senior Pharmaceutical Quality Assessor
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality/CDER/FDA
meenal.chavan@fda.hhs.gov

Meenal Chavan, Ph.D. is Senior Pharmaceutical Quality Assessor within OPQ's Office of Lifecycle Drug Products in CDER/FDA. She performs secondary review assessment of ANDAs, Pre-ANDAs and DMFs including ANDA submissions of complex dosage forms such as Transdermal drug delivery systems, Modified & Immediate release solid oral formulations, Implants & Intra-Vaginal ring. She is responsible for quality review of the ANDA's as an Application Technical Lead. She is a member of Transdermal working group and development of New Inspection Protocol Program (NIPP). Meenal joined FDA in 2016. She works on Developmental Technical Committee of PQRI to promote advancements in drug product development. Prior to joining FDA, she worked as a Sr. Manager R&D (Transdermal) at Sun Pharma, NJ. She has 20 plus years of complex product formulation products experience. She received her Ph.D. in Pharmaceutical Sciences from University of Mumbai, India.

Today's Presenters

Cedar Boakye, Ph.D., Drug Product Quality Assessor
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality/CDER/FDA
cedar.boakye@fda.hhs.gov

Cedar Boakye, Ph.D. is a drug product quality assessor within OPQ's Office of Lifecycle Drug Products in CDER/FDA. She performs quality assessment of prospective generic transdermal and topical drug delivery systems (TDS), implants, vaginal systems, intrauterine systems, and modified- & immediate-release solid oral products. Since joining the Agency in 2015, she has been particularly active in TDS regulatory assessment activities. She is a member of the CDER Transdermal Working Group and maintains an active interest in research associated with TDS quality. Her work to evaluate intrinsic safety issues associated with fentanyl reservoir transdermal systems led to removal of these products from the US market, and she was recognized with the FDA Scientific Achievement Award for Excellence in Review Science and the CDER Group/Team Honor Award due to the impact of this work. She also serves as a Government Liaison to the USP Expert Committee for Complex Excipients and the Polymer Subcommittee. She earned her PhD in pharmaceutical sciences from Florida A & M University, Tallahassee, Florida, and she is the author of over ten publications.

Today's Presenters

Gyorgy Vas Ph.D., Business Technical Scientific Liaison
Intertek Pharmaceutical Services
gyorgy.vas@intertek.com

Gyorgy Vas has over 25 years of experience in scientific research, pharmaceutical and medical device product development, and laboratory management. Over 15 years was spent in a cGMP environment, where that scientific expertise was applied to solve problems related to finished pharmaceutical products and medical devices. In his current position, he is advising regulatory filing strategy for multiple clients, and his group provides solutions for mitigate deficiency letters.

He is serving as an internal scientific consultant to the laboratory operations, evaluating new analytical techniques, software products for extractables and leachables testing. As part of his current role he is involved to evaluate and implement non-routine analytical instrumentations and methods for cGMP use. He published more than 20 analytical papers, related to various activities, including sample preparation, trace level method validation, molecular imaging, structure elucidation, and E&L testing. Those scientific publications papers have been cited more than 3000 times over the years.

Thank you for attending the webinar!

For more information on PQRI, visit our website at: www.pqri.org

Questions? Contact the PQRI Secretariat at:
PQRISecretariat@pqri.org

Call for Volunteers

If you or your company is a member of a PQRI member organization (CHPA, ELSIE, FDA, Health Canada, IPEC-Americas, IPAC-RS, PDA or USP) and you would like to participate in any of the PQRI Technical Committees, please contact the PQRI Secretariat (PQRISecretariat@pqri.org) for further information.