PQRI BTC/DTC Webinar Series

Development and Biopharmaceutics of Long-Acting Injectables

Moderators: Ajit Narang, Ph.D., Genentech

Diane Paskiet, West Pharmaceutical Services

Presenters: Liang Zhao, Ph.D., US Food and Drug Administration

Viera Lukacova, Ph.D., Simulations Plus, Inc.

PQRI

Product Quality Research Institute

April 2021

Agenda

I. Welcome and Overview of Webinar

Moderators: Ajit Narang, Ph.D., Genentech

Diane Paskiet, West Pharmaceutical Services

II. Application of Quantitative Clinical Pharmacology in the Development of Long Acting Injectable (LAI) Drug Products

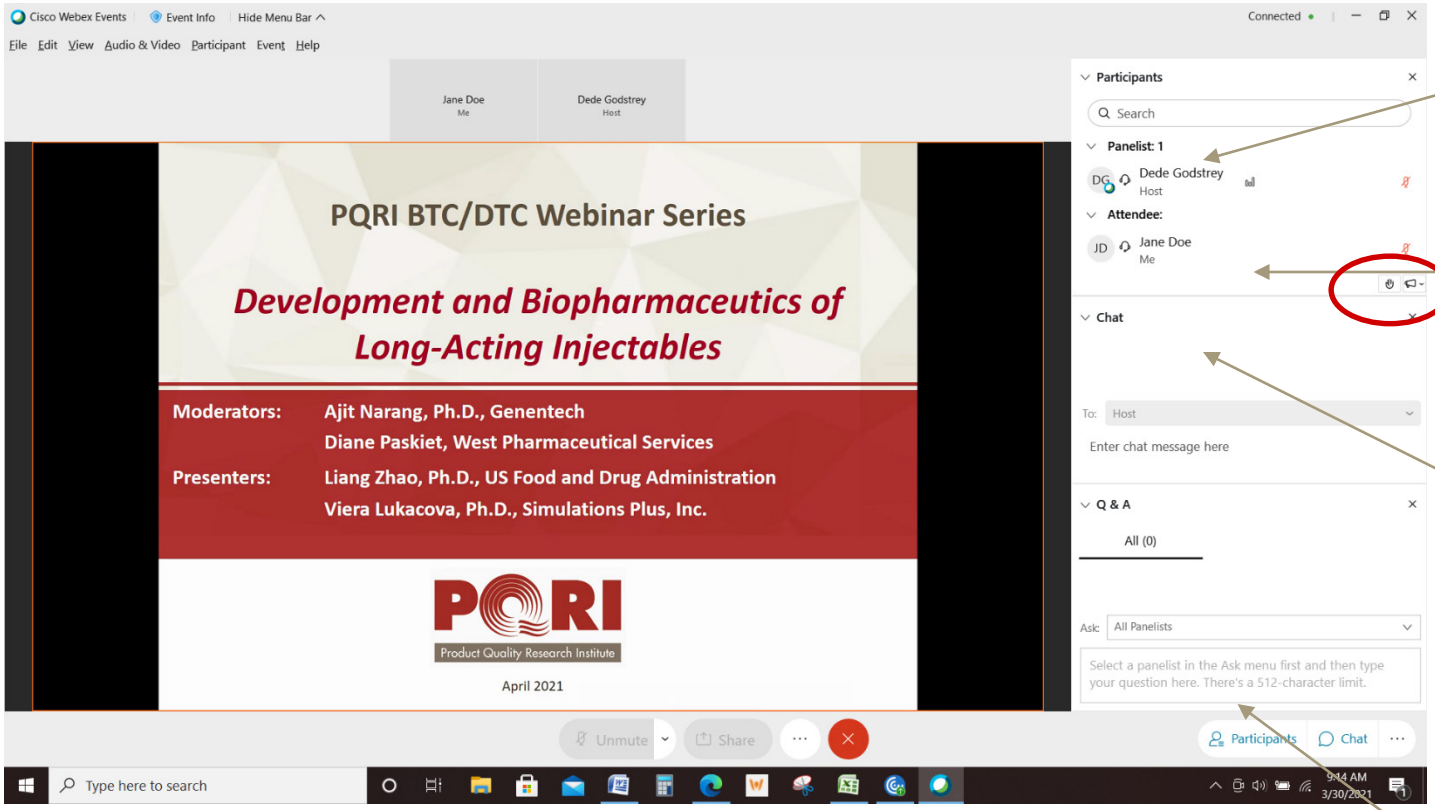
Presenter: Liang Zhao, Ph.D., US FDA

III. Physiologically Based Pharmacokinetic (PBPK) Modeling of Long Acting Injectables (LAI): Challenges and Opportunities

Presenter: Viera Lukacova, Ph.D., Simulations Plus, Inc.

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.

All Attendees are muted.

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

PQRI
Product Quality Research Institute

Product Quality Research Institute (PQRI)

Mission:

PQRI is a non-profit consortium of organizations working together to generate and share timely, relevant, and impactful information that advances drug product quality, manufacturing, and regulation.

CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

FDA U.S. FOOD & DRUG ADMINISTRATION

INTERNATIONAL PHARMACEUTICAL EXCIPIENTS COUNCIL IPEC AMERICAS

PDA Parenteral Drug Association

Health Canada

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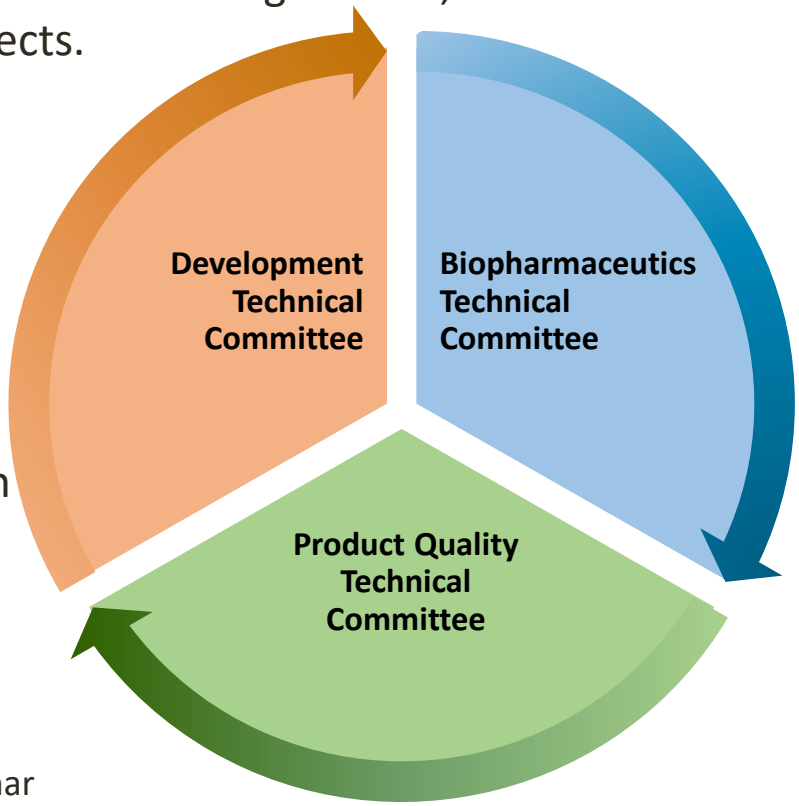
PQRI Product Quality Research Institute

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 broad consensus among a diverse collection of industry organizations and 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 co-sponsored by the **BTC and DTC**.
- You can find out more information about the TCs on the PQRI website: https://pqri.org/about-pqri/



PQRI Webinars

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

2021 Webinars

- ***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

2019 Webinars

- ***The Expanding IVIVC Toolbox to Enable Drug Product Quality and Clinical Pharmacology – Complementary Traditional and PBPK Based Approaches (June 7, 2019)*** Presenters: Xianyuan (Susie) Zhang, Ph.D., FDA and Filippos Kesisoglou, Ph.D., Merck
- ***Holistic QbD to Enable Product Quality Webinar (October 10, 2019)*** *Presenters:* Ajit Narang, Ph.D., Genentech; Rakhi Shah, Ph.D., FDA; Xavier Pepin, Pharm.D, Ph.D; Divyakant Desai, Ph.D., BMS; Xavier Pepin, Pharm.D, Ph.D., AstraZeneca

Conference Tracks

- *Day #1 Focus: Biopharmaceutics*
- *Day #2 Focus: Development*
- *Day #3 Focus: Product Quality*
- *Poster Session and Networking*

5th PQRI/FDA Conference on Advancing Product Quality: *Advancing Quality & Technology of Future Pharmaceuticals*

Save the Dates:
December 1 – 3, 2021

More information to be posted on the PQRI website: www.pqri.org.

100% Virtual Event

Today's Presenters

Liang Zhao, Ph.D., Director, Director of Division of Quantitative Methods and Modeling

Office of Research and Standards (ORS)/Office of Generic Drugs (OGD)/CDER/ US Food and Drug Administration

Liang.Zhao@fda.hhs.gov

Dr. Liang Zhao is currently the Director of Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards, Office of Generic Drugs, CDER/FDA. Dr. Zhao has a broad spectrum of scientific and management experience from industry and the regulatory agency. Through his 16-year professional career, he has established his leadership in industrial R&D, quantitative methods and modeling, and model based strategic decision makings in regulatory and industrial settings for generic and new drugs.

Dr. Liang Zhao has been serving as Director of DQMM since 2015. He initially joined the FDA as a clinical pharmacology reviewer in the Office of Clinical Pharmacology in 2009 and worked as a team leader in the Division of Pharmacometrics in 2013-2015. Prior to joining FDA, he worked at Medimmune for biotech products, BMS for small molecule drug development, and Pharsight as an associate consultant for new drug R&D. Dr. Zhao has authored and coauthored 80 peer reviewed articles and book chapters, and has been a seasoned speaker in FDA workshops, major national and international conferences.

Today's Presenters

Viera Lukacova, Ph.D., Chief Scientist
Simulations Plus, Inc.
viera@simulations-plus.com

Dr. Lukacova is Chief Scientist at Simulations Plus, Inc. Over the last decade she has been contributing to the research in the area of mechanistic absorption and PBPK modeling and the development of GastroPlus®, DDDPlus™, and MembranePlus™ software packages widely used throughout the pharmaceutical industry in early drug development, formulation, pre-clinical, and clinical research. She also contributes to modeling studies helping companies with their drug development programs in the early discovery stage, formulation development, clinical pharmacology applications and interactions with regulatory agencies.

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, FDA, Health Canada, IPEC-Americas, 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.