PQRI Product Quality Research Institute

FDA U.S. FOOD & DRUG ADMINISTRATION

# 5th PQRI/FDA Conference on Advancing Product Quality

## *Advancing Quality & Technology of Future Pharmaceuticals*

**December 1 – 3, 2021**

# *Welcome to the Conference and Overview of PQRI*

*Ajit Narang, Ph.D., ORIC Pharmaceuticals*

# Welcome on behalf of the Conference Co-Chairs

- PQRI Conference Co-Chairs
  - Ajit Narang, ORIC
  - Jen Ahearn, ESi
- FDA Conference Co-Chairs
  - Steven Kozlowski, FDA
  - Susan Rosencrance, FDA
  - Lawrence Yu, FDA

# 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.

**Our Members:**

PDA Parenteral Drug Association

CHPA Consumer Healthcare Products Association — Taking healthcare personally.

International Pharmaceutical Excipients Council — IPEC Americas

FDA U.S. Food & Drug Administration

IPAC-RS International Pharmaceutical Aerosol Consortium on Regulation & Science

Health Canada

usp

# 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

# Thank you to the Organizing Committee

- Nina Cauchon, Amgen
- Dede Godstrey, PQRI Secretariat
- Tere Gutierrez, FDA
- Wenlei Jiang, FDA
- Rajan Jog, FDA
- Filippos Kesisoglou, Merck
- Doug Kiehl, Eli Lilly and Company
- Bob Meyer, Merck
- Diane Paskiet, West
- Dave Schoneker, IPEC-Americas
- Vinod Shah, Consultant
- Janeen Skutnik-Wilkinson, Biogen
- Cat Vicente, Janssen
- Mehran Yazdanian, Teva

# THANK YOU…

- We would like to thank all PQRI members & attendees for supporting PQRI and contributing to its mission.
- Contact the PQRI Secretariat (PQRISecretariat@pqri.org ) regarding membership inquiries or volunteer opportunities.

For more Information on PQRI, download a copy of the PQRI brochure at the 

icon.

Visit the PQRI website at: www.pqri.org.

# Special Thanks to our Sponsors

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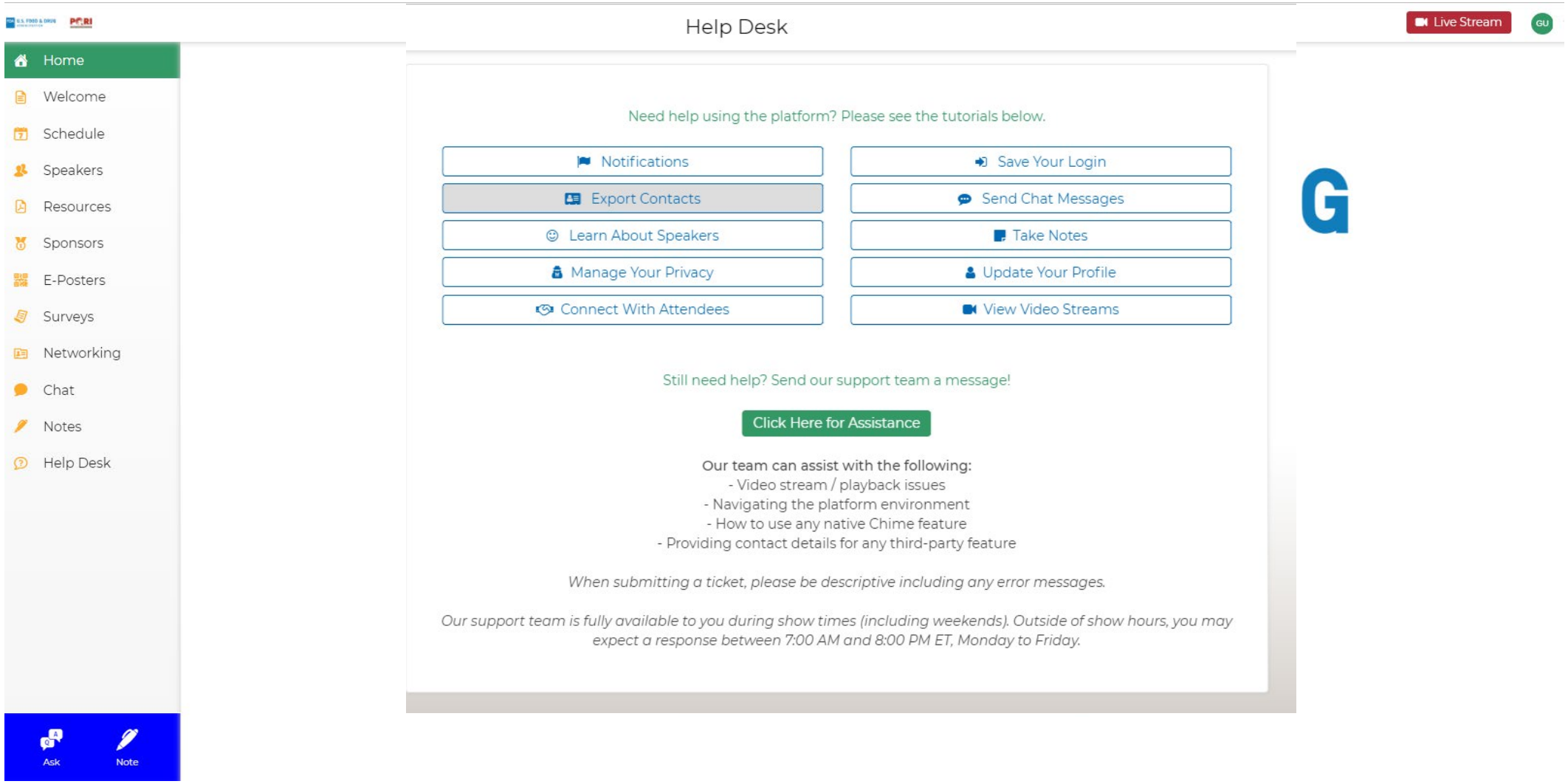
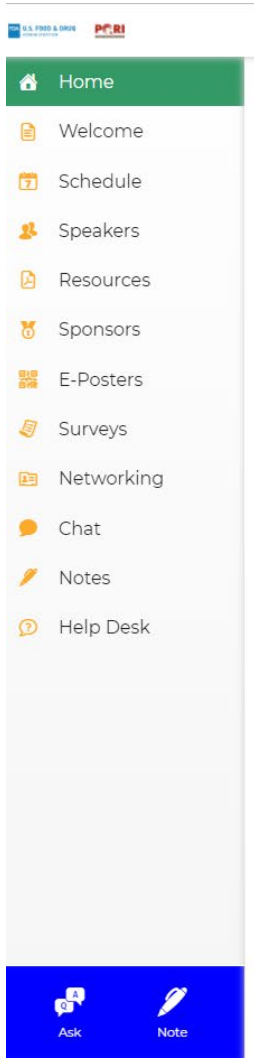


# Housekeeping Items

Click the Ask icon to submit a question during a presentation

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# Extras

- POSTERS
  - You can visit the posters at your convenience. We have also set aside time during the breaks for you to visit the posters. E-Posters
- NETWORKING
  - Click on the Networking icon to create your profile. You can opt in to chat with the other attendees.
- RESOURCES
  - Click on the Resources icon for a copy of the Conference program, PQRI brochure, and the Conference Welcome letter.
- RECORDINGS
  - Recordings will be available approx. 48 hours after the day is complete (i.e., Dec. 1st presentations available on Dec. 3rd., Dec 2nd and 3rd available around Dec. 6th/7th (see replay button under each day, or link in Resources )

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# *Introduction to the Conference*

*Lawrence Yu, Ph.D., FDA*

# Conference Overview

Each day will focus on a particular track

***Day 1: Biopharmaceutical Considerations for Product Design and Development***

- Development of robust pharmaceutical products requires comprehensive/orthogonal evaluation of the link between critical quality attributes (e.g., dissolution, release) and absorption properties along with the use of computational tools to predict in vivo performance. The judicious use of physiological based pharmacokinetic modelling and simulation (PBPK) along with patient-centric approaches for drug product development is essential to the delivery of transformative therapies.

***Day 2: New Horizons for Pharmaceutical Development***

- The future direction of pharmaceutical development for small and large molecule drug products has been profoundly influenced by recent events and technological advances. Prominent on the horizon are emerging modalities for novel therapeutics, and innovative approaches for applying knowledge and data to expedite meaningful decision-making. This track will explore opportunities and challenges represented by these areas, superimposed on a landscape of rapidly evolving industry practice and regulatory expectations.

***Day 3: Innovation in Quality & Technology Beyond the Pandemic***

- In a post-pandemic world, developing agile and innovative solutions that adapt to the pace of change is critical for all aspects of the pharmaceutical product lifecycle including regulatory, manufacturing, and quality. This Track will explore current developments in modernization of regulatory submissions, in advanced manufacturing, and in remote site evaluations which are each evolving in real-time to address these future challenges.

# Today's Presentations

***Biopharmaceutical Considerations for Product Design and Development***

Keynote: ***Advancing Product Quality***

- Michael Kopcha, Ph.D., R.Ph. FDA

**Session 1: Patient-centric Dissolution and International Harmonization** (Moderator: Filippos Kesisoglou, Ph.D., Merck and Co., Inc.)

- ***How Do We Improve Predictions of Drug Concentration-Time Profiles?***
  - Swati Nagar, Ph.D., Temple University
- ***The Link Between the Human Gastrointestinal Tract and Oral Drug Absorption: Theory and Case Examples***
  - Bart Hens, Ph.D., Pfizer
- ***Risk-based Approach to Establishing Patient-Centric Dissolution Specifications***
  - Elsbeth Chikhale, Ph.D., FD

**Session 2: Biopharmaceutics for Complex Drug Products** (Moderator: Wenlei Jiang, Ph.D., US FDA)

- ***Biopharmaceutics and Inhaled Drugs - Development of an iBCS***
  - Jayne E. Hastedt, Ph.D., JDP Pharma Consulting, LLC; PQRI iBCS WG
- ***Modeling and Simulation of Long-Acting Injectable Psychiatric Products***
  - Hao Zhu, Ph.D., FDA
- ***Biopharmaceutics of Complex Parenteral Drug Products - IVIVC and Development In Vitro Release Testing***
  - Diane J. Burgess, Ph.D., University of Connecticut

**Hot Topic:** ***Overlooked Biopharmaceutics of Nanomedicines/NanoVaccines Impacts Clinical Dose/Efficacy/Safety***

Moderator: Mehran Yazdanian, Ph.D., Teva Pharmaceuticals

- Duxin Sun, Ph.D., University of Michigan