



## **4<sup>th</sup> FDA/PQRI Conference on Advancing Product Quality**

# **Advancing Product Quality Patient-Centric Product Design, Drug Development, and Manufacturing**

**Susan Rosencrance, FDA**

**Mehran Yazdanian, Teva**

**Lawrence Yu, FDA**

**Co-Chair**

**Co-Chair**

**Co-Chair**

April 9-11, 2019

Hilton Rockville

# Tracks

**Track #1: NOVEL APPROACHES TO IMPROVE TREATMENT OUTCOME AND PATIENT SAFETY**

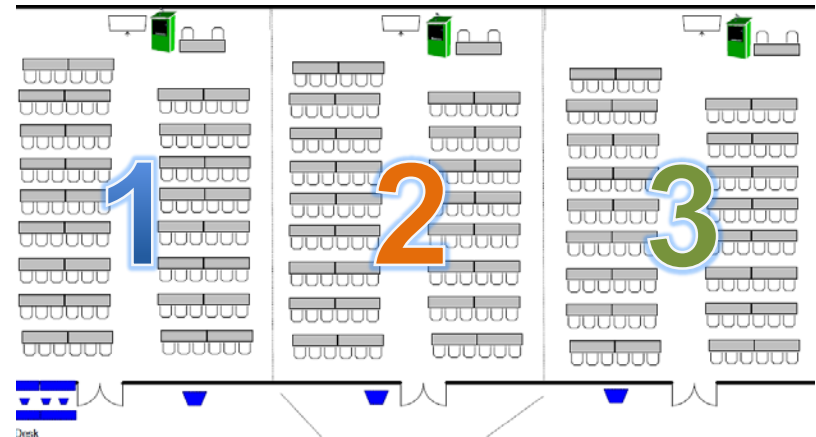
*Sit in Left Section*

**Track #2: EMERGING TECHNOLOGIES AND PATIENT CENTRICITY IN EARLY DRUG DEVELOPMENT**

*Sit in Middle Section*

**Track #3: NOVEL MANUFACTURING TECHNOLOGIES AND CHALLENGES FOR THE PRODUCTION OF PATIENT-CENTRIC DRUG PRODUCTS**

*Sit in Right Section*



# Thank you to the Organizing Committee

Andreas Abend, Merck  
Jillian Brady, PQRI Secretariat  
Nina Cauchon, Amgen  
Dede Godstrey, PQRI Secretariat  
Wally Hirth, Procter & Gamble  
Wenlei Jiang, FDA  
Filippos Kesisoglou, Merck  
Bob Meyer, Merck

Ajit Narang, Genentech  
Diane Paskiet, West  
Dave Schoneker, Colorcon  
Vinod Shah, Consultant  
Allen Templeton, Merck  
Cat Vicente, Janssen  
Glenn Wright, Consultant  
Geoff Wu, FDA

# Housekeeping Items

- Wireless Internet Connection Instructions
  - Connect to “Hilton\_Meeting” wireless network
  - Open your browser
  - Enter PIN: [to be added]
- Conference Website
  - <http://pqri.org/4th-fda-pqri-conference/>
  - Scroll down to Presentations and click on **Click Here to Access Conference Presentations**
  - Password: **PQRI2019**
  - Presentations not posted will be uploaded after the Conference
- Poster Session – across the hall in Regency Room
- Networking Reception tonight – Atrium
  - 5:30 – 7:30 PM

# Poster Session – Regency Room

- View posters during coffee breaks, lunch and networking reception
- Available through close of break on Wednesday (3:30 PM)
- Topics are directly applicable to Conference objectives
- Awards for Top 3 posters
  - *Be sure to vote*



**1999-2019**

*Please join us this evening to celebrate 20 years of working together to generate and share timely, relevant, and impactful information that advances global drug product quality, manufacturing and regulation.*



# MISSION

The Product Quality Research Institute (PQRI) is a non-profit consortium of organizations working together to generate and share timely, relevant, and impactful information that advances global drug product quality, manufacturing, and regulation.

# VISION

PQRI will be the leading organization in creating best practices and conducting joint research in support of pharmaceutical and biopharmaceutical regulation, through a unique global collaboration among academia, industry, and regulatory agencies, leveraging their intellectual, scientific and technical resources to advance drug development and regulation to benefit patients.



# Who We Are – Our Members



Health  
Canada





# PQRI's Impact: Publications & Regulation

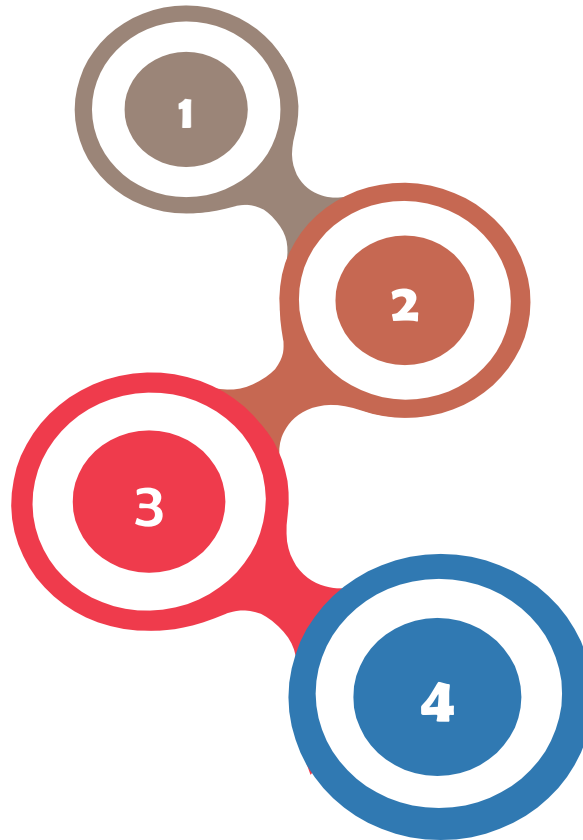
- Shelf Life Stability
- Leachables & Extractables
- Permeability of BCS Class III Compounds
- Stability & Dissolution Media
- Process Robustness
- POPD
- DMC in Pharma Manufacturing
- Container Closure
- Biosimiliars
- Elemental Impurity Requirements
- Process Validation
- Blend Uniformity



# Looking Forward: The Next 20 Years...

Promote science-based regulation by developing and delivering a portfolio of projects and public platforms of high value to industry and regulators

Enhance member organization benefits through PQRI work product



Expand membership and outreach internationally to industry and regulatory agencies, to enhance and further diversify expertise and information sharing

Build and maintain international recognition as a leading forum for advancing science in support of regulation



# THANK YOU...

- We would like to thank all PQRI members & attendees, past and present, for supporting the organization and contributing to its mission.
- We look forward to what the next 20 years will bring!
- Contact the PQRI Secretariat ([PQRIsecretariat@pqri.org](mailto:PQRIsecretariat@pqri.org)) re membership inquiries or volunteer opportunities.



# More Housekeeping Items

- Please turn off or mute your cell phones
- Issues/Comments/Concerns
- Need a Parking Pass?
  - Please stop by the registration desk

*Thanks for attending!*