4th FDA/PQRI Conference on
Advancing Product Quality
Patient-Centric Product Design, Drug Development,
and Manufacturing

April 9-11, 2019

Hilton Washington DC/Rockville Hotel & Executive Meeting Center
1750 Rockville Pike, Rockville, MD 20852

Visit the PQRI website for more details: http://pqri.org/4th-fda-pqri-conference/

Use this color guide as a reference:
Track #1 Biopharmaceutics: Novel Approaches to Improve Treatment Outcome and Patient Safety
Track #2 Development: Emerging Technologies and Patient Centricity in Early Drug Development
Track #3 Manufacturing: Novel Manufacturing Technologies and Challenges for the Production of Patient-Centric Drug Products
## DAY 1 – TUESDAY, APRIL 9, 2019

### 7:30 – 8:30 AM REGISTRATION

### 8:30 – 10:15 AM Plenary Session
- **8:30 – 8:45 AM** | **Welcome**
  - Mehran Yazdanian, Ph.D., Senior Director of Scientific Strategy and Operations, Teva Pharmaceuticals
- **8:45 – 9:15 AM** | **Keynote**
  - Patrizia Cavazzoni, MD, Deputy Director for Operations, CDER, US FDA (Invited)
- **9:15 – 9:45 AM** | **Innovating to Accelerate the Delivery of Transformative Therapies to Patients**
  - Stephanie L. Krogmeier, Ph.D., Vice President, Global Regulatory CMC Strategy, Vertex Pharmaceuticals, Inc.
- **9:45 – 10:15 AM** | **Future Drug Development: Evolving Regulatory Landscape**
  - Lawrence X. Yu, Ph.D., Deputy Director, Office of Pharmaceutical Quality/CDER/FDA

### 10:15 -10:45 AM Coffee Break

### TRACK #1 NOVEL APPROACHES TO IMPROVE TREATMENT OUTCOME AND PATIENT SAFETY

<table>
<thead>
<tr>
<th>Time</th>
<th>Session 1: Complex Generics – Challenges and Opportunities</th>
<th>Session 1: Early Drug Development: A Vision for the Future</th>
<th>Session 1: Novel Manufacturing Technologies and Challenges for Cell and Gene Therapies</th>
</tr>
</thead>
<tbody>
<tr>
<td>10:45 – 11:15 AM</td>
<td>Considerations for Biologics and Non-biological Complex Drugs</td>
<td>Early Drug Development, Regulatory Perspective</td>
<td>Regulatory Expectations for Cell and Gene Therapies</td>
</tr>
<tr>
<td>11:15 – 11:45 AM</td>
<td>An Overview of Complex Drug Substances and Complex Formulations – A Quality Perspective</td>
<td>Accelerating Drug Product Development Using Small Scale, Data Intensive, Iterative Design Approaches</td>
<td>Manufacturing and Validation Challenges</td>
</tr>
<tr>
<td>12:15 – 12:30 PM</td>
<td>Panel Discussion (above speakers)</td>
<td>Panel Discussion (above speakers)</td>
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### TRACK #2 EMERGING TECHNOLOGIES AND PATIENT CENTRICITY IN EARLY DRUG DEVELOPMENT

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

### 12:30 –1:30 PM Lunch
<table>
<thead>
<tr>
<th>Time</th>
<th>Track #1 Novel Approaches to Improve Treatment Outcome and Patient Safety</th>
<th>Track #2 Emerging Technologies and Patient Centricity in Early Drug Development</th>
<th>Track #3 Novel Manufacturing Technologies and Challenges for the Production of Patient-Centric Drug Products</th>
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</table>
| 1:30 – 3:15 PM | Session 2: Developments in Biopharmaceutical Characterization of Injectable and Implantable Products  
Moderator: Nan Zheng, FDA | Session 2: Designing for Delivery: Drug Discovery and the Early Development Interface  
Moderator: Diane Paskiet, West Pharmaceutical Services | Session 2: Implementation and Regulatory Impact of Continuous Manufacturing (Analytical, Quality)  
Moderator: Bob Meyer, Merck & Co., Inc. |
| 1:30 – 2:00 PM | • Physicochemical Characterization of Nanomedicines  
  • Jeffrey Clogston, Nanotechnology Characterization Laboratory | • Value Driven Development  
  • Christopher Breder, FDA | • In Silico Modeling Approaches Towards Robust Design, Specification Setting and Establishing Control Strategies - Bio/Pharma Industry Perspective  
  • Cenk Undey, Amgen |
| 2:00 – 2:30 PM | • Challenges and Considerations in the Development and Validation of In Vitro Drug Release Testing for Intravaginal Rings  
  • Karl Malcolm, Queen’s University Belfast | • Discovering and Developing Non-Traditional Drug Modality Molecules with Optimal Pharmaceutical Properties  
  • Mike Hageman, University of Kansas | • Use of Computational Modeling in Specification Setting and Establishing Control Strategy – Regulatory Perspective  
  • Thomas O’Connor, FDA |
| 2:30 – 3:00 PM | • FDA Perspective on Non-oral Delivery Biopharmaceuticals Aspects  
  • Wenlei Jiang, FDA | • Designing for Delivery: The Use of Mathematical Modeling  
  • Ronald Iacocca, Eli Lilly and Company | • PAT for Model Based Design, Optimization, Monitoring and Control of Continuous Manufacturing  
  • Thomas De Beer, Ghent University, Belgium |
| 3:00 – 3:15 PM | Panel Discussion (above speakers) | Panel Discussion (above speakers) | Panel Discussion (above speakers) |
| 3:15 – 3:45 PM | Coffee Break | | |
| 3:45 – 5:30 PM | Session 3: A Novel Approach for Overcoming Barriers to Improve Patient Access for Topical Drugs  
Moderator: Filippos Kesisoglou, Merck & Co., Inc. | Session 3: Drug Device Combination Products – Emerging Technologies & the Evolving Regulatory Landscape  
Moderator: Ajit Narang, Genentech | Session 3: Implementation and Regulatory Impact of Continuous Manufacturing (Process and Validation)  
Moderator: Pramod Kotwal, Merck & Co., Inc. |
| 3:45 – 4:15 PM | • The Premise of a Topical Drug Classification System as an Alternative to Clinical Endpoint Bioequivalence Studies  
  • Vinod Shah, Pharmaceutical Consultant | • Drug Device Combination Products Evolving Regulatory Landscape  
  • Susan Neadle, Johnson & Johnson | • Continuous Manufacturing – Large Molecule Drug Substance  
  • Arthur Hewig, Amgen |
| 4:15 – 4:45 PM | • In Vitro Release and Q3 Measurements for Semisolid Drug Products  
  • Flavian Rădulescu, Carol Davila University of Medicine and Pharmacy | • Emerging Drug-Device Combinations: A Digitally Enhanced Patient Experience  
  • Kristina Lauritsen, FDA | • Continuous Manufacturing – Small Molecule Drug Substance or Drug Product  
  • Paul Collins, Eli Lilly and Company |
| 4:45 – 5:15 PM | • Bioequivalence of Topical Products: Scientific Considerations  
  • Tannaz Ramezanli, FDA | • Inhaled Product Advances for Aerosolization, Breath Coordination and Patient Monitoring  
  • Alan Watts, Savara Pharmaceuticals | • Regulatory Considerations – What to Register?  
  • Sharmista Chatterjee, FDA |
| 5:15 – 5:30 PM | Panel Discussion (above speakers) | Panel Discussion (above speakers) | Panel Discussion (above speakers) |
| 5:30 – 7:00 PM | Reception | | |
### DAY 2 – WEDNESDAY, APRIL 10, 2019

- **7:30- 8:00 AM** Continental Breakfast

- **8:00 – 10:00 AM** Plenary Session
  - **Topic Summaries from Day 1** (40 minutes per Track; 10 minutes per Topic)
    - **8:00 – 8:40 AM**  Track #1 Summary
    - **8:40 – 9:20 AM**  Track #2 Summary
    - **9:20 – 10:00 AM** Track #3 Summary

### 10:00 AM – 10:30 AM Coffee Break –

### 10:30 AM – 12:15 PM

<table>
<thead>
<tr>
<th>TRACK #1 NOVEL APPROACHES TO IMPROVE TREATMENT OUTCOME AND PATIENT SAFETY</th>
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<td>SESSION 4: PREDICTIVE APPROACHES TO GAIN INSIGHT INTO THE CLINICAL PERFORMANCE OF INHALED MEDICINES</td>
<td>SESSION 4: DEVELOPMENT CONSIDERATIONS FOR EVOLVING NON-TRADITIONAL DRUG MODALITIES</td>
<td>SESSION 4: REGULATORY SUBMISSION LIFECYCLE MANAGEMENT</td>
</tr>
<tr>
<td>Moderator: Mehran Yazdanian, Teva</td>
<td>Moderator: Allen Templeton, Merck &amp; Co., Inc.</td>
<td>Moderator: Susan Rosencrance, FDA</td>
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<tr>
<td><strong>10:30 AM – 11:00 AM</strong></td>
<td><strong>11:00 – 11:30 AM</strong></td>
<td><strong>11:30 AM – 12:00 PM</strong></td>
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<tr>
<td>• Biopharmaceutical Classification of Inhaled Medicines: Development of an iBQS</td>
<td>• Unlocking the Promise of Immunoncology and Combination Therapies</td>
<td>• Overview of ICH Q12 Guideline Development: Current Status</td>
</tr>
<tr>
<td>○ Jayne E. Hastedt, JDP Pharma Consulting</td>
<td>○ Rubi Burlage, Merck &amp; Co., Inc.</td>
<td>○ Andrew Chang, NovoNordisk</td>
</tr>
<tr>
<td>• Modeling Aspects Related to Inhaled Medicines</td>
<td>• Delivery of Nucleic Acid Sequences in Mammalian Cells Mediated by Phosphorothioate DNA or RNA Transporter Elements</td>
<td>• The Concept and Proposed Global Applicability and Benefit of PACMP (Post-Approval Change Management Protocol)</td>
</tr>
<tr>
<td>○ Per Bäckman, Emmace Consulting</td>
<td>○ Serge Beaucage, FDA</td>
<td>○ Mahesh Ramanadham, FDA</td>
</tr>
<tr>
<td>• Regulatory and Scientific Challenges in Establishing Bioequivalence for Orally Inhaled Drug Products</td>
<td>• Developing Next Generation Technologies in the Context of a Public Private Partnership</td>
<td>• Established Conditions and its Application</td>
</tr>
<tr>
<td>○ Bing Li, FDA</td>
<td>○ Kelvin Lee, NIIMBL/University of Delaware</td>
<td>○ Bhagwant Rege, FDA</td>
</tr>
<tr>
<td><strong>12:00 – 12:15 PM</strong></td>
<td>Panel Discussion (above speakers)</td>
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### 12:15 – 1:15 PM Lunch
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| 1:15 – 1:45 PM  | • PBPK-based and Traditional IVIVC as Complementary Tools to Quality by Design in the Biopharmaceutics Space  
  o **David Good, Bristol-Myers Squibb** | • What do Petroleomics, Jet Fuel and Pharmaceuticals Have In Common? Visualization and Characterization of Complex Mixtures of Extractables/Leachables and Other Pharmaceutically Relevant Compounds using High Resolution 2-D and 3-D Mass Mapping  
  o **Douglas Kiehl, Eli Lilly and Company** | • Types and Handling of Product Complaints for Combination Products  
  o **John Towns, Eli Lilly and Company** |
| 1:45 – 2:15 PM  | • The US Food and Drug Administration Perspective on Physiologically-Based Absorption Modeling in Biopharmaceutics  
  o **Yang Zhao, FDA** | • Advanced Analytical Techniques for Characterizing Amorphous Solid Dispersions  
  o **Eric Munson, Purdue University** | • Regulatory Perspective on Applying Human Factors Engineering Considerations to Post Approval Changes  
  o **QuynhNu Nguyen, FDA** |
| 2:15 – 2:45 PM  | • Mechanistic Absorption Modeling and Clinically Relevant Specifications for Enabling Formulations Technologies  
  o **Christophe Tistaert, Janssen Research & Development** | • Beyond the Big Crunch of Excel: The Big Bang of Digital Visualizations  
  o **Marcus Adams, Merck & Co., Inc.** | • Challenges based on Differences in Global Regulatory Filing Requirements  
  o **Doug Mead, Janssen** |
| 2:45 – 3:00 PM  | Panel Discussion (above speakers) | Panel Discussion (above speakers) | Panel Discussion (above speakers) |
| 3:00 – 3:30 PM  | **Panel Discussion (above speakers)** | **Panel Discussion (above speakers)** | **Panel Discussion (above speakers)** |

3:30 – 3:55 PM

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| 3:30 – 3:40 PM  | • Advancing the Dissolution Toolbox in Drug Development: Novel Bio-predictive Dissolution Methodologies for Novel Product Development  
  o **Greg Amidon, University of Michigan** | • Challenges in the Opioid Epidemic Crisis  
  o **Douglas Throckmorton, FDA** | • Regulatory Framework and Industrial Initiatives – A European Perspective  
  o **Sven Stegemann, Graz University of Technology** |
| 3:40 – 3:50 PM  | • Use of 3D-printed Tablets as a Biopharmaceuticals Investigation Tool  
  o **Adam Procopio, Merck & Co., Inc.** | • The Expanding Universe of Patient Adherence Solutions: Long-acting Implantables, Micro-Chip, Smart Packaging, Apps, and Social Robotics  
  o **Stephanie Barrett, Merck & Co., Inc.** | • Pharmaceuticals and Medical Devices Agency (PMDA) Perspective  
  o **Yoshihiro Matsuda, PMDA** |
| 3:50 – 4:00 PM  | • Advancing Biopharmaceutics Knowledge and Toolkit to Improve the Quality of Pediatrics Medicines  
  o **Gilbert Burkart, FDA** | • New Formulation Technologies for Patient Adherence: Solid Oral Dosage Forms  
  o **Ali Rajabi-Siahboomi, Colorcon** | • FDA Perspective  
  o **Celia Cruz, FDA** |
| 5:00 – 5:15 PM  | Panel Discussion (above speakers) | Panel Discussion (above speakers) | Panel Discussion (above speakers) |
# 4th FDA/PQRI Conference on Advancing Product Quality (April 9-11, 2019)

## Conference At-A-Glance

### Day 3 – Thursday, April 11, 2019

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<th>Time</th>
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<td>7:30 – 8:00 AM</td>
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<tr>
<td>9:00 – 9:30 AM</td>
<td>Track #3 Summary</td>
</tr>
<tr>
<td>9:30 – 10:00 AM</td>
<td>Coffee Break</td>
</tr>
<tr>
<td>10:00 – 11:30 AM</td>
<td>Introducing FDA’S New Initiative: KASA (Knowledge-aided Assessment and Structured Application)</td>
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<tr>
<td>Moderator:</td>
<td>Lawrence Yu</td>
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<tr>
<td>Presenters:</td>
<td>Susan Rosencrance, Andre Raw, Derek Smith, and Mary Ann Slack</td>
</tr>
<tr>
<td>Panelists:</td>
<td>Susan Rosencrance, Sharmista Chatterjee, Mahesh Ramanadham, Paul Seo, Ramesh Sood, Geoffrey Wu, and Larisa Wu</td>
</tr>
<tr>
<td>11:30 AM – 12:00 PM</td>
<td>Poster Award Announcement and Presentations</td>
</tr>
<tr>
<td>12:00 PM</td>
<td>Closing Remarks</td>
</tr>
</tbody>
</table>

## Faculty

### Speakers and Moderators

- **Marcus Adams**, Senior Specialist, Merck & Co., Inc.
- **Andreas Abend**, Ph.D., Director-Analytical Sciences, Merck & Co., Inc.
- **Gregory E. Amidon**, PhD., Research Professor of Pharmaceutical Sciences, University of Michigan
- **Per Bäckman**, PhD, Senior Inhalation Consultant, Emmace Consulting AB
- **Stephanie E. Barrett**, Ph.D., Senior Principal Scientist, Merck & Co., Inc.
- **Serge L. Beaucage**, Ph.D., Supervisory Research Chemist, CDER, US Food and Drug Administration
- **Christopher D. Breder**, MD., Ph.D., Medical Officer, US Food and Drug Administration
- **Matthew D. Burke**, Ph.D., Senior Director, Head of Drug Delivery, GlaxoSmithKline
- **Gilbert J. Burckart**, Pharm.D., Associate Director for Pediatrics, Office of Clinical Pharmacology, Food and Drug Administration
- **Rubi Burlage**, Ph.D., Executive Director, Merck & Co., Inc.
- **Nina S. Cauchon**, Ph.D., Regulatory Affairs – CMC, Amgen Inc.
- **Patrizia Cavazzoni**, M.D., Deputy Director of Operations, CDER, US Food and Drug Administration
- **Andrew C. Chang**, Ph.D., Vice President, NovoNordisk, Inc.
- **Sharmista Chatterjee**, Ph.D., Division Director, Division of Process Assessment II/OPF/CDER/FDA
- **Jeffrey D. Clogston**, Ph.D., Principal Scientist, Physicochemical Characterization Section Head, Nanotechnology Characterization Laboratory
- **Paul C. Collins**, Ph.D., Senior Director, Small Molecule Design and Development, Eli Lilly and Company
- **Daan J.A. Crommelin**, Ph.D., Professor Emeritus, Department of Pharmaceutics, Utrecht University
- **Celia Cruz**, Ph.D., Director, Division of Product Quality Research, Office of Testing and Research/OPQ/CDER/FDA

### Additional Faculty

- **Thomas De Beer**, Ph.D., Professor, Ghent University, Belgium
- **David J. Good**, Ph.D., Associate Director, Bristol-Myers Squibb
- **Michael J. Hageman**, Ph.D., Valentino Stella Distinguished Professor, University of Kansas
- **Jayne E. Hastedt**, Ph.D., Managing Director, JDP Pharma Consulting, LLC
- **Michael Havert**, Ph.D., Senior Director, Regulatory CMC, bluebird bio
- **Arthur Hewig**, Ph.D., Director, Process Development, Amgen Inc.
- **Ronald G. Iacocca**, Ph.D., Research Fellow, Eli Lilly and Company
- **Xiaohui (Jeff) Jiang**, Ph.D., Deputy Director, Division of Therapeutic Performance, ORS/OGD/CDER/ U.S. Food and Drug Administration

(Continued below)
CONFERENCE AT-A-GLANCE

Wenlei Jiang, PhD, Senior Science Advisor, Office of Research and Standards/OGD/CDER/ US Food and Drug Administration
Filippous Kesiosoglou, Ph.D., Distinguished Scientist, Merck & Co., Inc.
Douglas E. Kiehl, M.S., Research Advisor, Eli Lilly and Company
Stephanie L. Kroghmeier, Vice President, Global Regulatory CMC Strategy, Vertex Pharmaceuticals
Kristina J. Lauritsen, Ph.D., Combination Product Policy Advisor, CDER/Food and Drug Administration
Kelvin H. Lee, Ph.D., Director, National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)
Bing V. Li, Ph.D., Director, Division of Bioequivalence I, Office of Bioequivalence, OGD/CDER/US Food and Drug Administration
R. Karl Malcolm, Ph.D., Professor of Drug Delivery, School of Pharmacy, Queen’s University Belfast
Yoshihiro Matsuda, Ph.D., Senior Scientist for Quality, Pharmaceuticals and Medical Devices Agency (PMDA)
Douglas Mead, M.S.BME, RAC, Senior Director, CMC RA, Devices, Janssen R&D, LLC
Robert Meyer, PhD, Principal Scientist, Merck & Co., Inc.
Eric J. Munson, Ph.D., Professor, Purdue University
Ajit Narang, Ph.D., Senior Scientist, Genentech
Susan W. Needle, MS, Sr. Director, Global Value Chain Quality Design; Head, Johnson & Johnson Combination Products CoP, Johnson & Johnson
QuynhNhu T. Nguyen, M.S., Commander, U.S Public Health Service, Associate Director for Human Factors/Division of Medication Error Prevention and Analysis/OSE/CDER/FDA
Thomas F. O’Connor, Ph.D., Senior Chemical Engineer, Office of Testing Research, OPQ/CDER/Food and Drug Administration
Palani Palaniappan, Ph.D., Sr. Vice President, Head of Global Technical Operations, Sarepta Therapeutics, Inc.

Diane Paskiet, Director of Scientific Affairs, West Pharmaceutical Services
Adam T. Procopio, Ph.D., Senior Principal Scientist, Merck & Co., Inc.
Flavian S. Rădulescu, PhD, Associate Professor, University of Medicine and Pharmacy Carol Davila Bucharest
Ali Rajabi-Siahboomi, Ph.D., Vice President and Chief Scientific Officer, Colorcon
Tannaz Ramezanli, Ph.D., R.Ph., Staff Fellow, FDA
Andre Raw, Ph.D., Supervisory Chemist, Office of Lifecycle Drug Products, OPQ/CDER/U.S. Food and Drug Administration
Bhagwant Rege, Ph.D., Division Director, Office of Lifecycle Drug Products, OPQ/CDER/U.S. Food and Drug Administration
Susan Rosen crance, Ph.D., Director, Office of Lifecycle Drug Products, OPQ/CDER/U.S. Food and Drug Administration
David R. Schoneker, M.S., Global Regulatory Director-Strategic Relationships, Colorcon
Paul Seo, Ph.D., Director, Division of Biopharmaceutics, ONDP/OPQ/CDER/Food and Drug Administration
Vinod P. Shah, Ph.D., FAAPS, FFIP, Pharmaceutical Consultant
Michael Skidmore, Independent Consultant, Pharmaceutical Quality Consulting, Inc.
Mary Ann Slack, Director, Office of Strategic Programs, US Food and Drug Administration
Derek Smith, Ph.D., Director, Division of Inspectionsal Assessment/OPF/OPQ/CDER/US Food and Drug Administration
Ramesh K. Sood, Ph.D. Senior Scientific Advisor (acting), Office of New Drug Products, FDA
Sven Stegemann, Ph.D., Professor, Graz University of Technology
Sandra Suarez Sharp, PhD, Master Biopharmaceutics Reviewer, Division of Biotherapeutics, ONDP/OPQ/Food and Drug Administration
Allen C. Templeton, Ph.D., Vice President, Pharmaceutical Sciences, Merck & Co., Inc.
Douglas Throckmorton, MD, Deputy Director for Regulatory Programs, US Food and Drug Administration
Christophe Tistaert, Ph.D., Principal Scientist, Janssen Research & Development
John K. Towns, Ph.D., Senior Research Fellow, Eli Lilly and Company
Gregory M. Troup, Ph.D., Senior Principal Scientist, Merck & Co., Inc.
Katherine M. Tyner, Ph.D., Associate Director for Science (acting); CDER/OPQ, FDA
Cenk Undeyi, PhD, Executive Director, Amgen
Ramjay S. Vatsan, Ph.D., Team Leader, Office of Cellular Tissue and Gene Therapies, CBER, Food and Drug Administration
Alan B. Watts, PhD, Senior Scientist, Savara Pharmaceuticals
Geoffrey Wu, PhD, PMP, CPH, Associate Director for Science and Communication, OLDP/OPQ/CDER US Food and Drug Administration
Larisa Wu, Ph.D., Senior Chemist and Special Assistant, Office of Pharmaceutical Quality, CDER, FDA
Mehran Yazdani an, Ph.D., Senior Director of Scientific Strategy and Operations, Teva Pharmaceuticals
Lawrence X. Yu, Ph.D., Deputy Director, Office of Pharmaceutical Quality/CDER/Food and Drug Administration
Nan Zheng, Ph.D., Senior Staff Fellow, OCP/OTS/CDER/US Food and Drug Administration
Yang Zhao, Ph.D., Pharmacologist, US Food and Drug Administration
PQRI Members

Consumer Healthcare Products Association (CHPA)
U.S. Food and Drug Administration, Center for Drug Evaluation and Research (FDA/CDER)
Health Canada (HC)
International Pharmaceutical Excipients Council of the Americas (IPEC-Americas)
Parenteral Drug Association (PDA)
United States Pharmacopeia (USP)

Conference Organizing Committee Members

Susan Rosencrance, FDA  Co-Chair
Mehran Yazdanian, Teva  Co-Chair
Lawrence Yu, FDA  Co-Chair
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 Shoneker, Colorcon
Vinod Shah, Consultant
Allen Templeton, Merck
Cat Vicente, Janssen
Glenn Wright, Consultant
Geoff Wu, FDA

About PQRI

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 drug product quality, manufacturing, and regulation. To learn more or to join, contact us at PQRISecretariat@pqri.org, call +1(202) 230-5199 or visit www.pqri.org.