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

4th FDA/PQRI Conference on Advancing Product Quality (April 9-11, 2019)

CONFERENCE AT-A-GLANCE

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, PhD, Senior Director of Scientific Strategy and Operations, Teva Pharmaceuticals***
- 8:45 – 9:15 AM **Keynote**
  - ***Patrizia Cavazzoni, MD, Deputy Director for Operations, CDER, US Food and Drug Administration***
- 9:15 – 9:45 AM **Innovating to Accelerate the Delivery of Transformative Therapies to Patients**
  - ***Stephanie L. Krogmeier, PhD, Vice President, Global Regulatory CMC Strategy, Vertex Pharmaceuticals, Inc.***
- 9:45 – 10:15 AM **Pharmaceutical Product Development: Evolving Regulatory Landscape**
  - ***Lawrence X. Yu, PhD, Deputy Director, Office of Pharmaceutical Quality, CDER, US Food and Drug Administration***

10:15 -10:45 AM Coffee Break

	TRACK #1 NOVEL APPROACHES TO IMPROVE TREATMENT OUTCOME AND PATIENT SAFETY	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
10:45 AM – 12:30 PM	**SESSION 1: COMPLEX GENERICS – CHALLENGES AND OPPORTUNITIES** Moderator: ***Wenlei Jiang, FDA***	**SESSION 1: EARLY DRUG DEVELOPMENT: A VISION FOR THE FUTURE** Moderator: ***Geoffrey Wu, FDA***	**SESSION 1: NOVEL MANUFACTURING TECHNOLOGIES AND CHALLENGES FOR CELL AND GENE THERAPIES** Moderator: ***Michael Skidmore, Pharmaceutical Quality Consulting, Inc.***
10:45 – 11:15 AM	• Considerations for Biologics and Non-biological Complex Drugs ○ ***Daan Crommelin, Utrecht University***	• Early Drug Development: A Regulatory Perspective ○ ***Ramesh Sood, FDA***	• Regulatory Expectations for Cell and Gene Therapies ○ ***Ramjay Vatsan, FDA***
11:15 – 11:45 AM	• An Overview of Complex Drug Substances and Complex Formulations – A Quality Perspective ○ ***Katherine Tyner, FDA***	• Accelerating Drug Product Development Using Small Scale, Data Intensive, Iterative Design Approaches ○ ***Gregory Troup, Merck & Co., Inc.***	• Manufacturing and Validation Challenges ○ ***Palani Palaniappan, Sarepta Therapeutics***
11:45 AM - 12:15 PM	• Overview of Complex Generics – Regulatory Perspective ○ ***Jeff Jiang, FDA***	• Challenges and Opportunities with Patient-Centric Drug Product Design: Industry Perspectives ○ ***Matthew Burke, GlaxoSmithKline***	• Testing Strategies for Ex-vivo Gene Therapies ○ ***Michael Havert, bluebird bio***
12:15 – 12:30 PM	Panel Discussion (above speakers)	Panel Discussion (above speakers)	Panel Discussion (above speakers)

12:30 –1:30 PM Lunch

4th FDA/PQRI Conference on Advancing Product Quality (April 9-11, 2019) CONFERENCE AT-A-GLANCE

	TRACK #1 NOVEL APPROACHES TO IMPROVE TREATMENT OUTCOME AND PATIENT SAFETY	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
1:30 – 3:15 PM	**SESSION 2: DEVELOPMENTS IN BIOPHARM CHARACTERIZATION OF INJECTABLES 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 (PART I)** Moderator: ***Bob Meyer, Merck & Co., Inc.***
1:30 – 2:00 PM	• Physicochemical Characterization of Nanomedicines ○ ***Jeffrey Clogston, Nanotechnology Characterization Laboratory***	• Value-Driven Drug Development ○ ***Christopher Breder, FDA***	• *In Silico* Modeling Approaches Towards Establishing Robust Design and 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***	• Perspective on the Validation of Computational Models for Establishing Control Strategies ○ ***Thomas O'Connor, FDA***
2:30 – 3:00 PM	• Complex Injectable and Implantable Drug Products: Bioequivalence Considerations ○ ***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 (PART II)** Moderator: ***Pramod Kotwal, Merck & Co., Inc.***
3:45 – 4:15 PM	• In Vitro Release and Q3 Measurements for Semisolid Drug Products ○ ***Flavian Rădulescu, Carol Davila University of Medicine and Pharmacy***	• Drug Device Combination Products: Evolving Global Regulatory Landscape ○ ***Susan Neadle, Johnson & Johnson***	• Transforming Biopharmaceutical Production Through the Deployment of Next Generation Manufacturing: Opportunities and Challenges ○ ***Arthur Hewig, Amgen***
4:15 – 4:45 PM	• The Premise of a Topical Drug Classification System as an Alternative to Clinical Endpoint Bioequivalence Studies ○ ***Vinod Shah, Pharmaceutical Consultant***	• Emerging Drug-Device Combinations: A Digitally Enhanced Patient Experience ○ ***Kristina Lauritsen, FDA***	• Continuous Manufacturing – Framing a Future for Patients ○ ***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***	• Novel Technologies to Support Patient Centric Product Development: FDA Perspective ○ ***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 –

	TRACK #1 NOVEL APPROACHES TO IMPROVE TREATMENT OUTCOME AND PATIENT SAFETY	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
10:30 AM– 12:15 PM	**SESSION 4: PREDICTIVE APPROACHES TO GAIN INSIGHT INTO THE CLINICAL PERFORMANCE OF INHALED MEDICINES** Moderator: ***Mehran Yazdanian, Teva***	**SESSION 4: DEVELOPMENT CONSIDERATIONS FOR EVOLVING NON-TRADITIONAL DRUG MODALITIES** Moderator: ***Allen Templeton, Merck & Co., Inc.***	**SESSION 4: REGULATORY SUBMISSION LIFECYCLE MANAGEMENT** Moderator: ***Susan Rosencrance, FDA***
10:30 – 11:00 AM	• Biopharmaceutical Classification of Inhaled Medicines: Development of an iBCS ○ ***Jayne E. Hastedt, JDP Pharma Consulting***	• Unlocking the Promise of Immunoncology and Combination Therapies ○ ***Rubi Burlage, Merck & Co., Inc.***	• Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management: ICH Q12 ○ ***Andrew Chang, Novo Nordisk***
11:00 – 11:30 AM	• Modeling Aspects Related to Inhaled Medicines ○ ***Per Bäckman, Emmace Consulting***	• Delivery of Nucleic Acid Sequences in Mammalian Cells Mediated by Phosphorothioate DNA or RNA Transporter Elements ○ ***Serge Beaucage, FDA***	• The Concept and Proposed Global Applicability and Benefit of PACMP (Post-Approval Change Management Protocol) ○ ***Mahesh Ramanadham, FDA***
11:30 AM – 12:00 PM	• Regulatory and Scientific Challenges in Establishing Bioequivalence for Generic Orally Inhaled Drug Products ○ ***Bing Li, FDA***	• Developing Next Generation Technologies in the Context of a Public Private Partnership ○ ***Kelvin Lee, NIIMBL/University of Delaware***	• Established Conditions and its Application ○ ***Bhagwant Rege, FDA***
12:00 – 12:15 PM	Panel Discussion (above speakers)	Panel Discussion (above speakers)	Panel Discussion (above speakers)

12:15 – 1:15 PM Lunch

4th FDA/PQRI Conference on Advancing Product Quality (April 9-11, 2019) CONFERENCE AT-A-GLANCE

	TRACK #1 NOVEL APPROACHES TO IMPROVE TREATMENT OUTCOME AND PATIENT SAFETY	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
1:15 – 3:00 PM	**SESSION 5: ENABLING PATIENT-FOCUSED QUALITY STANDARDS VIA MODELING AND SIMULATION FOR ORAL PRODUCTS** Moderator: ***Sandra Suarez Sharp, FDA***	**SESSION 5: NEW VISUALIZATION AND ANALYSIS TECHNIQUES IN DRUG DEVELOPMENT** Moderator: ***Bob Meyer, Merck & Co., Inc.***	**SESSION 5: CHALLENGES WITH DRUG DEVICE COMBINATION PRODUCTS POST APPROVAL** Moderator: ***Susan Neadle, Johnson & Johnson***
1:15 – 1:45 PM	• PBPK-based and Traditional IVIVC as Complementary Tools to Quality by Design in the Biopharmaceutics Space ○ ***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 ○ ***Douglas Kiehl, Eli Lilly and Company***	• The Role of Human Factors Engineering in Combination Product Post Approval Changes ○ ***QuynhNu Nguyen, FDA***
1:45 – 2:15 PM	• Application of Physiologically Based Biopharmaceutics Modeling in Support of Drug Product Quality ○ ***Yang Zhao, FDA***	• Advanced Analytical Techniques for Characterizing Amorphous Solid Dispersions ○ ***Eric Munson, Purdue University***	• Types and Handling of Product Complaints for Combination Products ○ ***John Towns, Eli Lilly and Company***
2:15 – 2:45 PM	• Mechanistic Absorption Modeling and Clinically Relevant Specifications for Enabling Formulation Technologies ○ ***Christophe Tistaert, Janssen Research & Development***	• Beyond the Big Crunch of Excel: The Big Bang of Digital Visualizations ○ ***Marcus Adams, Merck & Co., Inc.***	• Challenges based on Differences in Global Regulatory Filing Requirements ○ ***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 Coffee Break			
3:30 – 5:15 PM	**SESSION 6: ORAL BIOPHARMACEUTICS: CHALLENGES, OPPORTUNITIES, AND ADVANCEMENTS** Moderator: ***Andreas Abend, Merck & Co., Inc.***	**SESSION 6: EMERGING TECHNOLOGIES FOR IMPROVING PATIENT ADHERENCE** Moderator: ***Dave Schoneker, Colorcon***	**SESSION 6: CMC INNOVATION IN THE 21ST CENTURY – GLOBAL REGULATORY PERSPECTIVES** Moderator: ***Nina Cauchon, Amgen***
3:30 – 4:00 PM	• Advancing the Dissolution Toolbox in Drug Development: Novel Bio-predictive Dissolution Methodologies for Oral Products ○ ***Greg Amidon, University of Michigan***	• Challenges in the Opioid Epidemic Crisis ○ ***Douglas Throckmorton, FDA***	• A European Perspective on Global CMC Innovation ○ ***Sven Stegemann, Graz University of Technology***
4:00 – 4:30 PM	• Use of 3D-printed Tablets as a Biopharmaceutics Investigation Tool ○ ***Adam Procopio, Merck & Co., Inc.***	• The Expanding Universe of Patient Adherence Solutions: Long-acting Implantables, Micro-Chip, Smart Packaging, Apps, and Social Robotics ○ ***Stephanie Barrett, Merck & Co., Inc.***	• Pharmaceuticals and Medical Devices Agency (PMDA) Perspective ○ ***Yoshihiro Matsuda, PMDA***
4:30 – 5:00 PM	• Advancing Biopharmaceutics Knowledge and Toolkit to Improve the Quality of Pediatrics Medicines ○ ***Gilbert Burckart, FDA***	• New Formulation Technologies for Patient Adherence: Solid Oral Dosage Forms ○ ***Ali Rajabi-Siahboomi, Colorcon***	• FDA Perspective ○ ***Celia Cruz, FDA***
5:00 – 5:15 PM	Panel Discussion (above speakers)	Panel Discussion (above speakers)	Panel Discussion (above speakers)

DAY 3 – THURSDAY, APRIL 11, 2019

7:30 – 8:00 AM Continental Breakfast

8:00 – 9:30 AM **Topic Summaries** (30 minutes per Track; 10 minutes per Topic))

8:00 – 8:30 AM	Track #1 Summary
8:30 – 9:00 AM	Track #2 Summary
9:00 – 9:30 AM	Track #3 Summary

9:30 – 10:00 AM Coffee Break

10:00 – 11:30 AM **Introducing FDA'S New Initiative: KASA (Knowledge-aided Assessment and Structured Application)**

A creative regulatory approach for modernizing the quality assessment and enhancing submission format

Moderator: Lawrence Yu

Presenters: Susan Rosencrance, Andre Raw, Derek Smith, and Mary Ann Slack

Panelists: Susan Rosencrance, Sharmista Chatterjee, Mahesh Ramanadham, Paul Seo, Ramesh Sood, Geoffrey Wu, and Larisa Wu

11:30 AM – 12:00 PM **Poster Award Announcement and Presentations**

12:00 PM Closing Remarks

FACULTY Speakers and Moderators

Andreas Abend, PhD, Director-Analytical Sciences, Merck & Co., Inc.

Marcus Adams, Senior Specialist, 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, PhD, Senior Principal Scientist, Merck & Co., Inc.

Serge L. Beaucage, PhD, Supervisory Research Chemist, CDER, US Food and Drug Administration

Christopher D. Breder, MD., PhD, Medical Officer, US Food and Drug Administration

Gilbert J. Burckart, PharmD, Associate Director for Pediatrics, Office of Clinical Pharmacology, US Food and Drug Administration

Matthew D. Burke, PhD, Senior Director, Head of Drug Delivery, GlaxoSmithKline

Rubi Burlage, PhD, Executive Director, Merck & Co., Inc.

Nina S. Cauchon, PhD, Regulatory Affairs – CMC, Amgen Inc.

Patrizia Cavazzoni, MD, Deputy Director of Operations, CDER, US Food and Drug Administration

Andrew C. Chang, PhD, Vice President, Novo Nordisk, Inc.

Sharmista Chatterjee, PhD, Division Director, Division of Process Assessment II, OPF, CDER, US Food and Drug Administration

Jeffrey D. Clogston, PhD, Principal Scientist, Physicochemical Characterization Section Head, Nanotechnology Characterization Laboratory

Paul C. Collins, PhD, Senior Director, Small Molecule Design and Development, Eli Lilly and Company

Daan J.A. Crommelin, PhD, Professor Emeritus, Department of Pharmaceutics, Utrecht University

Celia Cruz, PhD, Director, Division of Product Quality Research, Office of Testing & Research, OPQ, CDER, US Food and Drug Administration

Thomas De Beer, PhD, Professor, Ghent University, Belgium

David J. Good, PhD, Associate Director, Bristol-Myers Squibb

Michael J. Hageman, PhD, Valentino Stella Distinguished Professor, University of Kansas

Jayne E. Hastedt, PhD, Managing Director, JDP Pharma Consulting, LLC

Michael Havert, PhD, Senior Director, Regulatory CMC, bluebird bio

Arthur Hewig, PhD, Executive Director, Process Development, Amgen Inc.

Ronald G. Iacocca, PhD, Research Fellow, Eli Lilly and Company

Xiaohui (Jeff) Jiang, PhD, Deputy Director, Division of Therapeutic Performance, ORS, OGD, CDER, US Food and Drug Administration

(Continued below)

Wenlei Jiang, PhD, Senior Science Advisor, Office of Research and Standards, OGD, CDER, US Food and Drug Administration

Filippos Kesisoglou, PhD, Distinguished Scientist, Merck & Co., Inc.

Douglas E. Kiehl, MS, Research Advisor, Eli Lilly and Company

Pramod Kotwol, PhD, Director, CMC Policy, Merck & Co., Inc.

Stephanie L. Krogmeier, Vice President, Global Regulatory CMC Strategy, Vertex Pharmaceuticals, Inc.

Kristina J. Lauritsen, PhD, Combination Product Policy Advisor, CDER, US Food and Drug Administration

Kelvin H. Lee, PhD, Director, National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)

Bing V. Li, PhD, Director, Division of Bioequivalence I, Office of Bioequivalence, OGD, CDER, US Food and Drug Administration

R. Karl Malcolm, PhD, Professor of Drug Delivery, School of Pharmacy, Queen's University Belfast

Yoshihiro Matsuda, PhD, Senior Scientist for Quality, Pharmaceuticals and Medical Devices Agency (PMDA)

Douglass Mead, MSBME, RAC, Senior Director, CMC RA, Devices, Janssen R&D, LLC

Robert Meyer, PhD, Principal Scientist, Merck & Co., Inc.

Eric J. Munson, PhD, Professor, Purdue University

Ajit Narang, PhD, Senior Scientist, Genentech

Susan W. Neadle, 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, US Food and Drug Administration

Thomas F. O'Connor, PhD, Senior Chemical Engineer, Office of Testing Research, OPQ, CDER, US Food and Drug Administration

Palani Palaniappan, PhD, Sr. Vice President, Head of Global Technical Operations, Sarepta Therapeutics, Inc.

Diane Paskiet, Director of Scientific Affairs, West Pharmaceutical Services

Adam T. Procopio, PhD, Senior Principal Scientist, Merck & Co., Inc.

Flavian S. Rădulescu, PhD, Associate Professor, University of Medicine and Pharmacy Carol Davila Bucharest

Ali Rajabi-Siahboomi, PhD, Vice President and Chief Scientific Officer, Colorcon

Mahesh R. Ramanadham, LCDR, PharmD, Acting Senior Scientific and Policy Advisor for the Office of Process and Facilities, OPQ, CDER, US Food and Drug Administration

Tannaz Ramezanli, PhD, PharmD, Staff Fellow, US Food and Drug Administration

Andre Raw, PhD, Acting Senior Scientist and Policy Officer, Office of Lifecycle Drug Products, OPQ, CDER, US Food and Drug Administration

Bhagwant Rege, PhD, Division Director, Office of Lifecycle Drug Products, OPQ, CDER, US Food and Drug Administration

Susan Rosencrance, PhD, Director, Office of Lifecycle Drug Products, OPQ, CDER, US Food and Drug Administration

David R. Schoneker, MS, Global Regulatory Director-Strategic Relationships, Colorcon

Paul Seo, PhD, Director, Division of Biopharmaceutics, ONDP, OPQ, CDER, US Food and Drug Administration

Vinod P. Shah, PhD, 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, PhD, Director, Division of Inspectional Assessment, OPF, OPQ, CDER, US Food and Drug Administration

Ramesh K. Sood, PhD, Senior Scientific Advisor (acting), Office of New Drug Products, US Food and Drug Administration

Sven Stegemann, PhD, Professor, Graz University of Technology

Sandra Suarez Sharp, PhD, Master Biopharmaceutics Reviewer, Division of Biopharmaceutics, ONDP, OPQ, US Food and Drug Administration

Allen C. Templeton, PhD, Vice President, Pharmaceutical Sciences, Merck & Co., Inc.

Douglas Throckmorton, MD, Deputy Director for Regulatory Programs, US Food and Drug Administration

Christophe Tistaert, PhD, Principal Scientist, Janssen Research & Development

John K. Towns, PhD, Senior Research Fellow, Eli Lilly and Company

Gregory M. Troup, PhD, Senior Principal Scientist, Merck & Co., Inc.

Katherine M. Tyner, PhD, Associate Director for Science (acting), CDER, OPQ, US Food and Drug Administration

Cenk Undey, PhD, Executive Director, Amgen

Ramjay S. Vatsan, PhD, Team Leader, Gene Therapy Branch, Division of Cellular & Gene Therapies, OTAT, CBER, US 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, PhD, Senior Chemist and Special Assistant, Office of Pharmaceutical Quality, CDER, US Food and Drug Administration

Mehran Yazdanian, PhD, Senior Director of Scientific Strategy and Operations, Teva Pharmaceuticals

Lawrence X. Yu, PhD, Deputy Director, Office of Pharmaceutical Quality, CDER, US Food and Drug Administration

Yang Zhao, PhD, Pharmacologist, US Food and Drug Administration

Nan Zheng, PhD, Senior Staff Fellow, OCP, OTS, CDER 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 Schoneker, 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.