3rd FDA/PQRI Conference on
Advancing Product Quality

March 22-24, 2017

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

Use this color guide as a reference:

Track #1 Drug Classification, Release, and Modeling for Setting Clinically Relevant Specifications
Track #2 Achieving Drug Product Quality: Novel Approaches and Applications
Track #3 Enhancing Product Quality Through Continuous Manufacturing

3RD FDA/PQRI CONFERENCE ON PRODUCT QUALITY

DAY 1 – WEDNESDAY, MARCH 22, 2017

7:30 – 8:15 AM REGISTRATION

8:15 – 10:00 AM Plenary Session

- **OPENING** (15 minutes) 8:15 – 8:30 AM ***Conference Organizing Committee Co-Chairs: Ganapathy Mohan, Merck; Tony DeStefano, PQRI; Lawrence Yu, FDA***
- **OFFICE OF PHARMACEUTICAL QUALITY PROGRESS UPDATE** – ***Michael Kopcha, Food & Drug Administration (FDA)*** (8:30 -9:00 AM)
- **ICH Q12 : A Unique Opportunity to Realize 21st Century Quality Vision**– ***Moheb Nasr, GlaxoSmithKline*** (9:00 – 9:30 AM)
- **Clinical Relevance: Connection, Context and Collaboration**– ***Sarah Pope Miksinski, Food & Drug Administration (FDA)*** (9:30-10:00 AM)

10:00 -10:30 AM Coffee Break

	TRACK #1: *DRUG CLASSIFICATION, RELEASE, AND MODELING FOR SETTING CLINICALLY RELEVANT SPECIFICATIONS*	TRACK #2: *ACHIEVING DRUG PRODUCT QUALITY: NOVEL APPROACHES AND APPLICATIONS*	TRACK #3: *ENHANCING PRODUCT QUALITY THROUGH CONTINUOUS MANUFACTURING*
10:30 AM – 12:15 PM	**Session 1. Biowaivers and Harmonization Guidelines for Class 1 and 3 Drugs** *Moderator:* ***Mehran Yazdanian, Teva*** • Where are we on the latest draft Guidance on BA/BE waivers for Class 1 and Class 3 Drugs o ***Mehul Mehta, FDA*** • BCS Biowaiver Case Studies o ***Barbara Davit, Merck & Co., Inc.*** • The BCS and Biowaivers – A Global Overview o ***Raimar Löbenberg, University of Alberta*** • Q&A Discussion	**Session 1. Oligonucleotide Therapeutics: Quality, Standards, and Regulation** *Moderator:* ***Larisa Wu, FDA and Mohan Sapru, FDA*** • Challenges and Approaches Used in Current Process Development of Oligonucleotide Therapeutic APIs o ***Joe Guiles, Agilent*** • A High-Throughput Process for the Solid-Phase Purification of Synthetic DNA Sequences o ***Serge Beaucage, FDA*** • CMC Regulatory Considerations for Oligonucleotide Drug Products: FDA Perspective o ***Mohan Sapru, FDA*** • Panel Discussion	**Session 1: Where Are We Now** *Moderator:* ***Stephen Tyler, AbbVie*** • Perspectives on Continuous Manufacturing: Where Are We Now, Where Are We Going o ***Michael Thien, Merck*** • Continuous Manufacturing as an Emerging Technology o ***Celia Cruz, FDA*** • Continuous Manufacturing: An Industry View o ***Diane Zezza, Novartis*** • Panel Discussion

12:15 –1:15 PM Lunch

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1:15 – 3:00 PM	**Session 2: Dissolution Challenges for BCS Class 2/4 Drugs** *Moderator: **Allen Templeton, Merck & Co., Inc.*** • BCS Class 2 Immediate Release (IR) Dissolution in Two-Phase Media o ***Rik Lostritto, FDA*** • FDA Experience in the Application of IVIVC/IVIVR for Setting Clinically Relevant Drug Product Specifications o ***Sandra Suarez-Sharp, FDA*** • Development of Dissolution Methods for Class 2/4 Drugs – A USP Perspective o ***Erika Stippler, USP*** • Q&A Discussion	**Session 2: PQRI PODP Working Group Recommendations on Extractables and Leachables** Moderator: ***Diane Paskiet, West*** • General Recommendations on PODP Extractables & Leachables o ***Diane Paskiet, West*** • Parenteral Drug Products Best Practices o ***Dennis Jenke, Triad Scientific Solutions, LLC*** • Ophthalmic Drug Products Best Practices o ***Christopher Houston, iuvo BioScience*** • Q&A and Panel Discussion	**Session 2: API Focus** Moderator: ***Robert Meyer, Merck & Co., Inc.*** • Development and Implementation of Continuous Manufacturing Processes for API o ***Paul Collins, Eli Lilly and Company*** • Scientific Considerations for Continuous API Manufacturing o ***Thomas O'Connor, FDA*** • Exploring the Drug Substance/Drug Product Interface—Opportunities to Innovate Toward Enhanced Performance and Efficiency o ***Aaron Côté, Merck & Co., Inc.*** • Panel Discussion
3:00 – 3:30 PM Coffee Break			
3:30 – 5:15 PM	**Session 3. In-Vivo Predictive Dissolution Methods and Modeling** *Moderator: **Greg Amidon, University of Michigan*** • Building an Enhanced Analytical Toolbox for In-Vivo Predictive Dissolution o ***Justin Pennington, Merck& Co., Inc.*** • Development of Biorelevant Dissolution Methods o ***Nikoletta Fotaki, University of Bath*** • Dissolution Coupled with Oral Absorption Modeling to Predict Clinically Relevant Performance o ***David Sperry, Eli Lilly and Company*** • Panel Discussion	**Session 3. Extractables and Leachables: The Future** Moderator: ***Reggie Saraceno, Boehringer Ingelheim*** • Application of ICHQ9 Risk Management Principles to Assess the Risk of Leachables Adversely Impacting the Quality and/or Safety of Complex Biopharmaceuticals o ***Michael Hodgson, Baxter*** • Novel Delivery Systems/Future Delivery Systems; Implantable Medical Devices – Landscape, Current Challenges/Issues o ***John Iannone, AMRI*** • Dealing with Extractables and Leachables from a Regulatory Perspective o ***Timothy Robison, FDA*** • Panel Discussion	**3. Drug Product Focus** Moderator: ***Sharmista Chatterjee, FDA*** • Overview of the session **(3:30 – 3:35 PM)** • Considerations for CM Implementation for a New Molecule **(3:35 – 4:00 PM)** o ***Eleni Dokou, Vertex*** • Considerations for CM Implementation in a Legacy Product **(4:00 – 4:40 PM)** o ***Eric Sanchez and Gilfredo Navarro, Janssen*** • Excipient Considerations for CM Implementation **(4:40 – 5:05 PM)** o ***Dave Schoneker, Colorcon*** • Scientific Considerations for Continuous Manufacturing Implementation for Drug Product **(5:05 – 5:30 PM)** o ***Arwa El Hagrasy, FDA***
5:30 – 7:00 PM Reception			

DAY 2 – THURSDAY, MARCH 23, 2017

8:00- 8:30 AM Continental Breakfast

8:30 – 10:00 AM Plenary Session

- **PQRI: A STRONG FOUNDATION TO EMBRACE AND ENGAGE CHANGE** - ***Stephen Tyler, AbbVie; PQRI Steering Committee Chair*** 8:30 – 9:00 AM
- **OPPORTUNITIES FOR STANDARDIZATION IN CONTINUOUS MANUFACTURING-** ***Robert Femia, United States Pharmacopeia (USP)*** 9:00 – 9:30 AM
- **FUTURE OF PHARMACEUTICAL QUALITY AND THE PATH TO GET THERE -** ***Lawrence Yu, Food & Drug Administration (FDA)*** 9:30 – 10:00 AM

10:00 AM – 10:30 AM Coffee Break

	TRACK #1: *DRUG CLASSIFICATION, RELEASE, AND MODELING FOR SETTING CLINICALLY RELEVANT SPECIFICATIONS*	TRACK #2: *ACHIEVING DRUG PRODUCT QUALITY: NOVEL APPROACHES AND APPLICATIONS*	TRACK #3: *ENHANCING PRODUCT QUALITY THROUGH CONTINUOUS MANUFACTURING*
10:30 AM – 12:15 PM	**Session 4. Drug Release from Non-Oral Routes** *Moderator:* ***Wenlei Jiang, FDA*** • An *In Vitro* Approach to Model Specific Events Occurring at Injection Sites o ***Randy Mrsny, University of Bath*** • Drug Release from Liposomes: Role of Mechanism-Based Models o ***Bradley Anderson, University of Kentucky*** • Setting Size Specifications for PRINT® Particles o ***Douglas Mar, Liquidia Technologies, Inc.*** • Panel Discussion	**Session 4. Elemental Impurities** Moderator: ***Tony DeStefano, PQRI*** • Implementing ICH Q3D and USP 232/233 for Drug Products – Challenges and Opportunities o ***Nancy Lewen, Bristol-Myers Squibb*** • PQRI/USP Workshop on Implementation Status and Progress Report on Collaborative Studies o ***Donna Seibert, Perrigo*** • A Reviewer's Perspective on the Monitoring of Elemental Impurities o ***Danae Christodoulou , FDA*** • Q&A Panel Discussion	**Session 4. Strategies to Support Continuous Manufacturing** Moderator: ***Linda Evans O'Connor, Lachman Consultant Services, Inc.*** • cGMP and Regulatory Considerations of Continuous Manufacturing Processes o ***LCDR Patric C. Klotzbuecher, FDA*** • Integrated Product-Process Design to Minimize Expense, Time, and Material o ***Fernando Muzzio, Rutgers University*** • Enhancing Product Quality through CM – An Industry Perspective for Transitioning CM from Technology Evaluation to a Default Manufacturing Platform o ***Ahmad Almaya, Eli Lilly and Company*** • Q&A Panel Discussion

12:15 – 1:15 PM Lunch

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1:15 – 3:00 PM	**Session 5. Modeling for Oral and Non-Oral Routes** *Moderator:* ***Filippos Kesisoglou, Merck & Co., Inc.*** • Modeling Long Acting Injectable Administrations o ***Roberto Gomeni, Pharmacometrica*** • Modeling Deposition in the Respiratory Tract: What Can We Learn That Impactors Don't Tell Us ? o ***Maureen Donovan, University of Iowa*** • Model Based Approaches to Target Special Populations with Rational Formulation and Clinical Design Strategies o ***David Good, Bristol-Myers Squibb*** • Panel Discussion	**Session 5. Drug/Device combination products: Quality** Moderator: ***Nina Cauchon, Amgen & Laura O'Brien, Boehringer Ingelheim*** • Introduction of Sessions 5 and 6 **(1:15 – 1:20 PM)** • Regulatory Perspectives on CQAs, CPPs, and Risk Analyses for Combination Products **(1:20 – 1:50 PM)** o ***Doug Mead, Janssen*** • Life Testing for Device Combination Products: Approaches and Challenges for Integrating Devices into a Comprehensive Stability Program **(1:50 – 2:20 PM)** o ***Clint Judd, Amgen*** • Ensuring the Quality of Some Drug-Device Combination Products - FDA Perspective **(2:20 – 2:50 PM)** o ***Ramesh Raghavachari, FDA***	**Session 5: Challenges to Implementing Continuous Manufacturing** Moderators: ***Larry Lee, FDA & Ganapathy Mohan, Merck*** • Regulatory Challenges to Implementing Continuous Manufacturing o ***Roger Nosal, Pfizer*** • Enabling Continuous Manufacturing: An FDA Perspective o ***Rapti Madurawe, FDA*** • Continuous Manufacturing: Challenges and Opportunities – EMA Perspective o ***Dolores Hernán Pérez de la Ossa, EMA*** • PMDA's Perspectives on Continuous Manufacturing o ***Yoshihiro Matsuda, PMDA*** • Panel Discussion
3:00 – 3:30 PM Coffee Break		**Break early 2:50 – 3:20 PM Track 2 only**	
3:30 – 5:15 PM	**Session 6. Topical Classification System** Moderator: ***Kailas Thakker, Tergus Pharma*** • The Science of Topical Drug Classification System o ***Vinod Shah, PQRI*** • Physiochemical Characterization of Acyclovir Topical Semisolid Dosage Forms Towards TCS Validation o ***Flavian Rădulescu, University of Medicine and Pharmacy Carol Davila*** • In Vitro Characterization of Topical Semisolid Dosage Forms o ***Sam Raney, FDA*** • Panel Discussion	**Session 6. Drug/Device Combination Products: Bioequivalence** Moderator: ***Bing Li, FDA and Andrew LeBoeuf, FDA*** • Bioequivalence of Locally Acting Orally Inhaled and Nasal Drug Products: Regulatory Histories and Milestones **(3:20 – 3:50 PM)** o ***Bing Li, FDA*** • Understanding BE Requirements for Combination Products–A Focus on Auto Injectors **(3:50 – 4:20 PM)** o ***Andrea Redd, Fresenius-Kabi*** • User Interface Considerations for Drug-Device Combination Products Submitted in an ANDA **(4:20 – 4:50 PM)** o ***Irene Chan, FDA*** • Joint Panel Discussion (Session 5 and 6) **(4:50 – 5:15 PM)**	**Session 6. Where Are We Heading in Continuous Manufacturing?** Moderator: ***Rich Levy, PDA*** • Introduction (5 minutes) ***Rich Levy, PDA*** • How are you getting ready? Future Vision o ***FDA CDER Perspective – Larry Lee, FDA*** • Timescales for Change – A Look at Innovation in the Pharmaceutical Industry o ***Robert Meyer, Merck & Co., Inc.*** • Navigating the Challenges of Integrated Continuous Bioprocessing o ***Charles Cooney, Massachusetts Institute of Technology*** • Panel Discussion: • Above speakers, plus: o ***Yoshihiro Matsuda, PMDA*** o ***LCDR Patric C. Klotzbuecher, FDA***

DAY 3 – FRIDAY, MARCH 24, 2017

7:30 – 8:00 AM Continental Breakfast

8:00 – 10:15 AM Topic Summaries (45 minutes per theme)

8:00 – 8:45 AM	Track #1 Summary
8:45 – 9:30 AM	Track #2 Summary
9:30 – 10:15 AM	Track #3 Summary

10:15 – 10:45 AM Coffee Break

10:45 AM – 12:00 PM Global Harmonization? Conversation with FDA, EMA, PMDA and Industry Leaders

Moderator: Louis Yu, Valeant

Panelists:

- Ashley Boam, FDA
- Dolores Hernán, EMA
- Robert Iser, FDA
- Yoshihiro Matsuda, PMDA
- Christine Moore, Merck
- Keith Webber, Perrigo

12:00 PM Closing Remarks

FACULTY Speakers and Moderators

Ahmad Almaya, Ph.D., Research Advisor, Eli Lilly and Company

Gregory E. Amidon, Ph.D., Research Professor of Pharmaceutical Sciences, University of Michigan

Brad Anderson, Ph.D., Professor-Pharmaceutical Sciences, College of Pharmacy, University of Kentucky

Serge Beaucage, Ph.D., Research Chemist, Food and Drug Administration

Ashley Boam, Director (Acting) Office of Policy for Pharmaceutical Quality, OPQ, FDA

Nina S. Cauchon, Ph.D., Global Regulatory Affairs CMC Lead, Amgen Inc.

Irene Z. Chan, Pharm.D., BCPS, CDR, U.S. Public Health Service, Deputy Director, Division of Medication Error Prevention & Analysis, CDER, OSE, OMEPRM, DMEPA, FDA

Sharmista Chatterjee, Ph.D., Division Director, Division of Process Assessment II/OPF/CDER/FDA

Danae Christodoulou, Ph.D., Acting Brach Chief, Office of New Drug Products/OPQ/CDER, FDA

Paul Collins, Ph.D., Senior Director in Small Molecule Design, Eli Lilly and Company

Charles L. Cooney, Ph.D., Robert T. Haslam (1911) Professor of Chemical Engineering, Emeritus, Massachusetts Institute of Technology

Aaron Côté, Ph.D., Distinguished Scientist, Merck & Co., Inc.

Celia Cruz, Ph.D., Director, Division of Product Quality Research, Office of Testing and Research, FDA

Barbara M. Davit, Ph.D., JD, FAAPS, Executive Director, Biopharmaceutics Group, Translational Medicine Department, Merck Research Laboratories

Anthony J. DeStefano, Ph.D., Consultant, PQRI

Eleni Dokou, Ph.D., Senior Director, Head of Formulation Development, Vertex Pharmaceuticals Incorporated

Maureen D. Donovan, Ph.D., Associate Dean and Professor, College of Pharmacy, University of Iowa

Arwa El Hagrasy, Ph.D., Acting Quality Assessment Lead, Office of Process and Facilities, FDA

Robert Femia, Ph.D., Senior Vice President, Chemical Medicines, USP

Nikoletta Fotaki, Pharmacist, MSc, Ph.D., Associate Professor, University of Bath

Roberto Gomeni, Ph.D., Founder, Pharmacometrica

David Good, Ph.D., Senior Research Investigator, Bristol-Myers Squibb

Joe Guiles, Head of Development, Agilent Technologies

Dolores Hernán Pérez de la Ossa, Ph.D., Quality Specialist, European Medicines Agency (EMA)

(Continued below)

Michael Hodgson, Ph.D., Global Extractables & Leachables Senior Manager, Baxter International Inc.

Christopher Houston, Ph.D., Director, Analytical Chemistry, iuvo BioScience

John Iannone, Director, Extractables/Leachables & Impurities, Albany Molecular Research Inc. (AMRI)

Robert Iser, M.S., Director, Office of Process and Facilities, OPQ/CDER/FDA

Dennis Jenke, Ph.D., Chief Executive Scientist, Triad Scientific Solutions, LLC

Wenlei Jiang, Ph.D., Senior Science Advisor, Office of Research and Standards/OGD/CDER, FDA

Clint Judd, Principal Quality Engineer, Amgen Inc.

Filippos Kesisoglou, Ph.D., Senior Principal Scientist, Merck & Co., Inc.

LCDR Patric Klotzbuecher, Investigator (Drug Specialist), U.S. Department of Health and Human Services, FDA, Office of Regulatory Affairs

Michael Kopcha, Ph.D., R.Ph., Director, Office of Pharmaceutical Quality (OPQ), FDA

Andrew LeBoeuf, Regulatory Counsel, Office of Generic Drug Policy, OGD, CDER, FDA

Sau (Larry) Lee, Ph.D., Deputy Director, Office of Testing and Research, OPQ, FDA

Richard V. Levy, Ph.D., Senior Vice President, Scientific & Regulatory Affairs, Parenteral Drug Association (PDA)

Nancy Lewen, Research Fellow and Supervisor – Atomic Spectroscopy Laboratory, Bristol-Myers Squibb

Bing Li, Ph.D., Director, Division of Bioequivalence I, Office of Bioequivalence, OGD, CDER, FDA

Raimar Löbenberg, Ph.D., Professor and Director, University of Alberta, DDIC

Richard (Rik) Lostritto, Ph.D., Acting Associate Director for Science, Office of Policy for Pharmaceutical Quality, FDA

Rapti Madurawe, Ph.D., Division Director, Office of Process and Facilities, FDA

Douglas Mar, Ph.D., Principal Scientist, Liquidia Technologies, Inc.

Yoshihiro Matsuda, Ph.D., Pharmacist and Senior Scientist, Pharmaceuticals and Medical Devices Agency (PMDA)

Douglass Mead, MSBME, RAC, Senior Director, Global Regulatory Affairs - CMC, Medical Devices and Combination Products, Janssen Research and Development, LLC

Mehul Mehta, Ph.D., Director, Division of Clinical Pharmacology I, FDA

Robert Meyer, Ph.D., Principal Scientist, Merck & Co., Inc.

Sarah Pope Miksinski, Ph.D., Director, Office of New Drug Products, Acting Director, Office of Surveillance, OPQ, FDA

Ganapathy Mohan, Ph.D, Head of Small Molecule Development Quality, Merck, Sharp and Dohme corp.

Christine Moore, Ph.D., Executive Director and Global Head, CMC Policy, Merck, Sharp and Dohme

Randy Mrsny, Professor, Epithelial Cell Biology, University of Bath

Fernando Muzzio, Ph.D., Distinguished Professor of Chemical Engineering, Rutgers University

Moheb Nasr, Ph.D., Vice President, CMC Regulatory Strategy, GlaxoSmithKline

Gilfredo Navarro, Associate Director, CMC Regulatory Affairs, Janssen Research and Development

Roger Nosal, Vice President and Head of Global Chemistry, Manufacturing & Controls, Pfizer

Laura O'Brien, Ph.D., Senior Research Fellow, Boehringer Ingelheim

Linda Evans O'Connor, M.B.A., Head of Business Processes & Regulatory, Lachman Consultant Services, Inc.

Thomas O'Connor, Ph.D., Chemical Engineer, Office of Pharmaceutical Quality, CDER, FDA

Diane Paskiet, Director, Scientific Affairs, West

Justin Pennington, Ph.D., Director w/in PSCS Analytical Sciences Department, Merck & Co., Inc.

Dr. Flavian Ștefan Rădulescu, Associate Professor, Center for Drug Sciences, Faculty of Pharmacy University of Medicine and Pharmacy Carol Davila

Ramesh Raghavachari, Ph.D., Chief, Branch I, Division of Post Marketing Assessment I, Office of Life Cycle Drug Products/OPQ/CDER, FDA

Sam Raney, Ph.D., Scientific Lead, Topical and Transdermal Drug Products, Office of Generic Drugs, FDA

Andrea C. Redd, Director, Regulatory Affairs Combination Products, Fresenius Kabi USA, LLC

Timothy W. Robison, Ph.D., D.A.B.T., Pharmacology and Toxicology Team Leader, Division of Pulmonary, Allergy Products and Rheumatology Products, FDA

Eric J. Sanchez, MS, Director, Janssen Supply Chain Global Technical Services, a division of Johnson and Johnson

Mohan Sapru, M.S., Ph.D., CMC Lead for Cardiovascular and Renal Products, Office of New Drug Products, FDA

Reggie Saraceno, Ph.D., Director, Chemical Analysis, Boehringer Ingelheim

David R. Schoneker, Director of Global Regulatory Affairs, Colorcon

Donna Seibert, Ph.D., Senior Manager, Analytical Research and Development, Consumer Healthcare, Perrigo Company

Vinod P. Shah, Ph. D., Consultant, PQRI

David C. Sperry, Ph.D., Research Advisor, Eli Lilly and Company

Erika Stippler, Ph.D., Director of the Dosage Form Performance Laboratory, USP

Sandra Suarez-Sharp, Ph.D., Master Biopharmaceutics Reviewer/Biopharmaceutics Lead (acting) , Office of New Drug Products/OPQ, FDA

Allen C. Templeton, Ph.D., Associate Vice President, Merck & Co., Inc.

Kailas Thakker, Ph.D., Co-Founder and Chief Operating Officer, Tergus Pharma

Michael P. Thien, Sc.D., SVP, Global Science, Technology & Commercialization, Merck & Co., Inc.

Stephen Tyler, Director, Quality Assurance, AbbVie

Keith Webber, Ph.D., Senior Director of Regulatory Affairs, Perrigo Company

Larisa Wu, Ph.D., Senior Chemist and Special Assistant, Office of Pharmaceutical Quality, CDER, FDA

Mehran Yazdanian, Ph.D., Sr. Director of Pharmaceutics, Teva Branded Pharmaceutical Products R&D, Inc.

Lawrence X. Yu, Ph.D., Deputy Director, Office of Pharmaceutical Quality, FDA

Louis W. Yu, Ph.D., Chief Quality Officer, Global Quality and Compliance, Valeant Pharmaceuticals

Diane J. Zezza, Ph.D., Vice President and Global Head Regulatory Affairs – CMC, Novartis Pharmaceuticals

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)
International Society for Pharmaceutical Engineering (ISPE)
Parenteral Drug Association (PDA)
United States Pharmacopeia (USP)

Conference Organizing Committee Members

Lawrence Yu, FDA	Co-Chair
Tony DeStefano, PQRI	Co-Chair
Ganapathy Mohan, Merck	Co-Chair

Nina Cauchon, Amgen
Sharmista Chatterjee, FDA
Dilip Choudhury, Consultant
Linda Evans O'Connor, Lachman Consultants
Eliza Fung, Bristol-Myers Squibb
Dede Godstrey, PQRI Secretariat
Lynn Gold, Camargo Pharma
Roy Haskell, Bristol-Myers Squibb
Rich Levy, PDA
Lee Nagao, PQRI Secretariat
Reggie Saraceno, Boehringer Ingelheim
Vinod Shah, PQRI
Ruth Stevens, Camargo Pharma
Allen Templeton, Merck
Stephen Tyler, AbbVie
Mehran Yazdanian, Teva
Louis Yu, Valeant

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.