SECOND
FDA/PQRI CONFERENCE ON
ADVANCING PRODUCT QUALITY

Conference Goals: To create a harmonized and value-added path toward global quality.

October 5-7, 2015
Bethesda North Marriott Hotel & Conference Center
5701 Marinelli Road
North Bethesda, Maryland 20852 USA

Hotel Reservations and Conference Registration
Hotel Reservations can be made online at https://resweb.passkey.com/go/51f140ae.
Conference registration can be made online at www.signmeup.com/105294.
Questions? Contact the PQRI Secretariat at: PQRISecretariat@pqri.org or +1(202) 230-5199.
Professor Bertil Abrahamsson, Senior Principal Scientist, Pharmaceutical Development, AstraZeneca R&D
Ilgaz Akseli, Ph.D., MBA, Senior Associate Director, Boehringer Ingelheim
Barbara M. Allen, Ph.D., Head of Global Quality Systems, Eli Lilly and Company
Gregory E. Amidon, Ph.D., College of Pharmacy, Univ. of Michigan
Stefan K. Baier, Ph.D., Principal Scientist, PepsiCo Long Term Research
Alfred Berchielli, M.S., Senior Principal Scientist, Pfizer
Ecevit Bilgili, Ph.D., Associate Professor & Associate Chair, Dept. of Chemical Engineering, New Jersey Institute of Technology
CDR. Tara Gooen Bizjak, Senior Science Policy Advisor, Office of Policy for Pharmaceutical Quality, Division of Regulation, Guidance, and Standards, FDA
Ashley Boam, MSBE, Director (acting) Office of Policy for Pharmaceutical Quality, OPQ, FDA
Lucinda Buhse, Ph.D., Director, Office of Testing & Research, OPQ, FDA
Monica J. Cahilly, President, Green Mountain Quality Assurance
Yanxi Tan Cain, Ph.D., Novartis Pharmaceuticals Corp
Margaret Caulk, MPH, MS, Associate Director of Science and Communication, Office of New Drug Products, OPQ, FDA
Sharmista Chatterjee, Ph.D., FDA
Jon E. Clark, M.S., Vice President, Chemical Medicines – External Development, U.S. Pharmacopeia (USP)
Tanya Clayton, MPH, Division Director (acting) Office of Program and Regulatory Operations, OPQ, FDA
Stephen Conway, Ph.D., Merck
Tom Cosgrove, Director, Office of Manufacturing Quality, FDA
Alberto Cuitino, Ph.D., Rutgers University
Dave Doleski, Deputy Director (acting), Office of Process and Facilities, OPQ, FDA
James K. Drennen, III, Ph.D., Duquesne University
Joseph C. Famulare, BS, Vice President Global Quality Compliance & External Collaboration, Genentech, a member of the Roche Group
Liam C. Feely, Ph.D., Vice President of Manufacturing, Science and Technology, AbbVie
Thomas Friedli, Professor, Dr., Professor of Production Management, University of St. Gallen
Scott Furness, Ph.D., Deputy Director, Office of New Drug Products, OPQ, FDA
Robert Gaines, PharmD, Division Director, Office of Program and Regulatory Operations, OPQ, FDA
Mairead Goetz, Novartis
John Groskopf, BS, MBA, Pfizer Inc.
Todd Halpern, Assistant General Counsel, Pfizer
Brian Hasselbalch, Deputy Director (acting) Office of Policy for Pharmaceutical Quality, OPQ, FDA
Henry Havel, Ph.D., Science Advisor, Nanomedicines Alliance
Steven Hoag, Ph.D., University of Maryland, School of Pharmacy
Robert Iser, M.S., Senior Scientific Advisor (Acting), Office of Process & Facilities, OPQ, FDA
Orlando Jaquez, Biogen
Bruce D. Johnson, Ph.D., Vice President, Consumer Healthcare Research & Development, Perrigo Company plc
Rob Ju, Ph.D., Associate Director, AbbVie
Paula Katz, J.D., Director, Manufacturing, Quality Guidance and Policy Staff, Office of Manufacturing Quality, Office of Compliance, FDA
San Kiang, Ph.D., Independent Consultant
A. Douglas Kinghorn, Ph.D., D.Sc., Professor & Jack L. Beal Chair, College of Pharmacy, The Ohio State University
LT Patric C. Klotzbuecher, M.S. (cand.) MBA, Office of Regulatory Affairs, New York District, FDA
Emanuela Lacana, Ph.D., Associate Director for Biosimilars and Regulatory Policy, OPQ, FDA
Sau Larry Lee, Ph.D., Associate Director and Botanical Review Team Leader, Office of Pharmaceutical Quality, FDA
Julie K. Lorenz, Ph.D., Associate Research Fellow, Head of Analytical Laboratory Sciences, Zoetis, Inc
Richard (‘Rik’) Lostritto, (acting) Associate Director for Science, Office of Policy for Pharmaceutical Quality, OPQ, CDER, FDA
Rapti Madurawe, Ph.D., (acting) Division Director, Office of Process and Facilities, OPQ, FDA
Jennifer A. Maguire, Ph.D., Acting Branch Chief, Division of Process Assessment I, Office of Process and Facilities, OPQ, FDA
Douglas M. Mans, Ph.D., Director, Chemical Catalysis and Continuous Processing, GlaxoSmithKline
Ingrid Markovic, Ph.D., FDA
Grace McNally, Office of Process and Facilities, OPQ, FDA
Mehul Mehta, Ph.D., FAAPS, Director, Division of Clinical Pharmacology I, Office of Translational Sciences, FDA
Sarah Pope Miksinski, Ph.D., Director (acting), Office of New Drug Products, OPQ, FDA
Anthony R. Mire-Sluis, Ph.D., Vice President, North America, Singapore, Abingdon, Contract and Product Quality, Amgen
Ganapathy Mohan, Ph.D., Head of Small Molecule Development Quality, Merck
Carlos Monteagudo, BS, Director, Quality Assurance, Amgen
### CONFERENCE SCHEDULE

**Monday, October 5**

**8:00 AM** Continental Breakfast

**8:30–10:15 AM** Plenary Session

**Moderators:** Margaret Szymczak, J&J and Lawrence Yu, FDA

**Speakers:**
- *Progress and Challenges in Pharmaceutical Quality* – Janet Woodcock, FDA
- *Challenges to Building Quality End to End* – Michael Thien, Merck
- *New Technologies for Enabling Continuous Manufacturing* – Bernhardt Trout, Massachusetts Institute of Technology

**10:15–10:30 AM** Coffee Break

**10:30–12:15 PM** Biopharmaceutics – BCS Biowaivers

**Moderators:** Vinod Shah, PQRI and Mehul Mehta, FDA

**Speakers:**
- *BCS Guidance and Biowaivers, BCS Monographs* – Vinod Shah, PQRI
- *InVivo Predictive Dissolution Testing – Scientific Progress in OrBiTo and Enhanced Industrial Application* – Bertil Abrahamsson, AstraZeneca
- *Generic Drug Industry’s Perspectives on BCS-based Biowaivers* – Yu Chung Tsang, Apotex Inc.
- *Implementation of BCS Guidance, Analysis of BCS Submissions to FDA and Guidance Update* – Mehul Mehta, FDA

**Panelists:** Speakers listed above

**10:30–12:15 PM** Breakthrough Therapy – CMC Challenges

**Moderators:** Ganapathy Mohan, Merck and Margaret Caulk, FDA

**Speakers:**
- *Breakthrough Therapy – CMC Challenges* – Ganapathy Mohan, Merck
- *Breakthrough Therapy Designation – An Industry Case Study* – John Groskoph, Pfizer Inc.
- *Review Considerations for Break-Through-Designated Products* – Olen Stephens, FDA

**10:30–12:15 PM** Current Challenges in the Characterization of Complex Drug Formulations Containing Nanomaterials

**Moderators:** Katherine Tyner, FDA and Henry Havel, Nanomedicines Alliance

**Speakers:**
- *Introduction* – Henry Havel, Nanomedicines Alliance
- *Quality Considerations and Regulatory Perspectives for Drug Products Containing Nanomaterials* – Katherine Tyner, FDA
- *Nanoparticle Size Analysis: A Survey and Review* – Marc Wolfgang, Cerulean Pharma
- *Industrial Perspective on Nanomedicine Characterization Strategies* – Donald Parsons, BIND Therapeutics, Inc.

**Panelists:** Speakers listed above

**10:30–12:15 PM** How to Prevent, Detect, and Respond to Data Integrity Events

**Moderators:** Paula Katz, FDA and Joseph Famulare, Genentech

**Speakers:**
- *Lifecycle Data Integrity: Consequences and Actions to Proactively Promote Good Documentation Practices* – Paula Katz, FDA
- *Building Business Processes that Optimize Accurate and Reliable Data* – Monica Cahilly, Green Mountain Quality Assurance
- *Benefits of Combining Quality Risk Management (Q9) with Pharmaceutical Quality System* – Joseph Famulare, Genentech

**12:15–1:15 PM** Lunch

**1:15–3:00 PM** Pharmaceutical Product Lifecycle Management – Q12

**Moderators:** Moheb Nasr, GlaxoSmithKline and Robert Iser, FDA

**Speakers:**
- *Introduction to Product Lifecycle Management* – Robert Iser, FDA/CDER
- *Innovator Industry Perspectives on Lifecycle Management* – Mark Rosolowsky, Bristol-Myers Squibb
- *ICH Q12: Opportunities for the Generic Drug Industry* – Keith Webber, Perrigo
Quality and Regulatory Considerations for Continuous API: A Case Study – Douglas Mans, GlaxoSmithKline

Quality and Regulatory Considerations for Continuous Drug Product: A Case Study – Hayden Thomas, Vertex

Panelists: Speakers listed above and Rapti Madurawe, FDA

3:00–3:15 PM Coffee Break

3:15–5:00 PM

Pharmaceutical Product Lifecycle Management – Q12 (Continued)

Pre-Approval and Surveillance Inspection (Continued)

Biosimilar Product Assessment – How Similar is Similar? (Continued)

Continuous Manufacturing (Continued)

5:30–7:00 PM Reception

Tuesday, October 6

8:00 AM Continental Breakfast

8:30–10:15 AM Dissolution Testing and Specification for BCSI and III Drugs in Immediate Release Product

Moderators: Richard Lostritto, FDA and Gregory Amidon, Univ of Michigan

Speakers:
The Future of In Vivo Predictive Dissolution Methods – Gregory Amidon, University of Michigan

Summary of Draft Guidance on Dissolution Testing and Specifications for BCS I and III Immediate Release Products – Rik Lostritto, FDA

FDA Research in Dissolution – Lucinda Buhse, FDA

8:30–10:15 AM Risk-based Regulatory Assessment

Moderators: G.K. Raju, Light Pharma and Ramesh Sood, FDA

Speakers:
Leveraging the Depth of Industry Knowledge with the Breadth of Regulator Knowledge – Roger Nosal, Pfizer

The Journey From Good to Great: Transforming the Pharmaceutical Regulatory System – Martin VanTrieste, Amgen

Panelists: Speakers listed above and Jeffrey Baker, FDA and Tara Gooen Bizjak, FDA
### 8:30–10:15 AM  Palatability and Swallowability-Benefits of Transdisciplinary Learning

**Moderators:** Arzu Selen, FDA and Rob Ju, AbbVie  
**Speakers:**  
- *The Role of Tribology in Oral Processing* – Stefan Baier, PepsiCo  
- *In-Vitro Taste Sensors: Methods, Uses and Opportunities* – Julie Lorenz, Zoetis  
*Panelists:* Speakers listed above and Hari Sachs, FDA; Andrew Mulberg, FDA; Debbie Avant, FDA; Gil Burckart, FDA; and Karen Thompson, Merck

### 8:30–10:15 AM  How to Monitor, Control, and Improve Product Quality using Process Capability

**Moderators:** Barbara Allen, Eli Lilly and Company and Larisa Wu, FDA  
**Speakers:**  
- *Pharmaceutical Product Quality, Quality by Design, cGMP, and Quality Metrics* – Lawrence Yu, FDA  
- *Using Control Charts to Evaluate Process Variability* – Daniel Peng, FDA  
- *Quality as Foundation for OPEX* – Thomas Friedli, University of St. Gallen  
- *The Journey From Good to Great: Process Monitoring Leads to Improving Product Quality* – Martin VanTrieste, Amgen  
- *Process Capability and Relationship to Supply Chain* – Bryan Winship, Mylan  
- *Process Capability and Relationship to Quality Management* – Barbara Allen, Eli Lilly & Company

#### 10:15–10:30 AM  Coffee Break

### 10:30 AM–12:15 PM  How Quality Risk Management can Enable a More Effective Pharmaceutical Quality System Resulting in Improved Product Quality

**Moderators:** Dave Doleski, FDA and Martin VanTrieste, Amgen  
**Speakers:**  
- *A Practical and Scientific Approach to Quality Risk Management is Integral to an Effective Quality System* – Fionnuala Walsh, Eli Lilly  
- *Applying Risk Management Principles to Drive Quality Management System Effectiveness* – Carlos Monteagudo, Amgen

### 10:30 AM–12:15 PM  Alternatives for Content Uniformity

**Moderators:** Geoffrey Wu, FDA and Siva Vaithiyalingam, Teva  
**Speakers:**  
- *USP <905> Uniformity of Dosage Units* – Jon Clark, USP  
- *Recommendations for the Assessment of Blend and Content Uniformity: Modern Approaches to Sampling and Testing* – James Drennen, Duquesne University  
- *Statistical Considerations for Establishing Acceptance Criteria for Content Uniformity and Stratified Sampling* – Alex Viehmman, FDA

### 12:15–1:15 PM  Lunch

### 1:15–3:00 PM  Quality Metrics

**Moderators:** Tara Gooen Bizjak, FDA and Louis Yu, Perrigo  
**Speakers:**  
- *Quality Metrics: An OPQ Perspective* – Tara Gooen Bizjak, FDA  
- *Quality Metrics: An OTC Perspective* – Paul Weninger, Perrigo  
- *Quality Metrics Initiative – The Journey So Far* – Máiréad Goetz, Novartis  
*Panelist:* Speakers listed above and Barbara Allen, Eli Lilly and Company
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<tr>
<th>Time</th>
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<tr>
<td>1:15–3:00 PM</td>
<td>FDA Integrated Quality Assessment: Common Deficiencies/Information Request</td>
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<td>How to Identify Critical Quality Attributes and Critical Process Parameters (Continued)</td>
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<td>5:00–6:30 PM</td>
<td>How to Interact and Communicate with FDA on Quality Issues</td>
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**Moderators:**
- Ashley Boam, FDA and Tony Tong, Teva
- Grace McNally, FDA and Ilgaz Akseli, Boehringer Ingelheim
- Scott Furness, FDA and Bruce Johnson, Perrigo Company plc
- Roger Nosal, Pfizer, Moheb Nasr, GlaxoSmithKline and Richard Lostritto, FDA
- Giuseppe Randazzo, FDA
- Roger Nosal, Pfizer, Moheb Nasr, GlaxoSmithKline and Richard Lostritto, FDA

**Speakers:**
- Sarah Pope Miksinski, FDA
- Susan Rosencrance, FDA
- Mike Saleh, Pfizer
- Ecevit Bilgili, New Jersey Institute of Technology
- Alberto Cuitino, Rutgers University
- San Kiang, Consultant, BMS
- Stephen Conway, Merck
- Ilgaz Akseli, Boehringer Ingelheim
- Jennifer Maguire, FDA and Daniel Peng, FDA
- Ajit Narang, Bristol-Myers Squibb, Co.
- Sau Larry Lee, FDA and Steven Hoag, University of Maryland
- Douglas Kinghorn, The Ohio State University
- Vikas Moolchandani, Amway Inc.
- Tanya Clayton, FDA and Robert Gaines, FDA

**Panelist:**
- Speakers listed above and Haibin Qu, Zhejiang University

**Identification of CPPs based on CQAs and Mechanistic Process & Product Understanding: A Case Study**
- Ajit Narang, Bristol-Myers Squibb, Co.

**Botanical Drug Development and Quality Standards**
- Sau Larry Lee, FDA

**Aspects of the Discovery and Development of Plant-Derived Drugs**
- Douglas Kinghorn, The Ohio State University

**Challenges in Botanical Supplements Product Development and Quality Testing**
- Vikas Moolchandani, Amway Inc.
- Panelist: Speakers listed above and Haibin Qu, Zhejiang University

**How to Identify Critical Quality Attributes and Critical Process Parameters**
- Jennifer Maguire, FDA and Daniel Peng, FDA

**Generic Pharma Perspective on the Identification of Critical Quality Attributes and Critical Process Parameters**
- Bruce Johnson, Perrigo

**A Structured Statistical Approach to Aid the Assessment of Process Parameter Criticality**
- Ke Wang, Pfizer
PQRI Mission Statement
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 and development. By virtue of its diverse membership, PQRI provides a unique forum to focus critical thinking, conduct research, exchange information, and propose methodology or guidance to pharmaceutical companies, regulators, and standard setting organizations.