Conference Website:
http://pqri.org/2nd-fdapqri-conference-on-advancing-product-quality/

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.

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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*

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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*

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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*

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Ingrid Markovic, *Ph.D., FDA*

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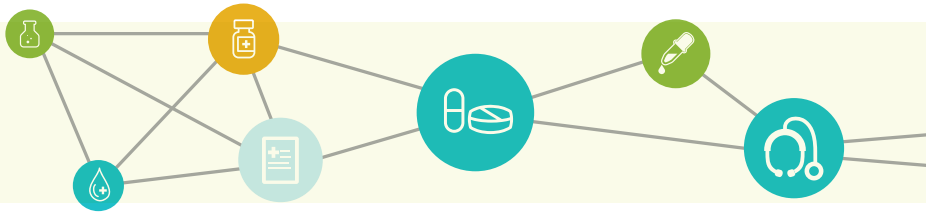
Ganapathy Mohan, *Ph.D., Head of Small Molecule Development Quality, Merck*

Carlos Monteagudo, *BS, Director, Quality Assurance, Amgen*



Vikas Moolchandani, *Ph.D., Amway Inc.*

Christine Moore, *Ph.D., Director (acting) Office of Process & Facilities, FDA*

Ajit S. Narang, *Ph.D., Principal Scientist, Drug Product Science & Technology, Bristol-Myers Squibb, Co.*

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

Roger Nosal, *Vice President of Global Chemistry, Manufacturing & Controls, Pfizer Inc.*

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

Mary Oates, *Ph.D., Vice President, Global Quality Operations and EHS, Pfizer*

Don Parsons, *Ph.D., BIND Therapeutics, Inc.*

Daniel Peng, *Ph.D., Division of Process Assessment II, Office of Process & Facilitiets, OPQ, FDA*

Jim Polli, *Ph.D., Professor, Pharmaceutical Sciences, Univ. of Maryland*

Yihong Qiu, *Ph.D., Volwiler Senior Research Fellow, Oral Drug Products, Science & Technology, AbbVie*

Haibin Qu, *Ph.D., Professor, Pharmaceutics Informatics Institute, Zhejiang University*

G.K. Raju, *Ph.D., CEO, Light Pharma*

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Fionnuala Walsh, *Eli Lilly and Company*

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Louis Yu, *Ph.D., Executive Vice President, Global Quality, Perrigo Company, plc*

Diane Zezza, *Ph.D., Global Head, Regulatory Affairs CMC, Novartis*

CONFERENCE SCHEDULE

CONCURRENT BREAKOUT SESSIONS
Use this color guide as reference

1. **Emerging Regulatory Initiatives**
2. **Regulatory Submission, Assessment, and Inspection**
3. **Product and Process Development**
4. **Manufacturing, Risk Management, and Quality Assurance**

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

Lifecycle Management: Future Vision / ICH Q12 – Moheb Nasr, GlaxoSmithKline

ICH Q12 / Change Management – Liam Feely, AbbVie

ICH Q12 / Knowledge Management – Ingrid Markovic, FDA/CBER

ICH Q12 / Regulatory Opportunities – Mahesh Ramanadham, FDA/CDER

Panelists: Speakers listed above and Ashley Boam, FDA/CDER

1:15–3:00 PM Pre-Approval and Surveillance Inspection

Moderators: Mary Oates, Pfizer and Brian Hasselbalch, FDA

Speakers:

BMS experience with QbD/PAT based PAI by the EMA and FDA – Ambarish Singh, BMS

An Industry View of Surveillance Inspections – Mary Oates, Pfizer

Risk Based Pre-Approval Inspections – Christine Moore, FDA

Risk-Based Surveillance Inspections – Russell Wesdyk

Todd Halpern, Pfizer

1:15–3:00 PM Biosimilar Product Assessment – How Similar is Similar?

Moderators: Anna Schwendeman, University of Michigan and Emanuela Lacana, FDA

Speakers:

Implementing the Biologics Price Competition and Innovation Act of 2009 and Quality Considerations for the Development of Biosimilar Products – Marjorie Shapiro, FDA

Physicochemical Characterization of Remicade and its Biosimilar Remsima – Anna Schwendeman, University of Michigan

Analytical Similarity: Lessons from the First US Biosimilar – Corinna Sonderegger, Sandoz

Challenges with Establishing a Control Strategy for Biosimilars – Barbara Rellahan, Amgen

The Making of Advanced Biosimilars: Enabling Advanced Biosimilars through Technical Development and Manufacturing – Orlando Jaquez, Biogen

1:15–3:00 PM Continuous Manufacturing

Moderators: Thomas O'Connor, FDA and Diane Zezza, Novartis

Speakers:

Scientific Considerations for the Assessment of Continuous Manufacturing Processes – Thomas O'Connor, FDA

Achieving Quality Beyond Compliance Through Continuous Manufacturing – Yanxi Tan Cain, Novartis

cGMP and Regulatory Considerations for Continuous Manufacturing Processes – Patric Klotzbuecher, FDA

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

CONFERENCE SCHEDULE

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 Dissolution Testing and Specification for Extended Release Products

Moderators: Paul Seo, *FDA* and Jim Polli, *Univ. of Maryland*
Speakers:

Designing Quality into ER Products: Technology Selection – Alfred Berchielli, Pfizer

Using Pharmacoscintgraphy to Elucidate In Vivo Performance of Extended Release Formulations – David Sperry, Eli Lilly & Company

Mitigating Patient Risks Using Dissolution Testing in Manufacturing ER Products – Yihong Qiu, AbbVie

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

Enforcement Perspective: How QRM and a PQS Can Help Maintain a State of Compliance – Tom Cosgrove, FDA

Applying Risk Management Principles to Drive Quality Management System Effectiveness – Carlos Monteagudo, Amgen

10:30 AM–12:15 PM Alternatives for Content Uniformity Acceptance Criteria and Stratified Sampling

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

10:30 AM–12:15 PM How to Monitor, Control, and Improve Product Quality using Process Capability (Continued)

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

1:15–3:00 PM FDA Integrated Quality Assessment: Common Deficiencies/Information Request

Moderators: Ashley Boam, FDA and Tony Tong, Teva

Speakers:

Evolution of the CMC Review for NDAs – Sarah Pope Miksinski, FDA

Evolution of the CMC Review for ANDAs – Susan Rosencrance, FDA

Evolution of Quality Assessments - Recent Trends in FDA Queries – Mike Saleh, Pfizer

Integrated Quality Assessment - ANDA Perspectives – Siva Vaithiyalingam, Teva

Challenges Integrating Regulatory Filings and Pre-Approval Inspection with the Expectations of Current Regulatory Guidance – Tony Mire-Sluis, Amgen

1:15–3:00 PM The Science of Tech Transfer/Scale-up

Moderators: Grace McNally, FDA and Ilgaz Akseli, Boehringer Ingelheim

Speakers:

Implementing Fundamental Pharmaceutical Science and Materials/Engineer Expertise in Scale-Up – Ecevit Bilgili, New Jersey Institute of Technology

Using Material Science Methodology and Modeling Predictive Tools to Enable Scale-up – Alberto Cuitino, Rutgers University

Integrated Product and Process Understanding and Control that Enables Flexible and Efficient Tech Transfer to Different Sites – San Kiang, Consultant, BMS

Risk Assessment and Troubleshooting Using Fundamental Science and Predictive Tools – Stephen Conway, Merck

Mitigating Product Risk in Manufacturing or During Formulation Development and Identify Opportunities to Maximize Efficiency – Ilgaz Akseli, Boehringer Ingelheim

Regulatory Perspective: Advantages of Science Based Pharmaceutical Development in Regulatory Review – Sharmista Chatterjee, FDA

1:15–3:00 PM How to Identify Critical Quality Attributes and Critical Process Parameters

Moderators: Scott Furness, FDA and Bruce Johnson, Perrigo Company plc

Speakers:

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

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

3:00–3:15 PM Coffee Break

3:15–5:00 PM Botanical Drug Development and Quality Standards

Moderators: Sau Larry Lee, FDA and Steven Hoag, University of Maryland

Speakers:

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

3:15–5:00 PM FDA Integrated Quality Assessment: Common Deficiencies/Information Request (Continued)

3:15–5:00 PM The Science of Tech Transfer/Scale-up (Continued)

3:15–5:00 PM How to Identify Critical Quality Attributes and Critical Process Parameters (Continued)

5:00–6:30 PM How to Interact and Communicate with FDA on Quality Issues

Moderators: Giuseppe Randazzo, FDA

Speakers:

How to Interact and Communicate with FDA on Quality Issues – Tanya Clayton, FDA and Robert Gaines, FDA

Wednesday, October 7

8:00 AM Continental Breakfast

8:30–10:15 AM Breakout Summaries

10:15–10:30 AM Coffee Break

10:30–11:30 AM Roundtable with FDA Leaders

Moderators: Roger Nosal, Pfizer, Moheb Nasr, GlaxoSmith-Kline and Richard Lostritto, FDA

11:30 AM Closing Remarks

Lawrence Yu
Food & Drug Administration (Chair)

Gregory Amidon
University of Michigan

Margaret Caulk
Food & Drug Administration

Dave Doleski
Food & Drug Administration

Joseph Famulare
Genentech

Don Henry
Food & Drug Administration

Ajaz S. Hussain
NIPTE

Robert Iser
Food & Drug Administration

Rob Ju
AbbVie

Emanuela Lacana
Food & Drug Administration

Tandra Latham
Food & Drug Administration

Lisa Matthews
Food & Drug Administration

Ganapathy Mohan
Merck

Moheb Nasr
GlaxoSmithKline

Cecily Nelson
Food & Drug Administration

Roger Nosal
Pfizer

Suzanne Pattee
Food & Drug Administration

Kristin Phucas
Food & Drug Administration

James Polli
University of Maryland

GK Raju
Light Pharma

Arzu Selen
Food & Drug Administration

Vinod Shah
Pharmaceutical Consultant

John Skoug
AbbVie

Margaret Szymczak
Johnson & Johnson

Lisa Tan
GPhA

Tony Tong
Teva

Katherine Tyner
Food & Drug Administration

Martin VanTrieste
Amgen

Russell Wesdyk
Food & Drug Administration

Geoffrey Wu
Food & Drug Administration

Larisa Wu
Food & Drug Administration

Louis Yu
Perrigo

CONFERENCE ORGANIZING COMMITTEE MEMBERS

PQRI MEMBER ORGANIZATIONS

American Association of Pharmaceutical Scientists

Consumer Healthcare Products Association

U.S. Food and Drug Administration, Center for Drug Evaluation and Research

Health Canada

International Pharmaceutical Excipients Council of the Americas

International Society of Pharmaceutical Engineers

Parenteral Drug Association

United States Pharmacopeia

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.

Conference Details:

Hotel Reservations:
https://resweb.passkey.com/go/51f140ae

Conference registration:
www.signmeup.com/105294

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