FDA/PQRI Conference on Evolving Product Quality

September 16, 2014

8:30 am – 12:00 pm Salon D
Plenary Session

8:30 am
Welcome and Introduction
Lawrence Yu, Ph.D.
U.S. Food and Drug Administration
Rachael Roehrig, Ph.D.
Product Quality Research Institute

8:45 am
FDA's Vision and Evolving Approaches to Pharmaceutical Quality
Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research
U.S. Food and Drug Administration

9:30 am
Ensuring the Quality of Pharmaceuticals
Azita Saleki-Gerhardt, Ph.D.
Senior Vice President-Operations
AbbVie , Inc.

10:00 am
Break

10:15 am
Ensuring the Quality of Pharmaceuticals
Tim Moore
Senior Vice President
Genentech/Roche

10:45 am
Generic and Over-the-Counter Perspective to Pharmaceutical Quality
Louis W. Yu, Ph.D.
Executive Vice President
Perrigo

11:15 am
Controlling Pharmaceutical Quality
Richard D. Braatz, Ph.D.
Professor of Chemical Engineering
Massachusetts Institute of Technology

12:00 pm – 1:00 pm Salon E
Lunch

1:00 pm – 5:00 pm
Concurrent Breakout Sessions

Theme: Risk Management and Quality Metrics **Salon A**
Session I Topic: Risk Management for Manufacturing and Inspection
Moderators:
Thomas Cosgrove
U.S. Food and Drug Administration
Joseph C. Famulare
Genentech

1:00 pm
GDUFA Implementation for Pre-approval and Surveillance Inspections
Alonza Cruse
U.S. Food and Drug Administration

1:30 pm
Risk Management from Development to Commercialization
Vincent E. McCurdy
Pfizer Inc.

2:00 pm
Managing Risk Through Manufacturing Audits
Paul N. D'Eramo, R.Ph.
Johnson & Johnson

2:30 pm
Supplier Oversight
Steven Lynn
Mylan Inc.

3:00 pm
Break

3:15 pm
PIC/S Approach for Risk-based Inspections
Vasiliki (Vee) Revithi, Ph.D.
F. Hoffman La-Roche Ltd.

3:45 pm
FDA Vision for Quality-focused and Risk-based Inspections
Neil A. Stiber, Ph.D.
U.S. Food and Drug Administration

4:15 pm
Panel Discussion

Theme: Performance-based Quality Assessment Salon B
Session I Topic: Clinically Relevant Specification
Moderators:
Lucinda Buhse, Ph.D.
U.S. Food and Drug Administration
Filippos Kesisoglou, Ph.D.
Merck & Co., Inc.

1:00 pm
BCS Sub-classification and In-Vivo Predictive Dissolution
Gordon L. Amidon, Ph.D.
University of Michigan

1:30 pm
Dissolution and Clinically Relevant Specifications: Linking Clinical Performance to Dissolution
Talia R. Flanagan, Ph.D.
AstraZeneca

2:00 pm
Clinically Relevant Specifications: A Regulatory Perspective
Richard Lostritto, Ph.D.
U.S. Food and Drug Administration

2:30 pm
Linking Dissolution to Product Quality: A Case Study Involving a Novel Cross-linked Enzyme Therapy
Evan M. Hetrick, Ph.D.
Eli Lilly and Co.

3:00 pm
Break

3:15 pm
Monitoring API Phase in Solid Dosage Forms: Considerations for Method Sensitivity to Inform Bio-performance Risk
Wei Xu, Ph.D.
Merck & Co.

3:45 pm
Regulatory use of (Q)SAR Models for Assessing the Safety of Known and Potential Impurities
Naomi L. Kruhlak, Ph.D.
U.S. Food and Drug Administration

4:15 pm
Panel Discussion

Theme: Innovation in Manufacturing and Regulatory Assessment Salon C
Session I Topic: Continuous Manufacturing for Clinical Supplies and Commercial Production
Moderators:
Sau (Larry) Lee
Mansoor Khan
U.S. Food and Drug Administration
Hayden Thomas, Ph.D.
Vertex Pharmaceuticals

1:00 pm
Enabling Technologies for the Continuous Manufacturing of APIs: Continuous Crystallization
Bernhardt L. Trout, Ph.D.
Massachusetts Institute of Technology

1:30 pm
Quality by Design (QbD) for the Continuous Manufacturing of Solid Oral Dosage Forms
David Emiabata-Smith, Ph.D.
Vertex Pharmaceuticals Inc.

2:00 pm
Utilization of Process Models for Process Development and Understanding Process Dynamics
Fernando Muzzio
Rutgers University

2:30 pm
PAT Systems for the Online Characterization of Continuous Manufacturing Systems
Thomas F. O'Connor, Ph.D.
U.S. Food and Drug Administration

3:00 pm
Break

3:15 pm
Dynamic Process Control: Implementation of Feedback/Feedforward Control for Continuous Systems
Mojgan Moshgbar, Ph.D.
Pfizer Inc.

3:45 pm
Case Study for the Implementation of a Continuous Pharmaceutical Process
Eric J. Sanchez, M.S.
Janssen Ortho, LLC

4:15 pm
Panel Discussion

Theme: Emerging Topics Linden Oak
Session I Topic: Breakthrough Therapy for Large and Small Molecules
Moderators:
Manu Lacana
Sarah Pope Miksinski
U.S. Food and Drug Administration

1:00 pm
What We Can Learn from Breakthrough Drugs
Richard Pazdur, M.D.
U.S. Food and Drug Administration

1:30 pm
Industry Perspective on Small Molecule Breakthrough Therapies
Susan C. Berlam, R.Ph.
Pfizer Inc.

2:00 pm
Challenges and Opportunities for Commercial Manufacturing Readiness and Launch of Large Molecule Breakthrough Products
Dana Andersen
Genentech

2:30 pm
Industry Perspective on Presenting Risk Benefit Solutions to Enable Accelerated Approvals
Eric S. Thostesen
Johnson & Johnson

3:00 pm
Break

3:15 pm
Quality Challenges for Breakthrough Therapies: FDA Perspective
Mahesh R. Ramanadham, Pharm. D.
U.S. Food and Drug Administration
Sarah Pope Miksinski
U.S. Food and Drug Administration

4:15 pm
Panel Discussion

5:00 pm – 6:30 pm
GDUFA Implementation **Salon D**
Moderator:
Lawrence Yu, Ph.D.
U.S. Food and Drug Administration

Speakers:
FDUFA and Generic Drug Chemistry
Susan Rosencrance
U.S. Food and Drug Administration

GDUFA Implementation
Keith Flanagan
U.S. Food and Drug Administration

6:30 pm – 8:00 pm **White Oak**
Networking Reception
Hosted by ISPE and PQRI

September 17, 2014

8:30 am – 12:00 pm
Concurrent Breakout Sessions

Theme: Risk Management and Quality Metrics Salon A
Session II Topic: Risk Management in Drug Development and Review for Small and Large Molecules
Moderators/Speakers:
Jeff Baker
Andre Raw
U.S. Food and Drug Administration
G.K. Raju
Light Pharma Inc.
Paul McCormac
Pfizer Global Supply

8:30 am
Framing the Workshop: Origins, Activities, and Deliverables

9:00 am
Workshop Session I: Small Group Analysis of Risk Management Scenarios in Pharma Manufacturing

10:00 am
Break

10:15 am
Workshop Session II: Review of Outputs from Session I

11:15 am
Workshop III: Identify Hurdles/Enablers to Practical Implementation of Risk-based Management in Pharma Manufacturing

Theme: Performance-based Quality Assessment Salon B
Session II Topic: Contract Manufacturing Arrangements and Pharmaceutical Quality Systems
Moderators:
Dave Doleski
U.S. Food and Drug Administration
EJ Brandreth
Inovio Pharmaceuticals, Inc.

8:30 am
Contract Manufacturing and Quality Agreements
Tamara Ely
U.S. Food and Drug Administration

8:55 am
Managing the Quality Relationship for a Contractual Agreement
Susan Schniepp
Allergy Laboratories

9:20 am
Foundations for an Effective Quality Relationship with CMOs
Fionnuala Walsh
Eli Lilly

9:55 am
Break

10:10 am
Gap Analysis of CMO / Sponsor Relationships
EJ Brandreth
Inovio Pharmaceuticals, Inc.

10:35 am
Regulatory and Quality Considerations for Contract Manufacturing
David J. Jaworski, B.S.
U.S. Food and Drug Administration

11:00 am
Relationships with CMOs, from the Initial Vendor to Managing the Long Term Relationship
Rich Hameister
Genentech/Roche

11:25 am
Panel Discussion

Theme: Innovation in Manufacturing and Regulatory Assessment Salon C
Session II Topic: Innovations in Manufacturing and Regulation for Sterile Drug Products
Moderators:
Lynne A. Ensor, Ph.D.
U.S. Food and Drug Administration
Dave Hussong
U.S. Food and Drug Administration
Paul Stinavage, Ph.D.
Pfizer Inc.

8:30 am
Challenges and Solutions for the Quantification and Mitigation of Risk When Assessing Global Aseptic Manufacturing Operations
Michael C. Baumstein
Pfizer Inc.

9:00 am
Risk-based Approach to Environmental Monitoring Programs
Marsha Stabler Hardiman
Concordia Valsource

9:30 am
Risk-based Cleanroom and Environmental Controls for Terminal Sterilization Operations
Edward Tidswell
Baxter

10:00 am
Break

10:15 am
Advances in the Microbial Control for Biopharmaceutical Production
Edward S. Balkovic, Ph.D.
Genzyme

10:45 am
USP <1207> Sterile Product – Package Integrity Evaluation – 'Benefits of Technology'
Donald Singer
GlaxoSmithKline

11:15 am
Panel Discussion

Theme: Emerging Topics Linden Oak
Session II Topic: International Harmonization (ICH, Q3D, or QbD)
Moderators:
Ashley Boam
U.S. Food and Drug Administration
Stephen P. Miller, Ph.D.
U.S. Food and Drug Administration
Mark Rosolowsky, Ph.D.
Bristol-Myers Squibb

8:30 am
Introductions and Perspectives on International Harmonization
Mark Rosolowsky, Ph.D.
Bristol-Myers Squibb

9:00 am
ICH M7: Assessment and Control of Mutagenic Impurities
Elemental Impurities- Implementation of ICH Q3D
Mark G. Schweitzer, Ph.D.
Novartis Pharmaceutical Corporation
Stephen P. Miller, Ph.D.
U.S. Food and Drug Administration

9:30 am
EMA-FDA Pilot on QbD Applications: FDA Perspective
Sharmista Chatterjee
U.S. Food and Drug Administration

EMA-FDA Pilot on QbD Applications: Industry Perspective
Ambarish K. Singh, Ph.D.
Bristol Myers Squibb

10:00 am
Break

10:15 am
Opportunities for International Collaborations in Inspections
Peter Kitz
Bristol Myers Squibb

10:45 am
Challenges in Getting Global Approvals for Post-approval Changes
Andrew C. Chang
Novo Nordisk A/S

11:15 am
Panel Discussion

12:00 pm – 1:00 pm
Lunch Salons A-C

1:00 pm – 5:00 pm
Concurrent Breakout Sessions

Theme: Risk Management and Quality Metrics Salon A
Session III Topic: Quality Metrics
Moderators:
Russ Wesdyk
U.S. Food and Drug Administration

1:00 pm
OPQ/OPS Overview on Quality Metrics
Theresa Mullin
U.S. Food and Drug Administration

1:30 pm
Use Process Capability to Ensure Product Quality
Lawrence Yu, Ph.D.
U.S. Food and Drug Administration

2:00 pm
Quality Metrics: Current FDA View
Russ Wesdyk
U.S. Food and Drug Administration

2:30 pm
Industry View and ISPE Pilot
Diane Hagerty
ISPE

3:00 pm
Break

3:15 pm
Process Reliability in Industry
Barbara M. Allen, Ph.D.
Eli Lilly & Co.

3:45 pm
Quality Culture in Industry
Steven R. Mendivil
Amgen

4:15 pm
Panel Discussion
Robert Tollefsen will participate in the panel discussion.

Theme: Performance-based Quality Assessment Salon B
Session III Topic: Life Cycle Management and Post-approval Changes (Current Practice-Future Direction)
Moderators:
Susan Rosencrance
U.S. Food and Drug Administration
Gordon R. Johnston, R.Ph.
Generic Pharmaceutical Association (GPhA)

1:00 pm
Lifecycle Management and the Post-approval Change Landscape – Challenges and Opportunities
Gordon R. Johnston, R.Ph.
Generic Pharmaceutical Association (GPhA)

1:15pm
Industry Perspective on Lifecycle Management and Post-Approval Changes
Michael W. Kimball
Actavis

1:45pm
Experience with Health Canada's New Approach for Post-Approval Changes
Kiran Krishnan
Apotex

2:00 pm
Current Practice and Leveraging Scientific Advances to Change the Post-Approval Paradigm – FDA's Perspective
Geoffrey Wu
U.S. Food and Drug Administration

2:30 pm
Regulatory Commitment: FDA's Perspective
Daniel Y. Peng, Ph.D.
U.S. Food and Drug Administration

3:00 pm
Break

3:15 pm
Performance-based Regulation – Industry's Perspective
Roger Nosal
Pfizer Inc.

3:45 pm
How Research Can Help Us Rethink Lifecycle Management and Post-Approval Changes
James Polli

University of Maryland

4:15 pm
Panel Discussion

Theme: Innovation in Manufacturing and Regulatory Assessment **Salon C**
Topic: Question-based Review and the Future of Regulatory Submissions
Moderators:
Robert L. Iser, M.S.
U.S. Food and Drug Administration
Sivakumar Vaithiyalingam, Ph. D.
Teva Pharmaceuticals

1:00 pm
Question-based Review and Submissions: CDER Perspective
Jennifer A. Maguire, Ph.D.
U.S. Food and Drug Administration

1:40 pm
Question-based Review and Submissions: Industry Perspective
Sivakumar Vaithiyalingam, Ph. D.
Teva Pharmaceuticals

2:20 pm
Question-based Review and Submissions: CVM Perspective
Dennis Bensley, Ph.D.
U.S. Food and Drug Administration

3:00 pm
Review Practices for the Evaluation of Risk-based Submissions
Junichi Fukuchi, Ph.D.
Pharmaceuticals & Medical Devices Agency (PMDA), Japan

3:40 pm
Break

4:00 pm
Future of Question-based Review and Regulatory Submissions
Robert L. Iser, M.S.
U.S. Food and Drug Administration

4:30 pm
Panel Discussion

Mark Rosolowsky from BMS will participate in the panel discussion.

Theme: Emerging Topics Linden Oak
Session III Topic: Biosimilars: The Finish Line and Beyond
Moderators:
Steven Kozlowski, M.D.
U.S. Food and Drug Administration
Gustavo (Gino) Grampp
Amgen
Joerg Windisch, Ph.D.
Sandoz Biopharmaceuticals

1:00 pm
FDA Perspectives on Biosimilar Development with a Lens on Quality
Steven Kozlowski, M.D.
U.S. Food and Drug Administration

1:30 pm
Considerations for Global Approach of mAb Biosimilar Development: Case Study of Remsima
Stanley SeungSuh Hong, Ph.D.
Celltrion, Inc.

2:00 pm
Bioanalytics to Assess Residual Uncertainty in Biosimilar Development
Brian E. Collins, Ph.D.
Momenta Pharmaceuticals

2:30 pm
Statistical Tools for Similarity Assessment of Quality Attributes
Aili Cheng
Pfizer Inc.

3:00 pm
Break

3:15 pm
Keeping Biologics Under Control
Thomas Stangler, Ph.D.
Sandoz GmbH

3:45 pm
The Role of Standards in the Development and Post-approval Lifecycle of Biosimilars
Anthony R. Mire-Sluis, Ph.D.
Amgen Inc.

4:15 pm
Panel Discussion
Karen Rule from Pfizer Inc. will participate in the panel discussion.