2017 PDA Pharmaceutical Quality Metrics and Quality Culture Conference

February 21-22, 2017 | Bethesda North Marriott Hotel & Conference Center | Bethesda, MD

As of January 30, 2017

Tuesday, February 21, 2017

7:15 a.m. - 5:30 p.m.
Registration Open

7:15 a.m. - 8:30 a.m.
Continental Breakfast

8:15 a.m. - 8:30 a.m.
Welcome and Opening Remarks
Steven R. Mendivil, Senior Advisor, International Quality External Affairs, *Amgen, Inc.* and Chair, *2017 PDA Pharmaceutical Quality Metrics and Quality Culture Conference*

8:30 a.m. - 10:00 a.m.
P1: Opening Plenary Session: Quality Metrics Update
Moderator: Susan Schniepp, Fellow, *Regulatory Compliance Associates, Inc.*

Session Description: This session will highlight FDA's vision, long-term strategy and what has changed in the FDA's new reissued guidance as a result of comments received and both short- and long-term implementation plans. Industry will speak on potential challenges and benefits to the industry and patients.

8:30 a.m. - 9:00 a.m.
FDA's Vision for Quality Metrics
FDA's vision, aspirations and the benefits to the industry and patients will be shared, along with a look at what's new and different in the reissued guidance.
Lawrence Yu, PhD, Deputy Director, Office of Pharmaceutical Quality, OPQ, *FDA (Invited)*

9:00 a.m. - 9:30 a.m.
FDA Update on Reissued Quality Metrics Draft Guidance
Explore the specific details that are new and different in the reissued draft guidance, including metrics, definitions and reporting strategies.
Tara Gooen Bizjak, Senior Science Policy Advisor for Pharmaceutical Quality, CDER, *FDA*

9:30 a.m. - 10:00 a.m.
Panel Discussion
Lawrence Yu, PhD, Deputy Director, Office of Pharmaceutical Quality, OPQ, *FDA (Invited)*
Tara Gooen Bizjak, Senior Science Policy Advisor for Pharmaceutical Quality, CDER, *FDA*
Mary Malarkey, Director, CBER, *FDA (Invited)*
David Churchward, Expert GMP Inspector, *Medicines and Healthcare Products Regulatory Agency (Invited)*
Todd C. Ebert, MS, President & CEO, *Healthcare Supply Chain Association*
Alex Viehmann, Operations Research Analyst, CDER, *FDA (Invited)*

9:45 a.m. - 6:30 p.m.
Exhibit Area Open

10:00 a.m. - 10:45 a.m.
Refreshment Break in Exhibit Area

10:45 a.m. - 12:15 p.m.
P2: Perspectives on Quality Metrics and the FDA Proposal
Moderator: Steven R. Mendivil, Senior Advisor, International Quality External Affairs, *Amgen, Inc.*

Session Description: This session explores benefits and challenges for implementing quality metrics programs. It will focus on the specific challenges posed by the new reissued guidance for various segments of the pharmaceutical industry and will propose solutions to these challenges.

10:45 a.m. - 11:45 a.m.
Panel Discussion
Large Pharma: Barbara Allen, PhD, Senior Director, Global Quality Systems, *Eli Lilly and Company, S.A. Irish Branch*
Generics: Deborah Autor, JD, Member, *Generic Pharmaceutical Association*
API Supplier: Guy Villax, CEO, *Hovione*
OTC: Carol Montandon, MBA, Chief Quality Officer, Vice President, Quality and Compliance, *Johnson & Johnson Consumer, Inc.*
Biotech: Melissa Seymour, MBA, Vice President, Global Quality Control, *Biogen*
API/CMO: Harry Jeffreys, VP Regulatory Affairs and Compliance, *Catalent Pharma Solutions*

11:45 a.m. - 12:15 p.m.
Questions and Answers/Discussion

12:15 p.m. - 1:30 p.m.
Networking Luncheon

1:30 p.m. - 3:00 p.m.
P3: Analytical Approaches
Moderator: Pritesh R. Patel, MBA, Associate Director, Quality Risk Management Statistician, *Novartis*

Session Description: This session will explore various approaches on metrics analysis, focusing on what the FDA is proposing and industry's experiences thus far in analyzing quality metrics.

1:30 p.m. - 2:00 p.m.
FDA Update on Metric Analytics
Find out how FDA intends to compile and analyze the metrics data from pharmaceutical companies.
Alex Viehmann, Operations Research Analyst, CDER, *FDA (Invited)*

2:00 p.m. - 2:30 p.m.
Operationalizing Metrics to Enable Continuous Improvement: Industry Perspective
Hear firsthand from an industry expert about lessons learned from analyzing quality metrics and how to use metrics to drive continuous improvement and avoid unintended consequences.
Carol Montandon, MBA, Chief Quality Officer, Vice President, Quality and Compliance, *Johnson & Johnson Consumer, Inc.*

2:30 p.m. - 3:00 p.m.
Panel Discussion
Alex Viehmann, Operations Research Analyst, CDER, *FDA (Invited)*
Carol Montandon, MBA, Chief Quality Officer, Vice President, Quality and Compliance, *Johnson & Johnson Consumer, Inc.*
Tara Gooen Bizjak, Senior Science Policy Advisor for Pharmaceutical Quality, CDER, *FDA*

3:00 p.m. - 3:45 p.m.
Refreshment Break in Exhibit Area

3:45 p.m. - 5:15 p.m.
P4: Implementation Approaches
Moderator: Jan Paul Zonnenberg, Partner, *PriceWaterhouseCoopers, LLC*

Session Description: This session will explore plans, challenges and proposed solutions for gathering metrics data navigating the FDA gateway.

3:45 p.m. - 3:55 p.m.
FDA Update on Quality Metrics Data Submission and Collection Strategies
An overview of the QM data submission architecture and CDER Informatics Platform
Seyoum Senay, MS, Lead Informatics Platform - EDM, OBI, *FDA*

3:55 p.m. - 4:45 p.m.
Panel Discussion
Experts will share their experiences regarding the challenges and solutions for collecting and reporting metrics and using predictive analytics.
Seyoum Senay, MS, Lead Informatics Platform - EDM, OBI, *FDA*
Pritesh R. Patel, MBA, Associate Director, Quality Risk Management Statistician, *Novartis*
Robert Chrzanowski, MBA, Sr. Director, Supply Chain Data & Analytics, *Johnson & Johnson (Invited)*
Machelle Eppler, Vice President and Head of Global Quality Compliance & Regulatory, *Patheon (Invited)*
Richard Love, Founder, *HarborView, LLC*
Tom Foth, Director, Analytic Application Concept Development, *PriceWaterhouseCoopers LLC*
Thomas Friedli, Associate Professor of Management, *University of St. Gallen*

4:45 p.m. - 5:15 p.m.
Questions and Answers/Discussion

5:15 p.m. - 6:30 p.m.
Networking Reception in Exhibit Area

Wednesday, February 22, 2017

7:15 a.m. - 4:00 p.m.
Registration Open

7:15 a.m. - 8:15 a.m.
Continental Breakfast

8:15 a.m. - 9:45 a.m.
P5: Quality Culture and What We are Learning as an Industry
Moderator: Cylia Chen Ooi, External Affairs Sr. Manager, International Quality, *Amgen, Inc.*

Session Description: This session will exploring quality culture within the pharmaceutical industry and what we are learning about the relationship between quality metrics and quality culture.

8:15 a.m. - 8:45 a.m.
Quality Culture and Risk Management Behaviors (FDA)
Quality systems and quality metrics are elements of a complex environment where key decisions are also impacted by an organization's Quality Culture. Understanding and managing Quality Culture is critical to effective risk management and an emerging consideration in control strategy development and assessment.
Jeffrey C. Baker, PhD, Deputy Director, Office of Biotechnology Products, CDER, *FDA*

8:45 a.m. - 9:15 a.m.
Regulatory Perspective on Quality Culture (MHRA)
MHRA will share its thoughts on the importance of quality culture and how to assess it.
David Churchward, Expert GMP Inspector, *Medicines and Healthcare Products Regulatory Agency (Invited)*

9:15 a.m. - 9:45 a.m.
Panel Discussion
Jeffrey C. Baker, PhD, Deputy Director, Office of Biotechnology Products, CDER, *FDA*
David Churchward, Expert GMP Inspector, *Medicines and Healthcare Products Regulatory Agency (Invited)*

9:30 a.m. - 3:45 p.m.
Exhibit Area Open

9:45 a.m. - 10:30 a.m.
Refreshment Break in Exhibit Area

10:30 a.m. - 12:15 p.m.
P6: What Moves the Needle for Maturing Quality Culture?
Moderator: Robert McElwain, Consumer Safety Officer, *FDA*

Session Description: What has executive management used to mobilize and dramatically improve a company's quality culture?

10:30 a.m. - 10:55 a.m.
What Drives Quality Culture: A CEO's Perspective
Guy Villax, CEO, *Hovione*

10:55 a.m. - 11:20 a.m.
Innovative Approaches to Transforming Quality Culture
Anders Vinther, PhD, Chief Quality Officer, *Sanofi Pasteur*

11:20 a.m. - 11:45 a.m.
Appreciating Successes to Drive a Quality Culture
Gerhard Köller, PhD, Chief Quality Officer, *Boehringer Ingelheim (Invited)*

11:45 a.m. - 12:15 p.m.
Questions and Answers/Discussion

12:15 p.m. - 1:30 p.m.
Networking Luncheon

1:30 p.m. - 3:00 p.m.
P7: Assessing Quality Systems and Quality Culture
Moderator: Marci Goldfinger, MS, Director QA Integration, *Johnson & Johnson Consumer Inc, US OTC*

Session Description: Assessing quality culture is difficult. Get an update on PDA's Assessment Tool Pilot Program and academic approaches to measuring quality culture.

1:30 p.m. - 1:50 p.m.
Aspiring to Measure Quality Culture
Hear the latest on PDA's Quality Culture Assessment Tool Assessment Pilot Program.
Cylia Chen Ooi, External Affairs Sr. Manager, International Quality, *Amgen, Inc.*

1:50 p.m. - 2:10 p.m.
A Company's Experience in the PDA Quality Culture Assessment Pilot Program
This session provides a firsthand account of users' experiences with this new tool during PDA's pilot program.
Machelle Eppler, Vice President and Head of Global Quality Compliance & Regulatory, *Patheon*

2:10 p.m. - 2:30 p.m.
An Academic Perspective on Measuring Quality Systems and Quality Culture
Thomas Friedli, Associate Professor of Management, *University of St. Gallen*

2:30 p.m. - 3:00 p.m.
Panel Discussion
Cylia Chen Ooi, External Affairs Sr. Manager, International Quality, *Amgen, Inc.*
Machelle Eppler, Vice President and Head of Global Quality Compliance & Regulatory, *Patheon*
Thomas Friedli, Associate Professor of Management, *University of St. Gallen*
Jan Paul Zonnenberg, Partner, *PriceWaterhouseCoopers, LLC*
Brianna Peterson, Project Management Office, Corporate Division Quality Projects, *Boehringer Ingelheim*

3:00 p.m. - 3:45 p.m.
Refreshment Break in Exhibit Area

3:45 p.m. - 5:15 p.m.
P8: Closing Plenary: Quality Metrics and Quality Culture Wrap-up
Moderator: Sarah Pope Miksinski, PhD, Acting Director, Office of New Drug Products, CDER, *FDA (Invited)*

Session Description: This closing session will summarize the future of quality metrics and discuss quality culture as an enabler of continuous improvement in the pharmaceutical manufacturing industry.

3:45 p.m. - 4:05 p.m.
CDRH's Case for Quality and Quality Metrics
CDRH will share its approach to quality metrics
William MacFarland, MS, MBA, Supervisory Biomedical Engineer, *FDA (Invited)*

4:05 p.m. - 4:25 p.m.
PDA Quality Metrics/Quality Culture Next Steps
Learn about PDA's short- and long-term plans for quality metrics and quality culture.
Steven R. Mendivil, Senior Advisor, International Quality External Affairs, *Amgen, Inc.*

4:25 p.m. - 4:45 p.m.
Quality Metrics: Next Steps
CDER/CBER will discuss their short- and long-term plans for quality metrics and quality culture.
Ashley Boam, MSBE, Acting Director, Office of Policy for Pharmaceutical Quality, CDER, *FDA (Invited)*

4:45 p.m. - 5:15 p.m.
Questions and Answers/Discussion
William MacFarland, MS, MBA, Supervisory Biomedical Engineer, *FDA (Invited)*
Steven R. Mendivil, Senior Advisor, International Quality External Affairs, *Amgen, Inc.*
Ashley Boam, MSBE, Acting Director, Office of Policy for Pharmaceutical Quality, CDER, *FDA (Invited)*
Tara Gooen Bizjak, Senior Science Policy Advisor for Pharmaceutical Quality, CDER, *FDA*
Alex Viehmann, Operations Research Analyst, CDER, *FDA (Invited)*

5:15 p.m.
Closing Remarks
Richard M. Johnson, President & CEO, *PDA*