The Parenteral Drug Association presents the...

2017 PDA Pharmaceutical Quality Metrics and Quality Culture Conference

February 21-22, 2017 | Bethesda, MD

Bethesda North Marriott Hotel & Conference Center

Exhibition: February 21-22

#2017Metrics

Next Steps: Using Quality Metrics to Advance Quality Culture

pda.org/2017Metrics

This preliminary agenda is current as of January 31, 2017

RECORDINGS ARE PROHIBITED AT ALL PDA EVENTS

PROGRAM PLANNING COMMITTEE

Program Chair

Steven R. Mendivil
Amgen, Inc.

Diane S. Alexander
FDA

Cylia Chen Ooi
Amgen, Inc.

Marci Goldfinger, MS
Johnson & Johnson

Tara Gooen Bizjak
FDA

Robert D. McElwain
FDA

Pritesh R. Patel, MBA
Novartis

Siegfried Schmitt, PhD
PAREXEL Consulting

Susan Schniepp
Regulatory Compliance Associates Inc.

Alex Viehmann
FDA

Jan Paul Zonnenberg, MBA
PwC Consulting

Denyse D. Baker, PE, RAC
PDA

Molly O'Neill Moir, CMP
PDA Liaison to the Program Planning Committee

A MESSAGE FROM THE PROGRAM CHAIR

Steven R. Mendivil
Amgen, Inc.

Dear Friends, Colleagues and Peers,

Over the last several years, quality metrics have come to figure prominently in our industry. PDA has been actively involved in the discussion around quality metrics and quality culture since 2013. With the recent release of the FDA's revised draft guidance, PDA is poised to take the lead in continuing the conversation at the *2017 PDA Pharmaceutical Quality Metrics and Quality Culture Conference,* February 21-22 in Bethesda, MD.

The Program Planning Committee has built a robust agenda that will ensure attendees hear directly from the FDA and industry regarding what has changed in the revised guidance and plans for using the data. Industry leaders will also discuss how these changes will impact the industry.

The *2017 PDA Pharmaceutical Quality Metrics and Quality Culture Conference* builds on the foundation established at the three prior Conferences PDA hosted in 2013, 2014 and 2015. Through plenary sessions and panel discussions, regulatory and industry experts will take an in-depth look at the FDA's newest guidance, the benefits to industry and patients and potential challenges to implementation across various segments of the pharmaceutical industry.

Explore analytical approaches to quality metrics, including how to operationalize metrics to enable continued improvement, and hear firsthand from FDA and industry about utilizing the FDA gateway to submit and retrieve metrics data. Regulators will share their perspectives on quality culture, and you will get an update on PDA's Quality Culture Assessment Pilot Program and hear directly from participants.

Quality metrics and their effect on quality culture are important considerations for every aspect of our industry. Make sure you are staying up to date with the latest developments in this important area! Plan to join us at the *2017 Pharmaceutical Quality Metrics and Quality Culture Conference* in Bethesda.

We hope to see you there!

GENERAL INFORMATION, REGISTRATION

FOUR WAYS TO REGISTER

1. Click	**www.pda.org/2017Metrics**
2. Fax	+1 (301) 986-1093
3. Mail	PDA Global Headquarters Bethesda Towers 4350 East West Highway, Suite 600 Bethesda, MD 20814 U.S.A.
4. Phone	(301) 656-5900 ext. 115

VENUE

Bethesda North Marriott Hotel & Conference Center
5701 Marinelli Road
Bethesda, MD U.S.A. 20852
Phone: +1 (301) 822-9200
Website: http://www.marriott.com/hotels/travel/wasbn-bethesda-north-marriott-hotel-and-conference-center
Rate: Single: $199 plus applicable state and local taxes.
Cut-off Date: Monday, February 6, 2017. Requests will be processed on a first-come, first-served basis. Rates are guaranteed until the PDA block of rooms is sold out.

CONTINUING EDUCATION CREDITS

PDA is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Participants may sign up to receive Continuing Pharmacy Education (CPE) credits. To do so, participants must sign in at the beginning of the program, submit the provided evaluation forms and mail the CPE credit request to the address stated on the form. Attendees must be present at the full event to receive CPE credit.

ALERT: ACPE and the National Association of Boards of Pharmacy developed the Continuing Pharmacy Education (CPE) Monitor that allows pharmacists to electronically track their CPE credits. The CPE Monitor will reject any CPE credit requests submitted past 60 days from date of ACPE accredited activity. Always submit CPE activity claims as soon as possible and by the deadline specified on the CPE credit request form.

2017 PDA Pharmaceutical Quality Metrics and Quality Culture Conference
ACPE #0116-0000-16-036-L04-P | 1.225 CEUs
Type of Activity: *Knowledge*

LEARNING OBJECTIVES

At the completion of this event, attendees will be able to:

- Explain the FDA's revised draft guidance, submission of quality metrics data and how FDA intends to analyze the submitted data to help develop compliance and inspection policies and practices
- Describe how a mature quality metrics program can enable a state-of-the-art, innovative quality management system for pharmaceutical manufacturing
- Summarize how quality metrics programs are implemented and improved to resolve common quality issues
- Recognize the importance and measurement of quality culture in a robust pharmaceutical quality system and how quality metrics play a role in that system
- Discuss what PDA has accomplished thus far in terms of assessing quality culture based on an interim analysis and the experiences of participants in PDA's Quality Culture Assessment Pilot Program

WHO SHOULD ATTEND

Personnel from quality, manufacturing, supply chain and technical functions will find this level of direct information exchange with members of industry and regulatory agencies useful to their specific programs and to improve generally across the market.

CONFERENCE REGISTRATION HOURS

Tuesday, February 21: 7:00 a.m. – 5:30 p.m.
Wednesday, February 22: 7:15 a.m. – 4:00 p.m.

DRESS/ATTIRE

Business casual attire is recommended for the *2017 Pharmaceutical Quality Metrics and Quality Culture Conference*. Since the temperature in meeting rooms tends to be cool, please bring a jacket or sweater for your comfort.

SPECIAL REQUIREMENTS

If you require special accommodations to fully participate, please attach a written description of your needs with your registration form. Specific questions can be directed to registration@pda.org.

CONTACT INFORMATION

Conference Inquiries
Molly O'Neill Moir, CMP
Vice President
Programs & Meetings
Tel: +1 (301) 656-5900 ext. 132
Email: moir@pda.org

Exhibition/Sponsorship Inquiries
David Hall
Vice President
Sales
Tel: +1 (301) 760-7373
Email: hall@pda.org

Registration Customer Care
Tel: +1 (301) 656-5900 ext. 115
Email: registration@pda.org

Connecting People, Science and Regulation®

TUESDAY, FEBRUARY 21, 2017 AGENDA

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. Panelists will discuss regulatory approaches to metrics and payers' perspective on the metrics program and will answer audience questions.

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*
David Churchward, Expert GMP Inspector, *Medicines and Healthcare Products Regulatory Agency (Invited)*
Todd C. Ebert, MS, President & CEO, *Healthcare Supply Chain Association*
Mary Malarkey, Director, CBER, *FDA*
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

TUESDAY, FEBRUARY 21, 2017 AGENDA (CONTINUED)

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 cover proposed 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*
Generics: Deborah Autor, Esq., Member, *Generic Pharmaceutical Association*
API Supplier: Guy Villax, CEO, *Hovione*
OTC: Carol Montandon, MBA, Chief Quality Officer: Vice President Quality and Compliance, *Johnson & Johnson*
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 to 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

TUESDAY, FEBRUARY 21 – WEDNESDAY, FEBRUARY 22, 2017 AGENDA

3:45 p.m. – 5:15 p.m.
P4: Implementation Approaches
Moderator: Jan Paul Zonnenberg, MBA, Partner, *PwC Consulting*

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

3:45 p.m. – 3:55 p.m.
FDA Update on Quality Metrics Data Submission and Collection Strategies
This session will provide 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, *PwC Consulting*
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 explore quality culture within the pharmaceutical industry and what we are learning about the relationship between quality metrics and quality culture from a regulatory perspective.

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)*

WEDNESDAY, FEBRUARY 22, 2017 AGENDA (CONTINUED)

P5: Quality Culture and What We are Learning as an Industry *(continued)*

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 D. McElwain, Consumer Safety Officer, CBER, *FDA*

Session Description: This session will highlight the tools that executive management has used to mobilize staff 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, McNeil Consumer Healthcare Division, *Johnson & Johnson*

Session Description: Assessing quality culture is difficult. Get an update on PDA's Quality Culture Assessment 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 Pilot Program.
Cylia Chen Ooi, External Affairs Sr. Manager, International Quality, *Amgen, Inc.*

WEDNESDAY, FEBRUARY 22, 2017 AGENDA (CONTINUED)

P7: Assessing Quality Systems and Quality Culture *(continued)*

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, MBA, Partner, *PwC Consulting*
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*

2017 PDA Pharmaceutical Quality Metrics and Quality Culture Conference

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Bethesda North Marriott Hotel & Conference Center
Exhibition: February 21-22

Four easy ways to register –
Click: www.pda.org/2017Metrics
Fax: +1 (301) 986-1093 (U.S.A.)
Mail: PDA Global Headquarters
4350 East West Highway, Suite 600
Bethesda, MD 20814 U.S.A.
Call: +1 (301) 656-5900 ext. 115

Print

PDA® Parenteral Drug Association

1 Contact Information

PDA Membership Number

Prefix First Name Last Name

Job Title Company

Business Address

City State/Province ZIP+4/Postal Code

Country Email

Business Phone Fax

❒ Substituting for

(Check only if you are substituting for a previously enrolled colleague. The fee difference in the prevailing rate is due at the time of substitution. Please note that if you are a nonmember substituting for a member, you will be required to pay the difference in the nonmember fee.)

Special Dietary Requirements (Please be specific)

Please note: In order to receive the prevailing rate, your registration(s) with payment must be received by PDA by 5:00 p.m. ET on or before the date noted.

2 CONFERENCE Registration | February 21-22 *Please check appropriate fee (US$).*

	Before December 12, 2016	December 12, 2016 – January 6, 2017	After January 6, 2017
PDA Member	❍ $ 1,895	❍ $ 2,095	❍ $ 2,295
Nonmember	❍ $ 2,174	❍ $ 2,374	❍ $ 2,574
Government/Health Authority			
Member	❍ $ 700	❍ $ 700	❍ $ 700
Nonmember*	❍ $ 800	❍ $ 800	❍ $ 800
Academic			
Member	❍ $ 700	❍ $ 700	❍ $ 700
Nonmember*	❍ $ 800	❍ $ 800	❍ $ 800
Student			
Member	❍ $ 280	❍ $ 280	❍ $ 280
Nonmember*	❍ $ 310	❍ $ 310	❍ $ 310

* For this member type or discounted rate, online registration is not available and must be faxed in.

❍ **Check here to become a member and receive the member price for this event.** (add $279 to your total)

3 Payment Options *All cards are charged in US$.*

Group Registration: Register 4 people from the same organization as a group (at the same time) for the CONFERENCE and receive the 5th registration free. Other discounts cannot be applied. All forms MUST be faxed in together.

❍ By Credit Card – Clearly indicate account number, expiration date and billing address.

Please bill my: ❍ American Express ❍ MasterCard ❍ VISA
❍ Credit Card Guarantee Only

Total amount $ _____ Campaign Code _____

Account Number Exp. Date

Name (exactly as it appears on card) Signature

Billing Address (must match credit card statement)

City State Zip **PDA Federal Tax I.D. #52-1906152**

Country Wire Transfer Payments: If you require wire transfer, please contact registration@pda.org.

CONFIRMATION: A letter of confirmation will be sent to you once payment is received. You must have this written confirmation to be considered enrolled in a PDA event. Please allow one week for receipt of confirmation letter. If you have submitted a purchase order or requested an invoice, please be advised that a credit card guarantee is needed. Please be advised that if your payment or written cancelation notice is not received by **December 23, 2016**, your credit card will be charged the prevailing rate. **SUBSTITUTIONS:** If you are unable to attend, substitutions can be made at any time, including onsite at the prevailing rate. If you are a nonmember substituting for a member, you will be required to pay the difference in the nonmember fee. If you are pre-registering as a subsitute attendee, indicate this on the registration form. **REFUNDS:** Refund requests must be in writing and faxed to +1 (301) 986-1093. (Emails and phone messages are not accepted). **Refunds for Conference:** If your written request is received on or before **December 23, 2016**, you will receive a full refund minus a $200 processing fee. After that time, no refunds or credit requests will be approved. Onsite registrants are not guaranteed to receive Conference materials until all advanced registered attendees receive them. PDA reserves the right to modify the material or speakers/instructors without notice or to cancel an event. If an event must be canceled, registrants will be notified by PDA in writing as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancelation. For more details, contact PDA at info@pda.org or +1 (301) 656-5900. **PLEASE NOTE THAT PHOTO ID WILL BE REQUIRED IN ORDER TO PICK UP BADGE MATERIALS ONSITE. THIS IMPORTANT SECURITY PROCEDURE WILL PREVENT ANYONE OTHER THAN THE REGISTRANT FROM PICKING UP THEIR BADGES AND MATERIALS. RECORDING/PHOTO RELEASE:** By registering for these events, I authorize PDA to record and photograph me and to use the recordings/photographs in all formats and media for any purpose, including for education, marketing and trade purposes. I hereby release PDA from all claims arising out of the use of the recordings/photographs, including without limitation all claims for compensation, libel, invasion of privacy or violation of copyright ownership. Tape recordings are prohibited at all PDA Conferences.

PDA USE ONLY Date: _____ Check: _____ Amount: _____ Account: _____ **022117B**