The Parenteral Drug Association presents the...

2017 PDA PAC iAM Workshop

September 13-14, 2017 | Washington, DC

Renaissance Washington, DC Downtown Hotel

Exhibition: September 13-14

#2017PAC

PDA Parenteral Drug Association

Co-sponsored by

IFPMA

Science- and Risk-Based Approaches to Technical Change Management

pda.org/2017PAC

This preliminary agenda is current as of Jun. 22, 2017

RECORDINGS ARE PROHIBITED AT ALL PDA EVENTS

PROGRAM PLANNING COMMITTEE

Program Co-Chairs:

Ursula Busse, PhD, MBA
Novartis

Lisa M. Skeens, PhD
Pfizer, Inc.

Graham Cook, PhD
Pfizer, Inc.

Suzanne Kiani, MS
Mylan Inc.

Kevin O'Donnell, PhD
Health Products Regulatory Authority

Emma Ramnarine, MS
Genentech, Inc., A Member of the Roche Group

Mihaela C. Simianu, PhD
Pharmtech Associates, Inc.

Anders Vinther, PhD
Sanofi Pasteur

Denyse D. Baker, PE, RAC
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Molly O'Neill Moir, CMP
PDA

Brooke Schneider, CMP
Liaison to the Committee
PDA

A MESSAGE FROM THE PROGRAM CO-CHAIRS

Ursula Busse, PhD, MBA
Novartis

Lisa M. Skeens, PhD
Pfizer, Inc.

Following the initial launch and throughout a drug product's commercial life, post-approval changes (PACs) are introduced routinely to enhance the robustness of the manufacturing process, improve quality control techniques and upgrade to state-of-the-art facilities. However, today's global PAC regulatory environment becomes increasingly complex, which poses significant challenges to product realization and manufacturing innovation. Several international efforts are currently underway to address the lack of a harmonized approach, including work ongoing in ICH (ICH Q12). A PDA Task Force, PDA PAC iAM℠, was formed in 2015 and is actively supporting these efforts.

The *2017 PDA PAC iAM Workshop* will provide you with an overview of the principles of ICH Q12 and the PDA PAC iAM Task Force's℠ most recent activities and insights into several ongoing work items on practical aspects of PAC implementation. Through case studies and interactive participation, we will explore current concepts and tools proposed to better manage PACs. You will learn how to apply science- and risk-based approaches leveraging product and process knowledge for the management of PACs. Insights by experts will be given on how an effective pharmaceutical quality system, communication and knowledge exchange can reduce PAC notification requirements. Finally, you will hear from renowned thought leaders about international initiatives that drive convergence of PAC regulations globally. Come and listen to the most current thinking on the concepts and solutions proposed to facilitate PAC and spur manufacturing innovation throughout a product's lifecycle!

We encourage you to actively participate in this Workshop and leave your mark in driving for global regulatory convergence of PAC regulations. On behalf of the Workshop Program Planning Committee, we invite you to join us and look forward to meeting you in September!

GENERAL INFORMATION, REGISTRATION

FOUR WAYS TO REGISTER

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

VENUE

Renaissance Washington, DC Downtown Hotel
999 9th Street NW
Washington, DC 20001
Phone: +1 (202) 898-9000
Website: renaissance-hotels.marriott.com/renaissance-washington-dc-downtown-hotel
Rate: Single: $315 plus applicable state and local taxes.
Cut-Off Date: Friday, August 11, 2017 (Availability may be limited. Requests will be processed on a first-come, first-served basis. Attendees staying within the PDA block will receive the Conference rate.)

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 PAC iAM Workshop
ACPE # 0116-0000-17-013-L04-P | 0.925 CEUs
Type of Activity: *Knowledge*

LEARNING OBJECTIVES

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

- Describe prcinciples and tools that will support better post-approval change (PAC) management
- Summarize how to categorize PACs and apply established conditions using a risk/science-based approach
- Explain good change management as part of an effective pharmaceutical quality system (PQS), and how it can be measured and contribute to reducing regulatory burden
- Identify the PDA PAC iAM Task Force℠ activities that are contributing to development of practical tools for PAC management, including change management protocols
- Discuss how international efforts by the International Council for Harmonization (ICH), the World Health Organization (WHO) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) will support global regulatory convergence
- Interpret how global regulatory convergence of PAC regulations will support manufacturing innovation

WHO SHOULD ATTEND

Auditor, Inspector, Investigator, Reviewer | Biologist, Microbiologist, Virologist | Director | Engineer Manager | Operator | Product Manager | Qualified Person | Site Head/Plant Manager | Vice President, Department/Sector Head, Chief Scientific Officer, Office Director

Department
Biochemistry | Biology | Engineering | Manufacturing | Development | Quality | Regulatory Affairs | Technical Operations | Validation

Job Function
Biotech | Facilities and Engineering | Inspection Trends | Lyophilization | Process Validation | Quality Risk Management | Quality Systems | Regulatory Affairs | Supply Chain Management | Technology Transfer | Vaccines

WORKSHOP REGISTRATION HOURS

Wednesday, September 13: 11:30 a.m. – 5:30 p.m.
Thursday, September 14: 7:30 a.m. – 3:30 p.m.

DRESS/ATTIRE

Business casual attire is recommended for all events. The temperature in the meeting rooms tends to be cool, so a jacket or sweater is advised for your comfort.

SPECIAL REQUIREMENTS

For information regarding special needs accommodations, please inquire at the Registration Desk. PDA is committed to make all events accessible to all individuals.

CONTACT INFORMATION

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WEDNESDAY, SEPTEMBER 13, 2017 AGENDA

11:30 a.m. – 5:30 p.m.
Registration Open

1:00 p.m. – 1:15 p.m.
Welcome and Opening Remarks
Ursula Busse, PhD, MBA, Quality Intelligence, External Relations, *Novartis,* and Co-Chair, *2017 PDA PAC iAM Workshop* Program Planning Committee
Lisa M. Skeens, PhD, Vice President, Global Regulatory Affairs, *Pfizer, Inc.,* and Co-Chair, *2017 PDA PAC iAM Workshop* Program Planning Committee

1:15 p.m. – 2:45 p.m.
P1: Opening Plenary: Why is a Global Dialogue Important? Why Now?
Moderator: Emma Ramnarine, MS, Senior Director, Head Global Biologics QC Network, *Genentech, Inc., A Member of the Roche Group*

Session Description: Post-approval changes have been routine in the commercial life of a product. However, the complexity created by opposing forces of companies having to operate in increasingly global markets while health authorities continue to evolve their national regulations has increased, resulting in higher barriers for innovation, continuous improvement and raising the risk of drug shortages. This has elevated the need and urgency for finding global solutions to reduce the complexity and improve speed of post-approval change implementation. This Opening Plenary session will provide you with the case for change, why a global dialogue is essential, what changes are needed and some global solutions that are being discussed by industry and regulators.

1:15 p.m. – 1:35 p.m.
Innovation: Hurdle Race or Fast Track?
Anders Vinther, PhD, Chief Quality Officer, *Sanofi Pasteur*

1:35 p.m. – 1:55 p.m.
ICH Q12: Solutions for Addressing Complexity and Speed of PACs
Regulatory Representative Invited

1:55 p.m. – 2:15 p.m.
International Activities Related to Post-Approval Changes: Opportunities and Challenges
Isabelle Colmagne-Poulard, Senior Director, Regulatory CMC Strategic & Technical Advisor, Global Regulatory Affairs & Quality Assurance, *Merck & Co./Merck Sharp & Dohme,* and Member, IFPMA's Regulatory Policy and Technical Standards (RPTS) Committee

2:15 p.m. – 2:45 p.m.
Questions and Answers/Discussion

2:30 p.m. – 6:00 p.m.
Exhibit Area Open

2:45 p.m. – 3:15 p.m.
Refreshment Break in Exhibit Area

3:15 p.m. – 4:45 p.m.
P2: Established Conditions and Change Categorization
Moderator: Lisa M. Skeens, PhD, Vice President, Global Regulatory Affairs, *Pfizer, Inc.*

Session Description: An important concept to the new regulatory paradigm for post-approval changes is proactively defining the established conditions for a regulatory dossier. In this session, experts from the FDA and industry will explain established conditions and the subsequent categorization of post-approval changes in the new paradigm. The opportunities for leveraging this concept globally to drive efficiency and effectiveness for both regulators and the pharmaceutical industry will be discussed.

WEDNESDAY, SEPTEMBER 13 – THURSDAY, SEPTEMBER 14, 2017 AGENDA

P2: Established Conditions and Change Categorization *(continued)*

3:15 p.m. – 3:45 p.m.
The Anticipated Benefits of Established Conditions and How to Realize Them
Frank Montgomery, Global Head, Regulatory CMC, *AstraZeneca*

3:45 p.m. – 4:15 p.m.
A Regulator's View on the Value of Dossier Established Conditions
Robert L. Iser, MS, Director, Office of Process & Facilities, CDER, *FDA*

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

4:45 p.m. – 6:00 p.m.
Networking Reception in Exhibit Area

THURSDAY, SEPTEMBER 14

7:30 a.m. – 3:30 p.m.
Registration Open

7:30 a.m. – 8:30 a.m.
Continental Breakfast

8:30 a.m. – 10:00 a.m.
P3: Elements of Lifecycle Management Strategy
Moderator: Mihaela C. Simianu, PhD, Director of Regulatory Compliance, *Pharmtech Associates, Inc.*

Session Description: A harmonized approach regarding technical and regulatory considerations for lifecycle management (LCM) will benefit patients, industry and regulatory authorities. This session will discuss the concept of a Product Specific Lifecycle Management (PSLCM) Strategy document as a tool, serving as a central repository for the established conditions and the associated reporting category when making changes to established conditions. The document may proactively identify some of the anticipated post-approval changes to promote transparency between the firm and regulatory authorities. During this session, we will dive deeper into the technical elements of lifecycle management, the channels and value of proactive communication of LCM strategy with regulators/assessors.

8:30 a.m. – 9:00 a.m.
Product-Specific Lifecycle Management Strategy Documents
Emma Ramnarine, MS, Senior Director, Head Global Biologics QC Network, *Genentech, Inc., A Member of the Roche Group*

9:00 a.m. – 9:30 a.m.
Expectations and Incentives: LCM Strategy and Knowledge Sharing with Regulators: FDA Regulatory Representative Invited

9:30 a.m. – 10:00 a.m.
Panel Discussion
Andrew C. Chang, PhD, Vice President, Quality and Regulatory Compliance, Product Supply Quality, *Novo Nordisk*
Regulatory Representative Invited
Emma Ramnarine, MS, Senior Director, Head Global Biologics QC Network, *Genentech, Inc., A Member of the Roche Group*

9:45 a.m. – 4:00 p.m.
Exhibit Area Open

PDA Parenteral Drug Association *Connecting People, Science and Regulation®*

THURSDAY, SEPTEMBER 14, 2017 AGENDA (CONTINUED)

10:00 a.m. – 10:30 a.m.
Refreshment Break in Exhibit Area

10:30 a.m. – 12:15 p.m.
Concurrent Breakouts

Attendees will participate in both breakouts, each 45 minutes long. After Session 1, attendees will switch rooms and the breakouts will be repeated.

Session 1: 10:30 a.m. – 11:15 a.m. | **Session 2:** 11:30 a.m. – 12:15 p.m.

Breakout A: Established Conditions and Change Categorization

Facilitator: Gopi Vudathala, PhD, Head, Quality Advocacy Liaison, *GlaxoSmithKline Vaccines*

Scribe: Suzanne Kiani, MS, Senior Director, Regulatory Science, Biologics, Global Regulatory Affairs, *Mylan Inc.*

Discussion Leader: Sally L. Anliker, Regulatory Scientist, *Eli Lilly and Company*

Session Description: An efficient and effective process to manage post-approval changes encourages product and manufacturing innovation throughout a product's lifecycle. This session will provide practical tools and examples on how to leverage the concepts in FDA's draft guidance, which is anticipated to be included in ICH Q12, such as established conditions and change categorization. It will look at how established conditions are identified and applied, leveraging a risk-based change categorization decision model. It will also further explore how product/process knowledge can be leveraged and discuss ways to minimize the burden of reporting post-approval changes. The hands-on session will provide participants an opportunity to explore the principles of established conditions and change categorization, and share their perspectives on how it may further optimize the change management process for both industry and regulators.

Breakout B: Change Management and the Pharmaceutical Quality System

Facilitator: Ursula Busse, PhD, MBA, Quality Intelligence, External Relations, *Novartis*

Scribe: Marazban Sarkari, Director, Pharmaceutical Operations R&D, *Teva Pharmaceutical Industries Ltd. Israel*

Discussion Leader: Marcello Colao, Director, Quality Regulatory Compliance, *GlaxoSmithKline Vaccines*

Session Description: When changes are made during the commercial life of a product, robust implementation of the principles described in ICH Q10 (an effective PQS, product and process understanding and use of quality risk management) ensure that product quality, patient safety and adequate supply to patients are safeguarded. In this session, the different elements that contribute to effective change management and their inter-relationship will be explored. Using role plays and case studies, participants will be able to perform the change management steps and determine key elements for effective change management. They will experience how to leverage an effective PQS in conjunction with knowledge and quality risk management to test to which extent changes can be managed without review and approval by the regulator. Challenges and opportunities of the enhanced approach as proposed by ICH Q10, Annex 1, will be discussed.

12:15 p.m. – 1:15 p.m.
Networking Lunch

1:15 p.m. – 2:15 p.m.
Small Group Discussion

Session Description: Performing changes to commercial products and associated processes is essential for lifecycle management of a product. How can post-approval change protocols be prepared in the future to align with and take advantage of ICH Q10 and ICH Q12 concepts? In this session, participants can observe, comment on and engage in a dialogue on approach, structure and content of post-approval change management protocols (PACMPs) for one of the following case studies: a) Analytical Method Change (Biologics), b) Raw Material Change (Oral Drug Product) and c) Manufacturing Process Change to Isolator (Injectable). In addition to providing the first few examples of specific PACMPs in the upcoming PDA Technical Report, PDA will also establish a library of examples for specific global PACMPs that can be leveraged as templates. We will also collect your input on future examples to be used as case studies.

THURSDAY, SEPTEMBER 14, 2017 AGENDA (CONTINUED)

Small Group Discussion *(continued)*

Group 1: Analytical Method Change (Biologic)	**Group 2: Material Change (Oral Drug Product)**	**Group 3: Manufacturing Process Change to Isolator (Injectable)**
Alleviating Regulatory Burden of Post-Approval Method Change	**Raising Requirements in One Country to Achieve Harmonization across Many?**	**Will the PACMP Reduce Regulatory Filing Requirements and Alleviate Supply Chain Concerns?**
Moderator: Kassidy Polk Good, Manager, Global Regulatory Affairs CMC Biologics, *Mylan Inc.*	**Moderator: Kara Follmann,** Senior Director, Global Established Products, Regulatory Affairs Brand CMC, *Pfizer, Inc.*	**Moderator: Karolyn Gale,** Senior Manager Regulatory Affairs, *Emergent BioSolutions*

2:15 p.m. – 2:45 p.m.
Refreshment Break in Exhibit Area

2:45 p.m. – 5:00 p.m.
P4: Closing Plenary: Perspectives on PAC Regulatory Convergence and Manufacturing Innovation
Moderator: Ursula Busse, PhD, MBA, Quality Intelligence, External Relations, *Novartis*

Session Description: After an overview of key messages are collected from the breakout sessions, a panel discussion will bring together thought leaders from the FDA, the international trade association IFPMA, PDA and those in the manufacturing innovation space. Participants will hear firsthand from those involved how international initiatives in the post-approval space will foster regulatory convergence of PAC regulations, encourage adoption of shared principles and facilitate manufacturing innovation globally. This session intends to provide insights into global solutions to PAC regulatory complexity and leave the audience with an outlook into a bright future for manufacturing innovation.

2:45 p.m. – 3:30 p.m.
Breakout Debrief

3:30 p.m. – 4:30 p.m.
Panel Discussion
Regulatory Representative Invited
Regulatory Representative Invited
Susanne Martz, PhD, Senior Vice President of Quality Vaccines, *GlaxoSmithKline,* and Member, IFPMA Vaccines Heads of Quality Group
Morten Munk, Senior Technology Partner, *NNE*
Anders Vinther, PhD, Chief Quality Officer, *Sanofi Pasteur*

4:30 p.m. – 5:00 p.m.
Questions and Answers/Discussion

5:00 p.m.
Closing Remarks and Adjournment
Lisa M. Skeens, PhD, Vice President, Global Regulatory Affairs, *Pfizer, Inc.,* and Co-Chair, *2017 PDA PAC iAM Workshop* Program Planning Committee

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Renaissance Washington, DC Downtown Hotel | Washington, DC
Exhibition: Sept. 13-14 | Courses: Sept. 14-15

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Click: pda.org/2017Pac
Fax: +1 (301) 986-1093 (USA)
Mail: PDA Global Headquarters
4350 East West Highway, Suite 600
Bethesda, MD 20814 USA
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 non-member substituting for a member, you will be required to pay the difference in the non-member 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.

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

2 Premiere Package | 2017 PDA/FDA Joint Regulatory Conference & 2017 PAC iAM Workshop Registration | September 11-14

Please check appropriate fee (US$).

Save up to $750	Member	Non-member
Before June 30, 2017	☐ $ 3,740	☐ $ 4,219
June 30 – Aug. 1, 2017	☐ $ 4,190	☐ $ 4,669
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Complimentary conference registration does not qualify for discount offered for Workshop.
* For this member type or discounted rate, online registration is not available and must be faxed in.

3 2017 PDA PAC iAM WORKSHOP Registration | September 13-14

Please check appropriate fee (US$).

		On or before Aug. 1, 2017	After Aug. 1, 2017
	PDA Member	☐ $ 1,495	☐ $ 1,695
	Non-member	☐ $ 1,695	☐ $ 1,895
Government/ Health Authority	Member	☐ $ 700	☐ $ 700
	Non-member*	☐ $ 800	☐ $ 800
Academic	Member	☐ $ 700	☐ $ 700
	Non-member*	☐ $ 800	☐ $ 800
Student	Member	☐ $ 280	☐ $ 280
	Non-member*	☐ $ 310	☐ $ 310

4 2017 PDA Regulatory Course Series Registration | September 14-15

Please check appropriate fee (US$).

PDA #253 CMC Regulatory Requirements in Drug Applications (September 14)
PDA #524 Quality Culture and Investigations: Best Practices (September 14-15)
PDA #526 CMC Regulatory Compliance for Biopharmaceutical Manufacturing (September 14-15)
PDA #307 Preparing for Regulatory Inspections for the FDA and EMA (September 14-15)

	Course #253	Course #524	Course #526	Course #307
On or before July 31, 2017				
Standard Member	☐ $ 1,169	☐ $ 1,709	☐ $ 1,709	☐ $ 1,709
Non-member	☐ $ 1,403	☐ $ 2,051	☐ $ 2,051	☐ $ 2,051
Government/Health Authority/Academic Member/Non-member*	☐ $ 779	☐ $ 1,139	☐ $ 1,139	☐ $ 1,139
After July 31, 2017				
Standard Member	☐ $ 1,299	☐ $ 1,899	☐ $ 1,899	☐ $ 1,899
Non-member	☐ $ 1,559	☐ $ 2,279	☐ $ 2,279	☐ $ 2,279
Government/Health Authority/Academic Member/Non-member*	☐ $ 779	☐ $ 1,139	☐ $ 1,139	☐ $ 1,139

Have a Campaign Code?

5 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 WORKSHOP 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.
Total amount $

Please bill my: ☐ American Express ☐ MasterCard ☐ VISA
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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 **July 13, 2017,** your credit card will be charged the prevailing rate. **SUBSTITUTIONS:** If you are unable to attend, substitutions can be made at any time, including on-site at the prevailing rate. If you are a non-member substituting for a member, you will be required to pay the difference in the non-member 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/ Workshop:** If your written request is received on or before **July 13, 2017**, 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 ON-SITE. THIS IMPORTANT SECURITY PROCEDURE WILL PREVENT ANYONE OTHER THAN THE REGISTRANT FROM PICKING UP THEIR BADGES AND MATERIALS. REFUNDS FOR COURSES:** If your written request is received by **August 15, 2017**, you will receive a full refund minus a $200 processing fee. After that time, no refunds will be approved. **COURSE CANCELATION:** 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 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. **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.

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