2017 PDA PAC iAM Workshop

Science- and Risk-Based Approaches to Technical Change Management

September 13-14, 2017 | Renaissance Washington, DC Downtown Hotel | Washington, DC

Co-Sponsored by:

IFPMA

As of August 21, 2017

Wednesday, September 13

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

1:00 p.m. – 1:15 p.m.
Welcome and Opening Remarks from Conference Co–Chairs
Ursula Busse, PhD, MBA, Quality Intelligence, External Relations, *Novartis*
Lisa M. Skeens, PhD, Vice President, Global Regulatory Affairs, *Pfizer Inc.*

1:15 p.m. – 2:45 p.m.
P1: Opening Plenary: Why is a Global Dialog 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 dialog 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
Robert L. Iser, MS, Director, Office of Process & Facilities, OPQ, CDER, *FDA*

1:55 p.m. – 2:15 p.m.
International Activities Related to Post-Approval Changes: Opportunities and Challenges
Isabelle Colmagne-Poulard, PharmD, Senior Director Regulatory CMC, Global Regulatory Affairs & Quality Assurance, *Merck KGaA, and member of the IFPMA's Regulatory Policy and Technical Standards (RPTS)*

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.

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
Regulatory Representative Invited

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 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 the lifecycle management (LCM), 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
Mahesh R. Ramanadham, PharmD, Director (Acting), Division of Inspection Assessment, Office of Process and Facility, CDER, *FDA*

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*
Mahesh R. Ramanadham, PharmD, Director (Acting), Division of Inspection Assessment, Office of Process and Facility, CDER, *FDA*
Emma Ramnarine, 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

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

10:30 a.m. – 12:45 p.m.
Interactive Workshop Sessions
Attendees will participate in both breakouts, each 60 minutes long. After Session 1, attendees will switch rooms and the breakouts will be repeated.
Session 1: 10:30 a.m. – 11:30 a.m.
Session 2: 11:45 a.m. – 12:45 p.m.

Session 1: Established Conditions and Change Categorization **Facilitator: Gopi Vudathala, PhD**, Head, Quality Advocacy Liaison, *GSK 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 2: Change Management and the Pharmaceutical Quality System** **Facilitator: Marcello Colao,** Director, Quality Regulatory Compliance, *GlaxoSmithKline Vaccines* **Scribe: Marazban Sarkari,** Director, Pharmaceutical Operations R&D, *Teva Pharmaceutical Industries Ltd. Israel* **Discussion Leader: Morten Munk,** Global Technology Partner, *NNE*
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 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 workshop 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.	**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 as well as their inter-relationship will be explored. In role plays and using 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.

12:45 p.m. – 1:45 p.m.
Networking Lunch

1:45 p.m. – 2:45 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 and take advantage of ICH Q10 and ICH Q12 concepts? In this session, participants can observe, comment, and engage in a dialog on approach, structure, and content of post-approval change management protocols (PACMP) 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.

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

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

3:15 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 collected from the breakout sessions, a panel discussion will bring together thought leaders from FDA, the international trade association IFPMA, PDA, and manufacturing innovation. Participants will hear first-hand 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.

3:15 p.m. – 4:00 p.m.
Breakout Debrief

4:00 p.m. – 5:00 p.m.
Panel Discussion
Sharmista Chatterjee, PhD, Division Director, Office of Process & Facilities, OPQ, CDER, *FDA*
Robert L. Iser, MS, Director, Office of Process & Facilities, OPQ, CDER, *FDA*
Susanne Martz, PhD, Senior Vice President of Quality Vaccines, *GlaxoSmithKline,* and Member of IFPMA Vaccines Heads of Quality Group
Morten Munk, Global Technology Partner, *NNE*
Anders Vinther, PhD, Chief Quality Officer, *Sanofi Pasteur*

5:00 p.m.
Closing Remarks from Conference Co-Chair
Lisa M. Skeens, PhD, Vice President, Global Regulatory Affairs, *Pfizer Inc.*