PQRI-FDA Workshop on Process Drift

Agenda for Workshop

Wednesday, December 1, 2010

8:30 am -12:00 pm
Plenary Session

8:30 am
Workshop Introduction
Moderators
Avi Yacobi, Ph.D.
Taro Pharmaceuticals

Richard L. Friedman
U.S. Food and Drug Administration

8:45 am
Pharmaceutical Quality- How We Build and Maintain it Under a Robust Quality System
Juan JA Andres
Novartis International AG

9:30 am
Ramifications of Process Drift
Zena G. Kaufman
Abbott Laboratories

10:00 am
Coffee Break

10:30 am
Tools for Recognizing and Quantifying Process Drift - Statistical Process Control
J. Scott Tarpley, M.S.
GE Intelligent Platforms, Inc.

11:00 am
Control, Compliance, and Continuous Improvement
Fionnuala M. Walsh, Ph.D.
Eli Lilly and Company

11:30 am
Effect of Process Drift on Quality of Drug Products
Richard L. Friedman
U.S. Food and Drug Administration

12:00 pm
Lunch

1:00 pm – 5:15 pm
Process Drift and its Resolution in the Manufacturing of Active Pharmaceutical Ingredients

1:00 pm
Moderators:
Ira Berry, MBA/MA
International Regulatory Business Consultants, L.L.C.

Carmelo Rosa
U.S. Food and Drug Administration

1:15 pm
Process Drift in the Manufacturing of API's
Nandkumar K. Chodankar, Ph.D.
Excel Industries Limited

1:45 pm
Product Monitoring and Lifecycle Management of Biologic Products Licensed via QbD
Ron Taticek
Genentech

2:15 pm
Detecting, Diagnosing, and Controlling Process Variations: A Review of Modeling Options
Venkat Venkatasubramanian
Purdue University

2:45 pm
Coffee Break

3:15 pm
Case Studies on Process Drift and Resolution
Denise Rivkees, R.Ph., Ph.D.
Pfizer

3:45 pm
Regulatory Implications of Process Drift
David J. Jaworski
U.S. Food and Drug Administration

4:30 pm
Panel Discussion

5:00 pm
Closing Remarks
Avi Yacobi, Ph.D.
Taro Pharmaceuticals

6:00 pm – 7:00 pm
Reception

Thursday, December 2, 2010

8:30 am – 12:30 pm
Process Drift and its Resolution in the Manufacturing of Drug Products

8:30 am
Moderators
Mario L. Rocci, Jr., Ph.D.
ICON Development Solutions

Christine M.V. Moore, Ph.D.
U.S. Food and Drug Administration

8:40 am
Connection Between Quality, Safety, and Efficacy
Roger L.Williams, M.D.
U.S. Pharmacopeia

9:10 am
Tools for Monitoring and Controlling Uniformity of Solid Dosage Forms
Martin Warman
Vertex Pharmaceuticals

9:35 am
Transdermals
Lino A. Tavares, B.S.
Purdue Pharma, L.P.

10:00 am
Coffee Break

10:30 am
MDIs and DPIs
Edward Warner, M.Sc.
Merck

10:55 am
Topicals (Ointments, Suspensions, Creams)
Clarence T. Ueda, Pharm.D.,Ph.D.
University of Nebraska Medical Center

11:20 am
Process Controls in Aseptic Manufacturing: An Overview
Joerg Zimmermann
Vetter Pharma Fertigung GmbH & Co. KG

11:45 am
Process Drift Affects Specification and Shelf-life
Inna Ben-Anat, M.Sc.
Teva Pharmaceuticals USA

12:10 pm
Panel Discussion

12:30 pm
Lunch

1:30 pm – 5:15 pm
Break Out Sessions
– to be repeated four times to allow participants to attend 4 out of 5 sessions

1:30 pm – 2:15 pm
First Round of Breakouts

2:30 pm – 3:15 pm
Second Round of Breakouts

3:30 pm – 4:15 pm
Third Round of Breakouts

4:30 pm – 5:15 pm
Fourth Round of Breakouts

Breakout Session # 1: Definitions and Terms for Describing Process Variation and Process Drift
Moderators
Mario L. Rocci, Jr., Ph.D., ICON Development Solutions
Tara Gooen, U.S. Food and Drug Administration, *Invited*

Breakout Session # 2: What are the Most Frequent Causes of Variation (e.g., manual vs. automation, equipment choices, raw materials) in Pharmaceutical Manufacturing?

Moderators:
Eric W. Richmond, Ph.D., Lachman Consultant Services, Inc.
Vibhakar J. Shah, Ph.D., U.S. Food and Drug Administration

Breakout Session # 3: Current Strategies for Monitoring and Detecting Process Variability
Moderators:
Sonja S. Sekulic, Ph.D., Pfizer
Sharmista Chatterjee, U.S. Food and Drug Administration

Breakout Session # 4: What Evolutions in Industry Management Approaches and the Regulatory Environment Could Promote More Proactive Process Improvement Throughout the Life-cycle?
Moderators:
Glenn A. VanBuskirk, Ph.D., Nonclinical Drug Development Consulting Services, LLC
Steven M. Wolfgang, Ph.D., U.S. Food and Drug Administration

Breakout Session # 5: Impact of Process Drift on Product Performance (Bioavailability, Safety, and Efficacy)
Moderators:
Vinod P. Shah, Ph.D., Pharmaceutical Consultant
Frank Holcombe, Jr., Ph.D., U.S. Food and Drug Administration

Friday, December 3, 2010

8:30 am – 12:30 pm
Opportunities for Minimizing and Preventing Process Drift

8:30 am
Moderator
Raj Uppoor, R.Ph., Ph.D.
U.S. Food and Drug Administration

8:40 am – 10:00 am
Breakout Session Summaries

1: Definitions and Terms for Describing Process Variation and Process Drift
Mario L. Rocci, Jr., Ph.D., ICON Development Solutions

2: What are the Most Frequent Causes of Variation (e.g., manual vs. automation, equipment choices, raw materials) in Pharmaceutical Manufacturing?
Eric W. Richmond, Ph.D., Lachman Consultant Services, Inc.

3: Current Strategies for Monitoring and Detecting Process Variability
Sonja S. Sekulic, Ph.D., Pfizer

4: What Evolutions in Industry Management Approaches and the Regulatory Environment Could Promote More Proactive Process Improvement Throughout the Life-cycle?
Glenn A. VanBuskirk, Ph.D., Nonclinical Drug Development Consulting Services, LLC

5: Impact of Process Drift on Product Performance (Bioavailability, Safety, and Efficacy)
Vinod P. Shah, Ph.D., Pharmaceutical Consultant

10:00 am
Coffee Break

10:30 am
Managing Change in Manufacturing
Nigel Hamilton, B.Sc.
Sanofi-Aventis

11:00 am
Collaborations for Success
PQRI: An Industry, Regulatory, and Academic Consortium
Anthony J. DeStefano, Ph.D.
Chair, PQRI Steering Committee

11:30 am
Process Validation for Life-cycle Management of Product Quality and Product Performance
Grace E. McNally
U.S. Food and Drug Administration

12:00 pm
Panel Discussion

12:30 pm
Closing Comments
Richard L. Friedman
U.S. Food and Drug Administration