Monday, September 12, 2011

8:30 am – Cabinet/Judiciary Room
Workshop Introduction
Sonja S. Sekulic , Ph.D., Pfizer, Inc.
Karthyk B. Iyer, Ph.D., U.S. Food and Drug Administration
Fernando J. Muzzio, Ph.D., Rutgers University

8:45 am
Moderator:
Sonja S. Sekulic , Ph.D., Pfizer, Inc.

8:45 am
FDA Perspectives on Larger Sample Sizes – Role of Regulators vs. USP vs. ASTM
Keith Webber
U.S. Food and Drug Administration

9:15 am
The European Approach on Large Sample Sizes in the Context of a PAT Environment
Michael Wierer, Ph.D.
EDQM/ Council of Europe

9:45 am
The Role of USP
Anthony DeStefano, Ph.D.
U.S. Pharmacopeia

10:15 am – 10:30 am
Coffee Break

10:30 am
Designing and Optimizing Sample Plans
Swee-Teng Chin, Ph.D.
Dow Chemical Company

11:15 am
Underlying Quality Considerations
Terrence Tougas, Ph.D.
Boehringer Ingelheim Pharmaceuticals

12:00 pm
Lunch **Concours Terrace on Lobby Level**

1:00 pm Cabinet/Judiciary Room
Moderator
John Peterson, Ph.D., GlaxoSmithKline

1:00 pm
PTIT Approach: Developing Tolerance Interval Approach for Quality Assessment with Large Sample Sizes
Yi Tsong, Ph.D.
U.S. Food and Drug Administration

1:30 pm
Content Uniformity Acceptance Testing for Large Sample Sizes: Nonparametric Counting Test
Kim Vukovinsky
Pfizer Inc.

2:00 pm
The European Pharmacopeia Draft on Large Sample Sizes
Oyvind Holte, Ph.D.
Norwegian Medicines Agency

2:30 pm
Demonstrating Capability to Comply with a Test Procedure: The Content Uniformity and Dissolution Acceptance Limits (CuDAL) Approach
Jim Bergum
Bristol Myers Squibb

3:00 pm – 3:15 pm
Coffee Break

<u>Breakout sessions</u>
3:15 pm – 4:00 pm
Breakout Sessions will be repeated twice so all participants may attend both sessions.

Breakout 1: How Should We Be Testing for Pharmaceutical Process Control and Batch Release? **Cabinet/Judiciary Room**
Moderators:
Karthik B. Iyer, Ph.D., U.S. Food and Drug Administration
Kim Vukovinsky, Pfizer Inc.

Breakout 2: What are the Regulatory Risks and Benefits of Smaller vs. Larger Sample Size Acceptance Criteria? **Old Georgetown Room**
Moderators:
Lori Pfahler, Ph.D., Merck & Co., Inc.
Sau (Larry) Lee, U.S. Food and Drug Administration

4:00 pm – 4:45 pm
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4:45 pm – 5:30 pm
Day 1 Panel Question and Answer Session

6:00 pm – 7:30 pm
Reception Concours Terrace on Lobby Level

Tuesday, September 13, 2011

8:00 am Cabinet/Judiciary Room
Moderator
Karthik B. Iyer, Ph.D. , U.S. Food and Drug Administration

8:00 am
Focus Area: Blend Uniformity
Fernando J. Muzzio, Ph.D.
Rutgers University

8:45 am
Focus Area: Content Uniformity – Current Landscape
Steve Hammond
Pfizer Inc.

9:30 am – 10:00 am
Coffee Break

10:00 am
In-Process Particle Characterization – Regulatory Perspective
Zhigang Sun, Ph.D.
U.S. Food and Drug Administration

10:30 am

In-Process Particle Characterization – Industry Perspective
Gregory Connelly, Ph.D.
Vertex Pharmaceuticals, Inc.

11:00 am
Merck Case Study: Half a Decade of Real-Time Release Testing on a High Volume Product
Gert Thurau, Ph.D.
Merck & Co., Inc.

12:00 pm – 1:00 pm
Lunch **Concours Terrace on Lobby Level**

1:00 pm **Cabinet/Judiciary Room**
Moderator
Fernando J. Muzzio, Ph.D. , Rutgers University

1:00 pm
Process Validation Guidance – What Does 'Statistical Confidence' Mean?
Francis Godwin
U.S. Food and Drug Administration

1:30 pm
Challenges of Statistical Analysis/Control in a Continuous Process
Fernando J. Muzzio, Ph.D.
Rutgers University

2:00 pm
Continuous Manufacturing – FDA Perspective on Submissions and Implementations
Christine Moore, Ph.D.
U.S. Food and Drug Administration

2:30 pm – 2:45 pm
Coffee Break

Breakout Sessions
2:45 pm – 3:30 pm
Breakout Sessions will be repeated twice so all participants may attend both sessions.

Breakout Session #3: How Do We Integrate a Large Sample Size Approach into Pharmaceutical Quality Systems? **Cabinet/Judiciary Room**
Moderators:
Fernando J. Muzzio, Ph.D., Rutgers University
Zhigang Sun, Ph.D., U.S. Food and Drug Administration

Breakout Session # 4: Are Pharmaceutical Companies and Regulatory Agencies Prepared for a Lifecycle Approach to Product Quality? **Old Georgetown Room**

Moderators:
Christine Moore, Ph.D., U.S. Food and Drug Administration
Gert Thurau, Ph.D., Merck & Co., Inc.

3:30 pm – 4:15 pm
Breakout Session #3: How Do We Integrate a Large Sample Size Approach into Pharmaceutical Quality Systems? **Cabinet/Judiciary Room**
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4:15 pm
Breakout Reports Cabinet/Judiciary Room
Day 1 – BO Session 1
Day 1 – BO Session 2
Day 2 – BO Session 3
Day 2 – BO Session 4

5:00 pm
General Question and Answer Session

5:30 pm
Closing Remarks
Sonja S. Sekulic , Ph.D., Pfizer, Inc.
Karthyk B. Iyer, Ph.D., U.S. Food and Drug Administration
Fernando J. Muzzio, Ph.D., Rutgers University

SPECIAL MEETING
Wednesday, September 14, 2011
8:30 am – 4:30 pm Executive Boardroom
Workshop Planning Committee Meeting