Monday, September 12, 2011

8:30 am – Cabinet/Judiciary Room
Workshop Introduction
Sonja S. Sekulic, Ph.D., Pfizer, Inc.
Karthik 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  

Breakout sessions  
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

**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

4:45 pm – 5:30 pm

**Day 1 Panel Question and Answer Session**

6:00 pm – 7:30 pm

**Reception**  
Concours Terrace on Lobby Level

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**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**

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.

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.
Karthik B. Iyer, Ph.D., U.S. Food and Drug Administration
Fernando J. Muzzio, Ph.D., Rutgers University

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