

Agenda for 2007 Pharmaceutical Process Analytics Roundtable

Hosted by Merck & Co, Inc, West Point, PA

Merck Upper Gwynedd Site, 351 N Sumneytown Pike
North Wales, PA 19454
Room 2CDN107 & 2CDN108

Tuesday, 09 October 2007

7:00 – 10:00 pm Informal Reception

Cravings Restaurant, North Wales (cash bar)

155 Pennbrook Parkway, Lansdale, PA 19446
(across the street from Homewood Suites Hotel)

This provides an informal opportunity to relax and introduce themselves to the group or propose additional topics for discussion.

Wednesday, 10 October 2007

7:30 – 8:30 am	Breakfast
8:30 am	Introductions - Gert Thureau
8:30 – 8:45 am	Welcoming remarks - Mike Thien VP, Global Pharmaceutical Commercialization, Merck
8:45 – 9:00 am	PPAR Meeting introduction - Gert Thureau
9:00 – 10:15 am	What is the (current) definition of PAT, what is it's role in/relationship to QbD? (D. Low)
10:15 – 10:30 am	Break
10:30 – 12:00 pm	Experiences from a PAT implementation example in the pharmaceutical environment (S. Doherty) Including technology experiences and implementation lessons
12:00 – 1:30 pm	Lunch
1:30 – 3:00 pm	Experiences from a PAT implementation example in the bio-pharmaceutical environment (T. Larson) Including technology experiences and implementation lessons
3:00 – 3:30 pm	Transportation
3:30 – 5:00 pm	Plant/Laboratory Tour, Merck West Point GPC
5:30 – 8:30 pm	Reception, William Penn Inn

Thursday, 11 October 2007

8:00 – 8:30 am	Breakfast
8:30 – 10:30 am	PAT/QbD – Review of selected currently actively pursued standards/white paper/guidance documents (D. Low, G. Thureau, J. Gustaffson) Including ASTM E 55, ISPE white paper, PhRMA teams, etc.
10:30 – 10:45 am	Break
10:45 – 12:00 am	PAT implementation with contract manufacturers (A. Lange)
12:00 – 1:00 pm	Lunch
1:00 – 2:00 pm	Use of multivariate analysis/latent variable modeling for PAT (J. Ganguly)
2:00 – 3:15 pm	PAT Benchmarking 2007 Survey Results (K. Klopfer)
3:15 – 3:45 pm	PPAR 2007 Feedback from attendees and 2008 host suggestions
3:45 pm	Closing Remarks and Adjourn (G. Thureau)