



Association for GXP Excellence Meeting

When : Friday, May 15, 2015

Time: 9:00 AM to 3:30 PM

**Where: Harleysville Community Room, 290 Main Street
Harleysville, PA 19438**

----- Agenda Topics -----

Welcome & Logistics	Vince Ranieri – Manager Lab Analyst Training & Certification, J&J	9:00 – 9:10 am
Organization Update & Conference Information	John Lewis, Quality Engineer, Merck	9:15 – 9:45 am
Membership Share-to-the-Point (items that you are working on; areas you need additional information or help; things you want to share)	ALL	9:45 – 10:00 am
“Comparison of Quality by Design (QbD) of (Bio)Pharmaceuticals with Design Control process of Medical Device for Combination Product”	Himanshu Naik, RAC, CQA, QA Manager, BMS Pallavi Gandhi, M.S. RPh, RAC, QA Specialist, BMS	10:00 – 11:00 am
Vendor Share Out – Virtual Training on Technical Documentation: Investigation Reports and SOPs	Mike Mannon, President WD Communications	11:00 – 11:45 am
Lunch – Check out the Job Board!	ALL	11:45 – 12:45 pm
Speed Training – GMP Exercise	Terry McGinn – Sr. Mgr. Quality Training, Teva	12:45 – 1:15 pm
Training Effectiveness and 21CFR Part 211.25	Ken Petelinkar, Associate Director Compliance Systems, BMS	1:15 – 2:00 pm
Regulatory Updates (483s and Warning Letters) – a review of new and emerging trends in our industry	John Lewis, Quality Engineer, Merck	2:00 – 2:30 pm
Laboratory Training Requirements	Vince Ranieri – Manager Lab Analyst Training & Certification, J&J	2:30 – 3:00 pm
Meeting Close (Future Mtg. Sponsors, Topics and Presenters)		3:00 – 3:15 pm