



Association for GXP Excellence Meeting

When : February 19, 2016

Time: 9:00 AM to 3:30 PM

Where: Bristol-Myers Squibb Company - 3553 Lawrenceville Road
Princeton, NJ 08540 - Room K4-000-CR

Note: Use Parking Lot 1 - Visitors Parking

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

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Coffee and Network	All	8:30 - 9:00 am
Welcome & Logistics	Ken Petelinkar - BMS	9:00 – 9:10 am
Organization Update & Conference Information	John Lewis - Merck	9:10 – 9:30 am
GMP - Serialization Operator Readiness - an overview of the regulations and terminology in order to set the stage, but the core material will address how to train people to work in this highly integrated and automated environment which ties in to numerous internal and external systems and companies.	Patrick Boyle - Skillpad	9:30 – 10:50 am
Networking Break	ALL	10:50 – 11:15 am
GLP – Good Laboratory Practice (GLP) Overview training based on the FDA's 21 CFR 58	Vincent Ranieri – J&J	11:15 – 12:00 pm
Lunch – Check out the Job Board! Membership Share-to-the-Point (items that you are working on; areas you need additional information or help; things you want to share)	ALL	12:00 – 1:00 pm
ISO – Achieving and Maintaining ISO Certification	Al Madeley - Hibbert	1:00 – 1:30 pm
Emerging Inspection Trends at FDA	Jack Garvey – Compliance Architects	1:30 – 2:00 pm
Networking Break	ALL	2:00 - 2:20 pm
Solving Document Training Issues Using Your LMS	Daniel Duncan – J&J	2:20 – 3:15 pm
Meeting Close (Future Mtg. Sponsors, Topics and Presenters)	John Lewis - Merck	3:15 – 3:30 pm

Note: All Agendas are subject to change