

AMDM 2013 Focus Meeting

AMDM Focus Meeting
October 24– 25, 2013



Day 1 / Thursday October 24th Agenda:

8:00 – 8:30 am	Registration / Continental Breakfast	Room: Ballroom
8:30 – 9:00	Industry Update Jing Zhang, BD	
9:00 – 9:30	FDA Update on Guidance, Activities and Policy Issues Donald St. Pierre, Deputy Director, New Product Evaluation, OIVD, FDA <i>(Video Link)</i>	
9:30 – 10:00	Compliance/Inspections Trend Joshua Levin, Lead Consumer Safety Officer, SVGR, FDA <i>(Video Link)</i>	
10:00 – 10:30	Q&A Session	
10:30 – 11:00	Break	
11:00 – 11:30	Legislative Update James Boiani, Epstein, Becker, Green	
11:30 – 12:00	Next Generation Sequencing in the Clinical Laboratory Dr. Jamie Platt, Quest/Nichols Institute	
12:00 – 12:30	Update on Reimbursement for Molecular Tests Perry Dimas, Premier Source Diagnostics	
12:30 – 1:30	Lunch	
1:30 – 2:15	IVDD Recast Updates Sue Spencer, BSI	
2:15 – 2:45	IVDs in Brazil Carl McEvoy, McEvoy & Farmer LLC	
2:45 – 3:15	Regulations in China Jing Zhang, BD	
3:15 – 3:30	Break	
3:30 – 4:00	Recommendations for CLIA Waiver Applications for Manufacturers of In Vitro Diagnostic Devices Erika Ammirati, Ammirati Consulting	
4:00 – 4:30	Medical Device Reporting for IVDs Regina O'Mera, IVD Regulatory Consulting	

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Day 2 / Friday October 25th Agenda:

8:00 – 8:30 am	Continental Breakfast
8:30 – 9:00	FDA Guidance Hot Topics: Molecular Diagnostic Instruments with Combined Functions Lynne McBride, Life Technologies
9:00 – 9:30	FDA Guidance Hot Topics: Pre-Submission Guidance Review Elizabeth Hillebrenner, Policy Analyst, FDA (<i>Video Link</i>)
9:30 – 10:00	FDA Guidance Hot Topics: Unique Device Identifier Valynda Machen, NAMSA
10:00 – 10:30	FDA Guidance Hot Topics: Factors to Consider When Making Benefit-Risk Determinations Praful Deshmane, Sakura
10:30 – 11:00	Break & Hotel Check-Out
11:00 – 11:30	Companion Diagnostics: IDE Considerations for Cdx David Litwack, Personalized Medicine Staff, FDA (<i>Video Link</i>)
11:30 – 12:00	Companion Diagnostics: Successful Case Study Leslie Farrington, Roche Molecular Systems
12:00 – 12:30	Companion Diagnostics: Latest Challenges Pat Roche, Ventana Medical Systems
12:30	Adjourn / Box Lunches Available
