2013 AMDM Annual Meeting Agenda

Wednesday

April 17, 2013
11:00 a.m. – 5:45 p.m.

11:00 – 11:15 a.m.	**Welcome** Judi Smith, AMDM President Karin Hughes, AMDM Annual Meeting Co-Chair Donna Link, AMDM Annual Meeting Co-Chair	Room: White Flint Amphitheatre
11:15 – 12:15	**Roundtable Discussion with OIR Management Team** Alberto Gutierrez, Ph.D., Director, Office of In Vitro Diagnostics and Radiological Health *alberto.gutierrez@fda.hhs.gov*	
12:15 – 1:15	**Lunch**	White Oak
1:15 – 2:00	**IVD Industry Overview** Jonathan Kahan, Partner, Hogan Lovells *Jonathan.kahan@hoganlovells.com*	
2:00 – 2:30	**Pre-De Novo /De Novo Submission Process** Scott McFarland, Policy Advisor, CDRH, FDA *scott.mcfarland@fda.hhs.gov*	
2:30 – 2:45	**Break**	
2:45 – 3:15	**Ten Tips for IVD Manufacturers** Jeffrey N. Gibbs, Director, Hyman, Phelps & McNamara *jgibbs@hpm.com*	
3:15 – 3:45	**Mobile Medical Applications Guidance** Brendan O'Leary, Public Health Analyst, CDRH, OIR *brendan.oleary@fda.hhs.gov*	
3:45 – 4:00	**Break**	
4:00 – 4:45	**EP-17A CLSI Guideline on Determination Limits of Detection & Quantitation** (Focus on LoQ and total error specification) **Marina V. Kondratovich, Ph.D., Associate Director for Clinical Studies, Personalized Medicine, OIR, CDRH, FDA** ***marina.kondratovich@fda.hhs.gov***	
4:45 – 5:15	**How to Successfully Migrate Assays following the 2009 FDA Draft Guidance Policy** Christopher Bentsen, Manager, Regulatory Affairs, Quality Assurance and Clinical Affairs, Bio-Rad Laboratories *Christopher_bentsen@bio-rad.com*	
5:15 – 5:45	**AMDM Annual Business Meeting**	

2013 AMDM Annual Meeting Agenda

Thursday

April 18, 2013
9:00 a.m. – 3:00 p.m.

8:00 –9:00 a.m.	**Complimentary Breakfast Buffet**	White Flint Amphitheatre
9:00 – 9:45	**The Changing Regulatory Environment-What to Expect in 2013 and Beyond** Rick Naples, Sr. VP, Regulatory Affairs, Becton-Dickinson *Christine_ pasquariello@bd.com*	
9:45 – 10:30	**Personalized Medicine** Elizabeth Mansfield, Ph.D., Director, Personalized Medicine, OIR, CDRH, FDA *elizabeth.mansfield@fda.hhs.gov*	
10:30 – 10:45	**Break**	
10:45 – 11:30	**The Future of LDT's and their Impact on the IVD Industry** Bradley Merrill Thompson, Member of the Firm, Epstein Becker Green *BThompson@EBGLAW.com*	
11:30 –12:00	**Compliance Update: What's Old is New Again** Sheri Hall, Vice President, Quality & Regulatory Affairs, BD Bioscience *Sheri.hall@bd.com*	
12:00 – 1:00	**Lunch**	White Oak
1:00 – 1:30	**Changes to the IVD Regulations in Europe: What, When, Hot Topics and Areas of Uncertainty** Sue Spencer, Head of IVD BSI Group, United Kingdom *Sue.spencer@bsigroup.com*	
1:30 – 2:00	**Trends in IVD Deficiencies-A Compliance Perspective** Joshua Levin, Lead Consumer Safety Officer, SVGR, FDA *Joshua.levin@fda.hhs.gov*	
2:00 - 2:15	**Review & Wrap Up** Judi Smith, AMDM President Karin Hughes, AMDM Annual Meeting Co-Chair Donna Link, AMDM Annual Meeting Co-Chair	