2014 AMDM Annual Meeting Agenda

Online evaluation at: amdm.org/amevaluation.html

Wednesday

April 9, 2014
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, FDA *alberto.gutierrez@fda.hhs.gov*	
12:15 – 1:15	**Lunch**	Brookside
1:15 – 2:00	**IVD Industry Overview** Jonathan Kahan, Partner, Hogan Lovells *Jonathan.kahan@hoganlovells.com*	
2:00 – 2:30	**Use of Investigational Devices in Therapeutic Trials** David Litwack, CDRH, FDA *david.litwack@fda.hhs.gov*	
2:30 – 2:45	**Break**	
2:45 – 3:15	**Ten Tips for IVD Manufacturers in 2014** Jeffrey N. Gibbs, Director, Hyman, Phelps & McNamara *jgibbs@hpm.com*	
3:15 – 3:45	**Distribution of In Vitro Diagnostic Products Labeled for RUO & IVD Only Use** Shyam Kalavar, CDRH, OIR *Shyam.kalavar@fda.hhs.gov*	
3:45 – 4:00	**Break**	
4:00 – 4:45	**CLSI Guideline EP17 and EP12: Limits of Detection and Performance Near Cutoff for Qualitative Tests** Marina V. Kondratovich, Ph.D., Associate Director for Clinical Studies, Personalized Medicine, OIR, CDRH, FDA *marina.kondratovich@fda.hhs.gov*	
4:45 – 5:15	**The De Novo Process: Making It Work** Mark Del Vecchio, Sr. Director, Regulatory Affairs, BD Diagnostics *Mark_A_Del_Vecchio@bd.com*	
5:15 – 5:45	**AMDM Annual Business Meeting**	

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Thursday

April 10, 2014
9:00 a.m. – 3:15 p.m.

8:00 –9:00 a.m.	**Complimentary Breakfast Buffet**	White Flint Amphitheatre
9:00 – 9:45	**The Changing Regulatory & Policy Environment for Diagnostics - What to Expect in 2015 and Beyond** Rick Naples, Sr. VP, Regulatory Affairs, Becton-Dickinson *Christine_ pasquariello@bd.com*	
9:45 – 10:30	**Companion Diagnostics Update and Co-Development** Pamela Bradley, OIR, CDRH, FDA *Pamela.bradley@fda.hhs.gov* Jennifer Shen, OIR, CDRH, FDA *Jennifer.shen@fda.hhs.gov*	
10:30 – 10:45	**Break**	
10:45 – 11:30	**The future of FDA regulation of HIT, including mHealth** Bradley Merrill Thompson, Member of the Firm, Epstein Becker Green *BThompson@EBGLAW.com*	
11:30 –12:00	**Meeting the Clinical Utility Needs of Regulators and Payers for IVDs and Companion Diagnostics** Judi Smith, VP, In Vitro Diagnostics & Quality, Precision for Medicine *Judi.smith@precisionformedicine.com*	
12:00 – 1:00	**Lunch**	Brookside
1:00 – 1:45	**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*	
1:45 – 2:25	**UDI Implementation for IVDs** Steve Gitterman, FDA *steve.gitterman@fda.hhs.gov*	
2:25 - 3:00	**IQCP: How We Can Help Our Customers** Andy Quintenz, Scientific & Professional Affairs Manager, Bio-Rad Laboratories *Andy_quintenz@bio-rad.com*	
3:00 - 3:15	**Review & Wrap Up** Judi Smith, AMDM President Karin Hughes & Donna Link AMDM Annual Meeting Co-Chairs	