



2015 AMDM Annual Meeting Agenda

Online evaluation at: amdm.org/amevaluation.html

Wednesday

April 22, 2015

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 <i>alberto.gutierrez@fda.hhs.gov</i>	
12:15 – 1:15	Lunch	White Oak A
1:15 – 2:00	IVD Industry Overview Jonathan Kahan, Partner, Hogan Lovells <i>Jonathan.kahan@hoganlovells.com</i>	
2:00 – 2:30	MDSAP Single Audit Program Kim Trautman, FDA <i>kimberly.trautman@fda.hhs.gov</i>	
2:30 – 2:45	Break	
2:45 – 3:15	In Vitro Diagnostic Promotion: Social Media & Beyond Jeffrey N. Gibbs, Director, Hyman, Phelps & McNamara <i>jgibbs@hpm.com</i>	
3:15 – 3:45	In Vitro Companion Diagnostic Device – Case Studies Melissa Barhoover, Ph.D., Clinical & Regulatory Affairs Manager, Beaufort, LLC / <i>MBarhoover@BeaufortCRO.com</i>	
3:45 – 4:00	Break	
4:00 – 4:45	Flu Antigen Detection Test Systems Reclassification Stefanie Akselrod, CDRH, FDA <i>Stefanie.akselrod@fda.hhs.gov</i>	
4:45 – 5:20	Generating Evidence: A Critical Step in Diagnostic Test Development Katherine Tynan, President, Tynan Consulting, LLC <i>katherine.tynan@tynandx.com</i>	
5:20	AMDM Annual Business Meeting immediately followed by our Welcome Reception	



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Thursday

April 23, 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 Robert Di Tullio, Di Tullio Consulting Inc. <i>robert@ditullioconsulting.com</i>	
9:45 – 10:30	LDT and Risk Based Regulatory Framework & Personalized Medicine Update Liz Mansfield, OIR, CDRH, FDA <i>Elizabeth.mansfield@fda.hhs.gov</i>	
10:30 – 10:45	Break	
10:45 – 11:30	Risk-based Regulation of Diagnostics: LDTs, Transitional IVDs, CLIA Waivers, and Dreams of Regulatory Reform James Boiani, Epstein Becker Green <i>JBoiani@EBGLAW.com</i>	
11:30 – 12:00	UDIs for IVDs. The Letters, Numbers, and Barcodes of the Unique Device Identifier Requirements Lina Kontos, Hogan Lovells <i>lina.kontos@hoganlovells.com</i>	
12:00 – 1:00	Lunch	White Oak A
1:00 – 1:45	Changes to the IVD Regulations in Europe Ann Goodall, BSI Group <i>Ann.Goodall@bsigroup.com</i>	
1:45 – 2:25	Premarket Submissions and Cybersecurity Bakul Patel, FDA <i>Bakul.patel@fda.hhs.gov</i>	
2:25 - 3:00	eMDR Guidance Isaac Chang, FDA <i>Isaac.chang@fda.hhs.gov</i>	
3:00 - 3:15	Review & Wrap Up Judi Smith, AMDM President Karin Hughes & Donna Link AMDM Annual Meeting Co-Chairs	
