2015 AMDM Annual Meeting Agenda

Meeting materials online: *www.amdm.org/2015-am-presentations.html*
Evaluation at: *www.amdm.org/amevaluation.html*
Password: AMDM2015

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 *alberto.gutierrez@fda.hhs.gov*	
12:15 – 1:15	**Lunch**	White Oak A
1:15 – 2:00	**IVD Industry Overview** Jonathan Kahan, Partner, Hogan Lovells *Jonathan.kahan@hoganlovells.com*	
2:00 – 2:30	**MDSAP Single Audit Program** Kim Trautman, FDA *kimberly.trautman@fda.hhs.gov*	
2:30 – 2:45	**Break**	
2:45 – 3:15	**In Vitro Diagnostic Promotion: Social Media & Beyond** Jeffrey N. Gibbs, Director, Hyman, Phelps & McNamara *jgibbs@hpm.com*	
3:15 – 3:45	**In Vitro Companion Diagnostic Device – Case Studies** Melissa Barhoover, Ph.D., Clinical & Regulatory Affairs Manager, Beaufort / *MBarhoover@BeaufortCRO.com*	
3:45 – 4:00	**Break**	
4:00 – 4:45	**Flu Antigen Detection Test Systems Reclassification** Stefanie Akselrod, CDRH, FDA ***Stefanie.akselrod@fda.hhs.gov***	
4:45 – 5:20	**Generating Evidence: A Critical Step in Diagnostic Test Development** Katherine Tynan, President, Tynan Consulting, LLC *katherine.tynan@tynandx.com*	
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, Sr. VP of Global Regulatory Services, Beaufort *Rditullio@beaufortcro.com*	
9:45 – 10:30	**LDT and Risk Based Regulatory Framework & Personalized Medicine Update** Liz Mansfield, OIR, CDRH, FDA *Elizabeth.mansfield@fda.hhs.gov*	
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 *JBoiani@EBGLAW.com*	
11:30 –12:00	**UDIs for IVDs. The Letters, Numbers, and Barcodes of the Unique Device Identifier Requirements** Lina Kontos, Hogan Lovells *lina.kontos@hoganlovells.com*	
12:00 – 1:00	**Lunch**	White Oak A
1:00 – 1:45	**Changes to the IVD Regulations in Europe** Ann Goodall, BSI Group *Ann.Goodall@bsigroup.com*	
1:45 – 2:25	**Premarket Submissions and Cybersecurity** Bakul Patel, FDA *Bakul.patel@fda.hhs.gov*	
2:25 - 3:00	**eMDR Guidance** Isaac Chang, FDA *Isaac.chang@fda.hhs.gov*	
3:00 - 3:15	**Review & Wrap Up** Judi Smith, AMDM President Karin Hughes & Donna Link AMDM Annual Meeting Co-Chairs	