2016 AMDM Annual Meeting Agenda

Wednesday

April 20, 2016
11:00 a.m. – 5:45 p.m.

11:00 – 11:15 a.m.	**Welcome** Karin Hughes, AMDM President Donna Link, Karen Richard, Annual Meeting Co-Chairs	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** Susan Tiedy-Stevenson, Sr. Director of Reg. Sciences, Hogan Lovells *susan.tiedy-stevenson@hoganlovells.com*	
2:00 – 2:30	**ISO 13485 Update** Stefan Burde, IVD Product Expert, BSI Americas *Stefan.burde@bsigroup.com*	
2:30 – 2:45	**Break**	
2:45 – 3:15	**Two New Developments: Promoting IVDs and FDA Regulation of LDTs** Jeffrey N. Gibbs, Director, Hyman, Phelps & McNamara *jgibbs@hpm.com*	
3:15 – 3:45	**How Western IVD Manufacturers Can Succeed in Asia** Ames Gross, President, Pacific Bridge *adgross@pacificbridgemedical.com*	
3:45 – 4:00	**Break**	
4:00 – 4:40	**De-Identified Specimens and Implications of Proposed Rulemaking—What You Need to Know** Khatereh Calleja, JD, Sr. VP Technology & Reg. Affairs, AdvaMed *KCalleja@AdvaMed.org*	
4:40 – 5:20	**MDSAP Update** Neil Mafnas, Office of Compliance, CDRH, FDA *Neil.Mafnas@fda.hhs.gov*	
5:20	**AMDM Annual Business Meeting** immediately followed by our **Welcome Reception**	

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Thursday

April 21, 2016
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 2016 and Beyond** Thomas Soriano, President, DOCRO *Tsoriano@docro.com*	
9:45 – 10:30	**Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approvals and De Novo Classifications** Paula Caposino, FDA *Paula.Caposino@fda.hhs.gov*	
10:30 – 10:45	**Break**	
10:45 – 11:30	**Direct to Consumer Testing** Irene Tebbs, FDA *Irene.Tebbs@fda.hhs.gov*	
11:30 –12:00	**Direct De Novo Process Update** **(results of program and consideration of expedited access program, if time permits)** James Mullally, FDA *James.Mullally@fda.hhs.gov*	
12:00 – 1:00	**Lunch**	White Oak A
1:00 – 1:45	**Changes to the IVD Regulations in Europe** Stefan Burde, IVD Product Expert, BSI Group *Stefan.burde@bsigroup.com*	
1:45 – 2:25	**Impact of the Upcoming Changes to the IVDR: Meeting New Clinical Evidence Requirements** Carol Ryerson, Principal Advisor, RCRI *cryerson@rcri-inc.com*	
2:25 - 2:45	**Review & Wrap Up** Karin Hughes, Donna Link, Karen Richards, Annual Meeting Co-Chairs	