2018 AMDM Annual Meeting Agenda

Wednesday
April 18, 2018
11:00 a.m. – 5:45 p.m.

11:00 – 11:15 a.m.	**Welcome** Ann Quinn, AMDM Meeting Co-Chair Karen Richards, Carol Ryerson, Annual Meeting Co-Chairs	Room: White Flint Amphitheatre
11:15 – 12:15	**Roundtable Discussion with OIR Management Team** Donald St. Pierre / Elizabeth Hillebrenner, Office of In Vitro Diagnostics and Radiological Health, FDA *don.st.pierre@fda.hhs.gov* *elizabeth.hillebrenner@fda.hhs.gov*	
12:15 – 1:15	**Lunch**	Brookside A
1:15 – 2:00	**IVD Industry Overview** Jonathan Kahan, Partner, Hogan Lovells *jonathan.kahan@hoganlovells.com*	
2:00 – 2:30	**Regulatory Considerations for Genetic Apps on a Personal Genomics Platform- The Helix Story** Gloria Lee, Director, Regulatory Affairs & Quality Assurance, Helix *gloria.lee@helix.com*	
2:30 – 2:45	**Break**	
2:45 – 3:30	**Personalized Medicine Update/Apps as Medical Devices** Adam Berger, Office of Compliance, CDRH, FDA *Adam.Berger@fda.hhs.gov*	
3:30 – 4:15	**Diagnostics Update** Khatereh Calleja, JD, Sr. VP Technology & Reg. Affairs, AdvaMed *KCalleja@AdvaMed.org*	
4:15 – 5:00	**Statistical Considerations for Companion Diagnostic Studies** Marina Kondratovich, Office of Compliance, CDRH, FDA *Marina.Kondratovich@fda.hhs.gov*	
5:00	**AMDM Annual Business Meeting** Liz Lison, AMDM President	
5:15	**AMDM Welcome Reception**	

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Thursday
April 19, 2018
9:00 a.m. – 3:15 p.m.

8:00 –9:00 a.m.	**Complimentary Breakfast Buffet**	White Flint Amphitheatre
9:00 – 9:45	**Top 10 FDA Guidances for IVD Companies** Allyson Mullen, Hyman, Phelps & McNamara *amullen@hpm.com*	
9:45 – 10:30	**Challenges of CLIA Waiver Process as a First to Market Product – Sysmex XW-100** Tamara Pinkney, Office of Compliance, CDRH, FDA *Tamara.Pinkney@fda.hhs.gov* Peter Shearstone, VP, RA/QA/Clinical & Medical Affairs, Sysmex America *shearstonep@sysmex.com*	
10:30 – 10:45	**Break**	
10:45 – 11:15	**Replacement Reagent and Instrument Family Policy Guidance** Avis Danishefsky, CDRH, FDA *Avis.Danishefsky@fda.hhs.gov*	
11:15 –11:35	**De Novo Process Experience** Karin Hughes, Vice President Clinical & Regulatory Strategy, Astute Medical, Inc. *khughes@astutemedical.com*	
11:35 – 12:00	**Companion Diagnostics Experience** Lesley Farrington, Director of Global Regulatory Affairs Diagnostics, Janssen *LFarring@its.jnj.com*	
12:00 – 1:00	**Lunch**	White Oak A
1:00 – 1:30	**Program for FDA-CMS Parallel Review: What You Need to Know** Rochelle Fink, CDRH, FDA *Rochelle.Fink@fda.hhs.gov*	
1:45 – 2:25	**Reimbursement for Business Success** Tom Hughes, Sr. Principal Advisor Health Economics & Reimbursement, RCRI *thughes@rcri-inc.com*	
2:25 – 3:00	**IVDR Update** Judi Smith, VP, In Vitro Diagnostics & Quality, Precision for Medicine *Judi.smith@precisionformedicine.com*	
3:00 - 3:15	**Review & Wrap Up** Ann Quinn, Karen Richards, Carol Ryerson, Meeting Co-Chairs	