



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 <i>don.st.pierre@fda.hhs.gov elizabeth.hillebrenner@fda.hhs.gov</i>	
12:15 – 1:15	Lunch	Brookside A
1:15 – 2:00	IVD Industry Overview Jonathan Kahan, Partner, Hogan Lovells <i>jonathan.kahan@hoganlovells.com</i>	
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 <i>gloria.lee@helix.com</i>	
2:30 – 2:45	Break	
2:45 – 3:30	Personalized Medicine Update/Apps as Medical Devices Adam Berger, Office of Compliance, CDRH, FDA <i>Adam.Berger@fda.hhs.gov</i>	
3:30 – 4:15	Diagnostics Update Khatereh Calleja, JD, Sr. VP Technology & Reg. Affairs, AdvaMed <i>KCalleja@AdvaMed.org</i>	
4:15 – 5:00	Statistical Considerations for Companion Diagnostic Studies Marina Kondratovich, Office of Compliance, CDRH, FDA <i>Marina.Kondratovich@fda.hhs.gov</i>	
5:00	AMDM Annual Business Meeting Liz Lison, AMDM President	
5:15	AMDM Welcome Reception	



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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 <i>amullen@hpm.com</i>	
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 <i>Tamara.Pinkney@fda.hhs.gov</i> Peter Shearstone, VP, RA/QA/Clinical & Medical Affairs, Sysmex America <i>shearstonep@sysmex.com</i>	
10:30 – 10:45	Break	
10:45 – 11:15	Replacement Reagent and Instrument Family Policy Guidance Avis Danishefsky, CDRH, FDA <i>Avis.Danishefsky@fda.hhs.gov</i>	
11:15 – 11:35	De Novo Process Experience Karin Hughes, Vice President Clinical & Regulatory Strategy, Astute Medical, Inc. <i>khughes@astutemedical.com</i>	
11:35 – 12:00	Companion Diagnostics Experience Lesley Farrington, Director of Global Regulatory Affairs Diagnostics, Janssen <i>LFarrington@its.jnj.com</i>	
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 <i>Rochelle.Fink@fda.hhs.gov</i>	
1:45 – 2:25	Reimbursement: Understanding Key Concepts to Maximize Business Success Tom Hughes, Sr. Principal Advisor Health Economics & Reimbursement, RCRI <i>thughes@rcri-inc.com</i>	
2:25 – 3:00	IVDR Update Judi Smith, VP, In Vitro Diagnostics & Quality, Precision for Medicine <i>Judi.smith@precisionformedicine.com</i>	
3:00 - 3:15	Review & Wrap Up Ann Quinn, Karen Richards, Carol Ryerson, Meeting Co-Chairs	
