2017 AMDM Annual Meeting Agenda

Wednesday

April 26, 2017
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** 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 – 2:45	**IVDR** Stefan Burde, IVD Product Expert, BSI Americas *Stefan.burde@bsigroup.com*	
2:45 – 3:00	**Break**	
3:00 – 3:30	**Benefit-Risk Analyses and IVDs** Jeffrey N. Gibbs, Director, Hyman, Phelps & McNamara *jgibbs@hpm.com*	
3:30 – 4:00	**Building Cybersecurity into Medical Devices** Stephanie Domas, PE, CEH, Lead Medical Security Engineer, Battelle Device Secure Services *domas@battelle.org*	
4:00 – 4:40	**Diagnostics Update** 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** Karin Hughes, AMDM President	
5:40	**AMDM Welcome Reception**	

2017 AMDM Annual Meeting Agenda

Thursday

April 27, 2017
9:00 a.m. – 3:15 p.m.

8:00 –9:00 a.m.	**Complimentary Breakfast Buffet**	White Flint Amphitheatre
9:00 – 9:45	**Long Day's Journey into Night: IVDs and the Quest for Clinical Utility** Steve Gutman, Strategic Advisor, Regulatory Affairs, Illumina, Inc. *SGutman@illumina.com*	
9:45 – 10:30	**Personalized Medicine Update** Adam Berger, FDA *Adam.Berger@fda.hhs.gov*	
10:30 – 10:45	**Break**	
10:45 – 11:30	**510(k) Guidance Modifications for Devices** Marjorie G. Shulman, CDRH, FDA *marjorie.shulman@fda.hhs.gov*	
11:30 –12:15	**MDIC Contrived / Surrogate Sample Use Framework** April Veoukas, JD, Director Regulatory Affairs, Abbott Work Group Chair, MDIC *april.veoukas@abbott.com*	
12:15 – 1:15	**Lunch**	White Oak A
1:15 – 1:45	**Notified Body Challenges for Implementing IVDR** Stefan Burde, IVD Product Expert, BSI Group *Stefan.burde@bsigroup.com*	
1:45 – 2:25	**IVDR: Technical Documentation & Clinical Evidence** Carol Ryerson, Principal Advisor, RCRI *cryerson@rcri-inc.com*	
2:25 – 3:00	**510(k) Guidance: Modifications for Software** Linda Ricci, CDRH, FDA *Linda.Ricci@fda.hhs.gov*	
3:00 - 3:15	**Review & Wrap Up** Ann Quinn, Karen Richards, Carol Ryerson, Meeting Co-Chairs	