AMDM Focus Meeting
October 5-6, 2017

AMDM 2017 Focus Meeting

Day 1 Thursday October 5th Agenda

8:00 – 8:30 am	**Registration / Continental Breakfast / Welcome** *Event Co-Chairs: Liz Lison, Tiffany Levin*	Room: Ballroom
8:30 – 9:00	**FDA Update and Q&A** *via video link* *Elizabeth Hillebrenner, Associate Director for Programs and Performance, CDRH/OIR*	
9:00 – 9:30	**Industry Update** *Robert Di Tullio, Beaufort*	
9:30 – 10:30	**FDA's Cybersecurity Guidance and Approach to Cloud Computing** *Aftin Ross, Office of the Center Director, CDRH via video link*	
10:30 – 11:00	**Break**	
11:00 – 11:30	**Practical application of the FDA's Cybersecurity Guidance** *John Roche, RBC Group*	
11:30 – 12:00	**RFID Product Labeling – The New Generation of Automatic Identification** *Josh Miller, Computype*	
12:00 – 12:30	**How to Comment on FDA Guidance Documents** *Allyson Mullen, Hyman, Phelps & McNamara*	
12:30 – 1:30	**Lunch**	
1:30 – 2:00	**The FDA's New Digital Health Program** *Joel Centeno, Goldbug Strategies*	
2:00 – 2:30	**CE Marking of Clinical Trial Assays** *Stewart McWilliams, VP RA/QA, Almac Diagnostics*	
2:30 – 3:00	**A Review of the CDx Process in Japan and China** *Xiaolei Xu, Sr. Manager RA, Agilent Technologies*	
3:00 – 3:15	**Break**	
3:15 – 3:45	**The 510(k) Exempt Sphere Grows** *Erika Ammirati, Owner, Ammirati Consulting*	

AMDM Focus Meeting
October 5-6, 2017

AMDM 2017 Focus Meeting

Day 1 / Thursday October 5th Agenda Continued:

3:45 – 4:15	**The Development of an IVD-Compliant Quality System in a CLIA QMS Background** *Josh Levin, Personal Genome Diagnostics (PGDx)*
4:15 – 4:45	**CLIA Waiver Updates** *James Boiani, Epstein Becker & Green / General Counsel, Coalition for CLIA Waiver Reform*
4:45	**Adjourn for Welcome Reception**

Day 2	**Friday October 6th Agenda**
8:00 – 8:30 am	**Continental Breakfast / Welcome** *Event Co-Chairs: Liz Lison, Tiffany Levin*
8:30 – 9:00	**Hot Topics in Molecular Testing** *Donna Roscoe, CDRH/OIR via video link*
9:00 – 9:30	**Bridging Studies: Requirements for Demonstrating Non-Inferiority** *Marina Kondratovich, CDRH/OIR via video link*
9:30 – 10:00	**Strategies for Drug Approvals with no simultaneous CDx approval** *Reena Philip, CDRH/OIR via video link*
10:00 – 10:30	**Break & Hotel Check-Out**
10:30 – 11:15	**Companion and Complementary Diagnostics: Life after the PDL1 "Blueprint Initiative"** *David Stanforth, Sr. Director, CDx, Daiichi Sankyo, Inc.*
11:15 – 11:45	**Oncomine Dx Target Test: Approval of an NGS CDx panel** *Lynne McBride, Director Regulatory Affairs, Thermo Fisher Scientific*
11:45 – 12:15	**Update on the IVDR** *Stefan Burde, PhD, IVD Product Expert, BSI*
12:15	**Adjourn** / Box Lunches Available

Conference materials and an event evaluation are available at:
http://www.amdm.org/meetingmaterials.html
Password: 2017