AMDM Focus Meeting
October 13-14, 2016

AMDM 2016 Focus Meeting

Day 1 Thursday October 13th Agenda:

7:45 – 8:15 am	**Registration / Continental Breakfast / Welcome** *Event Co-Chairs: Liz Lison, Tiffany Levin, Michelle Roeding*	Room: Ballroom
8:30 – 9:00	**FDA Update and Q&A** *Elizabeth Hillebrenner, Associate Director for Programs and Performance, CDRH/OIR via interactive Video Link*	
9:00 – 9:30	**Industry Update** *Robert Di Tullio, Sr. VP, Global Regulatory Services, Beaufort*	
9:30 – 10:00	**Update on Regulation of Liquid Biopsy** *Reena Phillip, Director, Division of Molecular Genetics and Pathology, CDRH/OIR via interactive Video Link*	
10:00 – 10:30	**Liquid Biopsy – Approval of the First Liquid Biopsy Test** *Leslie Farrington, Director, Regulatory Affairs, Roche Molecular*	
10:30 – 11:00	**Break**	
11:00 – 11:30	**Reimbursement for Liquid Biopsy Tests, Pan-Cancer Panels and Complementary Diagnostics** *Girish Putcha, Director, Laboratory Science, Palmetto*	
11:30 – 12:00	**Update on the IVDR** *Stefan Burde, PhD, IVD Product Expert, BSI*	
12:00 – 12:30	**Deciding When To Submit a 510(k) for a Change to an Existing Device** *Erika Ammirati, Owner, Ammirati Consulting*	
12:30 – 1:30	**Lunch**	
1:30 – 2:00	**Leveraging Existing Clinical Data for Extrapolation of Pediatric Uses of Medical Devices** *Jacqueline Francis, PhD, Medical Officer, CDRH, FDA*	
2:00 – 2:30	**MDIC Survey on the Use of Contrived/Surrogate Samples–Rationale & Results** *April Veoukas, Working Group Chair, Medical Device Innovation Consortium*	
2:30 – 3:00	**21 CFR Compliance for Compliant Cloud Hosting** *Rebecca Santorios, Director of Compliance, Bytegrid*	
3:00 – 3:30	**FDA Pacific Region Compliance Update** *Sergio Chavez, Compliance Officer, ORA (Alameda), FDA*	
3:30 – 3:45	**Break**	
3:45 – 4:15	**FDA Submission of Laboratory-Developed Companion Diagnostic Tests - Experience with HDE Approval in Rare Disease** *Karen A. Heichman, Ph.D., Director, PharmaDx Program, ARUP Laboratories*	

AMDM Focus Meeting
October 13-14, 2016

AMDM 2016 Focus Meeting

Day 1 / Thursday October 13th Agenda Continued:

4:15 – 4:45	**Access to Specimens and Associated Data: the Changing Landscape** *Thomas Soriano, President, DOCRO*
4:45 – 5:15	**To Centralize or Decentralize Testing: Conflicting Trends in Infectious Disease Market** *Larry Worden, VP and Sr. Partner, Market Diagnostics International*
5:15	**Adjourn for Welcome Reception**

Day 2	**Friday October 14th Agenda:**
8:00 – 8:30 am	**Continental Breakfast / Welcome** *Event Co-Chairs: Liz Lison, Tiffany Levin, Michelle Roeding*
8:30 – 9:00	**Principles for Co-development of an In Vitro Companion Diagnostic Device with a Therapeutic Product** *Donna Roscoe, Molecular Genetics and Pathology, CDRH/OIR via interactive Video Link*
9:00 – 9:30	**Next Generation Sequencing Guidance** *David Litwack, Molecular Genetics and Pathology, CDRH/OIR via interactive Video Link*
9:30 – 10:00	**Direct-to-Consumer Testing** *Irene Tebbs, CDRH/OIR via interactive Video Link*
10:00 – 10:30	**The Case of the Unluckiest IVD Company / Compliance Case Study Part 1** *Jeff Gibbs, J.D., Director, Hyman, Phelps, & McNamara*
10:30 – 11:00	**Break & Hotel Check-Out**
11:00 – 11:30	**The Case of the Unluckiest IVD Company / Compliance Case Study Part 2** *Jeff Gibbs, J.D., Director, Hyman, Phelps, & McNamara*
11:30 – 12:00	**MDSAP Audits** *Stefan Burde, PhD, IVD Product Expert, BSI*
12:00 – 12:30	**UDI: EU v US Requirements** *Pashmi Vaney, RA Specialist, Nanostring Technologies*
12:30	**Adjourn** / Box Lunches Available