AMDM 2014 Focus Meeting

AMDM Focus Meeting
October 16-17, 2014

Day 1 / Thursday October 16th Agenda:

8:00 – 8:30 am	**Registration / Continental Breakfast / Welcome** Conference Co-Chairs: Liz Lison, Advocea, LLC & Tiffany Levin, 55th Parallel, LLC	Room: Ballroom
8:30 – 9:00	**Industry Update** Rick Naples, Sr. Vice President, Regulatory Affairs/Corporate Regulatory, BD	
9:00 – 9:45	**FDA Update on Guidance, Activities and Policy Issues and Q&A** Donald St. Pierre, Deputy Director, New Product Evaluation, OIR, FDA *(video link)*	
9:45 – 10:30	**Compliance/Inspections Trends and Q&A** Kennita Riddick, OIR Compliance, FDA *(video link)*	
10:30 – 11:00	**Break**	
11:00 – 11:30	**LDTs - Proposed FDA Regulation and Legislative Update** Jeff Gibbs, J.D., Hyman, Phelps, & McNamara	
11:30 – 12:00	**De Novo Classification Process Guidance** Erika Ammirati, Ammirati Consulting	
12:00 – 12:30	**Update on Changing IVD Regulations in the Asia-Pacific Region** Ivory Chang, BD Biosciences	
12:30 – 1:30	**Lunch**	
1:30 – 2:15	**IVDD/IVDR – Where are we now?** Stefan Burde, BSI	
2:15 – 2:45	**Technical Challenges of Clinical and Analytical Studies and Managing Them for Successful FDA Submissions** Lydia Blank, Beaufort	
2:45 – 3:15	**Considerations for International Clinical Trials for IVDs** Fred Siebert, Abbott Molecular	
3:15 – 3:30	**Break**	
3:30 – 4:00	**The 510(k) Program:** **Evaluating Substantial Equivalence in Pre-market Notifications Guidance** Allison Gannon, Roche Molecular Systems, Inc.	
4:00 – 4:30	**Evidence Development for a Novel POC Test** Katherine Tynan, Tynan Consulting	

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Day 2 / Friday October 17th Agenda:

8:00 – 8:30 am	**Continental Breakfast**
8:30 – 9:00	**Accelerated PMA Program** Deb Rasmussen, Janssen Pharmaceuticals
9:00 – 9:30	**Mobile Medical Applications Guidance** Bakul Patel, Office of Center Director, FDA *(video link)*
9:30 – 10:00	**Clinical Study Considerations for Mobile Medical Apps** Peggy McLaughlin, MPM Advisors
10:00 – 10:30	**UDI Implementation: Challenges and Experiences** Annemarie Belteu, Ph. D., Beckman Coulter
10:30 – 11:00	**Break & Hotel Check-Out**
11:00 – 11:30	**Next Gen Sequencing Update** Jennifer Dickey, OIR, FDA *(video link)*
11:30 – 12:00	**Regulatory Updates, Options and Challenges for NGS** Cathy Craft, Myraqa, Inc. *(video link)*
12:00 – 12:30	**Considerations for Validating Your NGS LDT** Girish Putcha, Toma Biosciences
12:30	Adjourn / Box Lunches Available