AMDM 2015 Focus Meeting

AMDM Focus Meeting
October 8-9, 2015

Day 1 / Thursday October 8th Agenda:

8:00 – 8:30 am	**Registration / Continental Breakfast / Welcome** Event Co-Chairs: Liz Lison, Tiffany Levin, Karen Richards, and Jing Zhang	Room: Ballroom
8:30 – 9:00	**Industry Update** Robert Di Tullio, Sr. VP, Global Regulatory Services, Beaufort	
9:00 – 9:30	**FDA Update and Q&A** Dr. Alberto Gutierrez, Director CDRH/OIR	
9:30 – 10:00	**FDA Single Audit Program** Kim Trautman, Associate Director, International Affairs, CDRH *via video link*	
10:00 – 10:30	**Recommendations for Premarket Notification Submissions for Nucleic Acid-Based HLA Test Kits Used for Matching of Donors and Recipients** Annette Ragosta, FDA/CBER *via audio link*	
10:30 – 11:00	**Break**	
11:00 – 11:30	**Legislative Update** Jeff Gibbs, J.D., Director, Hyman, Phelps, & McNamara	
11:30 – 12:00	**Me-Too Tumor Marker 510(k) Submission Criteria** Thomas Soriano, President & CEO, DOCRO	
12:00 – 12:30	**ALK IHC Follow-on CDx Approval** Abigail McElhenny, VP, Reagents and Assay Development, Ventana	
12:30 – 1:30	**Lunch**	
1:30 – 2:00	**NGS Regulatory Update** Dr. Alberto Gutierrez, Director CDRH/OIR	
2:00 – 2:30	**Next-Generation Sequencing for Personalized Medicine – Regulatory Perspective** Lynne McBride, Director Regulatory Affairs & Clinical, Life Sciences Solution	
2:30 – 3:30	**EU In Vitro Diagnostic Regulation (IVDR)** Stefan Burde, PhD, IVD Product Expert, BSI	
3:30 – 3:45	**Break**	
3:45 – 4:15	**Update on Japanese IVD Regulations** - *via audio link* Motoki Mikami, IVD reviewer, Pharmaceuticals & Medical Devices Agency, Japan (Q&A Panel featuring Motoki Mikami, Shinji Tokuhiro and Daisei Miyamoto)	
4:15 – 4:45	**New ISO 13485** Stefan Burde, PhD, IVD Product Expert, BSI	
4:45	**Adjourn for the day**	

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Day 2 / Friday October 9th Agenda:

8:00 – 8:30 am	**Continental Breakfast**
8:30 – 9:00	**Personalized Medicine Update** Dr. Alberto Gutierrez, Director CDRH/OIR
9:00 – 9:30	**PDL1-Multiple Drugs and Multiple Assays in Development/ Drug Company Perspective** Deb Rasmussen, Senior Director, Global Regulatory Affairs, Janssen Pharmaceuticals
9:30 – 10:00	**PDL1-Multiple Drugs and Multiple Assays in Development/ IVD Manufacturer's Perspective** Dave Stanforth, Director, Companion Diagnostics R&D, Dako North America
10:00 – 10:30	**Break & Hotel Check-Out**
10:30 – 11:30	**Diagnostic Regulation in Brazil** Leticia Fonseca, Executive Director, Latin American Alliance for the Development of in Vitro Diagnostics – ALADDIV
11:30 – 12:00	**Leveraging Post-Approval Studies to Support Earlier FDA Approval** Kristin Godfredsen, Director, Regulatory Affairs, Epic Sciences
12:00 – 12:30	**Specimen collection-whither the Class III Lancet?** Anna Longwell Esq, Principal, Longwell & Associates
12:30	**Adjourn** / Box Lunches Available

Conference materials and an event evaluation are available at:

http://www.amdm.org/meetingmaterials.html
Password: AMDM2015