

ASSOCIATION OF MEDICAL DIAGNOSTICS MANUFACTURERS
2019 FOCUS MEETING OCTOBER 3RD AND 4TH
LOS GATOS, CALIFORNIA

Session	Topic	Time	Speaker
Intro and Industry Updates	Registration / Continental Breakfast / Welcome	8:00-8:30	Meeting Chairs: Tiffany D. Levin, <i>55th Parallel</i> Lesley Farrington, <i>Janssen Dx</i>
	Industry Update / FDA Perspective	8:30-9:00	Courtney Lias, <i>FDA (video link)</i>
	Industry Update / Industry Perspective	9:00- 9:30	Allyson Mullen, <i>Hyman, Phelps</i>
FDA Guidance	Types of Sample Cohorts required to support Labeling of IVDs for a Specific Group or Class of Oncology Therapeutic Products	9:30-10:00	Reena Philip, <i>FDA (video link)</i>
BREAK 10:00-10:30			
Current Topics	Reimbursement	10:30-11:00	Girish Putcha, <i>Freenome</i>
	Common Regulatory Errors by IVD Companies — and how to avoid them	11:00-11:30	Jeff Gibbs, <i>Hyman, Phelps</i>
ROW Registration	Regulatory Aspects of IVD/Medical Device Regulations in Brazil	11:30-12:00	Tulius Rodriquez, <i>Janssen</i> Mr. Fabio Quintino, <i>ANVISA (video link)</i>
	China IVD Regulation Update	12:00-12:30	Amy Levin, <i>Roche Molecular Systems</i>
LUNCH 12:30-1:30			
IVDR	IVDR Update: Notified Body Perspective	1:30-2:00	Julien Senac, <i>TUV SUD</i>
	IVDR: Industry Perspective	2:00-2:30	H. Arien Pafford, <i>Hero Consulting</i>
	IVDD → IVDR: Evolution of the Essential Requirements	2:30-3:00	Karin Hughes, <i>Astute Medical</i>
BREAK 3:00-3:30			
IVDR cont.	IVDR Panel	3:30-4:00	Prior IVDR Presenters
AMDM	AMDM Regulatory Scholarship Program and Recipients	4:00-4:30	Liz Lison, AMDM President, <i>Advocea</i>
Networking Reception 4:30-5:30			
End of Day 1			

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Day 2: October 4, 2018			
	Topic	Time	Potential Speakers & Titles
Companion Diagnostics	Testing Landscape for Breast Cancer Screening	8:30-9:00	Martha Townsend, <i>Market Ready Rx</i>
	Therascreen PIK3CA RGQ PCR Kit Approval for Both Tissue <u>and</u> Liquid Biopsy	9:00-9:40	Debu Chatterjee, (Tissue Reviewer), <i>FDA</i> Francisca Reyes-Turcu, (Plasma Reviewer), <i>FDA</i> (<i>video link</i>)
	Consideration for running an IUO Companion Diagnostic Test in a CLIA Lab	9:40-10:10	Morteza Minae, <i>Guardant Health</i>
Break/Check-out: 10:10 – 10:30			
Genetic Technology	Mutation Testing: Current State of the Art, FDA Approved Assays and Future Directions	10:30-11:00	Kelly Oliner, PhD, <i>Wuxi NextCode</i>
De Novo	Apple Watch: DeNovo Clearance for First Direct-to-Consumer EKG Wearable	11:00-11:30	Peter Yang, <i>FDA</i> (<i>video link</i>)
Software	Identifying, Implementing and Verifying Data Integrity/ 21CFR Part 11 Controls for IVD Medical Device Software	11:30-12:00	Doug Shaw, <i>Halloran Consulting</i>
	Amazon Web Services/AWS	12:00-12:30	Sylva Krizan, <i>Amazon</i>
Box Lunch Provided			
End of Day 2			