

ASSOCIATION OF MEDICAL DIAGNOSTICS MANUFACTURERS

2022 FOCUS MEETING

LOS GATOS, CALIFORNIA

Day 1: October 20, 2022			
Session	Topic	Time (PST)	Speaker
Welcome	Open Portal - Welcome	8:30 am	Tiffany D. Levin , AMDM President/ 55 th Parallel Lesley Farrington , AMDM Bd. Mbr./ Janssen Dx
Industry Update	Legislative Update	8:45-9:15	John Stone* BGR Group
IVDD/R Update	General Update	9:15-9:45	Vivian Ngan-Winward TÜV SÜD
	Preparing for IVDR	9:45-10:15	Camilla Recke* Agilent
BREAK 10:15 -10:45			
IVDR Con't.	IVDR in Clinical Trials	10:45-11:15	Lubna Syed Janssen Diagnostics
	NGS Panels and IVDR	11:15-11:45	Eunice Lee Guardant
	IVDR Panel Discussion	11:45-12:15	IVDR Session Speakers
LUNCH 12:15p-1:15p			
Quality	CLIA LDT vs IVD Reporting	1:15-1:45	Jennifer Dickey PGDx
	QSR and ISO 13485 Transition	1:45-2:15	Josh Levin Asell
	FDA Guidance: Conducting Remote Regulatory Assessments	2:15-2:45	Jamie Wolszon* AdvaMed
BREAK 2:45 -3:00			
Regulatory Practices	Regulatory Options for Novel Markers	3:00-3:30	Erika Ammirati Ammirati Regulatory Consulting
	Navigating Clinical and Regulatory Efforts in Start-Up Environments	3:30-4:00	Carol G. Chen Ravel Biotechnology
	Breakthrough Device Designation Example	4:00-4:30	Michelle Roeding Michelle Roeding Consulting
INTRO TO AMDM SCHOLARSHIP RECIPIENTS		4:30-5:00	Regulatory Program Students
NETWORKING RECEPTION 5:00-6:00			

* Speaker will be presenting remotely

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2022 FOCUS MEETING

LOS GATOS, CALIFORNIA

Day 2: October 21, 2021			
Session	Topic	Time (PST)	Speaker Overview
	Open Portal - Welcome	8:50 am	Lesley Farrington , AMDM Bd. Mbr./ Janssen Dx Tiffany D. Levin , AMDM President/ 55 th Parallel
FDA Initiatives	OCE, LDTs and Single Site PMAs	9:00-9:30	Reena Philip (<i>invited</i>)* FDA
	Developing Assays for Rare Biomarkers FDA & FOCD	9:30-10:00	Megan Doyle* Amgen
Industry Update	Industry Update	10:00-10:30	Allyson B. Mullen* Hyman, Phelps & McNamara
BREAK 10:30-10:45			
Companion Diagnostics	Review of First PSMA-Targeted PET Imaging Application	10:45-11:15	Hayden Honeycutt* Amgen
	Review of First NGS Group Claim	11:15-11:45	Anika Schaedle Foundation Medicine Inc.
Reimbursement	US Reimbursement: Understanding Key Concepts to Maximize Business Success	11:45-12:15	Tom Hughes* LabCorp Inc.
CLOSE – BOX LUNCH PROVIDED			

* Speaker will be presenting remotely