ASSOCIATION OF MEDICAL DIAGNOSTICS MANUFACTURERS
FALL IVD FOCUS MEETING
OCTOBER 19 & 20, 2023

LOS GATOS, CALIFORNIA

Day 1: October 19, 2023				
SESSION	**TOPIC**	**TIME (PST)**	**SPEAKER**	*
	Registration & Breakfast	8:00 am	**In Lobby**	
Welcome	**Open Portal - Welcome**	8:30 am	**Michelle Roeding**, Co-Chair/Michelle Roeding Consulting **Lesley Farrington**, Co-Chair/Janssen Research & Development	*O*
U.S. Update	Industry Update	8:45-9:15	**Allyson B. Mullen** Esq, Director Hyman, Phelps & McNamara	*O*
	FDA Update	9:15-9:45	**Toby Lowe**, Acting Deputy Director, OIVD, FDA **Brittany Schuck**, PhD, Deputy Office Director, OIVD, FDA	*R*
	FDA Regional Compliance	9:45-10:15	**Mary R. Hole,** Supervisory Investigator, FDA	*O*
BREAK 10:15 -10:45				
Initiatives	eSTAR Template for IVD	10:45-11:15	**Lili Duan**, PhD, Tools & Templates Team Office of Regulatory Programs, CDRH / FDA	*R*
	AdvaMed Initiatives	11:15-11:45	**Jamie Wolszon**, VP, Technology & Regulatory Affairs AdvaMed Dx	*R*
	CLSI Update	11:45-12:15	**Jennifer K Adams**, Vice President, Standards & Quality Clinical and Laboratory Standards Institute (CLSI)	*O*
LUNCH 12:15p-1:15p				
Hot Topics	Overview of FDA Publication on Proposed Rules Regarding LDT's	1:15-1:45	**Sarah McManus,** Director Regulatory Affairs, Janssen Pharmaceuticals	*R*
	Software Submission Best Practice	1:45-2:15	**Karen Bijwaard**, Senior Policy Advisor, CDRH/OPEQ/OHTVII/DMGP	*R*
	Reimbursement	2:15-2:45	**Girish Putcha**, MD, PhD, Principal Precision Medicine & Diagnostics	*O*
BREAK 2:45 -3:00				
Point of Care	Point of Care – Conversion of EUA to 510K/De Novo	3:00-3:30	**Sue Thomas**, Sr. Regulatory Affairs Manager QuidelOrtho	*O*
	Usability Studies for POC Testing	3:30-4:00	**Heather Guerin**, Assoc. Director, Global Regulatory Affairs Janssen Pharmaceuticals	*R*
	CLIA Waiver – Industry Experience	4:00-4:30	**Carol M. Cooper**, Principal Consultant, CM Cooper & Associates	*R*
	Panel Discussion	4:30-5:00	**Sue Thomas**, QuidelOrtho **Heather Guerin**, Janssen Pharmaceuticals	
NETWORKING RECEPTION 5:00-6:00				

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*** *R* = Speaker will be presenting remotely / O = Speaker will be presenting on-site**

Day 2: October 20, 2023				
SESSION	**TOPIC**	**TIME (PST)**	**SPEAKER**	*****
	Breakfast	8:00 am	**In Lobby**	
	Open Portal - Welcome	8:50 am	**Michelle Roeding**, Co-Chair/Michelle Roeding Consulting **Lesley Farrington**, Co-Chair/Janssen Research & Development	
Companion Diagnostics	Guidance: Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program	9:00-9:30	**Brittany Schuck**, PhD, Deputy Office Director, OIVD, FDA	*R*
	IVDR: Supporting CDx Clinical Trials PEO / CE Mark HA Notifications EC Approvals	9:30-10:00	**Amanda Baker**, Clinical Development Leader Roche Molecular Systems, Inc.	*R*
	IVDR Panel Discussion: Part 1: MedTech Europe's eBook on IVDR Clinical Evidence Requirements Part 2: Q&A on CDx and eBook	10:00-10:30	**Amanda Baker**, Roche Molecular Systems, Inc. **Christian Zaugg**, Roche **Iana Slobodeaniuc**, MedTech Europe	*R*
BREAK 10:30-10:45				
SAMD	FDA Update on Cybersecurity	10:45-11:15	**Justin Post**, Policy Analyst, FDA/CDRH/OPEQ/OHTVII	*R*
	The FDA's Draft Guidance on AI/Machine Learning-Enabled Device Software Functions & the PCCP	11:15-11:45	**Monica Montanez**, MS, RAC CQ Principal Strategy Consultant, NAMSA	*R*
	Artificial Intelligence/ Machine Learning and Beyond: FDA's New PCCP Authority	11:45-12:15	**Sheila Walcoff**, CEO/Founder Goldbug Strategies, LLC	*O*
ADJOURN – BOX LUNCH PROVIDED				